A qualitative study to identify an appropriate regulatory framework for human stem cell research in Malaysia



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Abstract

Human stem cell research (hSCR) is known as the future of medical intervention of the 21st century. It is one of the most rapidly progressing emerging technologies in the areas of science, with promising and potential benefits to develop therapy to cure many degenerative diseases that are incurable by the conventional medical procedures. Notwithstanding its importance, this field is rather controversial and ethically contentious as well as legally challenging. Malaysia is among the countries that recognise the importance of this technology. However, its current regulatory system does not seem adequate to ensure ethical compliance. In the light of this situation, one would question as to what would be the appropriate and suitable regulatory approach to this matter? What ought to be done to ensure this area progresses in an ethical fashion?

This thesis was carried out with an aim to examine the regulatory landscape of this area, by looking at the roles and techniques of regulation and its application in hSCR arena across the globe, with a focus on Commonwealth countries. An empirical study was also undertaken, using qualitative interview methods, to find out more about Malaysia's system. The empirical findings obtained, supported by the comparative analysis between Malaysia's system and of other jurisdictions, suggest that Malaysia's framework is lacking of important regulatory measures that are necessary to secure compliance.

This thesis concluded that to achieve an optimal regulatory outcome, the framework would require some improvements by adopting a combination of different regulatory techniques and strengthening its rules enforcement strategies. In addition, there are regulatory options have been identified to improve the current framework including legal transplants, however, there are challenges that need to be recognised.

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1. Overview of the Introductory Chapter

This introductory chapter gives an overview of why the regulation of hSCR has been identified as a priority for Malaysia and the issues of regulation are of concern. It goes on to describe human stem cell research (hSCR), highlighting the factors that have motivated researchers to develop this promising area of biomedical science. It identifies the key ethical issues that have prompted public discourse and contributed to the development of regulation and the establishment of policy for stem cells science internationally are also briefly discussed. This chapter continues with a brief overview of the regulation of hSCR within Malaysia. Subsequently, this chapter introduces the chapters that follow.

The aim of this thesis is to assess the regulation of hSCR in Malaysia. The interest behind this thesis project is developed from a concern that is grounded from reading that demonstrates hESCs research is highly contentious. A regulatory system for hSCR particularly hESC research is crucial and critically needed to provide clarity and ensure ethical conduct. For instance, Isasi and Knoppers (2006a) argue, ethical compliance measures i.e. ethical justifications for the use of human embryos, ethics review, centralised and independent authority empowered to grant licences and monitor the conduct of research, are vital and they should be incorporated in a regulatory framework. This framework is not merely for ensuring compliance but studies have shown that it is equivalently important for researchers to work in an environment with a

clear ethical guidance, which would help their research progress. (Caulfield et al., 2012)

The establishment of the International Society of Stem Cell Research Society (ISSCR) in itself indicates the international effort to uphold such value. The ISSCR has produced guidelines that provide “a set of recommendations for researchers, clinicians, and oversight groups to aid their decision-making”, which aspires to facilitate the advancement of this area, particularly to translate stem cell science to the clinic ethically and safely. (Scadden and Srivastava, 2012; p. 149)

The measures discussed by Isasi and Knoppers (2006a) appear to be absent in Malaysia’s current framework i.e. there is no provision requiring justification for research activities, also not mentioned in the national guidelines. This may suggest that the current research practice may not be fully compliant with the existing international guidelines. Without these measures in the current regulatory framework, this suggests that it is inadequate and not on par with other countries that have a more established system. Given there are jurisdictions that have had established regulatory system to regulate this challenging area, Malaysia could potentially learn and benefit from them.

In so doing, this thesis sets its objectives (i) to study the literature on regulatory and enforcement techniques; (ii) to examine literature of and comparatively analyse the international regulation for hSCR across the globe with focus on Commonwealth countries; (iii) to explore the regulation of hSCR in Malaysia based on the opinions and attitudes of key stakeholders through qualitative interviews; and (iv) to bring together the information gathered from the literature review and findings from the interviews for an analysis that will

contribute in finding the different legal options that can be used as guideposts by Malaysian policymakers.

The aim of this thesis is not to produce a definitive list of recommendations as to how Malaysia should regulate hSCR activities, but rather to point out different legal options that can be considered by Malaysian policymakers to develop a regulatory framework for hSCR that is appropriate for the Malaysian context.

2. Socio-legal Perspectives

2.1 Malaysian Legal Backgrounds and the Commonwealth

Malaysia is a multi-racial, multi-cultural, and multi-faith nation. Its population consists of predominantly of Malays, Chinese, Indians and a number of other ethnicities. Its population of over 30 million is religiously diverse with 61.8% of the population practicing Islam, 19.8% Buddhism, 9.2% Christianity, 6.3% Hinduism, 1.3% Confucianism, Taoism, and a number of other traditional Chinese faiths. (2010c) It is worth noting, the Constitution declares Islam as the official religion while at the same time it embraces the freedom to practice other religions. (2010a)

Historically, Malaysia was a Malay Kingdom; part of the British Empire and therefore, the law of the land is heavily based on and influenced by the English common law, a direct result of colonisation. (Civil Law Act, 1956; Section 3(1)) However, the legal system is also built on Islamic law, from which has led to the current dual legal and judicial system of civil and sharia laws. (Federal Constitution, 2010a; Article 121(1) and 121(1A)) Therefore, Islamic

perspectives play an important role, especially when a social issue is considered to be of concern. Nevertheless, the application of Islamic law is rather limited, only applies to matters under the State jurisdiction (Federal Constitution, 2010a; Article 76(1)(2)(3)) and not those under the Federal Legislature. (Federal Constitution, 2010a; Article 77 and Ninth Schedule)

In addition, “central to the Malaysian legal system is a written Constitution based upon the Westminster model.” (Syed Ahmad, 2001; p. 1) Most of the English laws were imported into Malaysia prior to its independence in 1957, either by adopting it in the local legislation or used as case laws. The laws of Malaysia also influenced by other jurisdictions such as Australia and India. (Noordin, 2013) For instance, its Criminal Procedure Code is based on the Indian, which was introduced in the country by the British; its Contracts Act is based on the Indian model; and the Malaysian land law is based on the Australian Torrens System.

In view of its legal history, the Malaysian legal system is derived from English law but also has drawn upon on other Commonwealth jurisdictions that also come from the same British origins. Therefore, a comparative analysis of the legal system of hSCR in Malaysia with other Commonwealth countries can not only provide insights into the origins of some of the aspects of Malaysian law, but also provide a guide for how it might develop.

2.2 HSCR in Malaysia and the Commonwealth

Countries all over the world have heavily invested in the area of hSCR. Among these countries are Commonwealth countries such as the UK, Australia, Canada, India, South Africa, and Singapore, which are active in developing

hSCR. Of these countries, UK is often hailed as a world leader in stem cell research (Perrin, 2005) and Singapore in the recent years has been described as a 'haven' for stem cell researchers. (Arnold, 2006) Along with these countries, Malaysia also aspires to be part of this highly promising area. In 2013, the Academy Sciences of Malaysia together with the Universiti Putra Malaysia have published an advisory report (2013).

Based on the report, it can be said that Malaysia seeks to venture in this area mainly due to two factors; (i) the potential of cell therapy to address an increased population of senior citizens that is growing rapidly leading to increased healthcare cost and (ii) cell therapy has been identified as the key research field in the area of life sciences and biotechnology that could help to achieve Vision 2020. This Vision set forth by the 5th Malaysian Prime Minister, Tun Dr. Mahathir Mohamad, who aspires to see Malaysia becoming a fully developed nation by 2020.[1] In achieve this, a Taskforce was established to identify the status, and assess certain key aspects of this area to "enable the government to determine the priority for resource allocation based on the likelihood and magnitude of return on its investment." (Advisory Report, 2013; p. iii)

The advisory report highlights the importance of having a consistent investment policy in infrastructure and human capital for Malaysia to achieve its ambition to becoming a developed nation by 2020. It was emphasised that Malaysia does not have the resources to invest across widely and therefore, it is important to choose certain areas that will maximise the return on research

[1] See Working Paper: The Way Forward – Vision 2020 available at http://www.wawasan2020.com/vision/, accessed on August 3, 2015.

investment. Based on their assessments, the Taskforce has identified the top four chronic diseases that cause disability among the older population; dementia, musculoskeletal diseases, visual-bearing impairments, and cardiovascular diseases, which creates a drain on public healthcare spending. (Advisory Report, 2013)

To address this issue, stem cell research is seen as a potential solution that may provide treatments to reverse the conditions. Nevertheless, the Taskforce points out that Malaysia is said to be "at a distinct disadvantage when competing in a knowledge intensive field such as regenerative medicine and stem cell research" (Advisory Report, 2013; p. 33) due to its relatively restrictive policies regarding stem cell research, the lack of sufficient funding and skills in this area. In terms of its approach to policy, the Report suggests that Malaysia is more restrictive compared to other countries. The findings of this thesis have shown that in contrast, those working in this field regard the current framework as lacking regulation and enforcement.

2.3 Regulatory Frameworks of hSCR and Its Impact

It has been widely reported that frameworks governing hSCR across the globe are developed and shaped differently in different jurisdictions. Some countries have well-established and comprehensive framework, such as Australia, Canada, and particularly the UK. (EuroStemCell, 2011) As a result, hSCR in these countries can be regarded as being heavily regulated in many aspects. However, there are still some countries with no official policies and a regulatory framework that is dependent upon guidance rather than formal

legislation. For example, Malta, Cyprus, Malaysia, and India do not have legislation, although both Malaysia and India have guidelines in place.

The qualitative interviews in this study indicated, from the respondents' points of view, Malaysia lacks some important regulatory elements. The Advisory Report and research on the legal documents available on Malaysian legal websites further confirm this. For instance, according to the Advisory Report (2013; p. 31), "research on stem cells are not covered by any legislation" and there are also no provisions on stem cell therapy except that the practice must comply with the Private Healthcare Facilities and Services Act 1998. There is little regulation in the stem cells area in general – both non-clinical and clinical, and even less regulatory oversight with regards to the former.

This suggests that hSCR in Malaysia is being performed with little regulatory oversight. The findings also show there are no appropriate measures to ensure ethical conduct and provide protection for research subjects, as well as protecting the reputation and integrity of researchers working in this field.

This may not only put research subjects in Malaysia in a risky position of being misled or manipulated, but also raises the possibility of the area being tainted by unethical conduct of which might result in a loss of public confidence. This situation might potentially damage the reputation of Malaysia and local researchers at the international platform. The Hwang case in South Korea is an example of what a fraud and unethical conduct can do to a country's reputation. (Kakuk, 2009, Koreans Report, 2006e)

In 2004, Hwang and his research team announced, they have successfully derived pluripotent embryonic stem cell line from a cloned human

blastocyst (Hwang et al., 2004) – a technique, which could be used to clone human. This was considered as a ground-breaking news across the globe particularly, for the stem cell community. (Kolata, 2004) In the midst of his fame, there were some ethical objections and strong oppositions towards the technique used, for bioethicists are afraid that this could potentially open the door to the 'slippery slope' of human cloning. (Kolata, 2004)

Also, the nature of his research work was seen as suspicious, particularly with regards to the number of donated eggs (242 eggs) obtained and the number of women (16 women) whom allegedly 'volunteered' and prepared to undergo a painful and risky procedure. (Cyranoski, 2004) After a long process of scrutiny, in 2006, it was revealed that Hwang and some of his team members have fabricated the research data and involved in various ethical wrongdoings.

This exposed scandal is perceived to have shaken the world of and as 'a slap on the face of 'Science''. (Liu, 2005, Hong, 2008) The journal *Science* has retracted two of Hwang's published papers in 2004 and 2005 (Kennedy, 2006) and he was also dismissed from Seoul National University. (Wohn, 2006) Due to this incident, the South Korean's regulatory system, particularly its Bioethics and Biosafety Act 2005 was scrutinised and amended. (Gottweis and Triendl, 2006, Clay, 2013)

This scandal, therefore, can be used as an example and a reminder to policymakers and regulators that it is not only important to establish a regulatory framework to regulate this ethically controversial area, but also to ensure that the framework is appropriate and able to secure regulatory compliance.

3. Perspectives

3.1 Scientific Perspectives: The Science of Stem Cells

The stem cells in human body are the most basic cells and regarded as the 'body's natural reservoir'. (2010b) These cells have unique characteristics and abilities, namely, they able to self-renew - making copies of themselves, and differentiate to develop into more specialised cells - making tissues and organs. Their ability to differentiate varies and depend on their potency: (i) totipotency – these cells able to differentiate into any cell type of the inner cell mass or trophoblast (capable of becoming or and producing a whole new organism). Embryonic stem cells remain totipotent through its first few stages of cell division; (ii) pluripotency – capable of differentiating into all of cell types in a human body or matured organism but not the cells of trophoblast (embryonic stem cells fall under this category); (iii) multipotency – usually referred to adult stem cells, which capable to produce cells of a particular tissue. (Campbell et al., 2005) Essentially, the potency of the stem cells decreases as they become more mature, however, they still have the capability to self-renew.

Due to these abilities, researchers have argued that stem cells can be used for research purposes to bring benefit to humankind, particularly to cure diseases. The stem cells used in this endeavour are not limited to one type but it encompasses of many stem cell types from embryonic stem cells (ESCs), adult stem cells, which include mesenchymal stem cells (MSCs), cancer stem cells (CSCs), (Arney, 2008, Barker et al., 2009)[2] hematopoietic (blood) stem

[2] It was reported that stem cells are at the root of bowel cancer and research on these stem cells could lead to a better understanding to develop treatment.

cells (HSCs)[3] (Daley and Scadden, 2008), spermatogonial stem cells (SSCs), (Firlej et al., 2012) induced pluripotent stem cells (iPSCs), foetal stem cells, and many more. Nevertheless, due to its pluripotency, hESCs are regarded as important and known as the 'gold standard' in hSCR. (Crook et al., 2007, Gawrylewski, 2008, Heng et al., 2009)

A number of research techniques to derive human stem cells have been discovered, namely (i) ***In Vitro*** **Fertilisation (IVF)** – an alternative way to achieve pregnancy where sperms and eggs are fertilised on a petri dish to produce a number of embryos, among which only viable ones will be implanted into a woman's womb. Some researchers use surplus IVF-created embryos to procure embryonic stem cells; (Sills et al., 2005)[4] (ii) **Somatic Cell Nuclear Transfer (SCNT)** – this technique was used for reproductive cloning in animal. A somatic nuclear cell from the sheep's mammary gland was transferred into an enucleated egg of the same sheep to form an embryo, which was then used to create the first cloned organism, Dolly the sheep.[5] The technique is banned from being used in human reproductive cloning (human cloning itself is banned) but in some jurisdictions, it is acceptable to be used as a 'therapeutic cloning' for treatment purposes. The stem cells produced using this technique can

[3] The use of HSCs is one of the best-understood stem cells and its use in treatment is widely practiced to restore tissue function, and hailed as the 'gold standard'.

[4] The intact donated embryos produced by IVF for research are cultured to blastocyst stage. When the inner cell mass is formed, the blastocyst is disaggregated. The inner cell mass are isolated from the blastocyst and disaggregated to obtain individual blastomeres which were then plated on a feeder layer and in a cultured medium

[5] This breakthrough success (reproductive cloning) met with supports as well as ethical criticisms, worrying about another advanced step would be taken to clone human being. Notwithstanding this, after the breaking news announced, human reproductive cloning is banned across the globe in consensus. This decision does not put this technique to its end. It has been adapted to research for the medical benefits of human kind, later known as therapeutic cloning.

address the issue of immune rejection; (Wakayama et al., 2001, Wilmut et al., 2002)[6] (iii) **Altered Nuclear Transfer** (Hurlbut, 2005)[7] – a nucleus DNA is removed from a somatic cell, genetically altered[8] prior to transferring it into an enucleated egg, forming a non-viable embryo; (Tam and Rossant, 2003)[9] (iv) **Induced Pluripotency Reprogramming** (Evans and Kaufman, 1981, Takahashi et al., 2007, Yamanaka, 2012) – adult human somatic cells are induced to differentiate into undifferentiated pluripotent stem cells, demonstrating similarity to hESCs. This discovery has been awarded with a Nobel prize; (Holmes, 2012, Johnson and Cohen, 2012) (v) **Parthenogenesis** (Rougier and Werb, 2001) – stem cells are derived from embryos developed from eggs that are not fertilised but activated *in vitro* using electric, chemical and mechanical stimulations; (Brevini and Gandolfi, 2008) [10] and (vi)

[6] As an alternative to human pluripotent stem cells derived from IVF-created embryos, this technique generates stem cells that are compatible to the recipient avoiding immune rejection problem.

[7] Hurlbut articulates that this technique is developed with a proper consultation with leading scientists, moral philosophers, and religious authorities without having to deal with the most disputatious exploitation, which is the destruction of human embryos. There is no destruction of embryos involved as there is no creation of human embryos taken place.

[8] This alteration process can be done with different methods either by deleting or silencing the responsible genes that promote the formation of living being or manipulate the responsible genes to skip forward from the ability to form organism (the totipotent stage) to the pluripotent stage.

[9] The generated ANT hybrid entity lacks the characteristics and capability of an organism therefore the destruction of this altered entity is not similar to the destruction of unaltered embryo that is complete with functional structures and dynamic character of a potential organism. Notwithstanding this alteration, SCNT embryo yet able to produce pluripotent stem cells which is the main objective of the hESCs research that has been constantly emphasised by scientists and researchers to reasoning the aim of this research. Notwithstanding this beneficial manipulation, it is disputable as to whether this early interference at molecular level is safe and whether it will not cause any undesirable consequences down the line.

[10] With the absence of DNA from paternal cell, the egg undergo development forming a clone of the maternal cell thus causing abnormal development giving rise to incomplete

Blastomere extraction (Chung et al., 2006, Klimanskaya et al., 2006) – conceptually based on the pre-implantation genetic diagnosis. One or two blastomeres are extracted from blastocyst to be used in generating stem cell lines without interfering the potential development of the blastocyst.

3.2 Important Breakthroughs in hSCR: The Use of Human Stem Cells

Following the major breakthroughs by Ian Wilmut and his team in 1997, James Thompson's lab in 1998, and later the discovery of induced pluripotency stem cells by Shinya Yamanaka in 2007, hSCR is recognised as one of the most rapidly progressing newly emerging technologies in the areas of science. (Schnieke et al., 1997, Thomson et al., 1998, Takahashi et al., 2007, Wilmut et al., 2007) It has become a remarkable phenomenon among the medical community, deemed by some as the future of medical intervention among other emerging technologies such as whole genome sequencing, biomarkers, gene therapy, and nanotechnology. (Khoury, 1997, Sahoo et al., 2007)

As argued by scholars, this area has emerged "as one of the most high-profile and promising areas of 21st-century science." (Huang et al., 2013; p. 3320) Scientists all over the world have also reported and contended that this promising area offers a revolutionary medical intervention to treat degenerative diseases, which are mostly incurable by the conventional medical procedures today. (Daley and Scadden, 2008, Uccelli and Prockop, 2010, Banerjee et al., 2011, Wagers, 2012, Panizzo, 2011, Lodi et al., 2011)

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embryo-like structure unable to form an organism. Since the genomic imprinting is fully inherited from maternal cell, the new daughter cells are exclusively compatible to the egg source. Unlike SCNT, parthenogenetically derived stem cells are strictly compatible to oocyte donor. The use of parthenogenesis has been proposed as another possible alternative to procure embryonic stem cells.

On a similar note, Daley (2012; p. 740) further argues that the aging population today is in need of novel therapeutic approaches to cure medical conditions, which are "unlikely to be cured by drugs alone", and "novel cell therapies…represent major frontiers for the future." It is worth mentioning that among other discoveries, the major breakthrough of iPSCs technology has led to the opportunity for drug discovery and proof-of-concept studies in the development of new drugs. (Ebert and Svendsen, 2010, Ellis and Bhatia, 2011, Grskovic et al., 2011, Inoue and Yamanaka, 2011)

Due to its promising and potential benefits for the humankind, hSCR is currently being actively carried out on a global scale and over the years, many countries have joined in the 'stem cell race'. (Löser et al., 2010, The Telegraph, 2003a) In particular, it was reported "more nations are joining the human embryonic stem cell research (hesc) "race" by aggressively publishing in the peer-reviewed journals." (DeRouen et al., 2012; p. 1043) Researchers are endeavouring to translate their research from laboratory to clinical practice. (Brindley et al., 2012) [11]

3.3 Ethical Perspectives: The Moral and Legal Challenges in hSCR

Notwithstanding these anticipated benefits, contentious issues have surrounded the hSCR arena since its inception, particularly research activities involving hESCs. This is largely due to the destruction of human embryos to establish stem cell lines. For many years, the issue of moral and legal status of human embryos has been widely discussed by many scholars. (McLaren, 1984,

[11] Brindley and team argue, "Today, the translation of basic stem cell science into therapeutically and commercially meaningful outcomes is at the core of the emerging therapy industry." p. 492.

Lockwood, 1985, Walters, 1987, Braude and Johnson, 1989, Ford, 1991) It has also been a matter of dispute of which until today remains unresolved - there are opposing views on this matter, both in terms of ethical and religious perspectives. (Holland et al., 2001, Welin, 2002, Knowles, 2009)[12]

Given the existing mixture of different faith groups, the issue has resulted in varying support among the public globally. (Pardo and Calvo, 2008, Caulfield et al., 2009a) Whilst the promising benefits receive strong public support, the notion of the destruction of human embryos has resulted in a fierce opposition from some parties. (Brindley et al., 2012) A survey carried out by Spanish BBVA Foundation study captures the differing views – morality versus usefulness of this area that exists among the public in 15 different countries. (BBVA, 2008)[13]

This has also affected governmental policy, resulting in a regulatory phenomenon that is known as 'regulatory patchwork'. (Caulfield et al., 2009b) Whilst some countries have adopted regulatory approach to support the advancement of hESC research, others only encourage the use of non-embryonic stem cells, particularly adult stem cells and iPSCs. Unlike the former, the latter are universally and ethically accepted across the globe. (Eurobarometer, 2010) A survey conducted worldwide (fifteen countries in three continents) shows "acceptance of human embryonic stem cell research was

[12] Chapter 3 of the US President's Council on Bioethics (PCBE) report, *Monitoring Stem Cell* Research (2004) presents an analysis of three different moral claims regarding the embryonic stem cell research.

[13] This general population survey was conducted in 15 countries in three continents namely Austria, Czech Republic, Germany, Denmark, Spain, France, Ireland, Italy, Netherlands, Poland, United Kingdom, Sweden, Israel, Japan, United States.

higher when potential medical benefits were made clear to respondents." (O'Malley, 2014; see section 'worldwide')

The geographical distribution of research activities involving embryonic stem cells has expanded throughout the years. (Ben-David et al., 2012) HESC are known as the 'gold standard' of research involving human pluripotent stem cells.[14] Since the use of human embryos and the cells derived thereof has been the centre of ethical and regulatory dispute at the global level and have heavily influenced the formulation of regulation in many jurisdictions,[15] the discussion in this thesis is therefore, focusing mostly on this particular subject.

In addition, the discussion also touches on other pressing ethical issues that are relevant to hSCR, which are also imperative and need to be addressed such as ethical compliance with procedures for safe and appropriate clinical practice, and its impact on public safety. (Zarzeczny and Caulfield, 2009) This has become a worldwide phenomenon known as 'stem cell tourism' whereby patients often travel from their home country that has a more restrictive regulation to countries with less strict or no regulation. (Caulfield et al., 2012, Colen, 2012, Einsiedel and Adamson, 2012, Master and Resnik, 2011, Petersen, 2014, Tenenbaum, 2014) It is a shared concern that these patients are being exploited.

[14] Based on the literature, whilst haemapoetic stem cells can be considered as the gold standard for stem cell-based therapy, in terms of the basic research per se, hESCs are hailed as the 'gold standard' compared to many other pluripotent stem cells including the iPSCs.

[15] It is evidently clear from the literature that the use of human embryos and the derivation of its cell lines have sparked the formulation of regulation especially legislation in many jurisdictions.

A study conducted by Patra and Sleebom-Faulkner (2011; p. 160) in India reported on a case of patients being manipulated into believing in a fraudulent treatment services.

> *"Several clinics and hospitals that are providing stem cell therapy do use some patients as agents in order to influence desperate patients looking for treatment avenues. Sometimes, they are even fakes. Members of their office staff pretend to be cured patients…[pretend] as if they are real patients who have benefited from a therapeutic service and do influence others to take the therapy."*

This unethical practice may put patients, particularly those who are desperately in need of cure, in a danger situation by risking their life to try out any possible 'treatments'.[16] (Cyranoski, 2010, Gallagher and Forrest, 2007, Murphy and Blazar, 1999, Ryan et al., 2010) Also, if this led to unfortunate outcomes, it may jeopardise the reputation of this field. In view of this situation, one could see the importance to regulate this promising yet controversial field. (Cohen and Cohen, 2010, Hyun et al., 2008)

Accordingly, one would question as to what would be the appropriate and suitable approach to this matter. If this technology should be advanced given its potential benefits, what ought to be done to ensure this area progresses without compromising the issues at stake – public safety and the reputation of hSCR. There are many countries in the world that have established a regulatory system to govern this contentious field. However, the

[16] It has been argued that unproven 'treatment' could lead to medical conditions such as tumour formation, tissue rejection, permanent disability and even some death cases have been reported.

system is widely varied from one to another, representing the different views towards the use of human embryos for research purposes. Malaysia recognises the importance of developing this promising area and at the same time aware the need to address the ethical issues. However, its current system seems inadequate in various aspects.

Consequently, Malaysian researchers are concerned with regards to the adequacy of the regulatory system and the impact it has on the development of this area. Even though it is still at its infant stage in Malaysia, there are however, quite a number of research activities going on, as well as some unproven stem cell-based treatments have already been in practice but left unregulated. This indicates that both hSCR and therapeutic activities in Malaysia are under-regulated.

4. Value-added and Contribution

According to the available published evidence, this could be the first empirical study conducted to explore and examine Malaysian regulatory framework for this promising yet contentious field. When comparing the findings to the international regulatory practice, it has been shown that Malaysian framework is lacking of some important regulatory features that are pivotal in securing compliance and protecting this field from being blemished. It is through this thesis project that it is hoped to promote further study and academic discussion on the way forward to improve the system.

Furthermore, given there is little information about Malaysia available in the literature of hSCR regulation at the global level, this thesis adds value to the

existing literature. This would also promote Malaysian academics to produce more literature on ethical and legal issues of hSCR on the Malaysian context so that in future, Malaysia would be on the world stem cell policy map.

5. Outline of this Thesis

There are three individual stages involved in this research project that are brought together to make up the entire thesis: (i) comparative legal analysis conducted through literature review; (ii) qualitative study conducted through empirical work; and (iii) analysis of the findings obtained from the literature review and interviews to produce some basis for policy improvement, which is the culmination of this thesis.

As has been mentioned earlier, this chapter - **Chapter 1** functions as an introductory chapter. It gives an initial idea of the whole process involved and the background of this research project.

Part A. This part of this thesis aims to give an overview of the models of regulatory instruments adopted to regulate hSCR internationally.

Chapter 2 provides an overview and background of the concept and theory of regulatory techniques and enforcement strategies. This chapter is divided into three main sections. The first section explains the functions – advantages and disadvantages of different regulatory techniques. The second section focuses on the enforcement strategies by explaining how important the strategies are in ensuring the enforceability of rules with an understanding that

rules are not self-enforcing. The third section introduces the theory and the role of legal transplants as an important means in the development of legal system.

Chapter 3 provides an overview of the regulation of hSCR and explores the regulatory practice across the globe by mapping out the regulatory framework of a number of jurisdictions. This chapter examines the implementation of regulatory techniques and enforcement strategies discussed in Chapter 2 within the regulatory domain of hSCR. It starts by illustrating the regulatory practice across the globe and then the examination narrows down by focussing on commonwealth jurisdictions.

This chapter then briefly explores the literature on hSCR regulatory system in Malaysia and provides a comparison between Malaysian system and other jurisdictions, especially among the commonwealth countries. The under-regulated hSCR in Malaysia will be highlighted. This chapter also demonstrates the common practice of legal transplant in Malaysia's legislative development.

Part B reports the findings obtained from the qualitative interviews.

Chapter 4 reports the level of awareness on hSCR regulatory system among the respondents of this study before reporting on the respondents' views with regards to the awareness among the members of the public. This chapter also highlights the respondents' views on the current regulatory approach for hSCR. It then shows the concerns raised by respondents with regards to the implications of the current approach on the regulatory practice, research development, and compliance with the rules in place.

Chapter 5 further reports and develops issues reported in Chapter 4 in more depth. It examines the respondents' views on the implementation and enforcement of compliance measures in Malaysia by looking at the practice and issues of licensing system, informed consent, statutory sanctions, the 14-day rule, and monitoring system. In addition to the concerns over the awareness issues, the respondents also shared some concerns about the current measures, which they regard as inadequate and surrounded by various issues that need to be addressed.

Chapter 6 illustrates the respondents' views on regulatory measures that they felt necessary to be carried out to address the issues presented in Chapter 4 and 5. The discussion in this chapter focuses on different regulatory approaches: (i) the establishment of legislation; (ii) the introduction of national policy; (iii) the establishment of an independent regulatory body; and (iv) the importation of rules established in the developed countries or other countries that have more similar cultural or religious setting.

Part C, which is the final part of this thesis, presents the analysis and solutions to the issues identified in the preceding chapters.

Chapter 7 brings together the analysis of the comparative legal study in Part A and the findings reported in Part B for further examination and analysis, to find out what would be the appropriate regulatory framework that could be established in Malaysia. This chapter discusses different legal options that can

be considered by Malaysian policymakers based on the four aspects of the current system identified in the preceding chapter, as problematic.

To ensure the options are appropriate and in accordance with the local context, this chapter draws together the practice by other countries and views and propositions expressed by the respondents, who are among the key stakeholders in the country. Finally, this chapter summarises this thesis as a whole by demonstrating how the research question is linked to the findings reported. It also discusses the value of the contribution of this research project, the relevance of the findings reported, the research question arose from this project, and the research work that can be carried out in future.

Appendixes are attached at the end of this thesis for further explanation on the methodology used for this research project and accompanying documents used to obtain ethics approval for this project.

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Appendix 2: Ethics Committee Documents
Appendix 2.1: Information Sheet
Appendix 2.2: Interview Invitation Letter
Appendix 2.3: Interview Questions or Topic Guide
Appendix 2.4: Informed Consent Form
Appendix 2.5: List of Interviewees

PART A - OVERVIEW

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Introduction

This chapter aims to provide an overview and background of the conceptual and theoretical framework of regulatory techniques and enforcement strategies that have been extensively studied and scrutinised by regulatory scholars. Even though there are several categories of regulatory techniques that have been classified and explored by regulatory experts, in this thesis, the focus will be on five techniques, namely; command-and-control; communication-based; incentive-based; self-regulation; and enforced self-regulation. The benefits and pitfalls of these techniques will also be explored in the first part of this chapter.

These techniques of regulation have been highlighted in this thesis as they are of particular relevance to the governance of hSCR. Based on scholarly works, this chapter demonstrates that to have an optimal regulatory system, a state or government would need to adopt a hybrid regulation. Such technique could be more appropriate, especially for a regulated area that is ethically controversy and highly risky.

The second part of this chapter focuses on the enforcement strategies that are crucial to strengthen the regulatory system mentioned above and enforce established rules. Rules are not self-enforcing and therefore, techniques to enforce them are important. Discussion of the strategies primarily focuses on both formal (legal action) and informal practice. This thesis argues that both are crucial to ensure, if not the effectiveness, then at least the enforceability of regulatory requirements.

The third and final part of this chapter looks into how a jurisdiction develops its legal system by referring to legal scholarly works on legal transplants. Based on the theory of legal transplants, this thesis argues that given that the transplantation of a legal system is a common practice, newly emerging jurisdictions in the stem cells area, such as Malaysia could consider transplanting or importing legal systems or rules established in other countries to develop its own legal system. Nevertheless, there are other factors that have to be taken into account, such as the local cultural values and the expertise needed in order to implement the transplanted system.

1. Regulatory Techniques

By ensuring a certain activity is conducted according to certain rules, regulation is often thought to involve restricting actions and imposing threats to prevent the occurrence of undesirable activities and to demand conformity with established rules. However, regulation may also involve other methods or influences, which are not primarily based on restrictions and threats. As stated in (Turpin, 1988; p. 318), Ganz, a legal scholar argues, “statutes and statutory instruments are not the only available forms for the making of law and the regulation of society, although the law-creative effect of other forms depends ultimately on statute.”

Gunningham and Grabosky (1998) contend that there are a number of options a state may adopt as its regulatory system to regulate a certain sector. By using the example of pollution of a river, they point out that the state may decide to directly regulate through governmental agency or body, or it can be

left to polluting firms to self regulate, overseen by the state, or interest groups or third parties can be assigned to act as regulators.

To find out more about the different approaches available in the regulatory domain, this chapter examines the main regulatory techniques that a government can use to regulate. This is followed by a discussion of enforcement techniques to ensure compliance with the regulation. This chapter provides a background for a review of the regulation of hSCR across the globe in the following chapter.

1.1 Command-and-Control Regulation

Command-and-control regulation also known as classical regulation, is the most commonly adopted and familiar regulatory technique. Such a regime involves regulatory standards imposed by regulators on the regulatees. (Baldwin, 1997) In this regime, rules are promulgated through legislation by states to prohibit certain undesirable conduct, to stress desirable activities, and to lay down some provisions or requirements that have to be complied with in order to enter a certain sector. (Baldwin et al., 2012; p.106)

Baldwin and colleagues (2012; p. 106) describes this technique as a way '*to inform* – where legal authority and the command of law is used to pursue policy objectives' and the essence of this regulation is "the exercise of influence by imposing standards backed by civil or criminal sanctions" or as Morgan and Yeung (2007; p. 80) puts it, the prohibitions and rules stipulated in legislation are binding as well as backed up by legal force and "underpinned by coercive sanctions (either civil or criminal in natures)."

1.1.1 The Strengths and Weaknesses of Command-based Regulation

The force of law is the backbone of this regime for it gives the regulators the power to enforce rules as the system may bring criminal prosecutions against offenders who breach the regulation, which is regarded by legal scholars as the strength of this regime. The enforcement of law may require the regulators to screen entry to an activity through a licensing process and to oversee and ensure compliance. Nevertheless, there are difficulties accompanying this regime and a number of legal scholars identify these as weaknesses.

Firstly, the relationship between regulators and the regulated plays a significant role in regulation. Information on a regulated sector is key and subsequently, regulators may need to rely on the regulatees especially when drafting and enforcing rules. Therefore, “the regulator, accordingly, requires some assistance from the regulated firms” and there is a chance that the relationships might become too close and this arguably may lead to ‘capture’. (Hood, 1994; p. 21) According to Hood, ‘capture’ is the quest of the regulated firms to leverage this relationship in order to pursue their own interests rather than those of the public.

Secondly, this regime is perceived as unnecessarily complex with over-prescriptive rules, and the establishment of more rules over time can be seen as restrictive, causing over-regulation and legalism. This is due to the very nature of rule-making that tends to employ over-inclusive rules that are too general, made ‘across the board’, when addressing one particular issue. Due to this complexity and the phenomenon of over-regulation, it can be argued that

such a regime could inhibit development or competition as well as might discourage entry into a regulated sector.

Thirdly, as mentioned earlier, regulators require information in order to come up with an appropriate setting of standards. However, the standards or rules can be very broad since regulators usually produce a general rule instead of formulating rules specific to each regulated institution, which is technically difficult. (Baldwin et al., 2012) This brings the focus back to the point made earlier whereby the general rules result in a broad and over-inclusive regime. Also, it is worth noting, the rules set by regulators today may be appropriate and relevant today but they may not be in future, especially when the regulated sector involves a rapidly evolving technology.

Fourthly, since command-based regulation is a broad and complex system and can be compounded by the over-inclusive and prescriptive rules, enforcement in this regime can be difficult. Moreover, the regulatory scope can be too narrow or too broad and subsequently may result in regulators not able to regulate certain conduct or may also restrict certain activities that should not be restricted. In view of this disadvantage, one might find loopholes in the system and this may lead to 'creative compliance' – "the practice of avoiding the intention of the law without breaking the terms of the law." (Baldwin et al., 2012; p. 110, Gunningham, 1998)

In addition, it was mentioned that regulators would need to form a relationship with the regulated actors to obtain information about the regulated area. It is not only that this relationship may lead to 'capture' whereby the regulated take the advantage of the relationship, any frictions between the two, which would also be possible, may lead to resistance. Instead of having good

communication between them this might result in a poor flow of information, which in turn may jeopardise compliance. (Braithwaite and Makkai, 1994, Gunningham, 1998) In view of the difficulties described above, there are other alternative regulatory techniques, advocated in the regulatory literature than that of command-based regulation. The alternative regimes have features that would be able to facilitate regulators to address the difficulties that exist in the command regime.

1.2 Incentive-based Regulation: Dominium law

A classic form of regulation involving the central government "setting a standard or rule for behaviour and providing sanctions for non-compliance," (Morgan and Yeung, 2007; p. 81) – or referred to as imperium law,[17] as has been argued previously, has some weaknesses. The first alternative regulatory technique that can be considered by a state is an incentive-based regulation, which does not employ a highly restrictive and rule-bound regulatory environment. (Daintith, 1994, Ogus, 1994) By adopting such a regime, the regulator delegates the regulatory tasks to non-actor states to a certain extent.

For instance, instead of imposing restrictive rules in regulating pollution of a river, negative or positive taxes can be imposed on regulatees in order to persuade them to behave accordingly, (Baldwin et al., 2012) or the state could also opt to buying private compliance and policy by offering incentives i.e. grants or soft loans from public funds. Daintith (1994) describes this technique

[17] Morgan and Yeung used the term 'imperium' and 'dominium' law as another way to refer to command-based and incentive-based regulation respectively.

as dominium-based regulation. Another example is the differential tax on leaded and unleaded petrol. (Baumol, 1972, Ogus, 1999, Driesen, 2010)

This regulatory technique is also commonly practiced by states that have sufficient wealth and particularly if the regulated sector involves and requires significant public or federal funding, such as human stem cell research. As argued by Daintith (1994) and reiterated by Morgan and Yeung (2007), regulation through imperium laws could be the only option for government in earlier centuries, but today government has enormous resources of public funds as an alternative.

1.2.1 Imperium versus Dominium Law

Whilst the risk of regulatory capture is highly likely in command regime, this risk can be reduced if a state adopted dominium law. This is because in the latter regime, regulators do not have a close relations and do not have to be in constant communication with the regulated, as they would need to in command-based regulation.

As for the complexity, the two regimes are not so different. Markovits (1987) argues that the implementation of an incentive regime (or dominium law) involves highly complex systems of rules and taxation systems for instance, are not known for their simplicity. As for enforcement, this regime might have to use a similar approach, inspection and enforcement mechanisms as adopted in command-regulation, especially to ensure that the regulatees do not attempt to avoid their liabilities to taxation. (Braithwaite, 1981-82)

Theoretically, in terms of financial and compliance cost, it is more cost effective to regulate using imperium laws since the “cost of compliance are

placed wholly on those whose behaviour is to be affected. In contrast, dominium laws will cost the state and taxpayers" money since the incentives will be deployed from the public fund. (Daintith, 1994; p. 470) However, for regulated sectors which would require government funding, and when it is in the interest of the government to develop the sectors while having the wealth to do so, dominium law or an incentive-based regime would be a better option. Also, when legislative cost is considered, this system would be more cost effective.

Whilst some states prescribe some standards backed by legal force and accordingly require mandatory compliance, others might set out specific guidelines. It can be argued, as described earlier that a set of rules in legislation has legal force and therefore regulators have the mandate to enforce the rules, whereas guidelines are merely guidance and not binding. The adequacy of the latter method can then be questioned especially when it normally binds only those who fall within the ambit of the body who produced the guidelines.

For instance, ministries, which are entities in the public sector, may produce guidelines as an alternative regulatory approach to compel those involved in the regulated sector and receiving in funding from the government to obey the guiding rules. Therefore, others who are in the private sector and do not receive any funding would be left unregulated even though they are still involved in the regulated sector. It is also likely for them to be left totally unregulated if there is no law of the land in existence. Arguably, one could contend dominium regime alone would not be an effective approach.

However, one may counter argue by pointing out the current trend of collaborative work between two parties from public and private sectors due to some factors such as talents or funding or technologies that each of the sectors

may lack. In the area of scientific technologies, the Innovative Medicine Initiative in Europe is a prominent example of the public-private partnership. (Goldman, 2012, Laverty et al., 2012, Goldman et al., 2013) If the public party is funded or associated with the government, the obligation to obey the rules imposed by the funding body would be extended to the private party. This means the private party in this collaboration cannot escape but to abide with the rules.

In addition, a few court proceedings have been employed by legal scholars to show soft law such as guidelines or code of practice can sometimes be used and referred in legal proceedings. For instance, a legal study on secondary legislation by Ganz (1987) provides some instances where code of practice, which is a soft law or secondary legislation, has been given legal force by courts. Therefore, the argument that guidelines do not have a legal force can be said as not entirely accurate and absolute.

As has been shown above, whilst an imperium approach secures compliance with regulatory rules that have legal force through legislation and regulated firms and individuals are 'threatened' by the statutory sanctions, dominium approach relies on incentives and guiding rules, which inherently non-binding but can be adopted by court in certain circumstances. To some extent one would argue the former approach would be more effective especially it involves law that is applicable to all the associated stakeholders be they from private or public sector.

Nevertheless, it is also important to note such approach inevitably requires a high political cost whereby government or state would need to find existing relevant legislative power or to assume the burden to introduce new

legislation, which often involves a lengthy and complex process. It could also be quite a burden for regulators to collect information in order to draft appropriate rules, and the enforcement may involve high compliance costs. This study further discusses the benefits and limits of adopting either emporium or dominium law in regulating hSCR, in the subsequent chapter.

1.3 Communication-based Regulation

Communication-based regulation involves techniques adopted by state or government to "persuade and educate members of the regulated community or those affected by the regulated activity to act in a manner that will facilitate the achievement of regulatory goals. In so doing, targeted audience or groups are enriched with available information, which would then enable them to make informed choice." (Morgan and Yeung, 2007; p. 96) In this regime, actors in a regulated sector are required to fulfil their obligation "*to inform* – where information is deployed strategically." (Baldwin et al., 2012; p. 106) An example of a sector regulated through this regime is the supply of information on food and drinks. (Yeung, 2005)

Instead of regulating the production process and output, this regime aims to allow customers to make an informed-decision on the acceptability or satisfactoriness of the products or services. (Baldwin et al., 2012) This shows, unlike classical regulation as discussed earlier, the regulators' role and approach to create awareness or educate regulated firms or individuals or those who are affected by the regulated area is central to the communication-based regulation.

1.3.1 Mandatory Disclosure

In an effort to encourage providers to disclose information that is not false and misleading, the disclosure could be made a mandatory obligation. According to regulatory scholars, this instrument “may therefore be thought to combine both command and control regulation with market-based mechanisms” whereby it “compels disclosure, backed by some form of criminal or civil sanctions for non-compliance.” (Morgan and Yeung, 2007; p. 97) Yeung (2005) regards this regime as a creative regulatory regimes, which illustrates how a conventional and classical regulation – command-based regulation - can be combined with market-based techniques creating a hybrid policy instrument despite the rigid typologies of the regulatory tools and techniques.

1.3.2 Voluntary Disclosure

In some circumstances, providers may see the incentives to disclose information, such as the production process or the quality of the products and safety of a service, in an attempt to attract customers or purchasers for market competition. This is particularly prevalent when integrity could be used as one of the promotion factors especially when a community has certain strong moral, ethical, as well as cultural values. For instance, a cosmetic company would willingly or voluntarily disclose information of the production of cosmetic products that does not condone unethical activities (Lush, 2015, PETA, 2015, Royal Society for the Prevention of Cruelty to Animals, 2015) such as animal

testing of cosmetic products.[18] This is viewed by some sections of the public as unethical, unacceptable, and undesirable.

Another instance is the production of food that is in compliance with a fair trade policy to protect small-scale farmers and workers from being marginalised. (FAIRTRADE, 2015) One way of doing this is to attach a logo to indicate that a product or a service provider is produced in an ethical way or recognised by regulators as meeting the standards in place. This technique could assist members of the public in evaluating the quality of the products. Since voluntary disclosure technique involves self-voluntariness, it can be said that there is an element of self-regulation, another alternative regime, which is discussed in the following section.

1.3.3 Public Communications Management (Exhortation)

Alternatively, the regulators or state through government official could also supply information directly to the public. According to scholars, "…there are various distinct but related ways in which public communications management may be used to implement government policy…" (Yeung, 2005; p. 372) namely through guidance (explanation) and publicising compliance performance (exclamation and excoriation).

Whilst an explanation approach may involve a broad public consultation conducted by the state government, the latter approach involves a regulator's involvement in publicising performance indicators of the regulated actors (leaders and laggards) - to reveal the success or failure of the regulated to

[18] For instance, Lush operates with a policy against animal testing and condones ethical buying and has been openly and actively campaign for its policy through its products and printed materials.

comply with the rules, or regulators could also promote (naming) those who are exemplary in compliance or defaming (shaming) those who are not complying. The thought of being publicly known as unethical could be a threat for the regulated to avoid non-compliance.

1.3.4 Command- and Disclosure Regime: Overcoming Problems

As with other regulatory regimes discussed previously, the disclosure regime is not faultless. Legal scholars have identified a number of problems with the regime; it has been argued that "users of the information disclosed…may make mistakes…fail to use the information properly…lack the resources and expertise to research issues fully…" (Baldwin et al., 2012; p. 120) In addition, some sectors might be highly risky or ethically contentious and this method would be deemed as inappropriate. Particularly, when the disclosure is made voluntarily without additional measures taken by regulators to ensure the information disclosed is accurate.

One could argue that voluntary disclosure regime alone might not be adequate to safeguard the publics from being exposed to harm. It is therefore important for regulators to exercise mandatory disclosure. In addition, if policymakers feel that the risks associated with the regulated sector may be profound, and to only 'inform' affected parties would be deemed as inappropriate, then it may be justified to make all the necessary steps in information disclosure discussed above legally binding. (Ramsay, 1998)

1.4 Self-Regulatory-based Regulation

The next two sections focus on two different regimes built on a similar underlying principle, which is self-regulation. This thesis first discusses the first version, self-regulation, to give an idea of the basic concept and its advantages as well as highlighting its disadvantages to show why the second version, enforced self-regulation, would be a better option.

1.4.1 Self-Regulation

Self-regulation can be one of the regulatory mechanisms adopted by a state whereby the regulatory function is delegated to other entities or organisations. According to regulatory scholars, (Black, 1996, Ogus, 1995, Ayres and Braithwaite, 1992) self-regulation involves individuals (or a group of firms) who have the control over their membership and behaviour. A private association usually adopts this mechanism whereby compliance could be voluntary and incentives usually play a part within this system.[19]

Compared to a state or independent regulatory body, self-regulators have an easy access to the regulated members and are therefore able to command a higher level of expertise and technical knowledge, enabling them to understand the regulated area better than regulators from outside. Accordingly, they would be able to set standards that are acceptable and reasonable to the regulated parties. Therefore, this regime does not require a high cost to obtain information and due to a high level of acceptability, it should then lead to a higher level of compliance. The cost for monitoring and enforcement would be

[19] For instance, an association of medical practitioners who self regulate provides members with recognition in terms of licensing and certificates but in return, requires members to comply with the standards laid down by the self-regulators (the association).

low and any changes to the rules could be easily implemented due to informal nature of the regulatory process and instead of the public, the regulated members will bear the regulated costs.

Notwithstanding the advantages discussed above, it can be argued that it is uncertain for self-regulators to secure compliance by relying only on incentives. If this approach failed, they would need to seek help from the state, which indicates one of the limitations to this regime. For instance, the sector of estate agents is one examples of a self-regulated area, which it was argued requires legislative measures that are practised in command regime. (Graham, 1994; p. 196) In addition, the mandate and accountability of the self-regulated parties could also be questioned as to whether or not they recognise public interest other than their own ends, given that they are free from state controls and not liable to consult other parties who may be affected by their conduct.

With the absence of liability to consult other affected parties, the fairness in this system is also questionable. Regulatory scholars have pointed out a few problematic situations such as (i) the issue of anti-competitiveness in legal services with regards to the pricing and quality (Ogus, 1995, Abel, 1988, Domberger and Sherr, 1989); (ii) the introduction of a new regime as a result of complaints on the professionalism in legal services (Baldwin et al., 2004, Clementi and Great Britain. Department for Constitutional Affairs., 2004); and (iii) the exclusion of third parties in negotiations to establish self-regulatory regimes.

In the light of the concerns mentioned above, it was argued that these issues could be resolved with the implementation of legislation; [20] the involvement of individuals or groups with democratic legitimacy to ensure a justified mandate or objectives. It is also important to ensure self-regulators are subject to other controls such as statutory provisions and goals, ministerial guidelines, parliamentary oversight, judicial review, and a few more other ways to ensure accountability, (Baldwin et al., 2012; chapter 8) which are the features of enforced self-regulation.

1.4.2 Enforced Self-Regulation

Enforced self-regulation is similar to self-regulation except, in this regime, government has an active role to scrutinise and approve the rules set by the regulated firms and ensures the enforcement of the rules through auditing and inspection. (Parker, 2002, Coglianese, 2010)[21] Furthermore, the enforcement of the ratified rules is backed by legal force and therefore any violations are punishable by law. (Ayres and Braithwaite, 1992; chapter 4) Self-regulation lacks both of these attributes. In addition, the level of cost to obtain information and compliance is lower since the regulated firms can draft their own rules, but public interest can also be protected since the authority will scrutinise the rules and could demand for more stringent rules. (Coglianese, 2001)

[20] The Director General of Fair Trading's report, *Timeshare* (London, 1990) contends that legislation was necessary because the self-regulation of the Timeshare Developers' Association was not working.

[21] Ayres and Braithwaite's notion is similar to Parker's definition of 'meta-regulation', where the state regulatory authority does not regulate directly but rather delegates the regulatory task to corporations whose regulators will then be monitored and audited by the authority.

Regulatory scholars also argue this could be a better option for countries with lack of enforcement resources given that it may not cost the public purse, as the regulated will bear the cost. Also, non-compliance would initially be subject to disciplinary measures, rather than legal action. Unlike command-based regulation, the introduction of rules would not be broad and over-prescriptive but precise and institution-specific. Therefore, any changes or amendments to the rules can be easily made and enforced based on the specific needs tailored to the context of each of the regulated institutions. The enforcement of these tailored rules would also be more efficient and effective since the self-regulators would have more knowledge compared to the authority - external regulators.

However, similar to other regulatory techniques, enforced self-regulation also have disadvantages. (Ayres and Braithwaite, 1992, Fairman and Yapp, 2005) For instance, “ill-intentioned, ill-informed, or inefficient firms may fail to devise appropriate rules” and small regulated firms such as small and medium enterprise (SMEs), according to the scholars, are unlikely to do anything “until they are galvanized by the government regulator” (Baldwin, 1995; pp. 150-151, Baldwin et al., 2012) and they see compliance “as a periodic negotiation with an inspector.” (Fairman and Yapp, 2005, Baldwin et al., 2012; p. 151) It was also suggested that small industries tend not to favour this regime and therefore will be less compliant compared to when they are under command regime or when the system involves ‘education’ approach. (Fairman and Yapp, 2005; p. 512)

It shows it is not an easy task for regulators to determine which regulatory technique is optimal for a certain regulated sector. Furthermore, as has been clearly pointed out, each technique usually involves mixtures of

different techniques. The next section summarises the discussion of regulatory techniques by suggesting that a government may have to employ a hybrid regulation to formulate an optimal regulatory framework appropriate for a regulated sector.

1.5 Hybrid Regulation

As has been shown earlier, merely introducing rules backed with legal force to threaten regulated actors with the possibility of legal actions does not necessarily guarantee compliance. There are other regulatory techniques that can be adopted to ensure a more efficient and effective means to ensure compliance. Murray and Scott (2002) contend, mixtures of different regulatory instruments and institutions usually result in desirable regulatory outcomes.

A regulatory body which employs a command-based regulatory system as the backbone of a regulatory system would be able to increase the level of compliance by educating and giving guidance to the regulated members on the rules through communication-regulation instead of leaving them with the statutory rules, which are usually broad and complex. To address the nature of the rules mentioned, some regulators could also employ self-regulatory system that is enforced by law (enforced self-regulation) where more specific and less complex rules can be formulated. Furthermore, such a method would be more desirable and affordable for a jurisdiction that has the wealth instead of only relying on legislative measures, which would involve a lengthy and complex process.

By having these alternatives, a state could design a hybrid regulation, (see figure 1) which is more flexible and a state would have different

instruments to be employed appropriately according to the context and risk. As asserted by Gunningham and Grabosky (1998; p. 444), “certain instruments would be held in reserve, only to be applied as and when other instruments demonstrably fail to meet pre-determined performance benchmarks.” For instance, in enforced self-regulation, it has been mentioned earlier that violations to rules in this regime would initially be dealt with disciplinary steps but however, legal action, which is held in reserve as a last resort can be imposed if needed.

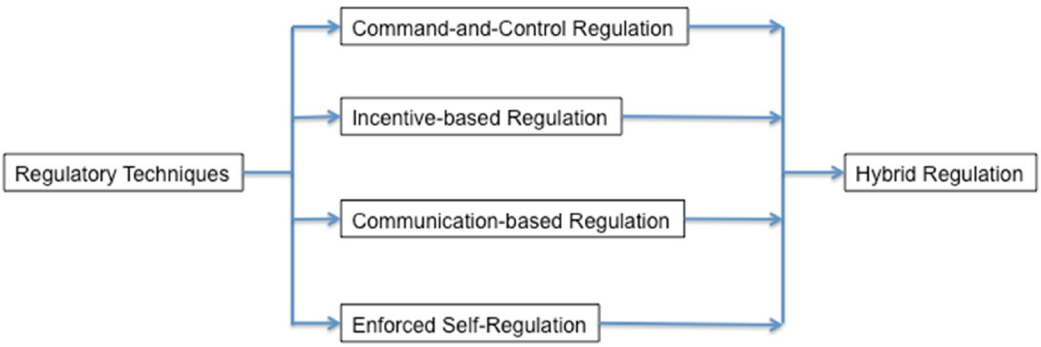


Figure 1: An example of a composition of a hybrid regulation

It has been shown that a state or government could achieve a desirable outcome by adopting more appropriate regulatory techniques. However, most importantly, regulators need to also consider appropriate techniques to enforce the rules because the rules are not self-enforcing.

2. Enforcement Techniques and Compliance Measures

Enforcing, according to Baldwin and Black (2008), is one of the five regulatory tasks outlined in their proposed DREAM framework, which aims to provide regulators with an understanding of the broader regulatory process. Through enforcement, regulators will apply the policies, rules, and tools established, on the ground. The previous section provides an overview of the range of regulatory techniques that can be used to achieve regulatory goals. After having established a desired regulatory technique appropriate for the regulated sector, the choice of enforcement strategies comes next in order to improve regulatory performance and secure compliance.

As with the traditional view on the use of legal force as the common or classical regulatory technique, Morgan and Yeung (2007; p. 151) point out, "there is a tendency in common parlance to equate enforcement with the prosecution of offences: the formal invocation of the legal process in order to impose sanctions for violating the law." As highlighted by Hutter (1997; p. 14), "enforcement of the law did not refer simply to legal action but to a wide array of informal enforcement techniques including education, advice, persuasion and negotiation. These were used by all law enforcement officials, but came into particular prominence in the regulatory arena." These different techniques are the features of smart regulation proposed by Gunningham and Grabosky (1998).

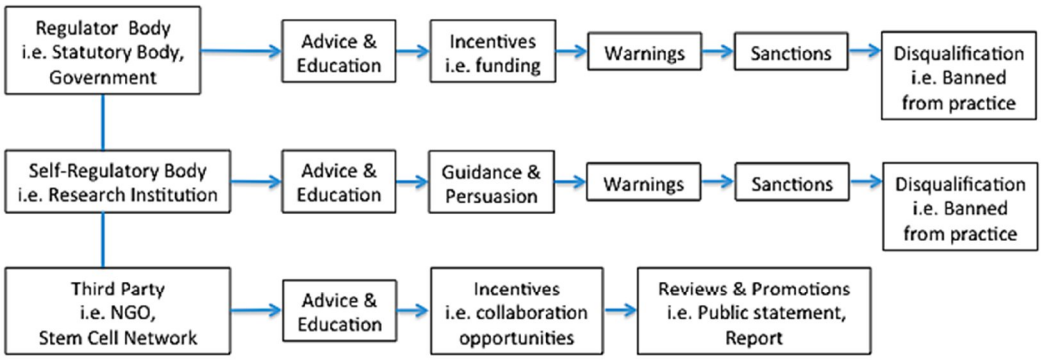


Figure 2: An illustration of a smart regulation based on the theory proposed by Gunningham and Grabosky (1998). It involves different regulators and different types of enforcement measures.

According to regulatory scholars, enforcement requires regulators to deploy a strategy or it may also involve a mixture of different strategies, which would facilitate regulators to achieve a desired outcome on the ground. (Hutter, 1997, Braithwaite, 1982, Hawkins, 1984, Ayres and Braithwaite, 1992)

2.1. Formal and Informal Practice: Sanctioning and Compliance Strategies

Hawkin (1984; p. 4) in his study, explains the two different strategies of enforcement, which he refers to as compliance and sanctioning strategies. On the one hand, a "***compliance strategy*** seeks to prevent a harm rather than punish an evil" and on the other hand, "central to a ***sanctioning strategy*** is a concern for the application of punishment for breaking a rule and doing harm." One could affiliate sanctioning strategy with formal practice, which heavily relies on legal action as an enforcement technique. Hawkins (1984; p. 4) further defines this strategy as a penal style, a term borrowed from Black, which is referred to as a regulatory approach that "prohibits certain conduct, and it

enforces its prohibitions with punishment." Compliance strategy can be seen as a form of informal practice, which "relies upon *bargaining* to attain conformity" - a conciliatory style, as observed by Hawkins (1984; p. 4).

In the formal practice of rules enforcement, the use of law is central to this style as it involves legal process, which could eventually lead to legal sanctions. The focus of the regulators with this style is to punish non-compliant regulatees. One could also argue that this technique falls within the description of act- and harm-based interventions, among the three-stage model of interventions proposed by Baldwin and others (2012). In this technique, the regulators intervene when dangerous act and harm can be identified and sanctions will then be applied.

Unlike formal practice, regulators who adopt informal practice prioritise the necessity to avoid or prevent harm. The focus is to achieve the broad aim of the regulation rather than its violation. In this strategy, regulators are more prone to secure conformity to rules and seek to prevent harm rather than focussing on punishment – compliance strategy. (Hawkins, 1984)

Instead of intervening at the stage when non-compliant activities can be identified and harm has been done, the intervention or regulatory actions are taken pre-emptively to prevent a dangerous act or undesirable situation – preventive action. (Baldwin et al., 2012) For instance, regulators with this strategy will require those who wish to enter into a regulated sector to obtain approval and licence beforehand. With such measure, regulators would be able to discourage violation of rules and avoiding harm (see figure 3).



Figure 3: The classification of different enforcement strategies

However, it does not mean, legal action such as sanctioning will not be engaged in the enforcement process, but it is a matter of last resort. Sanctioning strategy is also important especially to guarantee protection and to discourage violations or unethical conducts. Hence, instead of choosing one strategy, it seems that mixture of both would be more optimal and may strengthen the enforcement technique. As observed by Ayres and Braithwaite:

> *"This era of crude polarization of the regulatory enforcement debate between staunch advocates of deterrence and defenders of the compliance model is beginning to pass. Increasingly within both scholarly and regulatory communities there is a feeling that the regulatory agencies that do best at achieving their goals are those that strike some sort of sophisticated balance between the two models." (1992; p. 21)*

2.2 The Limits of Rules: Why Not Formal Practice?

Apart from legal action, as pointed out earlier, there are other mechanisms of enforcement techniques, regarded as informal practices that are central to the enforcement of rules. This section further discusses why it would not be sufficient and arguably not apt for regulators to only adopt formal practice that is heavily relying on regulatory rules and why informal practices

are adopted not only to overcome the issues of the latter but that their adoption can also be regarded as central to strengthening rules enforcement.

The discussion will focus on the question as to why legal or regulatory rules are not self-sufficient by employing Black's (1997) explanations of the limitations of rules in three forms of description. First, the *inclusiveness* in terms of the categories or definitions used in the rules, which could make it difficult to determine whether or not a certain subject to be regulated falls within the definition. Second, the *indeterminacy* as to whether or not the rules in place are applicable for a particular occasion, which can be problematic if the rules are perceived as vague or ambiguous. Third, the *interpretation* of the rules could be both a solution to the two limitations mentioned earlier and a limitation in itself.

This section also highlights Black's argument, which is based on Hart's observation as captured in (Morgan and Yeung, 2007; p. 156) that "rules cannot apply themselves, they rely on others for their application. To be applied, rules have to be interpreted…" In order to ensure a precise and accurate interpretation of a rule, it can be said that it is not only important for policy makers to provide an accurate interpretation but the interpretation also needs to be conveyed to the regulated community and those associated with the regulated area. This brings attention to the enforcement methods other than legal action - informal practices that could be used.

2.2.1 Regulatory Conversation

> *"A conversational use of rules is a further way in which some of the problem of rules, notably those of interpretation, inclusiveness and entrenchment, can be overcome…" (Black, 1998) in (Morgan and Yeung, 2007; p. 181)*

To overcome the limitations of rules discussed above, regulatory scholars particularly Black (1998), suggest 'regulatory conversations' between regulators and members of the regulated community. Such an approach is particularly relevant in the area of emerging technologies such as human stem cell research whereby the area is rapidly evolving and developing and can often result in the ambiguity of the application of an existing regulation. The practice could take place in three different ways, namely (i) rule application; (ii) supervised rule-formation; and (iii) monitoring and enforcement.

As described by Black (1998), through 'rule application', the regulated actors are given guidance on the application of rules and this process can be done informally or it may also be part of a formal process. It may or may not have legal status. Through this process, the regulated may get assurance and address any uncertainty about the application of the rules. Such a measure could ensure enforcement, which should be able to secure compliance.

As for the 'supervised rule-formation', it involves conversation on the application of a general set of rules, such as those laid down in primary legislation, to a particular regulated firm, in such a way that the firm could then formulate more specific rules in harmony with the general rules. This, however, is subject to approval by the authority – as described under enforced self-regulation. In this way, the rules can be less complex and this may encourage the regulated to be more compliant, hence, compliance could be secured. In addition, the rules formulated by firms can easily be adjusted as and when needed due to changes in the regulated sector. Regulators could then rely on the expertise and knowledge of the regulated firms to design the rules, which

means any changes needed can be made by the firms instead of going through a lengthy process in command-based regulation.

Conversation also occurs during the process of monitoring and enforcement. It may also involve guidance in terms of the application of the rules and what would happen in case of violations. Through this approach, regulators could promote and encourage as well as ensuring compliance with a particular set of rules – compliance strategy. As highlighted above, this approach involves early intervention and aims to secure conformity to rules and this measure may give more advantages to the regulators in order to stimulate compliance.

The discussion above has demonstrated that similarly to the regulatory techniques, there is no single optimal approach to enforcement of rules to ensure compliance. As noted by Black (1997), there are limitations to the rules. Further, as observed by Morgan and Yeung (2007; p. 152), these problems are "rooted in the uncertain and imprecise character of human communication" and they further stress that "communication is also the avenue through which some of the limitations of rules can be overcome."

Hence, it can be argued that it is comprehensible and justified as to why informal practices such as education, advice, et cetera, which can be regarded as forms of communication-based regulation, are being practised by regulators as captured in Ayres and Braithwaite's (1992) 'pyramid of regulatory strategies' and Gunningham's (1998) theory of smart regulation, as mentioned above.

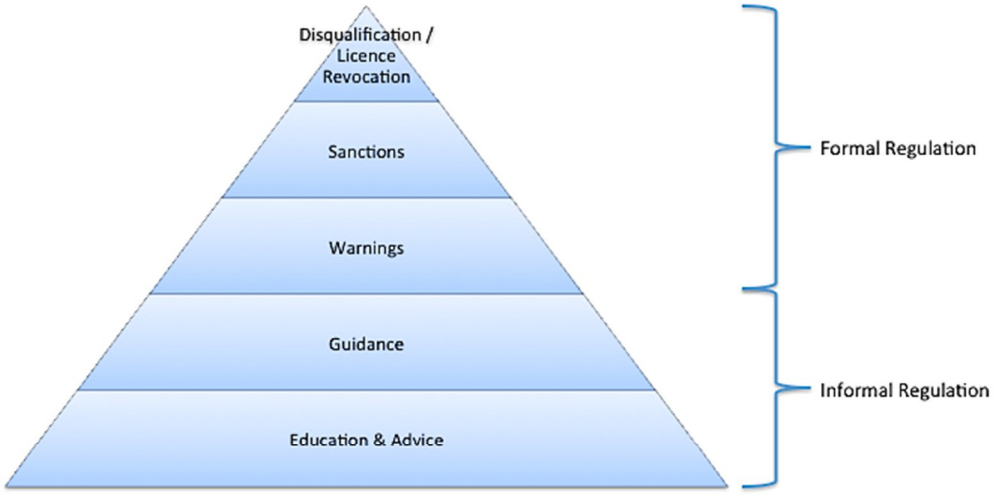


Figure 4: An illustration of the pyramid of enforcement strategies to show the rigorousness of enforcement strategies increases from informal to formal regulation

3. Legal Transplants

This section discusses the role and functions of legal transplants in aiding the development of a legal system. The discussion starts with a brief introduction of what legal transplants are, by referring to some earlier scholarship, before highlighting the potential of legal transplants. It also demonstrates how common this practice is, by giving some examples of the transplantation of law from one country to another that has been in practice in the past. More specific instances in the regulatory domain of human stem cell research will be given in the following chapter.

3.1 What is Legal Transplant?

Legal transplant is a term used to refer to the transfer of laws and legal or institutional structures and systems from one jurisdiction to another. It has

been argued that the transplant can be imposed by a more powerful or influential entity or voluntarily imported as desired by the host-countries. (Watson, 1993) Whilst in the past, the occurrence of legal transplantations were predominantly due to imposition through expansion of an empire, today, such a phenomenon largely and increasingly occurs due to international legal harmonisation projects in various sectors. The transfer could encompass entire legal systems or just a few or even single legal principles. (Gillespie, 2006)

However, it is worth mentioning that there are differing views among scholars with regards to this regulatory phenomenon, particularly between Legrand (1997) and Watson (1993). Whilst the former uses his 'mirror theory' [22] to argue that legal transplant is logically impossible, the latter, however, contends through his 'free transplant theory' that such a phenomenon is indeed possible given the plethora of legal transplants within Western countries that show the key approach to law changes is in fact through 'borrowing'.

This question, whether or not legal transplant is possible, is further challenged by Chen-Wishart (2013), who maintains that such a question is wrong or rather not the right question because both arguments are simultaneously right and wrong.[23] This thesis recognises the differing views on the theoretical debate highlighted in the above, but will not examine or explore the issue further, but will simply posit the fact that legal transplants have been utilised to develop legal systems across the globe.

[22] According to Legrand, rules are only skin-deep and words and he further argues that law only responds and 'mirrors' the society.

[23] According to Chen-Wishart, whilst 'Legrand's 'mirror theory' is contradicted by the plethora of successful transfers among western societies…Watson's 'free transplant theory' loses sight of the law's unavoidable susceptibility to some external pressures from culture and society'.

3.2 Legal Transplant: A Common Practice

The scholarly work of Watson above and many other scholars demonstrate that the phenomenon of transplantation exists both in the ancient and modern world. The legal systems and institutions across the globe can be said have developed through legal transfers from the earliest recorded history until today.

Watson (1993), for example, provides some instances of legal transplants during ancient times involving similar provisions concerning a goring ox identified in the Laws of Eshnunna (dated at least in the 18th century B.C.), the Babylonian Code of Hammurabi (dated not later than the early 17th century B.C.), and in Exodus that has no certain date but was believed to exist after the Code of Hammurabi. It was argued that the obvious similarities of style and substance eliminate the idea of parallel legal development and was believed to have an ultimate common source.

As for the legal transplants that occur in the modern age, it has been argued that "most of the private law of the Modern Legal System of the Western World, apart from the Scandinavian, derives more or less directly from either Roman Civil Law or English Common Law." (Watson, 1993; p. 22) A more recent example of legal transplantation in the Western world would be the extensive transfer between West and East Germany following the national reunification. (Horn, 1991)

Even though the conventional debates and comparative discourse on legal transfers, as argued by Gillespie, are largely focussing on Western industrial countries, it is worth noting that such a phenomenon is also

predominant in East Asian countries despite this being under-researched and under-theorised. (Gillespie, 2006) The legal transfer in this region is mostly due to the colonisation by Western countries.

For instance, whilst British commercial legislation and common law were transplanted into Myanmar, Malaysia, Hong Kong and Singapore during British colonial rule, the Dutch, French, and Spanish and Americans imported their civil law and jurisprudence in Indonesia, Indochina and the Philippines respectively. (Gillespie, 2006) This shows that the importation or transplantation of a legal system is common practice.

3.3 Developing Legal System Through Legal Transplants

As observed by Gillespie (2006), transfer of law does not only occur because a host-country has no choice but to accept the transplanted legal elements as happened during the period of colonisation. Such a practice also exists as a matter of choice particularly among the developing states, which are "motivated by a desire to 'catch up' with developed countries." (Gillespie, 2006; p.11)

For instance, Japan imported European civil law and state institutions, and China as well as Thailand, which were not entirely colonised compared to neighbouring countries, adapted or imported continental civil law systems. (Gillespie, 2006) It must be submitted that, given Malaysia has also received British laws and the fact that the country still retains the colonial laws today, despite them being amended or substantially revised, this indicates that legal transplantation could be continued to be used as an option to develop a legal system.

This is particularly relevant in the area of human stem cell research in Malaysia, where the legal system is yet to be established. Malaysian policymakers could consider looking into other countries' systems, especially those of commonwealth countries who share the same legal roots, to develop a legal system for human stem cell research. For instance, its neighbouring country, Singapore, which is also a former British colony, has in fact continued adopting a UK regulatory model.

3.3.1 Interpretation and Adaptation of Transplanted Rules

The Singaporean Bioethics Advisory Committee's Report on stem cell research clearly states that the country developed a regulatory approach that is based on the UK model, but with some modifications made to conform to the local cultural context. This shows that the transplant of laws does not mean same rules and interpretation will be used in the host-country.

Therefore, it is important for local regulators to adjust the application and interpretation of the law appropriate to the local sets of morality, cultural and legal traditions. Particularly, for countries in the Asian region that upheld a strong cultural values, including Malaysia and Singapore.

In Singapore, for instance, even though the English contract and commercial law are transplanted into the country's legal system, the Singaporean courts do not apply the same interpretation and application of the same law. Indeed, the local interpretation of this law is very different to the English tradition. This is due to the fact that unlike in the UK, Confucianism is a core component in Singaporean society and this cultural value has a strong place in the community. Consequently, court proceedings in Singapore and

interpretations of rules could be influenced by doctrine contradictory to the English courts.

Malaysia is comparatively similar to Singapore whereby both countries have an abundance of legal traditions. Whilst Confucianism is a core element of moral and cultural traditions in Singapore, Islamic principles and values are central and observed by the majority in Malaysia along with other important religious teachings such as Christianity and Buddhism (see Chapter 1). Any ethical and legal issues that involve religious matter such as the use of human embryos will inevitably require clarifications and consideration from religious groups.

Apart from the ability to interpret the imported law differently by taking moral and cultural values into account, it is also equivalently vital to have aptitude experts or stakeholders to cope with the development and complexities of the transplanted law. In his work, Salim (2009) argues and emphasises the importance of having scholars and experts who have the ability to keep up with the legal development. He contends that the inherent impossibility of legal transplants is not because of differences of legal culture but "the inability of lawyers in a post-colonial state to keep pace with the increasing complexities of the laws." (2009; p. 182)

His argument centred on the differing views identified in the rulings made by the High Court and Court of Appeal in the Malaysian case of *Soo Boon Siong @ Saw Boon Siong v Saw Fatt Seong & Soo Hock Seang*.[24] In addition

[24] For instance, Salim, in his analysis argues, using legal rulings made in the English jurisdiction on which the Malaysian companies act is based, to show that the issues of the companies as partnership assets and separate legal personality should not be discussed separately by both the courts and he points out that no reference was made to any legal precedents.

to that argument, he suggests that the Malaysian Companies Act 1965, which was based on the company legislation in the United Kingdom was only updated in 2007 – its first major update since its introduction, even though company legislation in the UK itself and other former colonies has undergone a series of major reforms. (Salim, 2009)

This final section of this chapter has shown that it is feasible for Malaysian policymakers to explore the potential of adapting the aforementioned regulatory systems of other countries, especially the commonwealth members, should Malaysia seeks to improve and develop its current regime, particularly for human stem cells research. Nevertheless, in order to do so, it is important to recognise that (i) it may be possible or rather required to adapt imported rules according to the local traditions and moral values and (ii) the ability of local authorities to keep up with the pace of the ever developing regulation for this area is also a fundamental feature that needs to be taken into account.

Conclusion

This chapter has provided a background of different regulatory techniques that could be adopted. As has been shown, even though the classic regulation has the legal force to ensure enforceability of the rules, the regime, however, could not guarantee compliance due to the limitations of the rules. This is compounded by other difficulties surrounding command regime such as the lengthy and complex legislative process involved and high legislative cost.

In view of the limitations and difficulties associated with the classical regime, instead of commanding regulated firms or individuals to adhere with

legal rules, regulators could also choose other alternative techniques. As has been discussed previously, regulators could offer incentives or attempt to communicate and persuade the regulated and educate those affected by the regulated activity or delegate the regulatory task to experts of the regulated sector.

Each of the alternative techniques mentioned here has its advantages that can be useful to address difficulties and limitations of command regime, nevertheless, they would still require legal force. For instance, as pointed out by regulatory scholars, communication-based regulation is an instrument that is based upon a requirement of information disclosure that is backed by sanctions for non-compliance, and aimed to create awareness among the regulated and those associated in the regulated area.

It is therefore, worth noting that even though communication-based theory fundamentally aspires to assist judgements that would result in compliance, sanctions nevertheless, still play an important role in securing compliance. This means that regulators could not solely depend on other alternative regimes and hoping to achieve regulatory goals without emphasising the penalty that would take place in case of non-compliance.

This thesis, therefore suggests that the adoption of different techniques would enable regulators to develop an optimal regulatory framework to achieve desirable regulatory goals. Similarly, rules could be enforced through formal or informal practice. However, to ensure more effective enforcement measures, regulators may need to adopt both practices. For instance, whilst regulators could encourage compliance through explanation and persuasion, legal threats

such as sanction could have a significant impact on ensuring and discouraging incompliance.

To conclude, this chapter not only provides background of the different techniques of regulation and enforcement measures, but also the analysis of the legal system development through legal transplantation. The final part of this chapter has borrowed a number of examples from different branches of law, such as commercial law, to present the relevance and the role of legal transplants, which could be applied for other areas, especially for human stem cell research, which is the focus of this study. The analysis of legal transplants theory will be revisited in the following chapter to illustrate the implementation of this technique in the case of human stem cell research.

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Introduction

The aim of this chapter is to map out the existing regulation of human stem cell research (hSCR) adopted by countries around the world in order to explore the breadth of current regulatory practice. This can be linked to the type of regulatory and enforcement techniques described in the previous chapter.

In so doing, firstly, this chapter discusses the role of regulation in the hSCR domain to show that many countries resort to legislation, and this is mainly due to concerns over biomedical activities involving human embryos. In view of this, the focus of the discussion in this chapter is primarily on the area of human embryonic stem cell (hESC) research.

Secondly, the examination continues to explore the regulatory framework at the global level. This chapter attempts to cover as many countries as possible by referring to existing databases available online and published literature as the main resources.

Thirdly, the examination of the framework focuses on a few selected Commonwealth countries where their regulatory system is studied in more detailed by examining their techniques from legally binding regulation, non-binding rules through guidelines to other techniques.

The Malaysian framework is also briefly explored to indicate the absence of a comprehensive framework resulting in research activities can be described as being under-regulated. This chapter explores the possibility to ‘borrow’ or ‘transplant’ rules or systems into jurisdictions with less developed frameworks, especially in the case of Malaysia. This is done by comparing the Malaysian

system with the frameworks in other countries that share a common root of a British colonial legal system (Commonwealth).

1. Regulating Human Stem Cell Research: The Role of Regulation

As has been widely discussed by regulatory scholars, regulation is adopted to control social behaviour, whether to permit or prohibit certain types of behaviour or activities. (Baldwin, 1997, Gunningham, 1998, Hood et al., 2001, Morgan and Yeung, 2007, Baldwin et al., 2012) Central to its role, in the context of stem cell research, the regulation introduced for this area is designed to regulate research activities by emphasising certain boundaries. More specifically, it can be said that its introduction is primarily a result of the need to address the ethical issues surrounding the area in general as well as the particular issues pertaining to the protection of human embryos and human subjects.

Based on the theoretical regulatory discussion in the preceding chapter, one could infer that regulation plays a crucial role through which policymakers and regulators can dictate whether certain activities are permitted or prohibited. Likewise, it can also be used as a means to mitigate the ethically challenging issues surrounding this promising area. According to regulatory theorists, there are two prominent views as to how regulation could function to influence desired behaviour and to achieve regulatory aims or goals.

The first view is a narrower view whereby it involves state-sanctioned actions “by establishing, monitoring, and enforcing legal rules.” (Morgan and Yeung, 2007; p. 3) The second view is a broader one, which does not

necessarily require legal sanctions, but “encompassing all forms of social control, whether intentional or not, and whether imposed by the state or other social institutions.” (Morgan and Yeung, 2007; p. 3) Instead of separating these different views, this thesis will demonstrate that both views are significant and they complement each other, at least in the area of hSCR.

As has been demonstrated earlier, even though classical regulation featuring legal action is important it is however, not always effective. There are other regulatory instruments and enforcement techniques that can be employed to complement command-and-control regime in ensuring an optimal outcome. Isasi and Knoppers (2006a; p. 2479) argue, “the recent South Korean scandal regarding fraud and gross ethical violations in stem cell research illustrates that legislative responses are neither necessary nor sufficient. What are needed are authoritative regulatory oversight, scientific integrity, transparency and accountability.”

2. Regulatory Framework at the Global Level

One should ask how countries at the global level regulate hSCR. Scholars have previously shown the clear and profound differences in regulatory approaches towards hSCR globally - a regulatory phenomenon known as ‘regulatory patchwork’. Some countries introduced legislation to legally dictate and draw the line between permitted and prohibited activities, others regulate through guiding rules reinforced through funding opportunities. (Knowles, 2004, Tauer, 2004, INCURABLE, 2006, Caulfield et al., 2009b, Peckman, 2009, Salter, 2007, Waldby and Salter, 2008)

The rest of this section briefly illustrates the regulatory approaches and techniques employed by a range of countries to illustrate regulatory variation. Information on this was obtained from a number of websites and online resources. For instance, the International Consortium of Stem Cell Networks, the Hinxton Group (Hinxton, 2006) and StemGen (Touché, 2015) have compiled databases of regulatory approaches for countries across the globe, whilst EuroStemCell [25] maintains a stem cell map among the European countries.

Based on the international surveys and scholarly works written on the regulatory aspects of hSCR, which largely focused on embryonic stem cell research, the varying regulatory frameworks can be mapped out by looking at (i) the regulatory strategy employed; (ii) the approach towards human embryonic stem cell research; (iii) and the enforcement mechanism.

2.1 Regulatory Strategy

Figure 5 below presents the data from the existing online databases and published literature to show the frameworks and approaches taken by countries worldwide. Most of the countries considered here have established legislation to regulate research activities involving the derivation and use of stem cells from human embryos. Moreover, there will be new emerging jurisdictions (in hSRC domain) such as Taiwan whose National Legislation of Human Embryo and Embryonic Stem Cell Research Act is currently under review (Taiwan Society for Stem Cell Touché, 2015, Research, 2012) and Portugal whose

[25] EuroStemCell is an initiative funded by European Commission's Seventh Framework Program, which "unites more than 90 European stem cell and regenerative medicine research labs in a coordinated effort to engage with the public about our science."

Portuguese Council of Ministers have approved a bill of law to regulate the use of stem cells for research. (Library of Congress, 2011)

Region	Country	Legislation
Asia	Japan	Law concerning regulation of human cloning techniques and other similar techniques 2001(Chen, 2009, Chen and Gottweis, 2013)
	Singapore	Human Cloning and Other Prohibited Practices 2004
	South Korea	Bioethics and Safety Act 2008 (Replace 2005 Act)
Australia and Oceania	Australia	Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (Amending 2002 Act)
	New Zealand	Human Assisted Reproductive Technology Act 2004-092
Europe	Belgium	Law on Research on Embryo in Vitro 2003
	Czech Republic	Act on Research on Human Embryonic Stem Cells and Related Activities and on Amendment to some Related Acts – 227/2006
	Denmark	Act on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects in 1992 Act on Medically Assisted Procreation in Connection with Medical Treatment, Diagnosis, and Research 1997
	Finland	No. 488/1999 Medical Research Act
	France	Research on the Embryo and Embryonic Cells (Law No. 2004-800 (Replace Bioethics Law 1994)
	Germany	Stem Cell Act 2002
	Greece	Law 3089: Medically Assisted Human Reproduction
	Iceland	Regulation No. 568/1997 on Artificial Fertilization
	Italy	Law 40 2004
	The Netherlands	Embryos Law 2002
	Lithuania	Law on Ethics of Biomedical Research was introduced in 2000 and later amended in 2004
	Malta	Bill for the Embryo Protection Act 2012
	Norway	Act Relating to the Application of Biotechnology in Human Medicine in 2003
	Poland	Medical Profession Act 1996
	Portugal	Law No. 32/2006 on Medically Assisted Procreation (new legislation has been proposed) (Kawakami et al., 2010)
	Russian Federation	Law on the Temporary Prohibition of Human Cloning 2002
	Slovakia	Law No. 277/1994
	Slovenia	Law on Biomedically Assisted Fertilization was enacted in 2000
	Spain	Law on Biomedical Research 2007 (Amending Law 35/1988 and Law 45/2003)

	Sweden	The Genetic Integrity Act 2006:351
	Switzerland	Federal Act on Research Involving Embryonic Stem Cells (StRA) in 2003
	United Kingdom	Human Fertilisation and Embryology Act 1990 (as amended in 2008)
North America	Canada	Act Respecting Assisted Human Reproduction and Related Research 2004
	US	Executive Order 13505 2009
Central America and the Caribbean	Costa Rica	Decreto de la Regulacion de la Reproduccion Asistida (No. 24029-s) (in Spanish)
	El Savador	Constitucion Politica de la Republica de El Salvado (in Spanish)
	Panama	Codigo de la Familia 1994 (in Spanish)
South America	Argentina	Clonacion (Decreto 200/97) (in Spanish)
	Brazil	Law No 11.105 (Bio-Safety Law)
	Chile	Law in 2006
	Colombia	Codigo Penal Colombiano (in Spanish)
	Peru	LEY No. 27337 and Ley General de Salud
	Ecuador	Constitucion Politica de la Republica de Ecuador de 1998 (in Spanish)
Middle East, North Africa, and Greater Arabia	Israel	Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 5759-1999
	Jordan	Jordanian Stem Cell By-Law No 10 2014
	Tunisia	Law 01-93 2001
Sub-Saharan Africa	South Africa	National Health Bill 2003

Figure 5: Legislation relevant to human embryonic stem cell research across the globe

As the title implies, some of the legislative enactments were introduced to regulate the derivation of hESCs and some were established to specifically regulate the use of established cell lines for research purposes. Some of this legislation has been amended a number of times for various reasons such as to reflect the policy changes of the jurisdictions (i.e. Australia), to address the rapid changes of the technology (i.e. UK), and to improve protection for research subjects (i.e. South Korea). (Clay, 2013) Some countries, such as Ecuador and El Salvador have not yet enacted legislation but could rely on relevant articles within their respective constitutions. Malta has not yet

legislated this area but a bill has been introduced (2012a). The development of its legislative process is unknown.

Other countries opt to express their moral stance through the ratification of international conventions. (Convention on Human Rights and Medicine, 1997b, Convention for the Protection of Human Rights and Dignity, 1997a) Article 18 of the Convention on Human Rights and Medicine 1997 [26] clearly dictates, "where the law allows research on embryos *in vitro,* it shall ensure adequate protection of the embryo" and "the creation of human embryos for research purposes is prohibited." It is noteworthy that the UK is not a signatory to this Convention particularly due to the latter provision.

Additionally, apart from law and the conventions, some countries have also promulgated non-binding guiding rules through Guidelines, Codes of Practice, or ethical recommendations published in the form of Reports, as presented in Figure 6 below.

Country	**Guidelines / Code of Practice/ Ethical recommendations**
Australia	NHMRC National Statement of Ethical Conduct in Human Research (2007)
China	Guidelines for Research on Human Embryonic Stem Cells 2004
India	Guidelines of Stem Cell Research and Therapy, introduced in 2007
Iran	Specific National Ethical Guidelines for Biomedical Research 2005
Saudi Arabia	The 2003 Fatwa (edict) issued by the Fiqh (Islamic Jurisprudence) Council of the Muslim World League[27]
Singapore	Ethics Guidelines for Human Biomedical Research 2015 Ethical, Legal and Social Issues in Human Stem Cell

[26] Article 1 of the Convention on Human Rights and Medicine states "Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respects for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."

[27] The fatwa or religious decree (binding rules) provides a regulatory framework from the religious perspectives for stem cell research in the Kingdom of Saudi Arabia.

	Research, Reproductive and Therapeutic Cloning 2002 (Report) Human-Animal Combination in Stem Cell Research 2010 (Report) * Guidelines for Private Healthcare Institutions Providing Assisted Reproduction Services (for the use of human embryos, not specifically for stem cell research)
Taiwan	Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research 2007
Japan	Guidelines for Derivation and Utilization of Human Embryonic Stem Cells 2009
Canada	Updated Guidelines for Human Pluripotent Stem Cell Research 2010
United Kingdom	Human Fertilisation and Embryology Authority's Code of Practice UK Stem Cell Bank Steering Committee's Code of Practice
USA	National Institute of Health (NIH) Guidelines of Human Stem Cell Research 2009

Figure 6: Guiding rules established to govern human stem cell research

Whilst some Guidelines were introduced as the only regulatory tool in certain countries (i.e. India and Japan), while in others (i.e. UK, Australia, Canada), they were established as supplementary rules. For instance, India has no law on hSCR and only promulgated rules on the derivation and use of human stem cells including embryonic stem cells through its national Guidelines.

In the UK, the law only governs the derivation of hESCs, but the regulatory power over the use of established hESCs lines is extended to another authority, which has established an additional set of rules i.e. the HFEA's Code of Practice, to supplement and complement the law. Another body, UK Stem Cell Bank is also mandated to regulate this area, particularly the use of established cell lines, even though unlike the HFEA, this body is not a statutory body and its regulation is not through formal law. Nonetheless, the

bank plays an important role in managing ethical concerns around hESC in the UK. Similarly, in Canada, the use of established stem cell lines does not fall within the law's ambit, but is governed instead by the Updated Guidelines. Also, in the US, the NIH Guidelines on stem cell research (2009d) were established to implement an Executive Order (2009c).

The scope of Guidelines varies from one country to another. Whilst the Japanese Guidelines only regulate the use of hESCs, the Canadian Guidelines on the other hand, govern all kinds of human pluripotent stem cells. Even though the stipulated guiding rules do not have legal force to ensure compliance, their application is supported with governmental funding schemes. For instance, the Canadian government requires researchers to comply with the Guidelines in order to receive government funding from their three central funding agencies.[28]

Similarly, any research proposals in China should comply with the rules stipulated in the Guiding Principles in order to receive funding from the government. In the US, the federal government also has adopted the same approach whereby researchers will be granted federal funding only if they comply with the NIH Guidelines. However, it is worth noting that, the guiding rules through this approach are not applicable to research activities that are funded by other sources.

[28] Namely the Canadian Institutes of Health Research (CIHR), the National Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council, also known as the Tri-Agencies.

2.2 Regulatory Approach

Even though the attempt to consensually put a ban on human reproductive cloning across the globe has not been achieved yet, almost every country in the world has expressed their stance against the procedure. Unlike reproductive cloning, the approach towards the derivation and use of hESCs is however strikingly diverse among the countries. Some countries allow hSCR using cell lines derived from embryos created through therapeutic cloning or *In Vitro* Fertilisation (IVF). Some other countries only permit the use of cell lines procured from 'spare' IVF embryos - prohibiting the creation of human embryos for research purposes.

At one end of the spectrum, there are countries that prohibit both activities mentioned above but allow the importation of established hESCs. At the other end, there are countries that prohibit any form of hESC work at all. However, within this category, some countries impose conditional prohibitions (marked with an 'X' in Figure 3 below). For instance, the prohibition in France comes with various qualifications, which means the prohibition is not absolute.

It is also worth mentioning about the uncertainty of the legal situation in some countries such as the Republic of Ireland. It was previously thought that embryo research was banned under the Constitution and there were attempts to enact legislation intended to explicitly ban embryo research, however, these did not succeed. It became obvious, when the Irish Supreme and High Court ruled in the *M.R. v T.R. case (Protection of Human Embryos Bill 2008b)*, that

embryos that are stored (cryopreservation) and created *in vitro* are not protected under the Constitution. (2009a, 2006c)[29]

Countries	Permit ES cells derivation from spare and created embryos	Permit ES cells derivation from spare embryos only	Prohibit ES cells derivation but allow importation	Prohibit ES cells derivation and use
Australia	X			
Brazil		X		
Canada		X		
China	X			
Chile				X
Denmark		X		
France				X*
Germany			X	
Iceland	X			
India	X			
Italy				X
Japan	X			
Lithuania				X*
Mexico	X			
The Netherlands				X
Norway				X
Poland				X
Singapore	X			
Slovenia		X		
Slovakia				X*
South Africa	X			
South Korea		X		
Spain	X			
Switzerland		X		
UK	X			
US		X		

Figure 7: Regulatory approach among countries in the world towards the derivation and use of human embryonic stem cells for research purposes. (Ireland, Report on Assisted Human Reproduction 2005a) Note on each jurisdictions' legislation.[30] (* Non-absolute prohibition)

[29] "Article 40.3.3 of the Irish Constitution provides constitutional protection for the 'unborn'. It is not clear whether protection applies from fertilisation or from some subsequent point in the process. This lack of clarity has implications for the provision of AHR services in Ireland. Clarification can only be sought in two ways: either from the Supreme Court or by way of constitutional referendum."

[30] **Australia's** initial legislation in 2002 only permitted the derivation of "excess ART embryos", however, changes were made in 2006 to allow therapeutic cloning through

Somatic Cell Nuclear Transfer (SCNT). **Brazil's** legislation allows the derivation of embryonic stem cells from excess IVF embryos that have been frozen more than 3 years. **Canadian government** introduced Guidelines that specifically prohibit the creation of human embryos including through SCNT for the purpose of deriving embryonic stem cells. The use of excess embryos to derive embryonic stem cells is permitted but researchers are encouraged to use embryonic stem cells that are established from research funded by the government through the national registries established by the CIHR. **China's** Guiding Principles allow the derivation of embryonic stem cells from "spare" IVF embryos and embryos created through IVF (donated and consented) and SCNT. **Chile's** law prohibits the derivation of human embryonic stem cells and any cloning of human beings for any purpose through any techniques. **Denmark** made changes to its legislation in 2003 to allow research involving the destruction of "spare" IVF embryos to derive stem cells that can later be used to improve treatment for human diseases. **French** law prohibits the derivation and use of human embryonic stem cells but subject to qualifications. **Germany** imposes a strict prohibition on the use of human embryonic stem cells, its derivation in the country and importation from other countries through its legislation (cite 27). Exception is however made on imported embryonic stem cell lines established before January 1, 2002, and they must be derived from "spare" embryos only. **Iceland** prohibits embryonic research in 1997. Changes were made in 2008 resulted in a more lenient rule whereby the derivation of stem cell lines is permitted provided it is licensed and only spare human embryos can be used. SCNT is also permissible provided such approach is essential. **India's** national Guidelines permit the establishment of cell lines from "spare" IVF embryos but restrict the creation of human embryos either by IVF or SCNT only to derive stem cells. If the latter is deemed necessary and essential by researchers, they need to offer justifications. **Italy** introduced a law that not only bans research on human embryos, which includes the creation of human embryos for research purposes and the derivation of embryonic stem cells but also aimed to prevent the use of "spare" embryos by limiting the number of embryos created for IVF purposes. **Japan** has amended its Guidelines, which allow the derivation of embryonic stem cells from "spare" IVF embryos. Therapeutic cloning through SCNT procedure is permitted but reproductive cloning is banned. In **Lithuania's** law is rather strict where not only it further prohibits the use of human embryos and its creation for biomedical research, but also its use is only permissible if "the medical risks for the embryo are not disproportionate to the potential benefits." **Mexico's** ban on stem cell research was reversed in 2004 and the government permits research on "spare" IVF and SCNT-created embryos. The law in **Netherlands** bans the creation of human embryos for research purposes. **Norway** prohibits research to be carried out on fertilized eggs, human embryos, and cell lines derived from fertilized eggs or human embryos. Cloning human embryos regardless for reproductive or research purposes is also banned. In **Poland**, hESCR is regarded as contradicting the constitution, which uphold "the legal protection of the life of every human being." Furthermore, the definition of "conceived children" in the Medical Profession Act 1996 includes human embryos resulting in a legal perspective, which concludes that both cloning and the derivation of embryonic stem cells are prohibited by the law. In **Singapore**, the permissibility of the creation of human embryos through SCNT and the use of "spare" IVF embryos to derive stem cell lines. However, the recommendations encourage researchers to use existing embryonic stem cell lines for research and the need to establish new cell lines is permitted if deemed as an alternative procedure. Therapeutic cloning is permitted on a case-by-case basis. **Slovenia** prohibits the creation of human embryos both for research and cloning. The law, however, allows the use of human embryos for research provided they were initially created for reproductive treatment but no longer used for that purpose. In **Slovakia**, the use of human embryos is prohibited if it is not for the embryos' benefit. The law states, "Research without medical indication is not

It is worth noting that laws of most of jurisdictions that allow hSCR using human embryos for research purposes clearly stipulate that the use is subject to and not beyond fourteen days. Also, it is subject to ethical approval and license.

2.3 Enforcement Mechanisms

Besides the differing approaches to the promulgation of rules, the establishment of a regulatory body also varies among the countries. Whilst countries with legislation established statutory regulatory bodies, others without legislation resort to non-statutory bodies including government agencies or ministries. Given that this technology involves multi-faceted issues i.e. moral, legal, religious and scientific aspects, ethics committees comprising members from different backgrounds and expertise also play an important role. Hence,

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permitted on human embryos or fetuses." **South Africa's** National Health Act permits research using human embryonic stem cells derived from "spare" IVF and SCNT-created embryos. The new **South Korea's** Act clearly stipulates provisions that ban human reproductive cloning and the production of embryos not for reproduction purposes. Nevertheless, the use of "spare" IVF embryos and SCNT are allowed provided the former have exceeded maximum storage and the latter is meant for research aimed to curing diseases. **Spain's** 2007 law allows SCNT research. Even though therapeutic cloning is allowed, the law maintains the banning of reproductive cloning. **Switzerland's** law allows the use of "spare" IVF embryos only for the derivation of stem cell lines. The creation of embryos for research purposes is forbidden (CITE 83). The law requires justification from researchers as to why there is a need to establish human embryonic stem cells instead using animal embryos in order to be granted with licence. **UK** through its legislation, which permits the derivation of human stem cells from "spare" IVF embryos, IVF- and SCNT-created embryos for research purposes, hybrid embryos, transgenic, chimeric as well as any other embryos that contain both human and animal DNA but the former is predominant. **US** President's Executive Order 2009 has lifted ban on funding for the use of human embryonic stem cells for research purposes. The Order allows the derivation and use of stem cells from "spare" IVF embryos.

the establishment of ethics oversight bodies is rather pivotal and may exist at different levels i.e. institutional, local, and national.

Country	Regulatory Body	Establishment
Australia	National Health and Medical Research Council (NHMRC)	Statutorily-mandated
Canada	Local Research Ethics Board The CIHR's Stem Cell Oversight Committee	Government-appointed
China	Ministry of Science and Technology (MOST) Ministry of Health.	Government-appointed
France	French Biomedicine Agency French National Consultative Committee of Ethics, which has issued a number of opinions on stem cell research	Statutorily-mandated
Germany	Central Ethics Commission on Stem Cell Research	Government-appointed
Iceland	Bioethics Committee	
India	National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) Institutional review committee	Both are government-appointed
Japan	The Ministry of Education, Culture, Sports, Science, and Technology Institutional Review Board	Both are government-appointed
UK	Human Fertilisaton and Embryology Authority (HFEA) UK Stem Cell Bank Steering Committee	Statutorily-appointed Government-appointed
US	National Institute of Health	Government-appointed

Figure 8: Regulatory bodies established to govern human stem cell research

As highlighted in Figure 8 above, the regulatory bodies play an important role to enforce the rules in place through reviewing and evaluating research proposals, granting licences, and monitoring and overseeing research activities. It should be noted that the figure does not include advisory committees or councils, which are not directly involved in rules enforcement.

2.4 Regulatory Strategy by International Organisations

The United Nations and the European Union are the intergovernmental organisation and a politico-economic union of 28 member states in Europe, respectively. They too are involved in the regulation of the use of human embryos for hSCR. On the one hand, the United Nations through its General Assembly has approved a non-binding Declaration on Human Cloning (2005b; paragraph d) attempts "to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life." The Declaration is however perceived as a weak and non-binding statement that does not affect the national policy of stem cell research of the member nations. (Jarrell, 2006, Caulfield, 2006, Langlois, 2013)

On the other hand, the European Union involves itself directly in the regional effort to advance this area through its series of framework programmes for research and technological development. The European Union has previously funded hESCR under the Sixth Framework Program except research activities involving the destruction of embryos. The human embryonic stem cell registry was also funded under the same programme in order to fully utilize the existing cell lines. The same position is retained in the Seventh Framework Programme.

The European Commission has also established an external advisory body, the European Group on Ethics in Science and New Technologies (EGE) through the European Political Strategy Centre (IPSC). The group is provided with a legal mandate through European Union's Commission Directive. Its function is to provide the Commission with independent and high quality advice on ethical aspects of science and new technologies including embryo and hSCR research in a form of Opinions.

In addition, there are European Union Directives (DIRECTIVE 2004/23/EC, DIRECTIVE 2006/17/EC, DIRECTIVE 2006/86/EC, DIRECTIVE 2012/39/EU) established to provide a unified regulatory framework for the use of tissue and cells for human application to ensure a high standard of quality and safety. (Hogle et al., 2014) These Directives require the European Community to ensure their jurisdictional regulation is benchmarked against the standards provided and the provisions stipulated in the Directives are implemented into national law of the Member States.

2.5 Variations of the Regulatory Framework at the Global Level

The variations of the framework discussed in the above sections are recaptured in Figure 9 below by using selected countries as examples to show that there is no single or uniform approach to regulate this area. There are countries that have established law to govern the use of human embryos in general, and specific law to regulate the use of established embryonic stem cells both of which are binding. Others have introduced guidelines that are not binding whereby funding control can be used as an alternative approach to encourage compliance.

	Framework	Countries
Type of Regulation	General Law (use of embryos for research)	Australia, Canada, Chile, Denmark, France, Lithuania, Netherlands, Norway, Poland, Slovenia, Slovakia, South Korea, Spain, United Kingdom
	Specific Law (use of stem cells for research)	Germany, Switzerland,
	Guidelines / Code of Practice (use of stem cell research	Australia, China, Canada, India, Japan, United Kingdom, Singapore, US
Enforcement Body	Government-appointed and affiliated body	Canada, China, Germany, India, Japan, US
	Statutorily-created	Australia, France, United Kingdom

Figure 9: Some examples of the variations of regulatory framework of hSCR at the international level

3. The Commonwealth Nations

This chapter proceeds by outlining the framework of the Commonwealth countries in more detail given they share similar colonial legal roots with Malaysia. The aim is to demonstrate that instead of adopting one regulatory technique, the countries studied employ different techniques to regulate hSCR. One could maintain, this provides opportunity for a comparative analysis of the strengths and weaknesses of the different options based on the theoretical study outlined in the preceding chapter.

In addition, the databases mentioned above i.e. StemGen, EuroStemCell cover only a few countries of the total 53 Commonwealth countries. This thesis

proposes that in future, it would be beneficial to have a similar database that is more comprehensive specifically for the Commonwealth nations.

Given the long list of Commonwealth countries, it would be ideal to explore the policy of each of the member countries in a future research project. However, for present purposes, this chapter highlights only a few Commonwealth countries that are already surveyed by the resources mentioned above as well as other literature works. These countries represent all of the five continents of the Commonwealth: (i) South Africa (Africa); (ii) India and Singapore (Asia); (iii) Canada (Americas); (iv) UK, Malta, Cyprus (Europe); and (v) Australia (Australia and Oceania).

3.1 Regulatory Framework and Approach Among the Commonwealth Countries

3.1.1 Europe

The United Kingdom can be deemed as “a leading jurisdiction for the advancement of human embryonic stem cell research.” (Isasi and Knoppers, 2006b; p. 449, Touché, 2015) The UK regulation allows stem cells derivation both from surplus human embryos and those specifically created for this purpose as clearly stipulated in the HFE Act (1990 (as amended in 2008)). The Act was established primarily to govern the use of human embryos for reproductive treatment and only secondarily for research purposes.

A statutory regulatory body, Human Fertilisation and Embryology Authority (HFEA) was established and given the mandate to implement and enforce the law. (Salter, 2007) The oversight for the use of established stem

cells falls under the governance of the UK Stem Cell Bank through its Committee. Apart from the HFE Act 1990 (as amended in 2008) and the HFEA's (Code of Practice), the UK Stem Cell Bank Committee has also published its own Code of Practice, to specifically govern the use of established cell lines in line with the former documents.

Unlike the UK, Cyprus prohibits creation of human embryos for research purposes and the procurement of hESCs for research. There is no specific law but it expresses its stance through the ratification of the Convention on Human Rights and Biomedicine (1997). Cyprus has its National Bioethics Committee that is statutorily established under the Bioethics (Establishment and function of the National Committee) Law of 2001.

As briefly mentioned earlier, Malta has not yet introduced legislation to regulate the use of human embryos and its derived stem cells. This was demonstrated in a recent study conducted by Busardò and colleagues (2014). However, there is a bill entitled 'Embryo Protection Act 2012', introduced to provide for the protection of human embryos and other ancillary matters. If it were passed, Malta's stance to prohibit the use and creation of human embryos for research purposes would have legal force.

Nevertheless, its Bioethics Consultative Committee has produced opinions on stem cell research to express its position towards hSCR. According to the report, the use of adult stem cells for research does not give rise to any ethical issues, but the use of human embryos as a source of stem cells regardless of whether they are specifically created or 'surplus' is equally ethically objectionable and presumably prohibited. The bioethics committee

also has produced opinions on the use of iPSCs (2004b) and the practice of stem cell banking (2011).

3.1.2 Asia

Unlike Malta and Cyprus, India and Singapore have a similar position to the UK. Both countries allow the procurement of stem cells from human embryos created for research as well as from surplus IVF embryos. The Indian Council for Medical Research has released its revised National Guidelines for Stem Cell Research (2013). The guidelines specifically require all research involving the use of human stem cells to be guided by the general principles stated in the Ethical Guidelines for Biomedical Research on Human Participants 2006.

Singapore has not yet introduced specific legislation for hSCR but its current framework is modelled on the UK system. The government chose to enact the Human Cloning and Other Prohibited Practices Act 2004 to forbid reproductive cloning as an initial step. It has established a Bioethics Advisory Committee (BAC), which is mandated as a policy advisory body to the government. (Arnold, 2006) The BAC has promulgated a report (2012c), which contains recommendations for hSCR. The committee has also recently released Ethics Guidelines for Human Biomedical Research in June (2015c).

3.1.3 Australia and Oceania

Similar to Singapore, Australia's regulatory framework is also based on the UK system, specifically the licensing system. Australia's response to the

proposed use of human embryos for research purposes began in 2001. (Harvey, 2008, Harvey, 2010) In the following year, the government enacted the Prohibition of Human Cloning Act (2002a) and Research Involving Human Embryos Act (2002b) to specifically regulate the use of human embryos for research purposes. The Acts banned all kinds of human cloning except IVF for reproductive purposes. Only 'surplus' embryos from infertility treatment can be used for research activities subject to National Health and Medical Research Council's (NHMRC) approval.

Nevertheless, a significant change was made to both acts in 2006 to allow the creation of human embryos for research purposes while retaining the ban on reproductive cloning. (Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act, 2006d) The NHMRC Licensing Committee is the mandated authority statutorily established.[31] Australian law requires the use of established cell lines to be in accordance with the relevant guidelines including the NHMRC National Statement of Ethical Conduct in Human Research (2007). [32]

3.1.4 Americas

In North America, the Canadian legal system governing the use of human embryos has also gone through significant development over time. After a number of national guidelines were introduced since 1978, the Assisted Human Reproduction Act was finally enacted in 2004 (hereafter, AHR Act). The Act governs the use of IVF-derived human embryos for all purposes, including

[31] As stipulated under section 13 of the Research Involving Human Embryos Act 2002.

[32] See Schedule 1(5).

for research. (Rivard and Hunter, 2005) The regulations of hSCR are laid out in the Updated Guidelines for Human Pluripotent Stem Cell Research in 2010, which supersedes all of the previously released guidelines. The mandate to approve and oversee research activities involving human pluripotent stem cells falls within the ambit of the Canadian Institutes of Health Research's (CIHR) Stem Cell Oversight Committee.

3.1.5 Africa

It has been reported that stem cell research is rather prominent in South Africa and the country has established the first stem cell bank in the region. (Kassah, 2011) The South African National Health Act (NHA) (2003b) include provisions specifically dealing with the use of human embryos and stem cells. The Act prohibits reproductive cloning[33] but allows therapeutic cloning, which means researchers are allowed to derive human stem cells from IVF-created embryos and from embryos specifically created for research purposes. (Kassah, 2011) This Act is also complemented by guidelines produced by the South African Medical Research Council. The National Health Research Ethics Council (NHREC) was established by the Act and mandated to promote and monitor compliance of other South African ethics committees within relevant legislation and regulations.

The distinctions of the differing regulatory techniques adopted among the countries are shown in the table below. It clearly demonstrates that whilst some countries employ both legislation and guiding principles, others only regulate through the latter. Some however have not introduced any rules but merely

[33] Chapter 8, Section 57 (commencement date of section 57: 1 March 2012)

ratified international conventions. It is questionable which approach is more appropriate and adequate to ensure compliance in this contentious research area. This is discussed in the forthcoming sections after the outline of Malaysia's current system.

Continent	Country	Stem cells derivation from surplus embryos	Stem cells derivation from embryos created for research	Legislation	Guidelines / Code of Practices/ Reports	Regulatory Body
European	UK	Allowed	Allowed	Human Fertilisation and Embryology Act 1990 (as amended in 2008)	HFEA Code of Practice Code of Practice for the Use of Human Stem Cell Lines 2010	Human Fertilisation and Embryology Authority (HFEA) Stem Cell Bank Steering Committee
	Cyprus	Prohibited	Prohibited	-	-	National Bioethics Committee
	Malta	Prohibited	Prohibited	-	-	Bioethics Consultative Committee
Asia	India	Allowed	Allowed	-	National Guidelines for Stem Cell Research 2013 Ethical Guidelines for Biomedical Research on Human Participants 2006	National Apex Committee for Stem Cell Research and Therapy
	Singapore	Allowed	Allowed	Human Cloning and Other Prohibited Practices Act 2004	Ethics Guidelines for Human Biomedical Research 2015 Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic	Bioethics Advisory Council

					Cloning 2002	
	Malaysia	Allowed	Prohibited	-	National Guidelines for Stem Cell Research and Therapy 2009	National Stem Cell Research and Ethics Sub-Committee
Australia and Oceania	Australia	Allowed	Allowed	Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006	National Statement on Ethical Conduct in Human Research 2007 Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2007	National Health and Medical Research Council
Caribbean and Americas	Canada	Allowed	Prohibited	Act Respecting Assisted Human Reproduction and Related Research 2004	Updated Guidelines for Human Pluripotent Stem Cell Research 2010	Canadian Institutes of Health, Research's Stem Cell Oversight Committee
Africa	South Africa	Allowed	Allowed	National Health Act 2003	Ethics in Health Research: Principles, Structures and Processes 2004	National Health Research Ethics Council (NHREC)

Figure 10: The regulatory framework for hSCR among selected Commonwealth countries

3.2 Regulation of Human Stem Cell Research in Malaysia

Unlike many other countries whose regulatory systems have been widely discussed and published, Malaysia's regulation in this domain has been under-examined in the literature. Since there are limited resources available with regards to the Malaysian system, most of the discussion here will be largely based on the national Guidelines, an Advisory Report (2013) produced by the Academy of Science of Malaysia, and information obtained from relevant governmental websites.

3.2.1 Ethical Issues and Regulatory Instruments

As with other countries, the ethical issues surrounding hSCR in Malaysia are mainly centred on human embryonic work and reproductive cloning as well as the use of remnants of aborted foetuses.[34] HSCR using adult stem cells is more ethically acceptable and less contentious. There is no specific legislation, but the Ministry of Health (MOH) has introduced the National Guidelines for Stem Cell Research and Therapy (2009b). The guidelines clearly stipulate that both therapeutic cloning and reproductive cloning are not allowed.[35] In addition to the national guidelines, Malaysian Medical Council also produced guidelines to regulate hSCR. One could argue that if compared with other countries' guidelines, the Malaysian guidelines might appear outdated, because they have not been revised or updated since their promulgation i.e. they do not cover new practices such as iPSCs.

[34] See Chapter 3, Section 1 of the Advisory Report.

[35] See paragraph 8, 9 and 10 of the Guidelines.

The Ministry of Health (MOH) is the authority responsible for regulating this field. In addition to the MOH, there are other agencies established under its patronage namely the Medical Research and Ethics Committee (MREC) [36] and the National Stem Cell Research Ethics Sub-committee (NSCRE sub-committee). The NSCRE sub-committee was established through the Guidelines specifically to govern hSCR. Between the two agencies, the former seems to have more authority especially in granting licence and/or approval for research, whereas the latter has the task to review research applications.

It should be noted that the ambit of MREC is only limited to research that involves staff members of the ministry, its facilities, and human subjects.[37] In view of this, it is questionable whether this means research activities especially in the private sector that do not involve the Ministry are subject to MREC's oversight and approval. Additionally, since the involvement of human subjects is the criteria for the involvement of MREC, does this mean non-clinical hSCR is also not subject to MREC's approval and oversight?[38] This could mean that there is a regulatory gap between the public and private sectors, as well as non-clinical and clinical research activities – a fragmented framework.

[36] MREC was established "with the primary purpose to ensure the protection of the welfare and rights of human participants. The objective of MREC is to provide independent guidance, advice and decision on health research / specific protocol involving human subjects conducted by staff members of Ministry of Health (MOH) or involving MOH facilities and is responsible for approval of involvement of human subjects in research."

[37] "MREC ethical approval is needed when you are using staff members of Ministry of Health (MOH)/ MOH facilities and involving humans as subjects in your research…"

[38] MREC defines human subjects as "living individuals whom an investigator conducting research obtains: (a) data through intervention or interaction with the individual or (b) identifiable private information."

The lack of regulations that are up-to-date with the current development of hSCR is compounded by regulatory framework that is fragmented, and the absence of legislation for regulators to legally impose rules, monitor, and take legal action. This is because unlike clinical research,[39] non-clinical research is only governed by the guidelines, which are not legally binding. In view of this, one could extrapolate; current research activities are not comprehensively regulated. As has been emphasised in Chapter 1, unregulated hSCR could not only jeopardise the protection of human embryos and human subjects, but also the development of hSCR.

This is similar to the situation in South Africa, before the enactment of chapter 8 of the National Health Act. Pepper (2009) argues that research activities in South Africa were operating in a regulatory vacuum due to the fragmented rules and guidelines. The term 'regulatory vacuum' is used by many scholars to demonstrate the regulation of stem cell research and therapy as well as other emerging technologies that is lacking of important measures i.e. legally binding rules, licensing, and monitoring system to secure compliance and ethical conducts.[40] (Faulkner et al., 2003, Kiatpongsan and Sipp, 2009, Mertes and Pennings, 2007, Salter, 2008, Salter et al., 2007, Webster and Eriksson, 2008)

Additionally, Sithole (2011; p. 57) reaffirmed this argument by stating that the government needed to "provide a proper regulatory framework in order for private, and in time, for public health establishments to advance the use of stem

[39] Clinical research including clinical trials and therapy are covered by an existing Private Healthcare Facilities and Services Act 1998, governing healthcare system in the country.

[40] Some scholars also use the term 'bioethical vacuum' and 'governance vacuum' to depict the same regulatory environment.

cells in the health industry." This thesis maintains that a similar argument can be applied to Malaysia, particularly non-clinical hSCR activities in the private sector that are not governed by the national Guidelines.

4. Regulatory Techniques for Human Stem Cell Research

This section proceeds to further explore the regulatory techniques and compliance measures adopted by the Commonwealth countries to enforce rules and secure compliance. Malta and Cyprus are not included in the analysis since these countries have not yet introduced their own rules.

4.1 Command-and-Control Regulation

Regulators in the jurisdictions that have law have the legal power to impose sanctions for non-compliance whereby the "law operates in its classical form - through rule-based coercion." (Morgan and Yeung, 2007; p. 81) Such a measure is clearly embodied in the legislation introduced in the respective jurisdictions, as shown in the figure below.

Country	Law	Sanction provisions
Australia	Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006	Section 9 – 23B - maximum penalty is imprisonment for 15 years Section 10A and 10B - maximum penalty is imprisonment for 5 years
Canada	Act Respecting Assisted Human Reproduction and Related Research 2004	Section 60 and 61 – fine (not exceeding $100,000 to $500,000) or imprisonment term (from 2 to 10 years) or both
Singapore	Human Cloning and Other Prohibited Practices Act 2004	Section 18 – fine (not exceeding $100,00) or imprisonment (not

		exceeding 10 years) or both
South Africa	National Health Act 2003	Section 57(5) – fine or imprisonment (not exceeding 5 years) or both
UK	Human Fertilisation and Embryology Act 1990 (as amended in 2008)	Section 41 – fine or imprisonment (not exceeding 10 years) or both Imprisonment term varies under section 41, subsection 4, 4A, 4B, 5, 9

Figure 11: Legal provisions on sanctions

On the one hand, one might argue, statutory provisions backed by legal force will be more efficacious since any offence will then have legal repercussions. Consequently, regulated parties would feel 'threatened' and therefore, they would be likely to conform to the rules. On the other hand, one could argue, 'classical' regulation might not be the most appropriate technique to rely on, given the intricacies of the system. In particular, the establishment of law often involves a complex procedure where it takes a long time to develop and it is problematic for the law to keep up with the pace of the technology.

This can be regarded as one of the challenges in the area of emerging technologies. Mandel in his study argues:

> *"Regulatory systems are designed to handle the technology in place when the regulatory system was developed. Emerging technologies disrupt these systems. It is not surprising that advances as transformative as those discussed here raise substantial problems for existing, mature (some would say 'ossified') regulatory systems." (2009; p. 81)*

The development of the UK legal system would probably the best representative of such a complex process. When the HFE Act 1990 was introduced, it was not anticipated that the derivation of stem cells from human

embryos would one day be possible for research. The discovery of the Nuclear Replacement (CNR) technique and the announcement of the birth of Dolly the cloned sheep by Wilmut and colleagues (1997) have led to the scope of the Act being questioned.[41] In the following year, the announcement made by Thomson (1998) and colleagues on the success of deriving stem cells from a human blastocyst raised more questions about the scope of the Act. (Morgan, 2007) [42]

It was anticipated that the technique could be used for therapeutic cloning, which was not within the list of the permitted research purposes resulting in a new regulation being introduced.[43] (Human Fertilisation and Embryology (Research Purposes) Regulations, 2001) A few years later, another new unanticipated and ethically controversial discovery arose - the creation of human-admixed embryos for research purposes. Despite an expert report (Chief Medical Officer's Expert Group 'Stem Cell Research: medical progress with responsibility', 2000) recommending prohibition, [44] the

[41] The technique was used to clone embryo and has successfully created a clone sheep, Dolly also known as Somatic Cellular Nuclear Transfer (SNCT).

[42] Because it was suggested for the first time that hESCs might be a viable research tool, adding a whole new dimension to embryo research for the HFEA to consider. Nevertheless, this concern did not have a strong ground to argue that deriving stem cells is not covered by HFE Act 1990 and HFEA due to the fact that such procedure still involves the use of human embryos. Nevertheless, this concern did not have a strong ground to argue that deriving stem cells is not covered by HFE Act 1990 and HFEA due to the fact that such procedure still involves the use of human embryos.

[43] It was introduced with an amended list of an extended research purposes. See op. cit n lxxvi at article 2 paragraph 2 provides the extension of permitted research purposes as follows: "(a) increasing knowledge about the development of embryo; (b) increasing knowledge about serious disease, or (c) enabling any such knowledge to be applied in developing treatments for serious disease."

[44] This report was published by an expert group led by the-then Chief Medical Officer, expressed disapproval of the new technique, stating that "mixing of human adult (somatic cells) with the live eggs of any animal species should not be permitted." Nevertheless, in line with the national policy approach, the UK government of that time allows such research work.

government allowed this technique and eventually the HFE Act 1990 was amended in 2008 to reflect these changes. Having to solely rely on legislation would not be the most convenient and effective means for making changes to the legislation is time consuming. Contrastingly, it would be easier to amend and update guiding rules. Countries with law such as the UK and Canada have clearly indicated that their guiding rules, in the HFEA Code of Practice and Updated Guidelines respectively, are evolving or living documents. With this system, the stipulated rules can be continuously revised and updated as and when necessary. [45]

4.2 Incentive-based Regulation

Mintrom (2013; p. 448) points out that "the primary predictor of a country hosting stem cell research is not the religious mix of the population but the wealth of the country and the commitments that successive governments have made to the funding of their research universities." It can be seen from the above whereby funding (or public wealth) is being deployed by some jurisdiction as the "incentive" by regulators to secure compliance and in advancing hSCR.

This shows that guiding rules complemented by funding schemes can be used as an alternative regulatory technique and could be particularly compelling in jurisdictions whereby researchers are mainly depending on government funding. This technique is being practised in both jurisdictions that have no

[45] See Foreword, "This Code of Practice should be regarded as an evolving document which will be revised and updated in line with both practice and the requirements arising from relevant UK and EU legislation such as the Human Tissue Act and the EU Tissue and Cells Derivative."

legislation such as India and jurisdictions that have legislation in place, such as the UK and Canada (see Figure 8).

Country	Law / Guidelines	Relevant Provision
Canada	Updated Guidelines for Human Pluripotent Stem Cell Research 2010	*Para 7.0 - "These guidelines apply to all research involving human pluripotent stem cells that is funded by the Agencies, or is conducted under the auspices of an Institution that receives any Agency funding." (paragraph 7.0)*
India	National Guidelines for Stem Cell Research 2013	*"These Guidelines apply to all stakeholders including individual researchers, organizations, sponsors..."(paragraph 2.0)*
UK	No specific provisions in the law and code of practice. There are certain requirements set by funding agencies.	i.e. Requirements for grant holders, Wellcome Trust: "*As with all scientific research funded by the Wellcome Trust, stem cell research will be funded on merit and scientific excellence after rigorous peer review and in line with the current legal and regulatory framework."*; *(text from website)* Terms and Conditions of Research Councils Grant, Medical Research Council's: "*The Research Organisation is responsible for ensuring that ethical issues relating to the research project are identified and brought to the attention of the relevant approval or regulatory body. Approval to undertake the research must be granted before any work requiring approval begins." (text from website)*

Figure 12: Provisions on funding scheme and requirement for compliance

Moreover, this mechanism would spare regulators from the burden of legislative procedures. Unlike legislation, the establishment of guiding rules does not need to go through parliament. Thus, it is often viewed by regulatory

scholars as flexible and therefore, this very attribute of the system is an advantage especially in terms of its ability to accommodate changes in policy and its implementation. It also does not require a high burden of information collection and can be revised as and when required. Additionally, incentive-based regulation would be able to encourage compliance without having to rely solely on sanction provisions since the latter may affect the relationship between regulators and the regulated.

Nevertheless, it can be argued that guiding rules for funding could only be imposed on firms or individuals that receive the funding. In view of this, one could maintain that legally binding rules are therefore, still important. This argument is accurate to some extent but it is worth highlighting that firstly, the binding effect that law has can be extended to the enforcement of guiding rules. For instance, such approach can be found in Australian system whereby its statutorily established body is required to regard relevant guiding rules before granting licence. [46] (NHMRC Embryo Research Licensing Committee - Information Kit)

Despite the existence of the HFE Act 1990, the regulatory body in the UK is also required to establish guiding rules to complement the enforcement of the law. (Human Fertilisation and Embryology Authority's Code of Practice)(Human Fertilisation and Embryology Authority's Code of Practice)(Human Fertilisation and Embryology Authority's Code of Practice)[47]

[46] Para 1.2.3 states, “The NHMRC licensing committee must regard the NHMRC guidelines when issuing and overseeing a licence”. One of the guidelines is Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2007.

[47] Section 25, Code of Practice states “The Authority shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a

Secondly, provisions on funding can also be extended to non-funded parties. For instance, Canada requires its Updated Guidelines to be applicable not only on parties that receive funding directly from the Agencies but also to those who do not receive the funding directly but conduct a research work under the auspices of any funded firms. In view of the strengths and weaknesses of command- and incentive-based regulation, one would argue that the combination of both techniques might be able to address the pitfalls of each technique.

Whilst the legislation has the legal and binding power, guiding roles supported by funding scheme may encourage regulated parties to comply with the rules and it would be much easier for amendments to take place without going through the complex and often bureaucratic process. Also, the regulators could extend the binding effect of a statute to the enforcement of guiding rules.

4.3 Communication-based Regulation

As has been pointed out in the previous chapter, substantial information is required for the promulgation of rules and once promulgated, they are not self-enforcing. In view of this, it can be argued that it is important to establish a body to enforce the rules and a system that able to facilitate the enforcement. Due to the limitations of rules, it is also important for the regulatory body to communicate with the regulated parties to ensure understanding on the rules' meaning, application, and implication. Based on the examination of the

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licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies."

jurisdictions' system, it shows that most of them adopt this crucial regulatory technique.

First, there are regulatory bodies established in respective jurisdictions (see Figure 10). Apart from enforcing the rules in place, they also communicate and disseminate any relevant matters and information pertaining to hSCR. Besides communicating with relevant stakeholders especially the public and researchers through websites, they also utilise other social media platforms such as Twitter i.e. UK HFEA; website: www.hfea.co.uk, Twitter: @HFEA Canadian CIRM; website: http://www.cihr-irsc.gc.ca, Twitter: @CIHR_IRSC; Australian NHMRC: https://www.nhmrc.gov.au. Through these cyber platforms, regulatory agencies could provide necessary information and at the same time allow easy access for any queries.

In addition, these countries also have established a network (or foundation) that would enable the relevant stakeholders to stay connected with each other. This initiative can be regarded as rather crucial since it provides a platform for both researchers and regulators to keep abreast with the technology and regulatory matters. Such aspiration can be seen embedded in the objectives of the establishment of one of the networks:

> *"To provide all interested parties with the opportunity to access information relating to scientific, medical and ethical advances in the broad field of stem cell research. A particular emphasis of The Society will be to communicate this information to the general public." (The Australasian Society for Stem Cell Research)(The Australasian Society for Stem Cell Research)(The Australasian Society for Stem Cell Research)*

The list of the networks established in respective jurisdictions is presented in Figure 13 below.

Country	Stem Cell Network/Consortium
Australia	Australian Stem Cell Centre New South Wales Stem Cell Network Australasian Society for Stem Cell Research
Canada	Stem Cell Network Canada
India	The Stem Cell Research Forum of India
Singapore	Singapore Stem Cell Consortium
UK	UK National Stem Cell Network Scottish Stem Cell Network North East England Stem Cell Institute East of England Stem Cell Network London Regenerative Medicine Network

Figure 13: Stem Cell Networks among Commonwealth countries

4.4 Disclosure Regime: Voluntary and Mandatory Disclosure

As discussed in the preceding chapter, disclosure can be done voluntarily or mandatorily. Whilst the former encourages the regulated to disclose information, the latter approach is more binding and often has repercussions for non-compliance. In view of the reported unproven 'stem cell treatment' and stem cell tourism cases, as briefly presented in the introductory chapter, and since this field is undoubtedly rather risky, therefore it can be argued that it would be inappropriate for regulators to only resort to a voluntary disclosure regime. Given this area is rapidly developing, it would be impossible for the public who may not be aware of this technology to have a good grasp or be able to make a grounded decision based only on the information provided by

regulated actors, who may, without interventions from regulators, might take advantage of the situation. Hence, it can be argued that mandatory disclosure would be more appropriate for this technology. Provisions based on such practice, namely informed consent and ethical review can be seen embedded in laws as well as guidelines governing this area.

Country	Provision on Consent	Provision on Ethical Review
Australia	Schedule 2, Subsection 24(1) of the Amendment Act 2006	Section 4 of the 2007 Guidelines
Canada	Section 8(1)(2)(3) of the 2004 Act	Section 1.0 and 5.0 of the Updated Guidelines
India	Section 4.1 and Section 13 of the 2013 Guidelines	Section 6.2.7.2 and 8.0 of the 2013 Guidelines
Singapore	Part III of the Guidelines 2015	Part II of the Guidelines 2015
South Africa	Section 57(4)(b) of the Act	Section 73(2) of the Act
UK	Schedule 3 of the HFE Act 1990 (as amended in 2008) Also see Section 12(1)	Para 49 – 51 of the Guide to Licensing laid down by the HFEA

Figure 14: Provisions on consent and ethical review[48]

[48] **Australia**. Subsection 24(1) of the Act stipulates, "a licence is subject to the condition that before an excess ART embryo or human egg is used, or any other embryo is created or used, as authorised by the licence: (a) each responsible person in relation to the excess ART embryo, human egg or other embryo must have given proper consent to that creation or use…"; (b) "the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject"; Section 4 of the Guidelines dictates, "Researchers, in the design and conduct of research, and HRECs, in their review of proposals, must apply these guidelines.

Canada. Section 8(1) of the Act states, "no person shall make use of human reproductive material for the purpose of creating an embryo unless the donor of material has given written consent…"; section 8(2) states, "no person shall remove human reproductive material from a donor's body after the donor's death…unless…has given written consent…"; section 8(3) states, "no person shall make use of an *in vitro* embryo for any purpose unless the donor has given written consent…"; Section 1 of the Guidelines stipulates, "no research with human pluripotent stem cells would be funded without the prior review and approval…in conformity with the CIHR guidelines", section 5 states, "… a Stem Cell Oversight Committee (SCOC) has been created to conduct ethical review of all human pluripotent stem cell research proposals recommended for approval by the Agencies' scientific peer review

Figure 14 shows that the requirement of disclosing information through informed consent and ethical review is a global practice in the regulation of hSCR. Researchers have to meet these requirements to obtain approval, licence, as well as funding. Through this technique, researchers are required to disclose and provide further information and explain possible and unprecedented risks of a research project to research subjects. By fulfilling the

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panels…SCOC can also, on request, provide ethical review of…proposals submitted by other public or private granting agencies or by industrial sponsors of research."

India. Section 4.1 of the Guidelines states, "Prior to procurement of stem cells for research, it is mandatory to obtain informed consent from the donor. Section 13 lays down further rules on consent; Section 6.2.7.2 states, "such proposal would need approval of the NAC-SCRT for additional oversight and review through IAEC and IC-SCR"; Section 8.0 states, "…oversight committees shall ensure that review, approval…is done rigorously and effectively as per the national guidelines."

Singapore. Recommendation 6 states, "for the derivation and use of ES cells, there must be informed consent from the donors of surplus human embryos, gametes or cells"; recommendation 9 states, "in obtaining consent from donors of cells, gametes, tissues, foetal materials, and embryos, the information provided to the donors must be comprehensive…"; the BAC reports state "there are no ethical reasons for an actual prohibition on research in advance. Individual research proposals will in any case need to be considered by ethics committees which will take into account both the details of the proposed procedures and its likely theoretical or practical benefit."

South Africa. Section 73(2) of the Act states, "A health research ethics committee must (a) review research proposals and protocols in order to ensure that research conducted…will promote health…"; and "grant approval for research…in instances where research proposals and protocol meet the ethical standards of that health research ethics committee."

UK. Schedule 3(2) of the Act states "a consent to the use of any embryo must specify one or more of the following purposes: (a) use in providing treatment services to the person giving consent, or that person and another specified person together, (b) use in providing treatment services to persons not including the person giving consent, or (c) use for the purposes of any project of research, and may specify conditions subject to which the embryo may be so used."; Para 49 of the HFEA's 'Guide to Licensing' states, "upon receipt of a complete application, the Authority commissions peer reviews of that application. The Authority normally commissions about two or three peer reviews of each application."

requirements, researchers would be able to satisfy regulators that a proposed research will be conducted in an ethical way.

The importance and significance of informed consent can be further stressed particularly after the reported fraud in South Korea. (Gottweis and Triendl, 2006, Notebook, 2006, Resnik et al., 2006, Jhalani, 2008) This case illustrates that the existence of law alone does not guarantee protection for research subjects and other measures such as informed consent that is made freely, voluntarily, and substantial understanding are important too.

Jhalani (2008; p. 720, 722) in his argument emphasises the failure of the South Korean Bioethics and Biosafety Act 2005 is because it "does not require that the consent obtained from research participants be voluntarily" and "does not require that research subjects understand the information presented to them before allowing them to participate in stem cell research."

As with informed consent, ethical review is also adopted as a legal and ethical requirement in the jurisdictions' regulatory system. With or without legislation and legal force, this requirement has to be met by researchers before research application could be granted a licence, funding, or both.

5. Techniques in Securing Compliance

One of the desired regulatory goals in the regulation of hSCR would be to provide protection for research subjects, embryo donors, and the publics who are going to enter into this ethically contentious area. In so doing, regulators would need to adopt measures to ensure that this area is properly regulated to ensure compliance with the rules. Based on the examination, the jurisdictions

under study employ both compliance and sanctioning strategies to enforce rules.

5.1 Sanctioning Strategy

It has been indicated in the above that legal prosecution through sanctioning strategy is a common approach adopted by many countries across the globe (see Figure 11). Also, it is worth reiterating that the forms of sanction vary from imprisonment, civil fines or both and some even constitute a criminal offence. One could argue that this strategy is appropriate particularly for highly contentious regulated areas such as hSCR, as this area involves human subjects. As has been argued by Isasi and Knoppers (2006a; p. 2479), “good governance calls for provisions contemplating sanctions and enforcement mechanisms.”

However, they also emphasise the importance of other mechanisms that can be adopted to ensure compliance and secure protections for research subjects. This is particularly relevant given the sanctioning strategy involves a high compliance cost and is not necessarily adequate and effective to deter non-compliance as has been shown earlier. These mechanisms can be categorised as compliance strategy as the spirit of its implementation is to deter non-compliance from the earlier stage of research activities.

5.2 Compliance Strategy: Licensing and Monitoring

Besides the coercive sanctions introduced by the Jurisdictions, there are also other mechanisms introduced to ensure compliance. A licensing system for example is adopted to certify that a research project is ethically acceptable and

as a warranty, or rather an agreement between the regulators and regulated, that a research work will be conducted according to the rules in place. It is apparent from the table that UK of all other countries, has a specific licensing body to carry out the task. Similarly, Australia has reformed its regulatory regime by following UK's approach in establishing a licensing system. Other countries do not seem to have specific licensing body except approval processes by funding or regulatory bodies.

This mechanism also involves a monitoring system, which requires applicants to adhere with the rules after being given a licence. To ensure licensees comply with the rules, the authorised regulatory body does not rely merely on legal force and sanctions, which usually take place only after non-compliance has occurred, but rather the regulators keep track on the licensee from the beginning and making sure that they comply with the rules through the monitoring system.

Among the jurisdictions, unlike the UK that has an established statutory body, the HFEA, to oversee compliance, most of the countries do not have a similar body. Their systems however, require the appointment of inspectors to carry out inspections and the power of appointment is given either to a Minister i.e. Canada, South Africa; a Director of Health i.e. Singapore; or a regulatory body established specifically for this area i.e. Australia's NHMRC.

Country	Licensing provision	Monitoring provision
Australia	**Authority:** NHMRC Licensing Committee Section 13 of the RIHE Act 2002 (as amended)	**Authority:** Inspectors appointed by NHMRC Licensing Committee Section 36 of the RIHE Act 2002 (as amended); Section 1.3, 1.7 of Licensing Committee Information Kit, Section 1.8 of the Guidelines 2007
Canada	**Authority:** No specific licensing body except approval by the federal funding Tri-Agencies	**Authority:** Inspectors appointed by Minister CIHR's Stem Cell Oversight Committee Section 46(1) of the AHR Act; Section 2 of the Updated Guidelines
India	**Authority:** No specific provision and licensing body	**Authority:** National Apex Committee for Stem Cell Research and Institutional Committee for Stem Cell Researcher
Singapore	**Authority:** No specific provision and licensing body except BAC's recommendation	**Authority:** Inspector appointed by Director of Medical Services Section 14 of the Prohibited Act 2004
South Africa	**Authority:** No specific licensing body except approval by institutional Health Research Ethics Committee registered with the National Health Research Ethics Council Section 72 and 73 of the Act 2003	**Authority:** Health Officer appointed by Minister Section 81 of the Act 2003
UK	**Authority:** Human Fertilisation and Embryology Authority Licensing Committee	**Authority:** Human Fertilisation and Embryology Authority

	Section 9(1) of the HFE Act 1990 (as amended)	Section 8 of the HFE Act 1990 (as amended)

Figure 15: Provisions on licensing and monitoring system

One would argue that with the establishment of a regulatory body playing important roles in communicating with the regulated through a monitoring system, this would be likely to result in the regulated being encouraged and facilitated to comply with the rules. The probability of non-compliance could be low, and therefore a greater chance of compliance could be secured. As shown in the table above, this compliance measure, in some jurisdictions, is embedded in legislation as one of the statutory requirements, which gives the regulatory body the mandate and statutory power to monitor and oversee research activities at any stage.

One could argue that this is an appropriate compliance measure and an effective strategy to secure compliance for a controversial area such as hSCR. For instance, Isasi and Knoppers (2006a; p. 2478) asserted, “the imposition of accreditation through licensing as a condition of operation is the one procedural mechanism with the greatest impact on embryonic research” and “probably the best-known model of effective oversight and licensing is the UK’s Human Fertilisation and Embryology Authority (HFEA).”

6. Hybrid Regulation

Previously, the theoretical chapter has concluded that based on the scholarly works on regulation, an optimal outcome could be achieved if regulators employed a combination of different regulatory techniques given the pitfalls and advantages of each technique. According to Gunningham and Grabosky (1998; p. 14), single regulatory instrument "approaches are misguided, because all instruments have strengths and weaknesses; and because none are sufficiently flexible and resilient to be able to successfully address all…problems in all contexts." They further argue (1998; pp. 14-15), "a better strategy will seek to harness the strengths of individual mechanisms while compensating for their weaknesses by the use of additional and complementary instruments. That is...a mix of instruments is required, tailored to specific policy goals."

The sections above have demonstrated that the jurisdictions reviewed do indeed employ a combination of different techniques from command-, incentive-, and disclosure- to communication-based regulation. For instance, some of the jurisdictions have not only made ethical rules for obtaining consent and ethical review obligatory (disclosure-based regulation) but also statutorily mandatory (command-based regulation).

In addition to that, regulatory bodies are also established to enforce rules and monitor the enforcement (communication-based regulation). Besides 'threatening' non-compliant parties with legal sanctions (command-based regulation), some countries also use funding scheme to facilitate rules enforcement (incentive-based regulation). This analysis verifies the argument made by regulatory scholars that the classification of the regulatory systems are

not watertight (Morgan and Yeung, 2007) [49] and the existing regulatory framework illustrated above, indicates a system of which relies upon different regulatory techniques mechanisms to ensure compliance in hSCR.

In his study, Mandel (2009; p. 78) argues "the widely varied contexts and characteristics of these technologies mean that traditional one-size-fits-all command-and-control regulation will not suffice." Similarly, Brownsword and Somsen (2009; p. 22) argue, "it needs to be appreciated that traditional command and control interventions…are not always an effective form or response…regulators to be aware of the range of regulatory instruments and the importance of putting in place an optimal mix." In addition to Mandel's observation, one would further argue that a hybrid regulation, which offers flexibility and alternatives is particularly important when emerging technologies such as hSCR are at play. The technologies are rapidly growing and developing, bringing about uncertain risks and ethical issues.

Mandel (2009) further argues designing a more flexible governance system that can respond to changing knowledge and information is necessary to optimally handle the benefits and risks of emerging technologies.[50] Based on the discussion above, this thesis maintains that a hybrid framework whereby regulators adopt and introduce legislation and complemented by guiding principles would provide regulators the legal power and some flexibility to update and amend regulation as and when required. Also, the employment of other techniques such as disclosure and communication-based is rather

[49] Morgan and Yeung state that "it is important to acknowledge, however, that scholars have sought to classify regulatory instruments in many ways, none of which can clam pre-eminence. No scheme of classification is watertight…" p. 79.

[50] Mandel asserts that "it is necessary that any emerging technology governance system be flexible enough to be able to adapt, as best as possible, to technological change and advances in scientific understanding of the technology." p. 89.

important in order to develop a comprehensive framework that is able to address any regulatory issues, highlighted previously.

Conclusion

This chapter has sought to map out the regulatory framework adopted by many different countries, specifically focusing on the selected Commonwealth countries. The frameworks were analysed based on the preceding theoretical chapter on regulation, in the context of hSCR. In addition to the variations among the existing frameworks across the globe, the analysis has shown that most of the Commonwealth countries discussed above adopt a hybrid or combination of regulatory techniques and enforcement mechanisms. It has also demonstrated that both narrower (state-sanctioned actions) and broader (other social controls) views of regulatory approach are significant and essential, at least in hSCR domain.

Accordingly, it can be argued that a hybrid regulation is probably an appropriate regulatory framework for an ethically challenging area such as hSCR. Such regime allows regulators some flexibility. They would have the options to carry out command-based, incentive-based, disclosure-based, and communication-based regulation within the same system including other techniques and measures. As such, they could ensure regulatory compliance, not only from the early-stage of research work, but also at the same time they have legal authority to carry out sanctions as the last resort.

By comparing Malaysia's framework with that of other countries, it can be seen that Malaysia's system is more closely similar to India than that of other countries in the Commonwealth. The Indian regulators rely on non-

binding rules and the enforcement is based on a funding scheme and monitoring by ethics committee. Since these techniques are not supported by legally binding provisions like those of other countries (UK, Australia, Canada, South Africa, and Singapore) the comprehensiveness and effectiveness of the enforcement can be questioned. Furthermore, since federal funding only requires those funded parties to adhere with the rules, this suggests those who are outside the remit of the funding scheme are likely conducting their research activities in a regulatory vacuum (especially those in private sector).

In most countries (UK, Australia, Canada, South Africa, and Singapore), there are legal provisions on the establishment of a regulatory body or the appointment of inspectors to monitor and inspect research activities in ensuring compliance. It is not certain as to whether similar approach is being practised in Malaysia, with the result that the adequacy of safeguarding research subjects, particularly human embryos, can also be questioned.

Moreover, it is not evident that Malaysia has similar regulatory bodies and 'networks' that exist in most of the countries including India, which play an important role in communicating with stakeholders with regards to ethical and regulatory matters, which is, as has been discussed, an important technique to promote compliance. The absence of such measures leads to the questions about the level and extent of awareness of regulatory matters among stakeholders in Malaysia.

Additionally, it seems Malaysia also lacks other important compliance mechanisms such as sanctions, licensing, comprehensive ethical approval, and monitoring systems that are being practised in other countries. This suggests that current research activities may not be fully compliant with the existing

guiding rules. In view of the situation, one would question whether Malaysia's current guidelines and regulatory system as a whole should be reformed to fit better with other jurisdictions' systems. It is worth noting again that Australia in its regulatory reform has adopted a UK-style licensing system and Singapore, in developing its own system, has also adopted the UK's system as a regulatory model. Should Malaysia take the same regulatory path?

Given the highlighted concerns over the inadequacy of Malaysia's current regulatory system in ensuring compliance, this thesis sought to determine what might be an appropriate regulatory framework for hSCR in Malaysia. In so doing, this research will also incorporate qualitative interviews with relevant Malaysian key stakeholders.

This empirical research is important as a means to further explore the current practices and views of Malaysian stakeholders especially in the light of limited resources available. The findings from this empirical research are reported in the following chapters (Chapters 4, 5, and 6) and the typology developed in this and the previous chapter will be brought together for further analysis in Chapter 7.

PART B – EMPIRICAL RESEARCH AND FINDINGS

Chapter 4: Regulation of Human Stem Cell Research in Malaysia

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Introduction

As described in Chapter 3, there is little publicly available information on Malaysia's regulatory system for hSCR, especially in the literature. This chapter and the following two empirical chapters aim to report the interview findings, the respondents' views, and recommendations with regards to the current regulatory framework for hSCR. The study respondents are key stakeholders and instrumental in enforcing hSCR regulation. Their perspectives carry significant weight and should be taken into account.

This chapter reports on the respondents' awareness of Malaysian hSCR regulation particularly that of regulators and researchers. The issue of public awareness emerged as a matter of concern and the factors leading to the current level of awareness are highlighted too.

The current system is examined to establish the origins of the present regulatory approach and an account of the respondents' perspectives is given. The chapter looks at the views given by the respondents on its application and the implications for (i) the regulatory environment; (ii) research development; and (iii) compliance with the rules in place.

The interviews were conducted in English and verbatim quotes are used in these empirical chapters. However, the respondents' first language is not English and there are some grammatical errors. To ensure clarity while preserving the authenticity of the verbatim quotes, some corrections were made by deleting and adding some words in a bracket '[…]'.

1. Awareness Among Respondents and Their Views on the General Public

One would contend, it is important for both regulators and regulatees to be aware of regulations and have the right knowledge and understanding. Without these, regulators may not be competent to fulfil their roles. Awareness among regulatees of their restrictions and responsibilities is important for them to comprehend what they can and cannot do. The findings from this study show the lack of awareness in two different spectrums - regulatory requirements and stem cell-based therapy.

Firstly, the findings of the interviews show there is a lack of awareness and understanding on the regulation of hSCR in the country among both regulators and regulatees, especially when asked about the requirements stipulated in the national guidelines. Secondly, many respondents expressed their concern over the lack of awareness among the Malaysian public and argued that members of public generally have a distorted understanding of stem cell treatments. The latter is not based on empirical evidence but the respondents' own views.

1.1 Awareness of Regulation

In general, it seemed most of the interviewees were aware of the existence of the national guidelines introduced to govern stem cell research and therapy in Malaysia. However, there were several who were unaware of the regulation or had not personally looked at it.

This demonstrates a lack of awareness among both regulators and regulatees, as shown in the quotes below.

> *I: Are you aware of the regulatory system that governs stem cell research in Malaysia?*
>
> *Respondent 9: I am not really aware of laws. I know we have national standards, we have guidelines…if you are doing research, normally, you have to apply to stem cell ethics committee right? [Ethics Committee Member]*
>
> *Respondent 21: No…I think Ministry of Health has come out with some guidelines but frankly I haven't looked at it yet. [Ethics Committee Member]*
>
> *Respondent 12: In Malaysia…I don't know the human embryonic stem cell policy and I thought maybe to use human embryonic stem cells is still okay because I don't see any kind of a very clear against towards usage of the human embryonic stem cells. But I do believe that there is a restriction on the isolation of the human embryonic stem cells. I mean the establishment of the human embryonic stem cells itself in Malaysia. [Stem Cell Scientist]*

The above quote demonstrates how respondent 12, a stem cell scientist shows limited awareness of human embryonic stem cell policy despite being aware of the guidelines. The quotes below demonstrate the range of awareness about the guidelines.

> *I: Do you know about the approach adopted by Malaysia – the guidelines on human stem cell research?*
>
> *Respondent 2: No, not familiar with that…to be honest with you, I haven't really explored this area. [Lawyer, Ethics Committee Member]*

I: Are you aware of the National Guidelines for Stem Cell Research and Therapy?

Respondent 17: No. [Non Governmental Organisation]

Even where respondents are aware of regulation, the degree of their understanding varies and often shows minimal awareness. Many of the researchers and regulators, particularly the ethics committee members do not have a clear understanding or substantial knowledge of the requirements set in the national guidelines. Though the guidelines stipulate that it is not permissible for human embryos to be created to derive stem cells and only surplus IVF-created embryos can be used,[51] one of the respondents demonstrated an opposite understanding of the regulatory requirement.

I. For embryonic stem cells you said that you are interested to use it in the future, but the fact that the guideline doesn't allow the creation of human embryos, do you think it's a challenge for you?

Respondent 1: I don't see it as a challenge because they, I don't think the guidelines state that you are not allowed to actually do embryonic cells.

I: I mean you cannot create embryos to derive the stem cells..

Respondent 1: Well you can actually, provided that you are not allowed after a certain number of days, the reason is then that embryo is now not considered as organism, of a living organism. [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]

This illustrates a lack of information and awareness on the existence of regulatory framework among both the regulators and regulatees. Notwithstanding the lack of clear understanding and awareness of the national

[51] Para 9 of the Guidelines stipulates that "Research on embryonic stem cells derived from surplus embryos is allowed" and para 10 further stated that "The creation of human embryos by any means including but not limited to assisted reproductive technology (ART) or somatic cell nuclear transfer (SCNT) specifically for the purpose of scientific research is prohibited"

regulatory regime, some are aware, to a certain extent, of the regulatory approaches adopted by other countries and the reasons for the existing regulatory patchwork at the global level.

> *Respondent 11: I think generally, the different approaches reflect the policy of the government and it also reflects the religious divide between the countries as well…when I was in the UK...there were protests against the use of hybrid embryo for the creation of stem cells…but at the same time, there were already patents involving hybrid embryos in Australia…some countries are more relaxed than the others…Singapore, very relax, liberal views on stem cell… [Lawyer, Stem Cell Policy Panellist]*

Some have a brief idea of the regulatory approaches adopted. Those who are aware, mostly refer to regulatory approach in the United Kingdom, USA (FDA's system in particular), and Australia.

> *Respondent 5: I think…there are permissive but some restrictive like for example, in the US like FDA, there are certain things that they allow, but there are certain things they don't allow. They stop embryonic as of April last two years ago, no, two years ago they allow…FDA don't allow pooling, must be from single donor… I'm sure in the UK, they have some regulations but I'm not so clear about it because I have not been or heard about that. But the FDA's is kind of accepted also elsewhere…and then Australians also, they have their own regulatory, they are quite stringent also… [Stem Cell Scientist]*

1.2 Public Awareness on Stem Cells Science

The findings also show that many respondents were concerned about public awareness of research development and treatments. They claimed that the Malaysian public had little understanding of both the research and therapy aspects, though they were generally aware of the stem cell therapy.

An example is that of basic stem cell science, for instance, the difference between embryonic and non-embryonic cells.

> *Respondent 10: When they talk about stem cells, stem cell research, most people, lay people, do not differentiate beyond embryonic and non-embryonic research. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

> *Respondent 5: I don't think the awareness is very high. If I want to estimate maybe 20% or less but how extensive it is…has anybody done survey on what kind of, how people are aware of stem cell research or not? I don't think so." [Stem Cell Scientist]*

The respondents argued that while the general public may be aware of the use of stem cells in treating diseases and injuries, this may not translate to basic knowledge of the science itself, and therefore this may affect their decision making. In other words, it shows respondents regard the public as poorly informed and therefore, prone to making injudicious decisions that might jeopardise their own safety. One of the respondents believed that there is as yet no research on public awareness, which if true, could be another potential area for research. With this, more insights and substantial information from the ground could be gained.

1.3 Fabricated Stem Cell Treatment: Patients Demand

Almost every respondent pointed out there are unproven or fabricated 'stem cell treatments' being carried out in the country. These 'treatments' are known from channels such as social media, word of mouth, and some are marketed through multilevel marketing (MLM) - a widely used business model in Malaysia.

Whilst most of the respondents only stated they had heard about and were aware of unproven 'stem cell 'treatments', one respondent in this study is directly involved in providing treatment that is currently not permitted by the national guidelines - xenotransplantation.

> *Respondent 14: Well, I am doing cell therapy…some people would call it feotal precursor stem cell xenotransplantation…the German would say xenocell therapy…I prefer to use 'live cell therapy'…it's live cells…but the thing is, it comes from animal sources…I am using progenitor cells.*
>
> *I: You're talking about Down syndrome treatment using xenotransplantation?*
>
> *Respondent 14: Yes.*
>
> *I: So, there's demand in Malaysia?*
>
> *Respondent 14: It is consumer driven…patients want it…there are some physicians [who do not agree with it]…you have to decide, it's your decision. [Medical Practitioner, Stem Cell Provider]*

It is worth mentioning that the other respondents regard this treatment negatively. The treatment involves injecting rabbit stem cells into human body, for reasons such as to curing Down syndrome, and treating injured or damaged knee joints. The effectiveness and safety of these procedures are not yet clear.

> *Respondent 3: [Institution X] funded the company for research and building up rabbit colony to do research on rabbit stem cells as potentials of therapeutic uses, this is what they claimed. So we said, 'well, do the research at the animal level, show the animal model'…we do hear they are moving faster than what was intended in terms of claims for therapeutics for human. It shows you how the regulations are not enforced…MOH has to clamp them down…yet I still don't hear of any regulators coming down so, I'm concerned. [Scientist, Ministry Official, Advisory Council]*

I: Are you aware of any treatments offered by private companies, which are not proven?

Respondent 18: Well, I can quote you a recent one, which is very unfortunate. There is a company that is actually…introduced rabbit stem cells for treatment for Down syndrome…we don't agree with that…we frown upon such tactic, which has no scientific basis. [Stem Cell Scientist, Advisory Council]

This study will not discuss why this 'treatment' is not regulated because of the scarcity of information and it does not involve human stem cells. However, it demonstrates how limited regulation and misinformation of the general public has led to the introduction of unproven treatments. Cases such as these cause concern among stakeholders, particularly with regards to the efficacy of the treatment and the safety of the patients. It is also not clear whether the patients involved and receiving 'stem cell-based treatments' are aware that the practice is not regulated.

Nevertheless, the respondent asserted that patients, and particularly in the case of people with Down syndrome, their families perceive this treatment as an opportunity to improve their condition. Moreover, according to the respondent, they are pleased with the outcome of the treatment.

Respondent 14: The adults would say 'doctor, after the treatment, I feel strong you know...if I can walk 100 metres, I can walk 300 metres now, 400 metres'…and mothers always say 'suddenly he goes to school, he mentions the principal's name, I couldn't imagine he could do that'. These are the outcomes. [Medical Practitioner, Stem Cell Provider]

There are also other entities providing 'stem cell-based treatments' claiming to treat a range of diseases and injuries. Similar to the case above, it can be argued that these treatments exist because of the demand from patients and the public who see an opportunity and hope to improve their conditions.

Since there is considerable hope associated with stem cell treatments, most of the respondents argued the very term 'stem cells', regardless of its sourcess (animals, plants, human), has become a commercial brand in the country. Private clinics and companies use the word to influence and attract customers to try their 'stem cell treatment' and buy their products.

> *Respondent 10: So they [the public] are very easily influenced by people [treatment providers] coming to sell that stem cells are good and then it looks very exciting…everybody is influenced by this word of stem cell. Anything got stem cell can sell…I did a Google trend search on stem cells. I found… all we have here are apple stem cells. That's what the public understands about it. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

Even though this study did not explore the actual level of understanding of stem cells and their use for therapy among members of the public, most of the respondents believed there is a lack of understanding. This stance is based on their recognition that unproven treatments are available and there is a demand in the market.

1.4 Factors Leading to Lack of Awareness

Most of the respondents argued that limited access to information could be the cause of the lack of awareness, and this is due to a number of factors. For instance, according to respondent 12, information on the regulatory system

is not easily accessible to the research community and therefore, they are not aware of how the system works in the country.

> *Respondent 12: …would be nice to actually have the guidelines distributed to the research institute so people aware of it…once I come back, this is my personal experience…I just don't know how things work here, I don't know whom I should contact, when I talked to all professors who are working on stem cells, they are not sure about the guidelines either. [Stem Cell Scientist]*

On the topic of limited access to information, the respondent cited the recent National Stem Cell Congress as a good initiative where information on regulatory matters could be obtained through meeting other stakeholders. The respondent described how it was a platform from which the scientific community could gain information.

> *Respondent 12: …last year when I went for a conference…last year October…the first National Stem Cell Congress. I would say it's a good initiative because we never had anything about stem cell, meeting or anything like in a public way but that was a good initiative by [a university-based research centre]…I got to know that you can use the human embryonic stem cells but you probably still restricted to isolate human embryonic stem cells so these are the clues and the views I got from people [whom] I talked to. [Stem Cell Scientist]*

Discussing a similar issue, respondent 5 referred to FDA practice, viewed highly because of how FDA regulators communicate and provide the necessary information to researchers. The system provides researchers with assistance from the initial stages of research to ensure time is not wasted pursuing work that would not ultimately be approved and to ensure compliance both at research and clinical trial stages.

> *Respondent 5: …the good thing about FDA is…you can write to them and you can have an initial discussion with…their officers who will guide*

> *you, how you can do, and what you should do so that you don't spend too much of your resources designing something that is out of the scope that can be approved by FDA. So I went to a meeting in New York, where we have one of the speakers from FDA, [speaker's name], she tells us about…how you should manufacture your cells in cell factories, which we are also doing, what can be done and what cannot be done, in terms of your research and the trial. [Stem Cell Scientist]*

It can be seen that the respondents, based on their own experience as researchers, felt there is a lack of access to information, leading to their own limited knowledge of the regulatory system.

Evaluating the current situation and considering respondents' views demonstrates how there are different ways to create awareness among stakeholders. It could be done in the form of communication-based regulation via a more active engagement between regulators and regulatees as well as other means such as conferences. The World Stem Cell Summit is a good example of an event showcasing scientific progress as well as providing allocated sessions for regulatory matters to be discussed among researchers, regulators, interested members of the public, and patient advocates.

2. Malaysia's Current Regulatory System

Chapters 1 and 3 illustrate how global policy towards hSCR particularly with regards to research involving human embryos, varies between jurisdictions resulting in 'a patchwork of policies'. (Knowles, 2004, Salter, 2007) Also, a number of studies have been conducted to report on the impact of these different regulatory approaches on stem cell research, particularly research involving human embryos. (Kawakami et al., 2010, Colman, 2008, Levine,

2008) For instance, a study conducted by Levine (2008) showed regulatory policy played an important role in shaping development of stem cell research.

This study will not take the same path as the studies mentioned above, which examined policy impact based on the number of research activities, number of patents filed, et cetera. Since this area is relatively new in Malaysia, this study will be focusing on Malaysian stakeholders' opinions of the impact of current prohibition and whether it presents an obstacle in their pursuit of their future research interests.

2.1 Malaysia's Approach Towards hSCR

According to the national guidelines, researchers in Malaysia are allowed to use any kind of adult human cells to establish cell lines for research purposes. However, when it comes to embryonic stem cells, they are only allowed to use 'surplus' embryos that are no longer needed for infertility treatment. One might question how such approach came about in a country such as Malaysia, a pluralistic society with several religious groups, and where contradicting religious views inevitably exist.

Respondent 11 explained how policymakers in Malaysia decided to adopt the current approach, regarded by the respondent as acceptable to the majority of those involved in the ethical debate regarding the use of human embryos. Islam is the official religion as stated in the constitution, but the National Fatwa Council did not impose its views without consulting other religious groups. As a result, the current approach does not only represent Islamic views.

The respondent further pointed out the approach was taken after the drafting committee considered the views of other religious groups i.e. Buddhists, Hindus, and Catholics, with regards to the moral status of human embryos. The views expressed by these groups are considered more stringent than those of Islam. In order to respect the opposing views, the Malaysian National Fatwa Council made a religious ruling that is presented as acceptable to all religious groups. It is now the basis of the current approach after being fully incorporated into the national guidelines.

> *Respondent 11: In Malaysia, when the matter was debated before the committee, who drafted the guidelines, we have the Hindus and the Buddhists whose views are generally more cautious than the Muslims…the Catholics have got very stringent views on what amounts to human. As far as Muslims are concerned, it's okay as long as the ensoulment has not occurred…but somehow the committee takes a very restrictive approach…which is acceptable to majority, they said, 'okay, we don't allow the extraction of stem cells yet but if you were to research on cell lines that have been developed you know, from other countries, it's okay'…I was involved in the committee, my impression is that they want to take a stand that basically satisfies everybody's interest. They want to take a safe stand that doesn't irk the Buddhists and the Hindus and the Christians. [Lawyer, Stem Cell Policy Panellist]*

The situation explained by the respondent above suggests, religious opinions carry significant weight in determining a regulatory approach in this controversial field. One could argue that consultation between religious groups on ethically problematic matters such as the use of human embryos is appropriate for Malaysia and good practice given the complex cultural context in the society.

After establishing the background to the current approach, the focus now shifts to other important questions; what does this mean for researchers in this area? How do the researchers actually perceive the approach – what impact

does it has on research development? How effective is the current system in safeguarding human embryos from being used unethically?

2.2 Implications of the Current Regulatory Approach

2.2.1 The Climate of Uncertainty: Written Regulation vs. Implementation

As explained above, the religious ruling produced by the National Fatwa Council has significantly contributed towards the prohibition on the creation of human embryos for research purposes in Malaysia. However, all of the respondents perceived the current approach as conservative and restrictive compared to other countries that are actively involved in embryonic stem cell research.

> *Respondent 10: …the guidelines…are actually fairly conservative. Compared to other countries in the world, our position on things like embryonic stem cell is actually much more restrictive compared to other countries that are active in stem cell research. So, we are considered like tier three in terms of regulation. Whereas countries, which are active for example the Singapore… they are the most liberal. China also, and India are very liberal UK, the continental Europe, they are also moderately liberal. Even US, which is supposed to be conservative, is more liberal than us, in terms of the guidelines. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

Unlike Singapore and a few other Asian countries, Malaysia's regulatory spectrum is not yet being discussed at the global level, especially in the Western literature, nevertheless, the respondents in this study adopted the terms (such as liberal, restrictive) used in the Western academic literature to discuss the position of Malaysia compared to other jurisdictions in the world. Despite claiming that the current approach would position Malaysia as

conservative and more restrictive than other countries, there is still a climate of uncertainty within the regulatory environment.

Most of the respondents contended that the actual regulatory practice does not reflect the current approach, which is portrayed as conservative and restrictive, because there is a lack of regulation. For instance, respondent 1 stressed that there is no real restriction in Malaysia for conducting stem cell research in general. This includes both embryonic and adult stem cells, and therefore, the current regulatory spectrum can be regarded as liberal,[52] contradicting the restrictive approach portrayed by the guidelines. (Walters, 2008)[53]

> *Respondent 1: The thing is, in this country, we are quite liberal in doing research for stem cell…There's no real restriction, if you look into it…Currently, I don't think there is any regulatory approach so they don't even know where they're heading because when looking at it…not restricted but we are not too liberalised. [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]*

On the same note, respondent 3 perceived the current regulatory framework as facilitative mainly because research activities in Malaysia particularly stem cell research, are not meaningfully monitored despite there being formal regulations - referring to the guidelines.

[52] Note, the use of the word 'liberal' by the respondent 1 is only referring to the absence of enforcement of regulatory requirements in the country. As a result, the researchers have the 'freedom' due to the lack of regulation and restriction. In this context, the word 'liberal' is not being used to categorise Malaysia's approach towards embryonic research.

[53] As per Walter's work, a liberal or permissive country "accepts the production of human embryos for research purposes through in vitro fertilization and/or nuclear transfer (cloning)." p. 92.

Respondent 3: Yeah, it's too facilitative, mainly because of the lack of monitoring. I think we do have…written regulations but a lot of it seems to me is really just I take your word from it. And then, there is no monitoring. [Scientist, Ministry Official, Advisory Council]

Without such monitoring, scientists could do almost anything. This shows not only that there is uncertainty or ambiguity among the researchers with regards to the regulatory requirements and boundaries, but inconsistency between the regulatory approach and its actual implementation. In view of this situation, one would question the impact that the current regulatory environment has on research development and ethical compliance.

2.2.2 Impact on Research Development

On the one hand, a few respondents claimed their work would not particularly be affected by the prohibition due to their interest in human adult stem cells research rather than human embryonic stem cells. They argued that given the lack of investment by the federal government into this area, and the fact that developing stem cell therapy using adult stem cells is more feasible compared to embryonic stem cells, the current approach is suitable for Malaysia.

I: So do you think Malaysia doesn't need to go into embryonic research?

Respondent 18: I don't think we need to spend money on embryonic stem cell, we will benefit from other more matured technology or more feasible one like iPSCs is certainly good, very good area to go in. I think I would recommend Malaysia government to support this iPSC research just like Japan. [Stem Cell Scientist, Advisory Council]

Respondent 10: If you look at the embryonic stem cell, so far there is not even one commercially successful application even after so many years…I myself would not suggest funding it for commercial research because there is not much return in terms of investment. You are unlikely to get any R&I for the state, for the reason I stated earlier. [Medical Practitioner, Stem Cell Scientist, Advisory Council]

Respondent 20: …embryonic definitely no doubt super cells...it shows miracles and all those things but you cannot apply. It stops with research, it stops with papers…there is no translation. [Scientist, Stem Cell Policy Panellist]

On the other hand, respondent 3 argued that the prohibition is meaningless and policymakers should consider its revision, given the potential benefits of using human embryos for research purposes. It is not certain whether cell lines established from surplus embryos are as scientifically useful as those established from human embryos, specifically created for research work. Based on this, the respondent further asserted that if a prohibition on creating embryos for research was given a legal effect in future, it might jeopardise research progress.

Respondent 3: There's more control, the problem with IVF surplus is not controlled embryos so you don't know what, whether they are viable or not so in fact you'll never progress by using in vitro embryos.

I: If the same provision introduced in an Act, do you think it will be difficult for scientists in Malaysia to advance in stem cell research?

Respondent 3: If we don't lift this restriction?

I: Yes. I mean if you bring this requirement into the law in future…

Respondent 3: Yes, yes, of course. [Scientist, Ministry Official, Advisory Council]

In the light of the potential benefits, respondent 10 argued that the creation of human embryos for research purposes should be considered in Malaysia. However, the respondent stressed that such deliberation should be made not only based on the possible benefits but also from an ethical perspective, analysing the impact on the entire field.

It was also suggested that if human embryo creation was to be allowed in the future, it should be subject to permission that can only be granted specially by an authorised expert body. This is similar to what has been done in the other jurisdictions that allow such procedures to be carried out.

> *I: Should we consider allowing creation of human embryos for research purposes?*
>
> *Respondent 10: So, that's what I think we should consider. The benefits of conducting such research must be weight against the drawbacks to the whole field. My own personal feeling is that if it is to be given, permission must be specially granted by a council of experts in this area. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

2.2.3 Implication on Ethical Compliance

Respondent 11 contended that the current regulatory approach is acceptable to all of the religious groups included in the consultation process prior to the introduction of the national guidelines. However, the other respondents have different opinions on this matter. In terms of the ethical concerns, one could argue that there is no difference between allowing the use of surplus embryos and using embryos specifically created for research.

Rather than prohibiting the creation of embryos, similar to the suggestion of a special permission made by respondent 10, it can be argued that instead there should be tight guiding principles and adequate monitoring. The current

regulatory system can be seen as problematic as one can argue that the lack of regulation does not safeguard human embryos regardless of the prohibition. The prohibition of their creation alone does not guarantee protection over the use of human embryos *per se*, due to the absence of adequate monitoring system.

Those who perceived Malaysia's approach as being inadequately regulated believed such a system/process would be advantageous to scientists. However, there are concerns this would lead to a 'slippery slope', used by irresponsible stakeholders and resulting in unethical behaviour. This is particularly pertinent given the lax controls and involvement of human subjects. For instance, unmonitored and uncontrolled non-clinical research could be dangerous and unnecessary when later translated into clinical research involving human subjects.

> *Respondent 1: And I think that's actually a good thing [no monitoring] but I don't think it's a good thing when you talk about having to experiment on humans, and you're not very clear on how it's done, so I think there must still be restriction but when it comes to human…the reason is before we exploit people we need to understand the science…At this point of time, they are not being very very restrictive but it's open to exploitation. That's the problem. [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]*

Similar to the views expressed by respondent 1, respondent 10 believed that under-regulation aids exploratory research but this may not be the case for everyone. Under-regulation presents an opportunity to exploit the 'facilitative environment', putting the entire field at risk. Citing the unfortunate incidents brought by under-regulated Gene Therapy (Spink and Geddes, 2004,

Friedmann, 2005) (XSCID and Gelsinger case)[54] that led to the deterrence of public and private investment in the field, respondent 10 argued that the same might happen to stem cell research, if under-regulation continued.

> *Respondent 10: In a short run, it's good because you can do anything. In a long run, it's bad because someone eventually will do something that will cast the whole thing into disrepute. It's like when you had the, think about, the gene therapy using viruses in the late 90s. That was actually very poorly regulated. And there was a number of deaths that occurred that actually stunted the entire field for whole decade, okay. So, and the field never really recovered really well because of that. So, this is the kind of thing that will happen in Malaysia. I mean if we are lack of regulation it's good if you want to get in and get started. It's very very bad if you got something good and someone else spoils the market for you. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

The respondents stressed that continuation of the current system, with limited monitoring and regulatory enforcement, jeopardise credibility and advancement in this area despite its less permissive approach. Hence, this suggests that the current regulatory system, which does not reflect policy, is not seen as able to guarantee ethical conduct and subsequently may put the field at risk. This suggests that without an established and appropriate regulatory framework, the current prohibition has minimal impact in the effort to protect human embryos from being misused.

Malaysian stakeholders, particularly respondent 10, are also wary of the problems that have blighted other promising but controversial scientific fields in the past. Such examples are as warnings of the future of stem cell research may unfold without appropriate regulation. This shows the use of arguments

[54] In 1999, Jesse Gelsinger died after being administered with an adenoviral gene therapy vector in a study at Penn State University. In addition, other serious adverse events reported and US gene therapy trials have been accused as the outcome of the lack of independent oversight. In 2002, two young boys were announced dead in a study of gene therapy for the treatment of X-SCID.

relating to global research environment as well as the local context when discussing the issues at stake.

2.3 Regulatory Gap and Comprehensiveness

Even though the national guidelines' remit covers both research and therapy, according to the respondents, there is a gap between the regulation of stem cell research (non-clinical research) and therapy (clinical research).

> *I: So what do you think of…the regulatory system?*
>
> *Respondent 10: There are a number of issues in terms of the stem cell research and therapy. The first thing is that we have to divide in two parts. One is the actual research itself and the other will be the clinical application of it. And both of these are governed by different sets of rules and regulations and expectations, okay. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

Respondent 10 further indicated that non-clinical stem cell research is under-regulated when compared to other research activities such as those involving animals and clinical practice.

> *I: Can it be said that stem cell research in Malaysia is under-regulated?*
>
> *Respondent 10: I wont say that it even regulated. It's not regulated at all.*
>
> *I: It's not regulated at all?*
>
> *Respondent 10: No, it's not. There is no regulation…you see unlike clinical research, where you have to go through ethical board, for pre-clinical research, there is no ethical board…If you are using animal, yes you have to go through animal care committee but that's not directly to ethics of stem cell research. So, we don't really have much in terms of [pre-clinical research]. And the current Practice Act, which Ministry of Health uses to regulate clinical providers, does not apply to pre-clinical. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

Similarly, respondent 5 explained how the current system does not require non-clinical research to be monitored or for researchers to seek approval from the national committee. This is because, according to the respondent, there are no provisions in the guidelines requiring non-clinical researchers to do so. However, based on a personal view, the respondent argued if non-clinical research were to be monitored, regulators should instead focus on avoiding the duplication of research activities to ensure the effectiveness in utilising research funds.

> *Respondent 5: But at our level, this level, the fundamental research is not monitored, not required, but I think if fundamental research is to be monitored like that, for me the monitoring is not for, the monitoring is just to make sure that there is no duplication, that the fund is fully utilized. If there is duplication [research duplication] why don't group together [they work together] to make it better. You know that is fundamental [non-clinical or basic] research. This one is on stem cell research and based therapy so at the moment although there is this guidelines, but we don't really go through the national ethics committee on stem cell, recommendation, there is no rule to say that we really have to do this... [Stem Cell Scientist]*

Even for stem cell therapy, there is no specific legislation or regulatory system introduced to govern such therapy except that there are other relevant laws such as the Private Practices Act, which can be used to govern stem cell-based therapy in general.

> *Respondent 10: In terms of regulation, there is very little. What we have is that we have Private Practices Act and that allows Ministry of Health to govern certain clinics that offer this but this from generally high level perspectives. There is no actual legislation or even regulation governing stem cell therapy specifically in Malaysia. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

One could argue that the gap in the regulatory process between non-clinical and clinical research in this field may not only result in ineffectiveness in ensuring ethical conduct, but also uncertainty among researchers. As has been argued by Bell and Devaney (2007) that a regulatory gap indicates the over-complexity of a regulatory system and this may not only impose an unnecessary burden on the researchers, but may also affect development on (stem cell) research activities. Respondent 10 argued there should be continuity in the regulatory pattern to ensure its effectiveness.

> *Respondent 10: I think…if you want to be effective, you need to actually control the process all the way from test tube right to clinical application. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

It is noted that most non-clinical research is conducted by public institutions and as such, directly or indirectly linked to the government. Therefore, even though the guidelines are non-binding, government could control them through federal funding. Nonetheless, it is important to note there are also private companies becoming active in research activities.

> *Respondent 11: Okay, just consider who conduct research in Malaysia? Who conducts research in Malaysia? Not these companies who offer the umbilical cord stem cell service, they don't conduct research. They are just there to get money from you. Right? So who conduct research in Malaysia? It's all these research institutes. And these research institutes are either the government institutes or affiliated to the government. [Lawyer, Stem Cell Policy Panellist]*

With non-binding guidelines, private entities have the 'freedom' of not having to comply with the requirements stated. Furthermore, unlike public institutions, they do not depend on government funding, they are not restricted to the Ministry's control, and are free to find alternative funding resources. One

may then ask, is the Ministry be able to competently govern this area only through guidelines and funding control alone?

Conclusion

This chapter has uncovered the current regulatory affairs of hSCR in Malaysia. It shows there is a mixed level of awareness and whilst some respondents show minimal understanding of the national guidelines, others do not have any knowledge on this matter. This phenomenon appears to be caused by limited access to information. The current regulatory system does not facilitate respondents to have a clear understanding of the regulatory process in place.

Furthermore, the respondents also expressed their concerns over the lack of public awareness, especially given presence of unproven treatments already in operation in the country. 'Stem cell' has become a marketing ploy, used by commercial entities to manipulatively attract the public and raising concerns over public safety.

The current prohibition on the creation of human embryos for research purposes is cause for disagreement. On the one hand, some respondents believed this to be a suitable approach due to their own interest in adult stem cells. On the other hand, others argued that this potentially inhibits future research. Also, enforcement of regulations including those relating to prohibition, is considered to be ineffectual and counter to the current regulatory approach.

Furthermore, most of the respondents considered the current regulatory system to be non-comprehensive. This is due to the gap identified between the regulatory measures for non-clinical and clinical research. A striking example is that of the national ethics committee, established to govern stem cell research and therapy. Despite this, only clinical research is required to be subject to the committee's ethical and approval process.

In view of these issues, one could question the effectiveness of Malaysia's framework, particularly in its function of facilitating researchers' understanding of the regulatory processes, building public awareness, and ensuring comprehensive governance to facilitate research development and ensure ethical conduct. The following chapters 5 and 6 further explain and develop some of the issues raised in this chapter in more depth.

Chapter 5: Compliance Measures and the Way Forward

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Introduction

The findings reported in the preceding chapter have given a brief account how the current regulatory system for hSCR in Malaysia came about, the awareness among some stakeholders, and an overview of the respondents' perspectives on the regulatory approach. It was pointed out that many of the respondents perceived the current approach as restrictive due to the prohibition on creating human embryos for research purposes. However, the implementation of the regulatory requirements appears as quite loose.

This has caused some concerns over the possibility of exploitation of the field. This is especially important when taking into consideration the lack of awareness among stakeholders and a lack of regulation. Non-clinical research in the private sector is being particularly prone to unethical conduct and exploitation. Improvements to safeguard embryos from being misused, the safety of the public, as well as ensuring compliance with the rules in place are needed in light of this possible non-compliance and exploitation. This chapter reports a more detailed account on how the respondents perceived the implementation and enforcement of compliance measures.

To find out the underlying factors that have resulted in the current system being viewed as lacking of regulation and inadequate, this chapter examines the ethical approval procedure for hSCR to be carried out in the country focussing on a number of regulatory measures namely licensing system, informed consent, statutory sanctions, the 14-day rule, and monitoring system.

1. Statutory Licensing and Ethical Approval for the Use of Human Embryos and Its Derived Stem Cells

This thesis notes that licensing requirement for clinical and non-clinical research can be two separate regulatory processes. For instance, in the UK, licensing system for research involving human embryos is carried out by the HFEA, and all clinical trials in the UK, whether involving embryo-derived stem cells or not, fall under the authorisation of the Medicines and Healthcare products Regulatory Agency (MHRA). (2015b)[55]

The purpose of this section is not to study the differing regulatory routes adopted by authority to regulate clinical and non-clinical research but mainly to point out that given the use of human embryos and its derived stem cells is highly controversial; its use whether for non-clinical or clinical research should be licensed.

Such practice is shown to be in practice among many of the commonwealth countries studied in Chapter 3. A license is required for non-clinical research work involving human embryos and embryo-derived stem cells to be regarded as ethically approved by a mandated regulatory body i.e. HFEA[56] and UK Stem Cell Bank[57] in the UK, NHMRC in Australia.

The purpose of this licensing system is for the regulatory body to ensure and be satisfied that research activities, particularly those involving human embryos and stem cell lines derived thereof, meet the ethical and regulatory

[55] See the MHRA's governance under 'Advanced therapy medicinal products: regulation and licensing' states, "In the UK, MHRA is the competent authority for clinical trial authorization for all medicinal products, including ATMPs…"

[56] HFEA is given the mandate to grant licence for the use of human embryos for research purposes.

[57] The Stem Cell Bank Steering Committee is given the responsibility to approve the use of human embryonic stem cell lines in the UK.

requirements. The regulatory bodies have a very important task and may not grant a licence if, for example, the envisaged findings could be obtained through other available means.

Based on the interviews, licensing is not one of the predominant regulatory requirements for non-clinical research, which may arguably also include embryonic work. A licence is, however required for clinical research because it involves human subjects. Thus, it can be said that the licensing requirement is not being comprehensively implemented throughout the entire continuum of human embryonic stem cell research in Malaysia.

1.1 The Implementation of a Licensing System

Respondent 5, stated that there is no license required as an academic. Instead of having to get a licence, ethical approval from institutional research ethics committee is sufficient in her capacity as a scientist at the institution.

> *I: So you don't have a licence for your research, just ethics approval?*
>
> *Respondent 5: …as a lecturer; I have to do research also, so the licence is the ethics approval.*
>
> *I: So, there is no specific licence?*
>
> *Respondent 5: Yes. [Stem Cell Scientist]*

Some stakeholders are aware of this situation. For instance, respondent 4 explained that the Ministry of Health, which is the authority that grants licences through its agency, the Ministry of Health Medical Research Ethics Committee (MREC), does not require laboratory-based research or non-clinical research to be licensed or approved.

Only research activities that involve human participants are subject to MREC's approval. (Medical Research & Ethics Committee's (MREC) Submission Form and Procedure)[58] This account further supports the point made earlier in Chapter 4 that the current regulation is not comprehensively implemented.

> *I: So what's the function of Ministry of Health? Who gives the licence or approval, is it MREC?*
>
> *Respondent 4: MREC. So all clinical trial that is to be conducted using stem cell must go through this MREC and get the [approval], all clinical trials.*
>
> *I: And the research as well?*
> *Respondent 4: The research, biomedical research, [no need], so if you're conducting some basic biomedical research, you do not need to involve patient, so you [don't have to] register with the MREC...you have got your institutional review board, IRB, like University have got their institutional review board…then they will just approve…until you do clinical trial then only you need the approval from the MREC. [Stem Cell Scientist, Stem Cell Policy Panellist, Advisory Council]*

Based on the explanations given by the respondents above, it shows that in general, hSCR in a non-clinical setting including research involving human embryos and established embryonic stem cells does not require a licence or approval from a government authority. Since respondent 4 is involved in the implementation of the regulation and confirmed that the current system does not require the authority at the national level to grant approval for non-clinical research, this indicates that the protection for human embryos and embryonic cell lines in such setting can be questionable.

[58] "It is the responsibility of the investigator to apply to MREC for approval to conduct research involving human subjects if the research is conducted in Ministry of Health Malaysia facilities or institutions."

1.2 Issues With The Licensing System

It is worth pointing out that with regards to the implementation of the licensing procedure, some respondents acknowledged that the Ministry, through its relevant agencies, adopted a facilitative and convenient system. The application procedure is available online and it is helpful for the researchers to go through the application process.

> *I: What is the current practice in granting licence, ethical approval? Are there any difficulties?*
>
> *Respondent 3: It is all done by the stem cell committee under MREC. So I think they are very competent…there is an online process, there is a procedure. It's all done by MOH. [Scientist, Ministry Official, Advisory Council]*

Even though the scope of the application of the licensing system is limited to or only focused on clinical research and trials, there are still issues of non-compliance within this research area. For instance, respondent 3 used 'stem cell therapy' for Down syndrome. Mentioned in the preceding chapter, as an example, the respondent argued, it should be considered as a clinical trial and accordingly, patients involved in the 'treatment' procedure should not get charged.

> *Respondent 3: …there had been complains that these companies have been charging some patients on the trial, in fact you should be paying them not they pay you, you know maybe at the discount of what, charges for the procedure, so that already transgresses the ethical rule so who should monitor them, granting body? We don't know about this but MOH [Ministry of Health] should always monitor clinical trials. I want to know…what is the MMA's [Malaysian Medical Association] role. [Emphasis added] [Scientist, Ministry Official, Advisory Council]*

One could argue, this shows an improved licensing system is needed, particularly to ensure all individuals who entered into this regulated area comply with ethical rules. In this case, if the treatment is not proven, it should be classified as a clinical trial and needs to be licensed and monitored accordingly. As being practised in other countries, with a licensing system in place, a licensee is subject to a monitoring system. With such measure, licensor (or the regulatory body) would be in the position to keep compliance in check. The monitoring system is discussed in more details in section 5.

Also, a number of respondents expressed concerns over the scope of rules enforcement involving private companies. As explained by respondent 19 below, the Medical Research Ethics Council's governing authority is limited to the public universities and research institutions, which are affiliated to the Ministry.

The council has no authority over the private companies or privately-funded researchers, which means their research activities do not need to be licensed. Moreover, the Private Healthcare Act [59] appears to have limited legal scope as argued by Respondent 11. Respondent 16 expressed worries over the growing number of private clinics operating without being regulated.

> *I: As of now, our Ministry of Health and also the national ethics committee for stem cell research, they don't actually monitor or govern stem cell research or therapy that being done by the private companies?*
>
> *Respondent 19: Not yet, that's why they wanted to have the act. So that they can at least you know see, govern, probably not to let them loose, loose in that sense they can do anything.*
>
> *I: Will it require license?*

[59] Private Healthcare Facilities and Services Act 1998, as introduced in Section 3.2.1, Chapter 3.

Respondent 19: It should be. That's one of the requirements. Before you can do anything, even the premises, the person's going to do it, they need to be licensed. [Stem Cell Scientist]

Respondent 11: …the Private Healthcare Act only regulates certain private healthcare institution…there is no way telling that some of these private clinics maybe selling the excess embryos for research because it's all suspicious. [Lawyer, Stem Cell Policy Panellist]

I: Do you know we have private companies from other countries coming into Malaysia…they are offering treatments?

Respondent 16: Yes, but then we have to regulate them very carefully. They can do whatever they want. It's dangerous unless there are regulations in place. Otherwise, they would be doing things that only countries that have no regulations do…we must not make regulation too tight as well. [Embryologist]

The quotes above provide some insights given by the respondents on the implementation of licensing system. According to them, this compliance measure is not being fully enforced within the public sector. It is only applicable to clinical research. Stakeholders in the private sector do not fall within the MREC's authority in approving and licensing a research project.

This shows in order to ensure the comprehensiveness of its enforcement, not only it should be extended to cover non-clinical research, but it has also need to be given legal effect in order to ensure its enforceability within the private sector too.

2. Informed Consent

Informed consent is one of the vital measures adopted by regulating authorities around the world to regulate hSCR. (Caulfield et al., 2007) Such a measure is particularly important in a contentious environment of research involving human embryos and scholars have researched and examined on its importance and appropriate application. (Caulfield et al., 2007, Knowles; Stem Cell Network's publication) One of the prerequisites for consent to be recognised as 'informed' is that it must involve a proper consultation process - a full and clear explanation of the research purpose and the risks involved must be provided.

The purpose of this section is to show respondents' perceptions of informed consent and the adequacy of its implementation, how they view its enforcement, how this compared to their views on licensing, and what are their concerns.

2.1 The Implementation of Informed Consent

When the respondents were asked about the importance of informed consent, they affirmed that it is a crucial ethical measure and it is one of the ethical prerequisites for a research project to be approved.

> *I: How important do you think informed consent is in this area?*
> *Respondent 9: Oh, very important. [Ethics Committee Member]*

> *Respondent 1: This is very very important and I think it's a must with any ethics… [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]*

> *Respondent 2: Yes, I suppose it is important… [Lawyer, Advisory Council]*

Unlike the implementation of licensing system, informed consent is required for all kinds of research whether or not they are clinical or non-clinical research.[60] (Medical Research & Ethics Committee's (MREC) Requirements)[61] For instance, respondent 5 gave a brief account on how samples for research work are procured from patients to demonstrate the implementation of informed consent in non-clinical research.

> *I: Where do you get the samples?*
>
> *Respondent 5: …we have an ethics approval for the sample collection…we get the samples from children patient, and also from adult, so they [have] given the consent…these are from extracted [sample]…we give them consent form and if they want to donate to us then we will collect the samples. [Stem Cell Scientist]*

The respondents believed that necessary information should be provided to ensure research subjects are well informed of the nature of the research project. This would reduce the possibility of having to disrupt research progress if research participants later changed their mind. This may be seen as a means to protect the progress of a research project.

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[60] This thesis notes that informed consent varies depending on the research. The informed consent practice for participating in clinical trials is different from informed consent to donate samples for non-clinical research as they involve different risks et cetera.

[61] Para 2 stipulates, "All research NOT involving human subject, as defined in (1) above, may be exempted from MREC review and approval. Such research is also automatically exempted from obtaining informed consent from study subject since by definition no human subject is involved."

Para 2(2.1) states, "There must be explicit separation of consent to surgery, or other forms of treatment/procedure from consent to use the tissues or tissues surplus for research."

Respondent 9: Yes, patients have to be told that 'maybe in the future, we might need to use your stem cell for other purpose, will you agree or not?' Some might say, 'no, I don't', you only use it one off', they might say, 'yes, only under certain conditions'…sometimes later they might say, 'oh, I didn't say yes', so you really need to get it on paper to explain to them properly. [Ethics Committee Member]

However, this measure is also being practised to protect the rights of the research subjects. There is a review by an independent review committee to ensure that informed consent is prepared in accordance to ethical requirements and able to provide adequate protection for research subjects. The committee would make recommendations for amendments if there were changes needed. It was also stressed that the enforcement is quite strict for some research areas i.e. clinical research/trials, whereby there is an investigation centre that steers a coordination of the rules enforcement.

I: What's the current practice of informed consent?

Respondent 20: We send our proposal to [Institute A]'s ethics committee…it's an independent review…how to improve our proposal even in our informed consent [form], what things to add, what things we should not be adding to make sure…the rights of the donors are should be always maintained and always protected… [Scientist, Stem Cell Policy Panellist]

I: What is the informed consent practice at the moment, in Malaysia?

Respondent 21: I don't know about stem cells but for all the research that we're doing…we are very very strict so most of the clinical studies…are coordinated by a centre called clinical investigation centre… [Ethics Committee Member]

There is an emphasis on the importance of written consent instead of verbal consent, even though the laws/guidelines only require the latter.[62] Respondent 18 believed that it is more beneficial for the researchers/physicians to obtain a written consent, and it is also crucial to provide patients with a proper counselling to ensure that the patients understand the risk involved, particularly in the new area such as stem cells science.

> *Respondent 18: We emphasise on written consent. So at all level actually from research, for donor consent to treatment consent, all are written consent. Although the provision of law says verbal consent is acceptable…we recommend all researchers...they must have written consent…patient must be properly counselled especially in new area like stem cell technology. [Stem Cell Scientist, Advisory Council]*

Another important feature in this practice is the consultation process when obtaining the consent. Respondents 5 and 19 asserted that patients are given the opportunity to ask questions. During the consultation, certain things are highlighted and emphasised to make sure that the patients are more likely to understand, among other things about the nature of the research project, the possible risks, and the status of the patient's and researcher's rights in future.

> *I: What is the current practice in Malaysia? Is it just ticking off boxes only or you have consultation?*
>
> *Respondent 5: Of course we allow the patient to ask…When they donate their [body sample], we did write there that if it becomes an investigational product whatever…they have given up their rights…but sometimes if they have nothing to ask, the part that we say you have given up your rights, we point out so that they understand that… [Stem Cell Scientist]*

[62] Even though the various guidelines, for instance, the Malaysian Guidelines for Stem Cell Research and Therapy 2009 and Guidelines on Human Biological Tissues 31 October 2006 do not specifically mention 'written consent', the requirement for investigators to include statements of information on the research automatically indicates that the consent has to be in written.

Respondent 19: …we have been working with the IVF patients…they need to sign a consent letter and usually before that the doctor will advise the patient, give, explain the procedure all these things, the ups and downs, the side effects…If need to be…the counsellors in the presence or witness, usually we have the nurses to be present. [Stem Cell Scientist]

2.2 Issues of the Implementation of Informed Consent

Even though the respondents above indicated that the implementation of informed consent is more comprehensive than that of the licensing system, there is room for improvements. There is a mix of opinions with regards to its implementation, as presented below.

2.2.1 Informed Consent in Clinical and Non-Clinical Research

According to respondent 21, informed consent is part of a Good Clinical Practice within the medical sector. It is strictly emphasised among physicians to an extent that there are workshops or classes organised to educate them on how to appropriately obtain an informed consent from patients. The respondent also emphasised that it is a mandatory requirement before clinical research can be carried out.

Respondent 21: …for doctors…to start research… you will need to explain the whole study [to the research subjects or patients]. I know because I'm with the [hospital]. I'm the lecturer for how to take informed consent, how to approach patients…how to make that information document to give to the subject so that they can read up and see whether they want to be in the study and how all the subjects should have autonomy in deciding for themselves…at the NCCR [National Committee of Clinical Research], it is already mandatory, you cannot start clinical research until the principal investigator has got the certificate [Good Clinical Practice]. [Ethics Committee Member]

However, when asked whether or not similar emphasis is being applied among non-medical researchers who are doing non-clinical research, the

respondent explained that such research is not under the purview of the medical-based ethics committee. It is under the remit of non-medical ethics committee whose training is uncertain. The respondent further expressed concern over the competence of the latter committee.

> *I: But is this practice or exercise applicable to medical researchers only or for non-medical as well?*
>
> *Respondent 21: …that's a good question…we have all been audited by Ministry of Health that we [clinical researchers] carry out according to good clinical practice…because it involves human [clinical research only], then it comes here. So if somebody [non-clinical scientists] at the Faculty of Science [university] wants to do this, as long as it doesn't involve human [non-clinical research] then it doesn't come here [ethics committee at Medical Faculty]…I always worry, because there's another committee now at Science [faculty]…we [ethics committee at Medical Faculty] all are quite well trained. I don't know who is training them [ethics committee at Science Faculty]… [Ethics Committee Member]*

This concern over the competency of the non-medical ethics committee is compounded by the issues of the standardisation of the implementation of informed consent within the stem cells area. Whilst some respondents mentioned that there is a standard format provided by the Ministry of Health, others argued differently. For instance, respondent 9 and 12 stated that there is a standard format of an informed consent form.

> *Respondent 9: Well, the informed consent…when you want to do research, of course there is the ministry's format… [Ethics Committee Member]*
>
> *Respondent 12: Essentially, the amniotic stem cells would involve that but basically, we do have a standard form for that because my collaborators is actually in [University] [Stem Cell Scientist]*

Nevertheless, respondent 2 clarified that there is indeed a standard format but it is limited to the standard consent form for medical purposes especially for surgery, whereas "*there is no standard formula as to how informed consent should be drafted"* for other areas, particularly non-clinical research. As has been argued above, it seems the implementation is more emphasised in the medical sector and clinical research than in basic sciences area - non-clinical-based hSCR.

2.2.2 Consultation Process

Whilst some claimed that there is a consultation conducted, at least based on experience from their own research activities, others argued that there is still lack of understanding of what informed consent is in general – among relevant stakeholders including researchers and public, and how the consultation process should be appropriately conducted. One group of respondents expressed concerns over the substantiality of the practice of informed consent.

Respondent 3 argued from the perspectives as a basic science researcher, due to the culture of 'trust the scientists', the public are in general, unaware of what informed consent actually means and thus do not know of their rights as research participants. The respondents noted the bio-bank project in Malaysia as an example of the public's excitement without much knowledge over the research. This demotes a more important matter that they should be aware of such as informed consent. Also, there is a doubt on the adequacy of consultations conducted for certain research projects.

> *Respondent 3: I think there's a big debate. I think there are many levels, unconcerned of informed consent…we have certain projects like biobank projects. I think the consultations may not be adequate. People are very excited, they trust these entities [bio banks]…means people may or may not understand what it actually means about informed consent and how far their material can be used… How do they [service provider] consult them [public or bio bank users]? I mean organ donation…or even blood donation, what is the informed consent procedure for that? Let alone stem cells…I think it's something we should look at institutionally. [Scientist, Ministry Official, Advisory Council]*

Whilst respondent 21 who expressed concern with regards to the training on informed consent in non medical sector, respondent 3 argued there is uncertainty of the standard of informed consent being practised in the country and concerned about it. The latter argued that there should be guidelines introduced to give guidance for obtaining a proper informed consent for all research without specifying which sector.[63]

It is uncertain whether there are sufficient counsellors who are well trained, not only in the practice of informed consent, but also who have the knowledge to be able to distinguish the substance and the suitability of consent provisions needed between different research projects.

> *Respondent 3: But, I'm concerned with what is the standard for informed consent?... I think [it] has to be really clear and make clear to the individuals [research subjects], their rights. We don't have enough counsellors…I am not sure the researchers are competent counsellors for informed consent. Are there guidelines on how informed consent should be done? That one should be developed for Malaysia for all ethical research. It should be independent; it should be by trained person who knows the limits, the differences of informed consent for different kinds of projects. [Scientist, Ministry Official, Advisory Council]*

[63] Note that there are format of statements that need to be included in an informed consent form, provided by different guidelines such as the Malaysian National Guidelines for Stem Cell Research and Therapy 2009 and Guidelines on Human Biological Tissues 31 October 2006. The MREC also includes the Declaration of Helsinki and the Belmont Report for research community's reference.

Respondent 20 argued many members of public are not aware of the importance of this practice and some of them would simply give consent. The respondent also argued for the role of the researchers themselves to curb this unethical exercise.

> *Respondent 20: I think the public needs to be aware. Some of them just simply sign…it's a very important thing for us to make sure that we [scientists] do everything with ethics, before we even try to get…your sample…we should advocate…I believe ethics, ethical way of doing research. [Scientist, Stem Cell Policy Panellist]*

This section further reveals the regulatory gap between clinical and non-clinical research and the incomprehensiveness of the current regulatory framework. As reported, even though informed consent is thought of as being comprehensively implemented but through further discussion it is shown that more emphasis is given within the medical sector. The ethics committee in this sector is given a proper training in the informed consent practice and audited by the MOH, but there is a concern expressed with regards to the committee in the basic science division. There is also concern about the awareness among the general public of the importance of this practice.

With regards to the former concern, it was suggested that guidelines on informed consent for hSCR activities should be introduced. This would particularly benefit the researchers and ethics committee in the basic science division. In view of this suggestion, there are guidelines introduced by the ISSCR with an aim to provide standardised guiding rules for the international community involved in hSCR. (2015a) Following the suggestion, Malaysian regulators could use these guidelines as a template to draft its own guiding

rules to suit its national context. In addition, the training system in which respondent 21 is involved could be also practised across the board regardless clinical or non-clinical research.

As for the latter issue – on the public awareness, the approach taken by the UK HFEA is another practice that could be considered. As pointed out in Chapter 3, the authority has its own website, and it is a channel used by the authority to disseminate information including the practice of informed consent. There is an allocated section specifically designed for patients and members of the public.

Nevertheless, the discussion above shows that it is predominantly important to address the issue of the incomplete enforcement – to ensure that a standardised protocol to be complied with across the board i.e. private and public player including clinical and non-clinical research. Similar to the licensing system, this measure would need to be backed by legal force to ensure that all relevant parties fall under the purview of the same regulatory provision.

3. Statutory Sanctions

As has been argued in Chapter 2 and 3, legal sanctioning is an important enforcement strategy. It has been shown in Chapter 3 that many countries that have enacted legislation to regulate stem cells area, incorporated penal sanctions for non-compliances. Nevertheless, there is no legal provision for penal sanctions that could be imposed on offenders in the area of hSCR in Malaysia, particularly non-clinical research.

One of the questions during the interviews was aimed to acquire opinions from Malaysian stakeholders on the possibility of introducing penal

sanctions as a compliance measure or strategy to enforce rules specifically for hSCR.

3.1 Views on the Implementation of Sanctions

One of the respondents was not certain how to react to the question and was taken aback of the idea that researchers have to face sanctions instead of mere warning if discovered of not complying with the regulation. It was argued that such notion would not be well received by the scientific community.

> *I: When we have law in the future, as a researcher, do you agree sanctions to be stipulated in the law?*
>
> *Respondent 12: …That's stressful to think about. Well you…can take action to give warning and stuff like that but more than that…well, I don't think like someone would happy to hear that... [Stem Cell Scientist]*

The respondent further reasoned that the implementation of sanctions would give an impression as though researchers are not to be trusted to be ethical. Instead of having statutory sanction, the respondent felt that actions should be taken through a regulatory body within a university, whereby warning would be given instead of applying sanctions through legal actions.

> *Respondent 12: …when we actually go for a very serious outcome for this particular action it sounds like, 'are you not trusting me?'...The first action should be by the university…the [ethics] committee…if you actually know what you're doing [is unethical] that should come [with a] big warning. But if you did by mistake…I think [sanction] sounds like very serious matter. No, I wouldn't agree because I feel…you don't trust me. [Stem Cell Scientist]*

The respondent above might be only speaking from the perspectives of a researcher who is university-affiliated, and who may be usually governed by

university ethics committee. However, after taking into account the fact there are entities especially those in private sector, which are not being regulated, and using the Hwang case as an example, the respondent felt that the implementation of sanctions is needed and understood its importance to discourage prohibited conduct.

> *I: In reality, there are people, there has been a case, in South Korea, there's a fraud.*
>
> *Respondent 12: Oh yes.*
>
> *I: Don't you think that sanction is important to avoid this…even to protect the scientist and also to protect the research subject. If that things are happening don't you think it will hamper advancement and public wont trust scientist anymore?*
>
> *Respondent 12: I [am] aware of that case and well I don't know how to say… can't you actually make a law once or make a decision based on the case rather than to have a general rules or whatever you know law on that particular one…*
> *[Interviewer explains on the application of sanctions by judge in different cases, which is depending on the severity of the incompliance]*
>
> *I: So do you agree that there should be sanctions for prohibited research conduct?*
>
> *Respondent 12: Yes, I do agree for that part I think we should know what, as a consequence if you actually happen to do that the things you are not suppose to do. [Stem Cell Scientist]*

After being asked the same question, most of the other respondents at first instance contended that sanctions are very much needed. For example, whilst respondent 16 believed that sanctions are crucial and needed to discourage people from violating regulation and acting unethically, with a similar argument, respondent 7 expressed support for the potential introduction of statutory sanctions so that offenders could be punished under the promulgated law.

I: You said the regulation should be flexible, not restrictive but at the same time do you think sanctions are important as well?

Respondent 16: Very. Deterrence is important. If you don't have deterrence, people will do whatever they like. That we cannot have there are many unscrupulous characters. If people can traffic human beings why wouldn't they trafficking stem cells. [Embryologist]

Respondent 7: I think, in this sanction issue, if this law is made, is drafted and passed by parliament. Then, this law must also include offenses for those who are violating, those who are carrying stem cell practice not in accordance with this act. So, it is punishable under this act. [Lawyer, Religious Authority, Advisory Council]

In addition, respondent 2 reasoned that sanctions are crucial especially to strengthen the restrictions in place. Without sanctions, restrictions can be regarded as not being effective. Nevertheless, it was also pointed out that it is important for sanctions to be enforceable.

I: Countries, for example UK and Singapore, they introduced sanctions… do you think that we should do in Malaysia in future, should we have a law?

Respondent 2: I think if you have restrictions…should always come with sanctions…otherwise the person is not motivated to comply the restrictions…but the sanction has to be provided in such a way that it is made for easier enforcement. That's my view. [Lawyer, Advisory Council]

As has been argued previously, at the moment Malaysia has no law that would enable the regulators to govern private actors who are not bounded by the national guidelines. Therefore, the respondents perceived the situation as a calling for the government to enact law with a provision on sanctions, which can be used to act on breaching parties including the private actors.

I: Do you think we should have sanctions?

Respondent 11: Oh, we should. At the moment…no sanctions. This is what we are telling the Ministry of Health. They don't have a bullet to go against the private clinics that is flouting with regulation…We don't have anything! So, we need to have that from laws to go against these private parties who you know all these guidelines are good for nothing. [Lawyer, Stem Cell Policy Panellist]

Respondents believed sanctions should be introduced because of the regulatory gap between medical practitioners and scientists. Whilst the latter are not strictly regulated, the former are subject to the monitoring by professional bodies such as Malaysian Medical Council and Malaysian Medical Association, as well as regulated by Medical Act 1971.

This shows that scientists from both the public and private sectors are not as strictly regulated as the medical doctors. Even though the public sector scientists are more or less restricted to some extent due to ethical requirements, which might affect research funding, the private sector scientists have the freedom to go about with their research activities without being subject to any sanctioning and prosecuting measures.

I: Do you think it should be sanction in legislation?

Respondent 18: It should be done. You see from the medical point of view, the Malaysian Medical Council and the Medical Act itself, all our regulation of misconduct, these are all in place so if a medical person doing a stem cell work…sort of in contradict with the law…they are actually liable to prosecution. So those are already in place for the medical doctor but the scientists are not…we got Medical Act to cover as far as doctors are concerned…if there is any misconduct…we all get caught by the MMC, Malaysian Medical Council, which oversees us and then there is this Medical Act 1971 that actually governs the whole thing…but the scientists, they are completely free. [Stem Cell Scientist, Advisory Council]

3.2 Possible Types of Sanctions

There are different opinions in terms of the type of sanctions. Respondent 2 explained that if the non-compliance were categorised under the criminal offence, the penalty would be either fine or jail sentence or both, as adopted by many countries.

> *I: What form of sanctions do you think normally would be appropriate for Malaysians?*
>
> *Respondent 2: Well if it's going to be criminal offence then obviously the sanction would be either fine, jail sentence or both but I think the researcher, either they should contribute a certain amount of money to some fund…to a some kind of central research fund of sorts…*
>
> *I: How do you actually determine for example how many years of imprisonment should be and how much fine it should be?*
>
> *Respondent 2: …normally what the law says is that you prescribe the maximum or you can prescribe the minimum and the maximum. Sometimes…zero to maximum.*
>
> *I: Who decides this?*
>
> *Respondent 2: The court on a case-to-case basis because different case will have different considerations, different extenuating factors, different aggravating circumstances, different litigating circumstances so no two cases will be the same…you may have the same offence committed but you can't have same sentence… [Lawyer, Advisory Council]*

There are also suggestions of suspending researchers as an initial stage of penalty except for a serious case, which would be deemed by the court as befitting for a more stringent action such as fine or imprisonment.

> *Respondent 10: …basically what you're looking at is initially, probably suspension of research privileges…but subsequently you will be looking seriously at fines or even jail terms for more serious and especially repeated infringements. Okay that is something that is reasonable. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

When asked about how, sanctions provisions were determined under the Biosafety Act, which was recently legislated, respondent 3 gave an idea as to how the judiciary system normally determines sanctions and the relevance behind it.

> *I: Sanctions stated in the biosafety act. How is it determined?*
>
> *Respondent 3: Apparently, they have standards that the AG chambers adopt…we said that it's too harsh…we did have public consultation on that part…there [were] a lot of objections by the AG from going too low because they said from their experience if it's predictive, it doesn't work, so…they go for maximum. They said 'you have to understand that that's the maximum and usually it's for repeat offenders or extreme cases'…but for scientists looking at that, that's really horrendous…When we did disagree, they lessen a little bit of the fine but they did not barge on the jail term because they said, 'that's maximum, what do you worry about? You can be jailed for 0 day if the judge so wishes. It's discretionary for the judge.' [Scientist, Ministry Official, Advisory Council]*

Based on the findings presented in this section, it can be seen that the absence of legal sanctions in the framework for hSCR has contributed to the shared views among the respondents that the current regulation is inadequate. They agreed that by introducing sanctions, the regulatory framework would be more adequate and comprehensive – all regulated parties be they medical practitioners or clinical researchers, scientists or non-clinical researchers, those in the private as well as public sector will be subject to the same prosecuting measure. Also, such measure would be able to deter noncompliance since it will provide regulators the authority to impose punishment on non-compliant researchers. The findings also demonstrate the possible levels of severity of legal sanctions and what would and would not be welcomed by researchers.

4. The 14-day Rule

As has been explained in the introductory chapter, the 14-day rule was introduced in the UK and many countries including Malaysia have adopted it. However, the application of the rule in Malaysia is only limited to the use of surplus embryos, (National Guidelines for Stem Cell Research and Therapy, 2009b)[64] whereas the application is much broader in the UK and a few other countries, which includes the creation of embryos for research purposes.

However, in many other countries in Europe, the application of the rule is much narrower where for instance, the embryo creation is prohibited for any purpose. This shows that the application of the rule varies to suit with respective jurisdictional context. When the rule was discussed during the interviews, some of the respondents drew a distinction between the effectiveness of the 14-day rule, and its relevance in the Malaysian society.

4.1 The 14-day Rule in Malaysian Context

From the permissive Islamic perspectives, which are predominantly valued by moderate Islamic scholars, they believe that ensoulment occurs on the 40 days or even 120 days after fertilisation. (Al-Hayani, 2008, Athar, 2008)[65]

[64] Para 8 stipulates, "Research on embryonic stem cells derived from surplus embryos is allowed." Para 15 further specifies, "Research that should not be permitted at this time: (a) Research involving in vitro culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever occurs first."

[65] See Al-Hayani, "Each of you is placed in your mother's womb for forty days, then he becomes a blood clot, then a lump, then God sends an angel who writes his future actions, then [God] infuses this lump with His spirit." p. 790; and Athar, "Verily, the creation of each one of you is brought together in his mother's belly for 40 days. Then it remains these as a leech like structure for another 40 days. Then it remains these as a lump of chewed flesh for another 40 days. Then angel is sent and it blows into him

[66] This means that the pragmatic approach - 14-day rule introduced by the UK Warnock Committee is more cautious compared to the moderate Islamic views.

> *Respondent 11: And as far as JAKIM [Jabatan Kemajuan Islam Malaysia / Department of Islamic Development Malaysia] is concerned, if you are testing or experimenting on excess embryos…and you do it before the 14 days, because 14 days is actually a very cautious, you know, very cautious fine line, this is okay. [Lawyer, Stem Cell Policy Panellist]*

One might wonder why did the fatwa committee not choose to apply 40-day or 120-day rule in governing the use of human embryos in Malaysia. It is important to note that as explained previously, the fatwa is not only based on Islamic views but it also incorporates views from other religious groups that have more restrictive views.

Hence, the application of the 14-day rule is only for the use of surplus IVF-created human embryos. In other words, it can be said that this is a pragmatic approach in the Malaysian context, given the sensitivity of this issue and the opposing views among the religious groups.

> *Respondent 3: But if you're a Muslim, you have to abide but actually…it's more than 14 days, 3 months I think, it's longest of all the religions. But Catholic is 0 days, in theory, if we take into account we can't do embryonic stem cell research. We can't do at all. The life is at conception. You know how sensitive Malaysia is about that. I don't know how people will do that…we are so sensitive to cultural and interreligious. [Scientist, Ministry Official, Advisory Council]*

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the spirit." Athar goes on and states that "Although ensoulment occurs later in conception, the embryo is respected from the onset of fertilisation and acquires consideration as a human fetus after implantation."

[66] Muslim scholars believe that each stage of development lasts for 40 days, and therefore, according to this hadith, Muslim scholars argue that ensoulment occurs at 120 days (the most liberal view). Nevertheless, there are others who contend that embryo gains its human status when it develops human features (the most popular view and close to primitive streak argument) and another group believe it begins at conception (the most strict view).

Notwithstanding, respondent 7 argued the rule can be changed provided that there is a necessity depending on the situation. The modified 14-day rule is seen, as an appropriate measure for today but there is a possibility that another measure could be adopted if there is a need and justification to do so, subject to the consideration by the fatwa committee and a consultation with other religious groups.

> *Respondent 7: And regarding this…40 days, 120 days as I have mentioned, that is a difference of opinions between the scholars. Up to our rulers [Sultans][67], the people of authority in Islamic affairs to choose which one of these opinions they want to hold, if they find there is a necessity…it is important to import one opinion […] during this time, they will pick that type of opinion but one day situation occurs maybe we have to consider instead of 14 days, there is another ruling by ulama, by the scholars that it can be extended up to 40 days or 120 days because of necessity. [Lawyer, Religious Authority, Advisory Council]*

Respondent 7 provided a legal scenario where a rule can be changed if there is a necessity. Malaysia allows the use of embryos according to the 14-day rule but no specific requirement for justification to use them. This could suggest the permission is open to a broad interpretation that scientists especially in the private sector are not being controlled to use spare embryos without having to provide justification.

Such perception would undermine and potentially against the spirit of the fatwa and the national guidelines in protecting human embryos. Therefore, one could argue that it might be a necessity to incorporate the requirement for justification under the 14-day rule provision even for the use of surplus embryos.

[67] Sultans are the Head of religion in their respective state.

I: …the creation of human embryo, they also, scientists need to justify why they need to do that. But here in Malaysia it's not stated in the guidelines.

Respondent 2: There's no qualification. It's a blanket 'no'. I suppose Singapore they apply, maybe in Singapore they applied what I would characterise as doctrine necessity, in other words, I will allow it but you prove to me that it's necessary. I think that's what their, their approach that they are taking. [Lawyer, Advisory Council]

I: Should we consider allowing creation of human embryos for research purposes?

Respondent 10: I would say that if we want to allow creation of human embryos then there must be a legitimate research reason to do so. One that cannot be satisfied using existing cell lines okay, so, the reason for that is that when you do create an embryo, you create an ethical issue, okay…The benefits of conducting such research must be weight against the drawbacks to the whole field. My own personal feeling is that if it is to be given, permission must be specially granted by a council of experts in this area. [Medical Practitioner, Stem Cell Scientist, Advisory Council]

This is because, the adoption of the 14-day rule itself is not adequate to ensure protection for human embryos from being used unethically without appropriate implementation and enforcement. Chapter 3 shows that in some jurisdictions, there is a requirement to provide justification in addition to adherence to the 14-day rule.

A research application will only be approved and licensed if it is necessary and justified to be the only way to achieve the expected outcome. Also, in some countries, this is also a statutory provision, which means it has a legal force unlike its current application in Malaysia.

5. Monitoring System

As has been discussed in Chapters 2 and 3, a monitoring system is not only one of the important compliance measures but also the key and essential for regulators to ensure adequate enforcement of established rules. Without a monitoring system, it would be difficult to certify that all of the other measures i.e. licensing, ethical approval, informed consent are being appropriately implemented and observed by regulatees.

Chapter 4 has briefly underscored that many of the respondents perceived the current regulatory system as lacking in monitoring. In view of this, one could argue this scenario might jeopardise the integrity of this promising area. This chapter continues to explore the current practice of monitoring in more details.

5.1 The Monitoring System for Informed Consent Practice

Most of the respondents raised the issue of the lack of monitoring within the current regulatory practice. This may explain the inconsistency of the implementation of informed consent as discussed previously. As has been mentioned, respondent 21 claimed its implementation is given a significant weight among the medical practitioners, and uncertain about the non-clinical scientists. For instance, respondent 1 expressed concern about the enforcement of the informed consent procedure and questioned the monitoring of the practice.

> *Respondent 1: No, it's not difficult to follow [informed consent procedure]. There is a very clear framework on how it's done, and the only problem is whether our people follow it or not. That's the problem. Which go back to monitoring, who actually monitors and ensure that they [non-*

> *clinical scientists] actually apply whatever they submitted to the ethics committee? Okay, so I don't think that's the framework that's very [worrying]. What I'm worried about is actually the enforcement. That's the problem. [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]*

In addition, without a monitoring system in general, regulators would not be able to know whether or not informed consent need to be updated or renewed if there were changes made to the research protocol. This would solely depend on the researchers' discretion. Even though it is stated in the regulatory provisions that any changes in the protocol and other supporting documents will result in MREC's approval become void or null. (Medical Research & Ethics Committee's (MREC) Submission Form and Procedure) [68]

The annulment of approval for a research project does not guarantee researchers to be ethical and comply with the rules for regulators would not be in the know unless there's an oversight mechanism. For instance, respondent 9 gave an example of a case where it wasn't certain whether or not informed consent was re-obtained for sample that has been kept for many years.

One could argue that if there were a consistent oversight measure, regulators would be able to ensure the researcher to stay in touch with the cells donor except in a circumstance where blanket consent was given. It is an ethical requirement for researchers to update participants' informed consent if it involves some changes. However, due to the lack of monitoring, one could argue the researchers are left to self-regulate and this may possibly lead to non-compliance.

[68] "Any subsequent changes to the protocol, patient information sheet, informed consent form, and other supporting documents, as instructed by other ethic committees, will result in the MREC's approval becoming null and void."

Respondent 9: Okay, you look at informed consent form and all that and you say 'okay, you know you can do this project, of course if you make any changes to the research protocol, you have to get new informed consent' …there are some cases where they don't or after so many years, research samples are there, they cannot track the patient or the person who donated the stem cells so whether they actually get a new informed consent or not, we don't know…because if there is no monitoring, then, it's just up to the researcher whether they feel [they do] the correct thing or not…sometimes they give blanket approval…the donor says 'yes, you can use my stem cells later on for any purpose for anybody', then you are covered, but if you didn't have that kind of willing, then you have to go back and get them to give another informed consent. [Ethics Committee Member]

What can be derived from the findings above is that monitoring system for the practice of informed consent is lacking to an extent there is a possibility for regulators being uncertain with the compliance.

5.2 The Monitoring System for Stem Cells-Based Treatment

A few other respondents also raised the issue of monitoring measure for unregulated commercialisation of stem cells both through medical interventions and supplement pills, which are now becoming a trend in the country. Given the fact that there is no enforcement, it was also highlighted that regulators can only take an action when there is complaint.

Respondent 1: …They [regulators] can only act when the complain comes in, not while they [researchers] doing the research, nobody checks on you… [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]

Respondent 21: …there's no enforcement, there's nobody to come knocking on your door unless the only thing that I can think of is that… maybe because of death only then they will investigate. But if not and nobody complains, it will just go uninvestigated. [Ethics Committee Member]

Respondent 5 explained that the National Ethics Committee for Stem Cell Research is only monitoring therapy and does not include non-clinical stem cell research.

> *Respondent 5: …there is the National Ethics Committee on Stem Cell Research but this is in terms of when you want to do therapy. But at our level, this level, the fundamental research is not monitored, not required, but I think if fundamental research is to be monitored… [Stem Cell Scientist]*

5.3 Monitoring Body

It is also important to highlight that many respondents do not know if there is an existence of a monitoring body. For instance, respondent 5 stated that there is no monitoring for non-clinical research and the enforcement of rules would only come to place if a research involves human subjects.

> *I: Who is the governing body and the monitoring body in Malaysia?*
>
> *Respondent 5: I don't know, not in existence. The scientists themselves monitor and make sure…so at the moment, your conscience probably…I don't see anybody monitoring me…Now in terms of research [non-clinical research], what you want to do in your laboratory, there is no real restriction because it maintains in the lab…It's when you want to do a trial, then the credibility of your data, they [MREC] will have a look. [Stem Cell Scientist]*

One would ask why there is no monitoring body when it is already known that there are research activities going on and why non-clinical stem cell research and private providers are being left unregulated. Respondent 3 pointed out that the lack of monitoring in Malaysia is due to the absence of law

enforcement that requires such system to be strictly implemented by a dedicated monitoring body.

> *I: What do you think of the monitoring system by the ethics committee?*
>
> *Respondent 3: I think it's lacking. I think because it's not institutionalized as an act, I don't think there is a permanent [regulatory body] monitoring these kinds of activities. [Scientist, Ministry Official, Advisory Council]*

Some respondents argued, non-clinical research activities should be monitored too. There is a suggestion made for an establishment of a monitoring body to monitor all kinds of research activities, be they non-clinical or clinical-based research.

> *I: Do you think it's important to monitor research as well?*
>
> *Respondent 20: Yeah we should have…we should have…a centre or body overlooking everything but mainly, Malaysia, is now at looking at the human side. [Scientist, Stem Cell Policy Panellist]*

Respondent 12 who has experienced working in the UK, which has an established regulation explained how Malaysian regulators in this area could learn from the UK. The respondent illustrated a series of monitoring process that needs to take place in making sure ethical standards are met by researchers.

> *I: what about the monitoring system? What can we learn?*
>
> *Respondent 12: … the monitoring comes from the course file and everything, the lab and there's audit…people do come and check the lab safety and whether everything right up to the level that, even the lab book…students actually have lab book which is checked; did they really follow the rules and everything. So those are the minor things that I'm aware of but not fully aware of how they do the monitoring because that*

would be the PI [Principal Investigator]…I guess it's like there could be a system actually like every year kind of like checking things are okay. [Stem Cell Scientist]

The quotes above indicate that current framework is lacking of monitoring system, it further strengthens the argument made earlier that the framework is inadequate and incomprehensive to ensure compliance with the rules in place. One could question, without a monitoring or oversight mechanism, how would regulators know or ensure that regulatees are complying with other important regulatory measures i.e. informed consent, licensing requirements, and the 14-day rule? Also, without a statutorily mandated regulatory body, how would regulators regulate inclusively and comprehensively – to govern across the board?

Conclusion

These findings show that regulatory measures i.e. licensing, informed consent, legal sanctions, the 14-day rule, and a monitoring system are recognised by the stakeholders as a vital ethical compliance measures, especially for the new emerging technologies such as stem cells science.

Whilst some measures are being implemented, there are also issues with the enforcement. As spelled out by the respondents: (i) the licensing system in not applicable to the non-clinical research; (ii) the informed consent is enforced across the board but more emphasis is given for clinical research; (iii) there are no sanctions in place that can be imposed on particularly non-clinical research and private actors; (iv) there is a disagreement with the prohibition of

embryos creation and the absence of justification requirement for the use of the 14-day rule; and (v) the enforcement of the compliance measures is missing an important or key feature of regulation, which is the oversight mechanism (monitoring).

This chapter has further highlighted the points demonstrated in Chapter 4. The current framework is not effective, non-comprehensive, and unable to ensure ethical compliance with the rules in place. Also, it does not facilitate awareness among relevant stakeholders. If there was a central regulatory agency that is mandated to regulate hSCR in Malaysia, this agency could run a public campaign using social media to raise awareness about good practice in this field and warn the public about fraudulent stem cell treatment providers.

Most importantly, the enforcement of the measures is also viewed as inadequate given there is no legal force. Therefore, it is essential to recognise the need to give these measures legal effect to ensure its enforceability across the hSCR domain. The following chapter provides the respondents' views on some regulatory options to address these issues.

Chapter 6: Regulatory Options for an Improved Regulatory Framework

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Introduction

The two previous empirical chapters (chapters 4 and 5) have reported respondents' views and opinions concerning Malaysia's current regulatory framework and the underlying reasons for it being perceived as problematic. Among the prominent factors identified are those pertaining to the issues of awareness; the regulatory gaps, the efficacy and scope of the current guiding rules, the non-comprehensivene nature of regulatory implementation;, and the absence of legal force within the system.

As a continuation, this chapter further highlights the respondents' views on how the system may be improved – in order to address the above factors. This chapter also describes concerns regarding the lack of clarity in the current guiding rules and provisions before discussing the different options suggested to address the issues.

The discussion considers the merits of different regulatory approaches to improve the current framework. These includes options to resolve the issue of the comprehensiveness and adequacy of rules in place by considering (i) legislation; (ii) an introduction of national policy; (iii) an establishment of an independent regulatory body; and (iv) importation of rules established in developed countries or countries with similar cultural or religious settings.

1. Malaysia's Current Framework: The Effectiveness and Adequacy of the National Guidelines

The preceding chapters capture from the respondents' accounts their awareness of national guidelines, their legal effect, and non-binding nature.

Ethical compliance with hSCR regulation in Malaysia is also voluntarily. Violation of the regulatory requirements does not result in guaranteed per se, instead there may be non-legal actions such as warnings from the universities or research institution in question or the withdrawal of funding. As such, one could still question the effectiveness of the guidelines to ensure ethical conduct and provide protection for members of the public.

However, the current guidelines may have some significance if their purpose is to govern the scientific community in the public sector. Their dependence on public funding facilitates indirect regulation through funding control and any violations of the guidelines could lead to funding revocation. However, this excludes those in the private sector who do not depend on federal funding and there are issues with the clarity of the guiding rules. The lack of legally binding rules in the implementation of the guidelines is compounded by the lack of clarity and updated rules within the current system.

1.1 An Updated and Clear Regulation

Many of the respondents who are aware of the guidelines argued that the guidelines are not up-to-date with stem cell science and as a result, many of the newer research activities are not covered.

> *Respondent 10: Our guidelines are limited to fairly standard forms of stem cell research but the newer forms of stem cell research are not really covered. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

In addition to their views on the system's limited coverage of both public and private parties, the respondents also found the guidelines to be lacking in

their incorporation of new technological advancements. Respondent 10 shared this view by drawing attention to ethically contentious activity such as therapeutic cloning.

> *Respondent 10: …the main thing is in terms of regulation of embryonic stem cells work, there is also very little that is actually given in terms of therapeutic cloning…is an area not very well addressed. Our guidelines and our regulation today are not so well developed compared to other countries. If we were to stream line those and bring it in line with what's been done in other developed countries, I think we should be fine. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

In the light of this, some respondents suggested that the guidelines should be revised so that the provisions are up-to-date with the rapid pace of research advancement. Particularly, respondent 10 emphasised the need for Malaysia to compare its guidelines against those of other jurisdictions whose regulation is considered more developed. Consequently, the current guidelines are not regarded as a comprehensive regulatory tool.

One of the respondents – respondent 12, had experience working in the UK, claimed by the respondent to be a clearer, more established system not only in terms of access to necessary information but also explanation of the rules in place. The respondent admired the capacity of the system to assist who have just entered into the regulatory field to understand the system easily.

> *I: Based on your experience in UK, what can we learn from the ethical, monitoring system in UK?*
>
> *Respondent 12: Well, there I feel…everything is clear-cut. I know where I need to go, whom I should contact, what kind of things I can do and don't, and things are actually come with a clear reasoning, why you can do this why you cannot do that. Theirs is [clearer]…they have a very good system. If I'm a newcomer, I will know easily. [Stem Cell Scientist]*

A clear understanding of system's regulatory requirements is important to researchers, for their assurance and confidence in their abidance with rules and regulation. As mentioned by respondent 12, a regulatory system that provides explanation would empower researchers to have a clear understanding about the rules in place.

This would also facilitate collaboration with other researchers at both the national and international level, which suggests that well-established regulation could simultaneously encourage compliance, ethical conduct, and research development.

> *Respondent 12: I would really happy to go for research without hesitating 'Can I do? Can I not? How are we going to go and collaborate?' [Stem Cell Scientist]*

An example of the lack of clarity within the current rules is the definition of 'surplus embryos', as stated in the guidelines. According to respondent 16's understanding, only non-viable surplus embryos can be used.

> *Respondent 16: You can get stem cells from non-viable embryo [surplus embryo]…and you can also induce pluripotency in vitro that means you can convert somatic cells which already differentiated towards undifferentiated state from which you can study a lot of things, investigate a lot but we must not create embryo because I think that is the area that you are not allowed/supposed to do. [Embryologist]*

It is worth mentioning here that the current Malaysian guidelines stipulate that researchers can use 'surplus embryos' for research purposes without specifying whether or not the surplus embryos need to be non-viable. There is no provision that stipulates only non-viable surplus embryos can be used to derive stem cells.

The respondent also mentioned a research technique – induced pluripotent stem cell technology, which is not explicitly included in the guidelines. This shows the importance of having accompanying explanations alongside the rules to avoid misunderstanding.

Such uncertainty could have a negative impact on collaboration. It is also imperative to revise out-dated rules, as they could also affect collaboration and research development if researchers themselves are not certain whether they can proceed with their work, and how it can be done, as argued by respondent 12. In addition, a system without an explanatory mechanism to provide the required interpretation of the rules could potentially result in a broad and quite varying range of understandings.

2. The Merits of Possible Regulatory Solutions

This chapter continues by setting out the advantages and disadvantages of different regulatory approaches to address the needs for regulatory improvement demonstrated at the start of this chapter. The following sections discuss the respondents' attitudes to forms of regulation; (i) legislating hSCR - primary vs. secondary law, (ii) the importance of national policy vs. legislation, (iii) whether there should be an independent regulatory body that is mandated to monitor hSCR, and (iv) whether Malaysia should adopt approaches from other countries and whether these should be developed or developing countries or a mixture of both.

2.1 Legislation

When discussing the possibility of introducing a law to regulate hSCR particularly non clinical embryonic and non-embryonic stem cell research, whilst many respondents argued that legislation should be introduced, for the benefit of the research community and the development of the field itself, others contended that the use of other relevant laws as a secondary legislation could be sufficient. This section explores these opposing views.

2.1.1 Legislating hSCR: The Pros and Cons

Respondents 1, 11, and 12 for instance, felt that legislation is a necessity. Respondent 1 and 11 argued that an umbrella act is needed for hSCR since the guidelines do not bind the private actors. With legislation in place, regulators would be able to monitor research activities that are going on in the country. The stem cells community would support this idea, according to respondent 12.

> *Respondent 1: …guidelines being guidelines, it won't be binding unless there is some legislation to the effect or unless there's some kind of compulsory… [Medical Practitioner, Stem Cell Scientist, Stem Cell Panellist]*

> *Respondent 11: We were telling them maybe an umbrella Act is needed…but, they don't see as a necessity because they say, 'okay, guideline that binds the relevant people is sufficient'. But what they don't see probably is the private players… So, we need to have that from laws to go against these private parties who you know all these guidelines are good for nothing. It's just basically binding people who are bound by it right, but not third parties, private parties, who are not the privy to it. It wouldn't. So we do need. [Lawyer, Stem Cell Policy Panellist]*

I: So do you think it's time for Malaysia…enact a law or establish a proper clear regulatory system to ensure ethical conduct and also at the same time to advance in this area?

Respondent 12: definitely, definitely that's something I look forward and I'm quite sure all the people in stem cell would like to have that developed regardless you're working on embryonic stem cells or not. [Stem Cell Scientist]

According to another respondent, legislation is important and needed not only to establish a proper procedure and monitoring system, but also as a measure to provide protection for the general public who have limited awareness of this technology.

They argued legislation would improve awareness among the public, as the act of legislating in itself signals to the public that the area should be taken seriously. As well as this effect, there would also be the actual impact of the law, protecting patients from being commercially exploited.

Respondent 1: If you ask me Malaysia should legislate law? Yes, because guidelines, people say, I just follow guidelines but if I don't follow the guidelines, it's not against the law, so you actually need to have law, and why? As I said before, it's very important because there are people ready to exploit public who are innocents and no matter how great scientist I am, I am still a doctor. Patients come first. [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]

Respondent 3: I think it has to be legislated and we have to have a proper monitoring and procedure in place. I don't like rules but sometimes you need it especially when you have a public, which is not well versed in the picture. [Scientist, Ministry Official, Advisory Council]

Respondent 2: "…some kind of control, so at least the public will be aware of what, or rather whether it works in the first place, and if it's going to work what are the risks associated with it." [Lawyer, Advisory Council]

Respondent 19: Yes, we should because we can manipulate so many things…you can make money and then the committee won't know, people wont know whether it's true…whether they have manipulated stem cells. Not all people are good you see. [Stem Cell Scientist]

I: You know that we have private companies from other countries coming into Malaysia and they are offering treatments?

Respondent 16: Yes, but then we have to regulate them very carefully. They can do whatever they want. It's dangerous unless there are regulations in place. Otherwise, they would be doing things that only countries that have no regulations do. For instance, it was the regulation that kept stem cell, because stem cell still not safe, so people cannot just go and do stem cell treatment unless we are 100% certain it is safe. That's why there are many countries still do not have stem cell treatment. Imagine, they grow the stem cells on a layer of mouse cells and then it is transferred to the human, I don't want that to happen to me. I don't want stem cell grown on mouse fibroblast coming into my body. I don't want that. So there are some concerns like this... [Embryologist]

A law not only informs people of the risks that exist in this area, but they will also know that they have a platform should they need to complain and exercise their right for protection. Regulators (or government) would have the authority to take legal action.

I: So, do you think it is time for us to have law?

Respondent 9: I think there should be some kind of, something that say, 'if you do this, you'll be fined for doing this or you can be put into prison, can be taken to court'. There must be that area where the public can have recourse. You know, if you want to complain, government can take action if they find that there is something wrong. But at the moment, it's a case of willing seller; willing buyer, okay, and you don't know what happens. [Ethics Committee Member]

Nevertheless, they also discussed a disadvantage of this approach – the time-consuming legislative process. For instance, respondent 10 gave the example of the time the government had taken to enact law to regulate medical devices and believed that introducing law for hSCR would also take a long time.

I: Do you think that Malaysia should have legal documents with legal effects like law, a piece of law?

> *Respondent 9: Yeah but to, you know, how long it takes to get something to become law in Malaysia? A few years but we have to make a start. Yeah they need to draft. [Ethics Committee Member]*

> *Respondent 10: …there should be regulation and legislation governing this, but it takes many years even the legislation of medical devices took almost ten years to come in, okay. So, I won't expect anything for the next five years like this. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

Due to the extensive time needed for the enactment of law, respondent 9 asserted that the legislative process should start as soon as possible. At the time of writing, there is currently no act relating to human cloning in Malaysia. Respondent 11 expressed bewilderment over the fact that the existing Human Cloning Bill is not yet passed despite there being a clear-cut understanding on the issue.

For instance, the government could just introduce law that prohibits human reproductive cloning, which is a worldwide consensus view. This is the approach taken by Singapore, whereby the government introduced law to regulate human cloning first, with plans to address hSCR legislation at a later date due to the issues relating to the former being more pressing.

> *Respondent 11: Just pass the Human Cloning Bill, you know because it's already there. Just pass it, it has a very clear, at least we know as far as human cloning, the stand is clear-cut right? Unlike stem cell, there may be differences in opinion as far as stem cell is concerned. But human cloning is very clear-cut…Why can't you just pass that one? [Lawyer, Stem Cell Policy Panellist]*

2.1.2 The Opposing Views on Legislative Approach

Even though majority of the respondents are in favour of legislating hSCR, it is not a consensus view. Respondent 20, for instance argued that there is no need for a specific legislation and that national policy would be sufficient. The respondent further added that stem cells should be governed as drugs, and therefore the issue would fall under the ambit of other relevant existing laws.

> *Respondent 20: The guidelines are there. The policy is coming, there's no special act.*
>
> *I: So, do you think that there's no need to have legislation?*
>
> *Respondent 20: …the policy is enough already…the policy is about how to make these stem cells as a safe drug…first to make sure it's safe and second thing, to make sure that it works as to what it has been claimed.*
>
> *I: The policy will involve research and the therapy?*
>
> *Respondent 20: The policy is not mainly [involving] the [non-clinical research, anyone can do research as long as you publish and all those things…the policy is that when you want to do any research using human on stem cells [clinical research] you need to go through MOH, and then when you go to MOH, what are the things required before you get your clinical trials approved? [Scientist, Stem Cell Policy Panellist]*

Respondent 10 disagreed with the use of other laws to secondarily govern the clinical research using human stem cells. They proposed that legislation for hSCR should be designed specifically according to and envisaging the views of the stakeholders.

> *Respondent 10: …the current Practice Act is insufficient for this. It was designed for a different purpose…you need proper regulations first and later legislation. And the regulation and legislation needs to be designed in concert with the stakeholders rather than something that is dropped on*

from on high." [Medical Practitioner, Stem Cell Scientist, Advisory Council]

In response to respondent 20's argument - although Malaysia has regulations for conducting research with human subjects as well as medical malpractice, these regulations however do not directly and specifically address stem cell therapy. Master and Resnik (2011) have discussed this issue pertaining to the regulatory matters concerning the stem cell tourism.

They argued, "additional regulations are needed, as there is little oversight of stem-cell research or therapy at present. Although most countries have regulations for conducting research with human subjects, as well as medical malpractice and licensing laws, these provide general guidance and do not directly address stem-cell therapy." (Master and Resnik, 2011; p. 992)

Moreover, referring back to the policy discussed, it seems its focus is the regulation and control of translational research and clinical trials. The regulation of activities at the non-clinical level was not mentioned. This thesis argues that based on the respondent 20's account, it seems the policy would give more emphasis to clinical research and fail to address concerns over the issue of regulatory gap identified in this study.

Therefore, legislation that governs both aspects of research seems the most appropriate way forward for Malaysia. However, this must be determined through a consultation process involving the relevant parties and does not negate the importance of having a national policy. The role of national policy, particularly in facilitating research development is discussed in section 2.2.

2.1.3 The Impact of Legislation on Research Development

Apart from the risk to public safety presented by unregulated commercially driven companies, the respondents who are researchers shared concerns about the safety of their work as it progressed. They perceived legislation as a measure that would provide a mechanism to facilitate research development. They felt that revising the system in Malaysia in line with those in developed countries would be conducive to developing their research.

> *Respondent 10: If we were to stream line those and bring it in line with what's been done in other developed countries, I think we should be fine. Having said that, is it going to cost a big stumbling block to our research? I don't think so. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

They are in need of a regulatory tool that functions as a source of clear information and can guide understanding of ethical requirements. They welcomed the idea of promulgating law for stem cell science with a belief that legislation would carry more weight and enable research activities both in their collaborative effort and research translation.

> *I: So do you think that it's time for Malaysia to have legislation?*
>
> *Respondent 5: I think so because like Singapore, very clear-cut, their policy and everything…of course we have our ethics approval, we have our IRB…that's about it. If we have a legislation, it's easier for us to do work and also to collaborate…when we want to get samples and materials also it's much better…but Malaysia, remain a guideline…so, I think it is important for us to have a legislation so that we can also be guided, how we want to do, what we can do, and it's not like wasted effort you know, trying to do this, and do that…if you do it properly, the translation is faster. [Stem Cell Scientist]*

For instance, two respondents gave an account as to why legislation would help advancement in the stem cells arena in Malaysia. They highlighted two prominent issues of other relevant areas of emerging technology. The first, biosafety, is another new area in Malaysia and an act, Biosafety Law, has been recently enacted. The respondent pointed out the difference in the effectiveness of biosafety control when the area was merely governed by guidelines and later when an act was enacted.

They stated that biosafety measures, particularly the monitoring system, were significantly improved only after the enactment of the new law and prior to that, the field risked of losing credibility because of the inefficiency of the previous regulatory framework.

> *Respondent 3: if you want to make a comparison to when something is effective because of an Act, is the Biosafety law…When it was a guideline, they issued report, there is almost nothing…only a few trials maybe were actually registered…but when the Act came up…there was a monitoring team, who were dedicated to implementing the Act…so the Act will give the mechanism…able to monitor and take action…now we have registered all the universities, private institutions, companies, we have a mechanism of distributing information because there are dedicated people who are looking at this. I think it has made huge of difference, there were a lot of resistance at the beginning because everybody thought we could self regulate but it didn't work…and we were losing credibility because of that. [Scientist, Ministry Official, Advisory Council]*

The second example was given earlier by respondent 10 in the previous chapter to show the lack of regulation has tarnished study of gene therapy. (Spink and Geddes, 2004, Friedmann, 2005)

In addition, a self-regulating system exists in the current regulatory framework, benefitting non-clinical research in which unproven and unregulated stem cell treatment providers operate independently without any control. This

situation could be potentially risky for the public, but may also jeopardise the reputation of the field. Malaysia's experience in improving the regulatory system of biosafety could be a valuable lesson and experience in how to similarly improve the hSCR field.

Furthermore, though most of the respondents of whom were researchers did not see promulgating a law to govern hSCR as a stumbling block, they did stress the importance of a balanced approach. They understood the importance of having law and guiding rules but the rules introduced should not be too restrictive of freedom for scientific exploration.

> *Respondent 1: I'm all for good science therefore if you look into this, what, whether we're going to be restrictive or liberal, I think they must be a balance between the two. [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]*

> *Respondent 12: People want to see something that you give freedom to research to go about to what they want to do rather than so much restriction I do understand for the law purpose, they should have some guidelines, but give a freedom is one. [Stem Cell Scientist]*

Another respondent argued that regulation that is too tight would discourage research activity. This may reduce interest among existing researchers to progress further, but also drive new talent away from venturing into this promising technology.

> *Respondent 16: …at the same time we must not have too tighter regulation. Too tight a regulation puts people off from research, makes things so difficult…it's too stressful so we must not make regulation too tight as well…must not destroy enthusiasm, make it reasonable… [Embryologist]*

2.2 National Policy in Stem Cells Science

As has been briefly introduced earlier, a national policy for hSCR was also discussed. As with legislation, some respondents also expressed support for introducing a national policy. For instance, respondent 7 explained the importance of a national policy in the hierarchy of a regulatory system. According to the respondent, the MOH should introduce a policy at the national level and other necessary measures of the policy implementation such as law or guidelines will follow.

I: How important policy is?

Respondent 7: The policy of the ministry is above all. Guideline is only a small piece of a policy…when the Ministry of Health determined one policy, for example, "all stem cell practice must be regulated starting from now on". That is the one policy of Ministry of Health. So, how to achieve this policy? By guidelines, by laws...so, these are all mechanisms; guidelines, seculars, laws, regulations, but the policy is above all…so guidelines only a small piece of mechanism. Policy is much more bigger. [Lawyer, Religious Authority, Advisory Council]

In addition to the necessity of having a clear and up-to-date regulation to facilitate collaboration, as mentioned earlier, it was also argued by respondent 5 that the absence of a national policy can have a negative impact on a collaborative work. This is based on the respondent's own experience in an attempt to procure cell line from a different jurisdiction.

Respondent 5: I got approval from Harvard for their cell line for their embryonic cell line to be transferred here but because we don't have any documentation about the government's policy, I have yet to receive. [Stem Cell Scientist]

This brings up an issue that is crucial as it demonstrates that the absence of a national policy can be an obstruction for local researchers to

pursue international collaboration. The respondent further pointed out that a governmental policy is perceived as an assurance of ethical conduct.

> *Respondent 5: …for example Harvard, they have their embryonic cell line, when I apply, they want the, what is the embryonic stem cell research policy, so even I give my ethics approval is not good enough…it must be the at the government level, so that they know the cell lines are not being used for other [things] but these are just simple guidelines, which cannot be used to stop anybody from doing further work or whatever, so until today I have not gotten the cell lines…because we don't have the policy…governmental policy…because US is very strict…they also want to see who's going to monitor... [Stem Cell Scientist]*

It is therefore important for the policymakers to recognise that the absence of a national policy could hamper the development of hSCR in Malaysia. Also, it is important to understand that ethical assurance is crucial to the credibility of international scientists and reputable research institutions. It is not surprising that Malaysian collaboration proposals are declined when there is no national policy to provide ethical assurance.

2.3 Regulatory body

In addition to the need for legislation, many respondents also argued that the legislation should set out the establishment of a regulatory body to address the lack of monitoring, as reported in section 5 of Chapter 5. A statutorily established regulatory with the mandate to oversee or monitor hSCR activities in the country, would have legal impact, whereas, without legal force to support the system, respondent 1 argued, it would become unrestricted. In so doing, respondent 7 suggested for Malaysia to learn from the UK.

> *Respondent 1: …unless there is legislation, for example designating a body, to control this research, the body can easily set guidelines that*

everyone has to comply…because it has a force of law behind it…if there's none…I suppose it's a free for all situation at this point. [Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panellist]

Respondent 7: I think that law…must include the establishment of this body by whatever name…committee or body or council to regulate this kind of practice. I think it's very relevant.

I: So, do you think that Malaysia should look at other countries to learn?

Respondent 7: Yeah, Malaysia can, we can conduct studies on [the] UK. [Lawyer, Religious Authority, Advisory Council]

There also seems to be a conflict of power with regards to the funding and monitoring of government funded research work, between the relevant ministries. A statutorily established monitoring body would address this issue, as pointed out by Respondent 3.

Respondent 3: Yes, monitoring of the companies offering services for stem cells really has to be stepped up. It doesn't seem to be adequate monitoring…It is a huge concern for me. When I was sitting in a committee, I ask them, 'why are you not taking action against this company?' and they said, 'why did you fund it?' I said, '[we funded the rabbits, I did not fund [it for] human therapeutic use'. MOH [Ministry of Health] has to clamp them down but they always blame MOSTI [Ministry of Science, Technology and Innovation] for funding. [Scientist, Ministry Official, Advisory Council]

Similarly, respondent 10 raised issues pertaining to the involvement of various regulatory bodies presently and the coordination between them. Based on a concern over this issue, the respondent has a different idea as to what kind of regulatory body should be established in Malaysia and suggested that there should be National Stem Cell Council introduced to act as a 'inter-ministry organisation'. This council should be vested with power to coordinate grant

allocation and processes between different relevant ministries. Apparently, a similar to the system is now used in cancer research.

> *Respondent 10: We need a National Stem Cell Research and Therapy Council. We need that very desperately if we are to play catch up in this game. We need to be able to co-ordinate, we need to be able to allocate resources in a way that is effective…that National Stem Cell Council should be given mandate to coordinate the grant, the grant processes from various ministries, from MOH [Ministry of Health] to MOSTI [Ministry of Science, Technology and Innovation] to the Ministry of Higher Education. I think that the cancer research has such arrangement…there's a cancer research centre in UKM [Universiti Kebangsaan Malaysia] if I am not wrong, that does this on behalf of the ministry. And for something like stem cell I think that should be done also… [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

The issue of competency of regulators particularly at the ministry level was also brought to attention. The respondent viewed the council as an important measure to address this issue to ensure the relevant expertise, rather than general ministerial or government officers evaluating grant applications. It was proposed that the power to evaluate research application as well as the allocation of funding is given to an inter-ministry made up of experts in this field.

> *Respondent 10: …no point having someone just for example if you are to apply for a grant for stem cell therapies, research, and the one who's evaluating it is an architect, which is what probably happens up in the ministries…people who are evaluating the grants, are not experts in this particular area and this area is very specialised, which is why it's good to have the national body to not only coordinate research but to coordinate funding for the research. It is sort of inter-ministry kind of committee or body. [Medical Practitioner, Stem Cell Scientist, Advisory Council]*

It can be seen from this section that the respondents' views on the importance of having a legally binding enforcement is not limited to the previously discussed measures, but it is also vital in the act of monitoring

relevant actors in this field. The establishment of the body is not in itself the solution, but it must also consist of experts with a specialised background relevant to hSCR. In light of the conflict of power between relevant ministries, it would be more appropriate to have an independent body with the authority to scrutinise research and applications for federal funding, and inspect research activities across the country.

2.4 The Importation of Rules

Instead of using Malaysian existing laws that are not specifically designed to regulate hSCR despite their relevance to a degree, Malaysian policymakers could also consider adopting hSCR-specific rules from other jurisdictions. The findings reported below show some of the respondents felt this could be a plausible regulatory idea.

> *Respondent 9: …if we are going to have laws or regulations, before we actually draft the law or the regulation, we need to look at other people. [Ethics Committee Member]*

According to respondent 2, most of the existing laws in Malaysia are adopted from other countries and modified to suit the societal and cultural setting. As has been pointed out in the literature chapters and as reiterated in the respondent's account below, it is apparently a common practice for Malaysia has learned and adopted rules from other countries, especially the UK, since the colonial era. The respondent further argued the value of importing rules, when they can be considered beneficial and useful.

> *Respondent 2: …most of our laws are actually adapted from other countries and provisions could be imported into here, subject to certain*

modifications to suit local circumstances, and I think it's not uncommon for us to look at other countries to try, to seek guidance from them, because sometimes the law works in other countries, why not have them here, particularly if it works. [Lawyer, Advisory Council]

Furthermore, respondent 20 highlighted the on-going practice of adopting rules from other countries in order to introduce a national policy (for clinical research involving stem cells) in Malaysia. However, the rules are subject to modification and may be refined through a consultation process.

I: Do you involve consultation to produce this policy?

Respondent 20: Yes…we are trying to brainstorm, that's what going on at the moment…trying to come out [with] the terms first, we're adopting FDA [US Food and Drug Administration], we're taking [on] the UK, FDA, and then from Australia, we're adopting some of the regulatory, then we try to modify to suit our country. [Scientist, Stem Cell Policy Panellist]

The relevance of this exercise – rules importation, was further emphasised by some other respondents. Both respondent 21 and 19 contended that Malaysia could adopt the existing rules in other countries as a model to formulate its own rules, instead of starting anew.

Respondent 21: …at the moment as with all other Biosafety Act, the Research Act, Biomedical Act, it will be based maybe on an existing act that has existed say in the west but we need to adapt it because I don't see that we need to reinvent the wheel. We already used something that the west already used and then put that into place. [Ethics Committee Member]

Respondent 19: …because we have looked at the other acts in the world, HFE Act, from the European countries, from Australia, from Singapore so they have all these examples that we can either follow, or to see… [Stem Cell Scientist]

Furthermore, of all countries in the world, UK and Australia were specifically mentioned as the ideal reference from which Malaysia may learn. Respondent 3 referred to the UK regulation as the 'gold standard' and expressed preference for the UK system. It is perceived as straightforward and clear, unlike other countries such as the US (not referring to the FDA's system per se but the variation between states, which also differs from the federal regulation).

> *Respondent 3: I think we should go for gold standards…that's why I always like to benchmark with Nuffield [UK bioethics council] and countries which are very established and we can re-adjust it to our cultural norms but you have to start with the gold standards. You know like US is very different we find it very hard to benchmark on US because of their states and their presidential decree…let's say biosafety of regulatory requirements in the US, it's huge because it involves 6 different departments, many different laws, conflicting laws, different states so I don't know what they are talking about. So like the UK one, is very straight forward, Australia, mainly UK, tend to be straight forward so I think set the gold standard of countries, which have advanced research in stem cells which has a clear regulatory framework, we should go for that one. It's easy right? Why start from bottom? [Scientist, Ministry Official, Advisory Council]*

The modification of adopted rules would be an important regulatory exercise to suit the local cultural and societal norm. This is particularly essential especially given that Malaysia predominantly embraces Islamic values. Therefore, respondent 16 argued that the adopted regulatory approach has to conform or at least not be in conflict with religious teachings and norms.

> *Respondent 16: Well, I think we need to look at what others have done, used that as our guidelines, and there must a bit of our own because we are Muslims, we have to follow our own guidelines as well, whether it complies with the Islamic… [Embryologist]*

As illustrated above, many respondents for instance respondent 3 mentioned the distinction between importing rules from developed countries rather than developing countries. Most developed countries are western countries with different cultural values than those of Malaysia, which might be similar to other developing countries that have 'eastern' values. This view could contradict respondent 16's views above. This would lead to the question of whether Malaysia should adopt rules from the developed countries or developing countries whose legal values could be inherently similar to the values in Malaysia.

Focusing primarily on countries with well-established regulations would involve considering developed countries whose systems might not share Malaysian values. To remain sensitive to these values, Malaysia would need to learn from countries that are similar, though the regulatory system in these countries are not necessarily as established as the former group. Modifying imported rules so they are in line with local contexts, especially the Islamic values, is important. Given that both approaches would in some way benefit Malaysia, it could then be beneficial for Malaysia to learn from both worlds.

Conclusion

This chapter has drawn attention to a number of challenges identified by respondents with regards to the current regulatory framework for hSCR in Malaysia. It has been shown that there were concerns with regards to the effectiveness of the national guidelines and the adequacy of the current framework. Based on their accounts, it seems the current rules do not

comprehensively bind everyone in this sector. In addition, the rules are lacking in clarity and are not up-to-date with current research development. This particular scenario is seen as a possible threat to research development and it is a great concern, especially among researchers who wish to progress with the right understanding rather than being uncertain of what would be ethically appropriate and vice versa.

In light of the issues above, there were suggestions for legislation. However, there were differing views regarding whether a specific law for hSCR should be introduced or if policy alone is required, (note that the majority are in favour of the former), or if existing laws can be used. In view of the majority opinion, this thesis maintains that both law and a national policy can be said as imperative. Their introduction is seen as a measure that would overcome the issues with the current system. Malaysian policymakers would also want to consider legislation that is primarily enacted for this area, particularly for the use of human embryos, as has been done by many countries in the world.

Legislation will offer a more comprehensive regulation through various regulatory measures and will be legally binding on everyone in the sector. Most importantly, it was underlined that it is vital to have a balanced approach. It should not be too restrictive as it may discourage research activities and consequently hinder advancement. Therefore, it would be ideal for the researchers if the regulation were designed to facilitate them to carry out ethical research activities and while ensuring dubious commercial practices are inhibited. (ISSCR Guidelines for the Clinical Translation of Stem Cells 2008a)[69]

[69] This is similar to the position of ISSCR that recognise the need to develop therapy and keep research open but at the same time there is a need to stop unregulated commercial activities. “The ISSCR recognizes a distinction between the commercial

The absence of a national policy has also been identified as a barrier to researchers' effort in securing international collaboration. A national policy functions as a 'regulatory umbrella' and its existence is important to outline the national standpoint and agenda. This could facilitate local researchers to gain credibility, aiding collaboration with reputable counterparts from other countries such as USA, UK, and other countries that are known for their established regulatory framework and commitment in ensuring ethical research work.

Apart from the law and policy, the lack of coordination and the inadequacies of an oversight system were also part of the concerns raised. Instead of the current system which involves different authorities i.e. ministries, the respondents prefer to have a body that could function in monitoring research activities across the country and coordinating the approval of federal funding. In order for the body to function efficiently, it has to have legal authority and be comprised of relevant experts. The UK HFEA was specifically referred to as an example of a desired regulatory body that could improve Malaysia's current system.

To improve the current system, it seems that rules importation would be an option as it is already a common practice in Malaysian jurisdictional practice. Many respondents specifically referred to developed countries such as the UK and Australia that have an established regime for this area. This measure however, has both advantages and challenges.

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purveyance of unproven stem cell interventions and legitimate attempts at medical innovation outside the context of a formal clinical trial. Responsible clinician-scientists may have an interest in providing medically innovative care to a few patients using stem cells or their derivatives prior to proceeding to a formal clinical trial. In these circumstances, the ISSCR strongly recommends that clinician-scientists follow the policy outlined…in section 7"

While it could be time-effective to adopt rules from developed western countries with established rules that are proven to work, the cultural values of the developed countries may not suit the Malaysian local context. Alternatively, Malaysia could also look to countries in the region that share more common values, but these countries may not be as established as the developed ones in the western world. Nevertheless, either approach would require public consultation with local stakeholders to ensure the rules are suitable to the local context.

PART C – ANALYSIS AND OVERALL CONCLUSIONS

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Introduction

This chapter reviews the findings reported in the empirical chapters and combines them with insights from the comparative legal study set out in the overview chapters to assess and discuss the opportunities and challenges for an improved regulatory framework for Malaysia. The review is fundamentally based on the respondents' observations, suggestions, and a comparative analysis of hSCR regulation between Commonwealth countries, to ensure the options for improvement measures can be considered as appropriate for the Malaysian context.

The discussion is structured around four main regulatory aspects, identified from the findings as problematic: first, the lack of clarity and comprehensive framework in regulating hSCR; second, the implications of the current prohibition on human embryo creation for research; third, the absence of a designated regulatory body at the national level; and fourth, the issues with regard to the implementation of compliance measures.

Accordingly, this chapter proceeds by discussing as to how policymakers in Malaysia could consider (i) a more comprehensive framework by enacting legislation; (ii) revising the prohibition on embryo creation; (iii) the importance of establishing a national regulatory body with a mandate to address relevant legal and ethical issues; and (iv) enforcement strategies to strengthen compliance measures that would enable regulators to achieve more optimal regulatory outcomes.

This discussion is followed by further deliberation on the possibility and challenges should Malaysian policymakers choose to transplant rules or adopt

legal system from other countries as an attempt to improve the current framework in Malaysia, before concluding this thesis project. The aim of this chapter is to highlight the different legal options and considerations that could be taken into account by Malaysian policymakers to develop a more appropriate regulatory framework in the future.

This thesis considers a framework as appropriate if the framework is in line with some of the common features in most, but not all, Commonwealth countries identified in Chapter 3. Although, this could not be considered as the standard regulatory practice, this thesis considers the common features as the standard of comparison.

Most importantly, it is based on the deliberation of the views and recommendations or suggestions offered by the respondents of this study, who are among the key stakeholders in this field, in Malaysia. Also, a regulatory framework would be regarded as appropriate if it meets certain key criteria and able to facilitate regulators to implement rules and secure compliance in the most effective way possible.

It is important to note that the analysis of the options presented in this chapter is not definitive but instead, they are constructed based on the respondents' accounts on the matters of concern, by demonstrating agreement and in some cases, disagreement on certain options and the challenges, as well as probable implications.

1. Comprehensive Research Governance: The Establishment of Legislation

At the international level, there are many countries that have adopted formal or command-and-control regulation - by enacting legislation, to regulate hSCR. Among the jurisdictions being studied in this research work, most of them have taken such approach except Malaysia, India, Cyprus, and Malta[70]. Based on the interviews findings, a majority of the respondents expressed concern over the effectiveness of the current regulatory system in Malaysia, which heavily relies on non-binding rules.

They mostly are in favour of a legislative system. According to their views, without legislation, the current regulation is not adequate enough to extend its rule enforcement to private sector. Accordingly, it would be difficult for regulators to prevent or mitigate unethical conduct i.e. unproven 'treatments' offered by private clinics, which at least some of the respondents believed are occurring. This could cause controversy, and thus, would blemish the reputation of this field.

One respondent specifically pointed out the fate of the area of genetic therapy that was badly affected by unethical conduct, as an example that should be learned, so that hSCR would not suffer a similar fate. It was also argued that public trust is important to ensure the development of this area. As noted by Critchley (2008; p. 117), according to Chalmers and Nicol (2004), "unless there is public trust in the scientists undertaking this research and the regulatory agencies charged with overseeing their work, the promise of the biotechnology revolution may never be realised."

[70] Note that Malta has already established a bill to regulate this area.

Since guidelines have no legal basis and are not legally binding, most of the respondents view compliance to the rules in place as optional or voluntary rather than mandatory. This argument is supported by the fact that under the current system, only government-funded or affiliated researchers and institutions are required to adhere to the guidelines. The guiding rules are not enforced in the private sector, and therefore, the authority - the Ministry of Health, tasked with policing this sector does not have the power to ensure or oversee compliance at the national level – to include both public and private sectors.

To address the concerns and views that the current existing regulation through guidelines were inadequate or too 'soft', many respondents put forward that there should be some form of legal oversight and provisions that are backed by legal force. They advocated that such measure would provide legal protection for research subjects and govern other actors involved in this area. Respondents, who proposed the establishment of a specific law for hSCR rather than depending on guidelines only, argued that this approach would result in more optimal regulatory outcomes.

As pointed out in Chapter 6, respondent 3 highlighted the effectiveness of the governance of biosafety that has significantly improved after the enactment of the Biosafety Act. The respondent noted that the recently established legislation provides mechanisms that were lacking when it was only governed by guidelines, for instance, monitoring and information dissemination system. The respondent also mentioned, the regulatory system of biosafety had to be changed from self-regulation to formal regulation namely command-based regulation.

Notwithstanding the arguments in favour of legislation, there were a few matters of concern raised by the respondents that need to be taken into account in deciding as to whether or not new legislation is needed.

1.1 The Complexity of Legislative Process

Even though there were suggestions that the establishment of legislation in Malaysia would provide legally binding rules and this, in turn, would result in more comprehensive governance, there were however, concerns raised by some respondents regarding excessive bureaucracy and the time it would take if there were new legislation to be introduced. It is rather important to take this point into consideration given the fact that other countries have already experienced lengthy procedures to enact their respective laws.

For instance, Canada took 15 years before the AHR Act came into effect. (Baylis and Herder, 2009)[71] In addition, it could also be quite a complex and challenging process due to the inevitable development in the technologies, which would disrupt the regulatory systems, as has been argued elsewhere (Mandel, 2009) and hence requires amendments, as has been experienced by the UK.

In view of this, one could argue that it would be more appropriate to enact legislation to comprehensively govern hSCR, but at the same time, one would also need to accept the downside of this approach. Nonetheless, guidelines would be useful amidst the complexity of the command regime, whereby instead of heavily relying on laws, legal force could be extended to

[71] On March 11 2004, Bill C-6, formerly Bill C-13 successfully completed all the legislative stages and finally, the federal government promulgated law after 15 years of developing policy and legislation.

guiding rules, which would be easier to be amended when needed. However, this does not mean that the law could remain unchanged, but simply suggesting that guidelines could be used as supplementary rules reflecting the spirit of the intended regulatory objectives. It has been shown that all of the jurisdictions that have law also deploy guidelines, which are updated periodically. The importance of this measure is discussed in section 1.4.

1.2 Taking on the Existing National and International Law

Whilst some respondents argued that there should be a new law established to govern this area, others contended that there is no need to introduce a new law when the existing ones could be used, even though no reference was made to which specific laws should be so-considered. In the light of the differing views on this matter, one of the options that could be considered would be amending the existing Biosafety Act to include hSCR under its remit.

This approach would reduce the legislative complexity, which could be arduous if a new law were to be introduced. Moreover, as highlighted previously, respondent 3 pointed out the improvement made to the governance of biosafety law after the introduction of the Biosafety Act and that the system is now performing. One could suggest for this positive regulatory outcome to be extended to the governance of hSCR.

Furthermore, it was also pointed out that if there were legislation to be introduced to govern hSCR especially the use of human embryos and hESCs for research purposes, Malaysian policymakers could adopt the rules that have been introduced in other countries instead of reinventing a new law. This could also be considered given, as shown in the literature and mentioned in the

interviews, that legal transplant is apparently rather common in Malaysian legal system dating back from the colonial era. In addition, the formulation of the National Guidelines (2009b) also considered the approach adopted by other countries.[72]

For instance, the 14-day rule introduced by the UK Warnock Committee (Warnock, 1985) is 'borrowed' and 'transplanted' into the National Guidelines.[73] Nevertheless, it was emphasised by some of the respondents that adaptation of the imported rules in the local context is important. This is due to the country's demographic structure that consists of multi-ethnic, multi-cultural and religious communities. The possibilities and challenges of legal transplant as an option for Malaysia are discussed in section 5.

1.3 Over-inclusive Rules Causes Over-regulation

Based on the opinions shared by the respondents, the enactment of law would be able to assuage the risks of the members of public from being manipulated and harmed when compared to the current system. The law is seen by most of the respondents as an appropriate regulatory tool, able to provide a more comprehensive regulatory mechanism for rule enforcement. It can be seen from Chapter 3, whereby jurisdictions with legislative systems have more comprehensive mechanisms for rules enforcement laid down, compared to those without legislation.

For instance, the former requires the establishment of a statutory or appointed authority, which is given the mandate to oversee regulated activities

[72] Paragraph 6 of the Guidelines, 'International Legislation on Human Embryonic Stem Cell Research'.

[73] See Section 15(a) of the Guidelines.

and granted the legal power to take action against rule infringement or non-compliance. Unlike non-binding rules, this system is enforceable to anyone who entered into the regulated sector be they in the public or private sector.

It is worth noting that even though many respondents welcome the notion of having this area regulated by law, they also expressed concerns that if the rules introduced were too strict, they might hamper scientific development. Therefore, it is important to take into consideration that there should be equilibrium between the two important regulatory goals - safeguarding public safety and facilitating scientific progress.

As argued by Kian and Leng (2005; p. 297), "any proposed laws and regulations must be sufficiently flexible to allow for an adequate response to the scientific and biotechnological advances that are currently being developed at a very fast pace. It is of the utmost importance to facilitate and not hinder worthy and deserving human stem cell research and therapeutic cloning, where there are tremendous potential curative cell-therapy treatments."

Such concern can be linked to the general views towards the command regime, which might involve unnecessarily over-prescriptive and over-inclusive rules, which could cause over-regulation. As highlighted by Fuller (1977), legal provisions should not be over-complex so that regulatees will know where they stand.

As pointed out in Chapter 2, this phenomenon could inhibit development and therefore, might discourage entry into hSCR, particularly hESC research. It is a concern shared by many respondents that excessive regulation would perhaps hinder further development. Nevertheless, this issue could be resolved if regulators sought information from the regulated and expertise when drafting

rules (communication-based regulation), as this would allow regulators to obtain necessary information to ensure the rules are reasonable and enforceable. The following sections considered the value of communication between regulators and the regulated in more detail.

1.4 The Revision of the National Guidelines: Clarity in Enforcing Rules

There were concerns raised by respondents pertaining to the clarity of the rules stipulated in the guidelines. According to them, there are a few newer research procedures i.e. iPSCs that are not covered by the guidelines and some provisions are not well addressed, which consequently resulted in uncertainty among researchers.[74] Interpretation of the rules was also raised as one of the issues requiring clarity whereby there are potentially quite varying interpretation of certain provisions i.e. the definition of 'surplus embryos', which was seen as rather broad and needed to be well-defined.

Despite the vital role of legislation, guidelines too have an important function in shaping a comprehensive framework. As has been pointed out earlier, there are weaknesses and limitations within the command-based system such as rules that are often too broad and often require clear interpretations. Since rules embedded in law are not self-interpreted, it is important for regulators to provide clear interpretations of the rules and this can be done through guiding rules - guidelines.

As can be seen in Chapter 3, jurisdictions that regulate hESC research through law also at the same time utilise guidelines; the UK, Canada, Australia,

[74] Note that countries such as Singapore and South Korea have published additional opinions on the use of iPSCs for research. Canada has also updated its guidelines to cover all human pluripotent stem cells.

and Singapore govern the derivation of embryonic stem cells and the use of established embryonic stem cells through law and guiding rules respectively – except South Africa's law – the National Health Act 2003, which governs both derivation and use of hESCs.

If Malaysia were to enact laws and maintain guidelines as supplementary rules, as is being practiced by the jurisdictions mentioned above, it is important to ensure that the guidelines are subject to continuous revision and updated as and when needed. This would enable regulators to ensure clarity in their task to implement rules as effectively as possible.

In the light of the issues of comprehensiveness and clarity, many of the respondents contended for guidelines to be revised and updated in line with the regulation adopted and similar practice in other countries. In so doing, it can be suggested for Malaysian policymakers to refer to the ISSCR guidelines to ensure the guiding rules are in line and of a similar standard with the core principles upheld at the international level. Its 2006 guidelines are now under review to be revised and updated. (ISSCR DRAFT Guidelines for Stem Cell Science and Clinical Translation, 2015a)

Chapter 3 has also shown that national guidelines of other countries such as Canada, UK, and India are required to be regularly revised and updated in order to be up-to-date and in accordance with recent developments in hSCR.[75] For instance, the Canadian Updated Guidelines are specifically

[75] For instance, UK Stem Cell Bank's Code of Practice states, "This Code of Practice should be regarded as an evolving document which will be revised and updated in line with both practice and the requirements arising from relevant UK and EU legislation…"; Canada's TCPS states, "No document designed to cover the ethical conduct of all types of research involving humans can hope to be definitive. As with the 1st edition of the TCPS, the 2nd is a work in progress and is designed to be a living document."

characterised as a living document, as clearly stipulated in the guidelines, which requires regulators to ensure the guidelines are up-to-date.

One could argue, given that guidelines are less complex and less difficult to be amended than that of law, regulators should take advantage of this to fully utilise the former, to ensure updated rules are in place. Since there are issues with the current guidelines as highlighted earlier, revising it would be a way forward as suggested by some of the respondents. As has been stressed by Fuller (1977) it is important to ensure rules are made available and clearly articulated, however, it is also important to note that rules should not be subject to constant revision. This may lead to confusion and uncertainty among the regulatees.

In addition, the respondents also suggested the revisions to be made in line with what have been done in other countries. Such an approach would enable Malaysia to have rules that are in harmony with other countries at the global level, which would as a result facilitate research collaboration. For instance, researchers in future would not have to face the same problem as respondent 5, whose request to import cell lines from other countries was denied (reported in Chapter 6). This is largely due to the absence of a framework to safeguard the cell lines from being used unethically.

2. Prohibitions on Creating Human Embryos for Research: Implications on Research Development and Regulatory Outcome

According to the National Guidelines, researchers in Malaysia are not allowed to create human embryos to derive stem cells for research purposes. Only stem cells derived from surplus IVF-created embryos can be used to pursue research activities**.** Notwithstanding the prohibition, it is worth noting that the views on the use of human embryos, especially their creation for research purposes, are not only distinctly diverse at the global level, but even in Malaysia, the interviews show that there are differing views on this issue.

It is also worth noting that even though the use of human embryos – from IVF surplus, is allowed in Malaysia, this permitted route is however, not widely employed in practice. In view of this situation, it is comprehensible when there are some respondents, who expressed support for the prohibition on the creation and argued that embryos are not needed, and that Malaysia should just focus on research using non-embryonic stem cells. According to them, it is more plausible and less arduous to translate non-embryonic stem cell-based research into clinical practice than that of embryonic.

Others argued otherwise, and according to them, the prohibition of establishing cell lines derived from embryos created for research purposes would not enable Malaysian researchers to be as competitive as their counterparts in other countries that allow such procedures. Indisputably, all of them acknowledged that it is crucial to protect research subjects and human embryos whilst advancing research activities. However, there were concerns raised by respondents over the outcome and effectiveness of the current prohibition, and there were also suggestions offered for an improvement.

First, some of the respondents argued that such prohibition could impede research advancement, especially when there may be some issues with the 'quality' of the cell lines established from surplus embryos, though this remains debatable. Gentry and Durand (2008; p. 58) state, "according to many of the most distinguished researchers in the field, the number and quality of existing cell lines from already destroyed embryos are inadequate for the essential studies that must be done." Additionally, some of the embryos produced for IVF treatment may be of less than desired quality and even the quality of existing stem cell lines i.e. imported cell lines is also a subject of debate. (Landwehr, 2009)

By ruling out the creation of human embryos for researchers that would enable them to establish viable and local cell lines, such measure, is seen by some respondents as obstructive - hindering research exploration in the future, which could be useful and beneficial. It also prohibits researchers from possibly advancing in this area should it become a required and a key technique for a successful translational research work in future.

Second, it is a commonly held view among most of the respondents that the current prohibition is not binding and therefore, is seen as not effective. It underestimates the importance of regulating this controversial area. Whilst the spirit of the prohibition is to prevent unethical use of human embryos and to protect them, in practice, the implementation of the rule is not in line with the underlying regulatory objectives, since researchers in the private sector are not subject to this prohibition.

2.1 Statutory Prohibition with Exceptions

There were suggestions offered by some of the respondents as to how human embryos could be better protected and at the same time allowing researchers some flexibility in their research work – to create human embryos for research, if it is needed in the future. Instead of banning the procedure, some of the respondents argued that it could be allowed but based on qualifications – if it is essential, and it has to be regulated by law and strictly monitored.

Referring back to Figure 7,[76] on one end of the regulatory spectrum, there are countries that put an absolute prohibition on the use and creation of human embryos for research. On the other end of the spectrum, there are countries that allow both procedures. If one carefully examined the provisions used by the countries to allow the creation of human embryos, they employ 'qualifications' as measures to approve such work.

Additionally, France also employs 'qualifications' in its prohibition on human embryo creation.[77] In other words, with the inclusion of 'qualifications' or 'justifications' - another term used in some countries, this shows that there are certain requirements need to be met before a regulated practice can be permitted or prohibited. These sorts of justifications are exactly the sorts of conditions that bioethicists can create and justify as ways of assuaging public concern as in Salter's account (2007).

One could also argue that the current prohibition is still inadequate to protect human embryos compared to other jurisdictions, which allow such

[76] See Chapter 3, page 79.

[77] See Figure 7 in Chapter 3, page 79 and footnote page 79 - 81.

procedure. As pointed out in the above, not only do those countries have legislation to safeguard embryos from being misused, but permission for such procedures will only be granted if the qualifications set by regulators are satisfactorily fulfilled. Permitted research work will then be heavily regulated and monitored by a designated authority. While in Malaysia, the prohibition is non-binding and it is not apparent if there was a designated monitoring body.

For instance, as shown in Chapter 3, the UK has permitted such procedures since the establishment of the HFE Act 1990 and the position is maintained throughout the amendment of the act until the present – HFE Act 2008 (amending HFE Act 1990). However, it can be seen from its regulatory procedure, the creation as well as the use of human embryos are strictly regulated. Such procedures will be strictly scrutinised by the HFEA to ensure that it is truly necessary before a license can be granted.

Australia has adopted the UK's licensing approach and changed its legal provision, from prohibiting creation of human embryos for research (as stated in 2002 statutes) to permitting the procedure (as stated in 2006 statutes),[78] provided it is considered essential. In the light of this new stance by Australia, one would argue that the Australia's approach shows that it might be practical to consider a *prohibition with exemptions* so that if there were a change of views towards this controversial procedure, policymakers do not have to go through the complex legislative procedure to amend legislation [emphasis added]. As has also been pointed out in Chapter 3, similar to the UK and

[78] Note provided under schedule 2, section 10A of the 2006 Act stipulates, "the creation of development of embryos mentioned in this section is prohibited under Part 2 of the *Prohibition of Human Cloning for Reproduction Act 2002*, unless authorised by a licence under this Act."

Australia's latest approach, Singapore also permits embryo creation for research but only if it is deemed necessary.[79]

Therefore, one could see that even though these countries (UK, Australia, Canada) allow the creation of human embryos, it does not mean the embryos are not protected. In fact, they can be argued as better protected compared to other countries that prohibit its creation with non-binding rules merely on the ground that it is ethically controversial and regarded as morally unacceptable. Meanwhile, in the UK, Australia, and Singapore, not only are embryos are protected by strict ethical and legal requirements that have to be met, but justification of its necessity is also imperative before such procedure could be granted approval and licence.

One could argue that such approach regards the need to protect human embryos from being misused, as a priority, but at the same time, it does consider the importance of recognising the potential benefits from allowing embryo creation if necessary. It is also noteworthy that the same principle is applied for the permission to use 'spare' human embryos where such procedures also requires justification. Nevertheless, such controversial issue, as this would be worth debated and discussed in a public consultation especially with a larger group of public. Their opinions are important to ensure the relevance of a national policy, and this is discussed in more details in section 3.5.

[79] See the BAC's report, part V, para 5.23 states, "the creation of human embryos specifically for research can only be justified when there is strong scientific merit in and potential medical benefit from such research." Part VII, para 7.10 states. "the Human Cloning and Other Prohibited Practices Act (Cap. 131B) was enacted in 2004 primarily to prohibit human reproductive cloning. This Act does not prohibit therapeutic cloning (research cloning)…"

Another option could be an approach adopted by Germany whereby the policy allows the importation of established embryonic stem cell lines from other countries. This option is apparently already included in the National Guidelines 2009,[80] but, as highlighted in the findings, the current regulatory system without a clear policy in place has caused difficulties for the local researchers to obtain cell lines from another country that has more established regulation. This situation alone indicates that improvement is needed for the system to make Malaysian research more reputable, which would then able to facilitate progress including the importation of established cells from other countries.

At any rate, without better regulations in place, it can also be argued that Malaysian scientists might also face difficulties to share their own cell lines with their counterparts in other countries or as mentioned earlier, take part in collaborations, which are all important aspects of developing basic stem cell research.

2.2 Regulating Human Embryonic Stem Cell Research: Key Aspects and Regulatory Target

This thesis recognises the differing views among the stakeholders on the creation of human embryos for research purposes and the probable ethical challenges faced by Malaysian policymakers to determine whether or not such practice should be allowed in future. Notwithstanding the challenges, this thesis argues that an improved regulatory framework that is backed with legal force is urgently needed in Malaysia to regulate especially human embryonic stem cell

[80] See Para 17 of the Guidelines, "all imported stem cells/tissue products for use in clinical trials and therapy shall be GMP certified and registered by the NPCB."

research. Nevertheless, it is important for policymakers to make distinctions between the regulation of non-clinical and clinical research.

As for non-clinical research, some examples of the key aspects of a potential regulatory regime for this level will focus on the source of the donated human embryos for research purposes, the creation of human embryos for research purposes (if this is to be allowed in future), the derivation of embryonic stem cells, its storage and destruction. With regards to clinical research, one of the key aspects would be the source and the procurement of the embryonic stem cell lines, and the use of the cell lines in clinical settings i.e. the implantation of embryonic cell lines into human patients.

The regulatory targets in this sector will be all parties, which are involved in this research such as both of the public and private universities, state supported actors, and private companies that are involved in both non-clinical and clinical research. It is also important to design a framework that is targeted to safeguard the moral sanctity of human embryos used by ensuring ethical acceptability, the cell lines derived from embryos are handled and protected with high ethical standards, which would later ensure patients' safety in clinical practice.

As has been discussed earlier, there are differing views on the importance of developing human embryonic stem cell research in Malaysia. Whilst some respondents felt that it would be useful for Malaysia to prioritise research using non-embryonic stem cells since this research would be more likely to be translated into clinical practice and to avoid the challenging issues surrounding human embryos, there are also views in favour of human

embryonic work. It is worth noting that both perspectives are shared among the respondents without significance of any professional association.

However, it is important to note that since most of the respondents acknowledged the importance of establishing legislation to safeguard human embryos and to protect both the reputation of this field and human patients, this would suggest that the level of acceptability of the idea to enact law for human embryonic stem cell research seems promising. However, it is important to ensure that the rules introduced can be regarded as appropriate. Section 6.1.2 discusses some key criteria that need to be met, which would define the appropriateness of an improved regulatory framework for human embryonic stem cell research in Malaysia

3. The Establishment of an Independent Regulatory Body

A few respondents demonstrated that they are not aware of the current regulation, and they also pointed out the lack of clarity with the rules in place. This study has identified two issues with regards to the lack of clarity. First, even though there is a National Stem Cell Research and Ethics sub-committee (NSCRE sub-committee) established to regulate stem cell research and therapy, only small numbers of the respondents have heard about the committee (but they are not really aware of its regulatory activities).

They also reported that they are not aware of any monitoring procedure, which according to some, is not in existence especially for non-clinical research work. One respondent further clarified this by pointing out that the NSCRE sub-committee apparently only regulates clinical research.

The National Guidelines 2009 are separated into two sections; research and therapy, and the involvement of NSCRE sub-committee is mentioned in both sections. One could argue that this actually implies that, as per the provisions, the committee would be expected to regulate both clinical and non-clinical research. The Guidelines however, do not specifically indicate the national committee's direct involvement in approving and monitoring research work.

The Guidelines only stipulate that the respective Institutional Review Board (IRB) and/or the Institutional Ethics Committee (IEC) have the authority to review and approve the use of stem cells if deemed as ethical,[81] and only specify that the NSCRE sub-committee retains the right to "review any research proposal as and when required."[82] If compared to the authority of other national regulatory body in other jurisdictions, and based on the respondents' account, it seems that one could regard the NSCRE sub-committee as not as actively involved with the regulatory procedure for non-clinical research as the former.

Second, from the Guidelines' provisions, one would be under the impression that the NSCRE sub-committee would be the only regulatory body at the national level that has the mandate to ensure ethical research using embryos and stem cells in the country. However, some respondents also mentioned about the involvement of the Medical Research Ethics Committee (MREC), whereas this is not mentioned anywhere in the Guidelines. Note that

[81] Para 2 of the Guidelines for Stem Cell Research "All stem cell research and applications must be reviewed by the respective Institutional Review Board (IRB) and/or the Institutional Ethics Committee (IEC) for approval to ensure ethical research and use of stem cells. The IRB and IEC must strictly adhere to the National Guidelines for Stem Cell Research and Therapy."

[82] Para 3 of the Guidelines for Stem Cell Research "A copy of all research proposals must be submitted to the National Stem Cell Research and Ethics Suc-Committee which shall retain the rights to review any research proposal as and when required."

both MREC and NSCRE sub-committee are established under the umbrella authority of the Ministry of Health (MOH).

3.1 National Regulatory Body: Government Body v. Independent Statutory Body

It can be argued that Malaysia would be able to address the issues discussed above by establishing one designated regulatory body with a more comprehensive regulatory remit to include clinical and non-clinical research. It was clearly indicated through suggestions offered by most of the respondents that there should be a regulatory body established through legislation to have legal authority in regulating hSCR including non-clinical research activities.

They believed that the establishment of such body will lead to an improved oversight system and the body could play an important role to provide interpretation of the rules in place – a measure, which would be able to address the issues of awareness among the researchers. However, there was also concern expressed by one of the respondents as to whether it would be beneficial to spend a significant amount of money to establish a regulatory body whereas the money could instead be used to funding research work.

In the light of the differing views above, it is worth noting that as shown earlier, the legislation introduced in other jurisdictions – the UK, Canada, Australia, and South Africa, have established an independent statutory body and laid out a mechanism for an appointment of inspectors that have statutory mandate to secure compliance. Even though India has no legislation to establish statutory authority, it however has a dedicated body, as with other

Jurisdictions (except Cyprus)[83] to oversee hSCR particularly the use of human embryos, both non-clinical and clinical-based.

As has been discussed above, Malaysia has a national committee as stipulated in the national guidelines and mentioned in Chapter 3 – the NSCRE sub-committee, to regulate hSCR, but as pointed out by some respondents, it does not regulate basic research and only regulates research projects that are under and/or affiliated to the Ministry. This suggests that there is a regulatory gap between the regulation of basic and clinical research and between public and private sector.

Since there is a regulatory gap, particularly due to the requirement of an affiliation of the ministry, it would be worthwhile to establish an independent body that has a broader authority domain to comprehensively oversee all hSCR in Malaysia. Nevertheless, given there are differing views on the establishment of a regulatory body; this would require further deliberation by policymakers and consultations with relevant stakeholders.

If there were legislation enacted, it would be worthwhile to either establish a statutory body or set a mechanism for inspection. This measure would result in a more comprehensive regulation and hence, able to close the regulatory gap. Otherwise, if the MOH remains as the umbrella authority, regulating through MREC and the NSCRE sub-committee, one would ask as to what would be the measures that can be adopted by MOH, as the umbrella authority to address the regulatory gap.

Another option that can be considered would be enforced self-regulation, whereby the MOH could delegate some or all of the regulatory tasks to

[83] As shown in Figure 6, Cyprus does not allow the use of human embryos for research purposes.

institutional ethics committee to enforce rules. This would not only result in a lower compliance cost since the institutional-based regulators have direct communication with researchers, but also may be able to address the issue of broad or over-prescriptive rules since this measure would allow regulators and policymakers to obtain technical and necessary knowledge directly from relevant key stakeholders i.e. researchers.

Furthermore, this technique would give the institutional-based regulators the advantages to formulate institution-specific rules, provided they are in line with the national guidelines and law. However, it is important to note that this measure would still require legal force and regular inspection by relevant national authority to avoid the 'periodic negotiation', which is commonly associated with this approach, as has been identified by scholars. (Ayres and Braithwaite, 1992, Fairman and Yapp, 2005)[84] Therefore, there would still a need for a clear indication as to who would carry out the inspection and on the remit.

3.2 Safeguarding the Reputation of Malaysian Research

In the light of the issue of lack of oversight within the current system, this might allow some room for unethical conduct, which then would affect the reputation of hSCR and other researchers who are dedicated to developing this area ethically. This concern is shared by many of the respondents and the findings show that majority of them believed that a stricter regulation including

[84] As explained in Chapter 2, it has been noted by scholars that self-enforced regulation may not work especially when it involves ill-informed or inefficient firms that may be only complying with rules periodically, when regulators inspect them.

the establishment of a statutory regulatory body - as long as it does not suppress research advancement, would improve the current system.

This measure would be able to prevent unwanted scandal that would blemish the reputation of this promising technology, which would also affect their reputation and career development. It is rather an important step to be considered by Malaysia, in the light of the risks involved even at the non-clinical stage and to join the global standard of practice to regulate hSCR from its early stages.

It might be pertinent to make reference to the study reported by Sleeboom-Faulkner (2014) with regards to the research governance in China. The reputation of Chinese research work was reported as ethically questionable because “ethical oversight was loosely carried out through local institutions. In the absence of a nationally recognized directive, skepticism arose internationally about the quality of Chinese laboratories’ working standards and regulating supervision.” (2014; p.65)

One could see the report as such suggesting that the standard of a jurisdictional regulation plays an important role in gaining confidence among other reputable institutions at the global level. This is also one of the concerns expressed by respondent 5 who shared personal experience, facing some difficulties in obtaining research samples from other institution due to the uncertainty expressed towards Malaysia’s current policy in protecting embryonic stem cells.

Therefore, it is important to take the Chinese experience as an example and the personal experience shared by the respondent into account in improving and strengthening the current regulatory system. The establishment

of a designated regulatory body would result in rigorous rules enforcement and monitoring system. As argued by Kian and Leng (2005; p. 297), “for an effective legal framework, the human stem cell research should be regulated and monitored in accordance with the relevant ethical considerations.” This would then improve the system to be on par with the global common practice, which consequently would be able to facilitate local researchers to initiate collaborative work with their counterparts from other countries.

3.3 Increasing Awareness through Communication-based Technique

Also, the establishment of a regulatory body would be able to address the issue of lack of awareness. By referring back to the theory of regulation in Chapter 2, communication-based regulation provides a platform for a communication between regulators and the regulated to be initiated. Respondent 5, for instance, shared her experience about the system adopted by the FDA, which according to the respondent, allows researchers to obtain information on the rules in place. Moreover, the system also provides a platform for communication even at the early stage of research planning in order to facilitate researchers to be aware of and comply with the rules in place.

Additionally, Chapter 3 has shown that other countries (UK, Canada. Australia, Singapore, and South Africa) have not only established dedicated regulatory bodies, but also a stem cell network (including India). This measure provides the regulators an appropriate platform to provide information about regulatory requirements, which can be seen as an informal approach that can facilitate regulators to secure compliance. Also, it is noteworthy that as an effort to communicate and reach out to a wider audience, most of the regulatory

bodies, for instance, the UK HFEA and Canadian CIHR, fully utilise social media platforms i.e. official webpage, Facebook, and Twitter.

This could be seen as a creative means as well as a resourceful way of utilising media, the same tool used by fraudulent stem cell providers to disseminate misleading information. Taking HFEA's website as an example, it provides information for all the relevant stakeholders of this area, from patients, embryos or gametes donors, researchers, to media. It also provides a mechanism for anyone to contact HFEA to query on any matters pertaining to this area.

3.4 Safeguarding the General Public

The issue of lack of awareness and misleading awareness among the public, as reported by the respondents, is not unique to the Malaysian context, as this also has been reported in Japan, which is a more advanced country than that of Malaysia in the field of hSCR. A study conducted in 2006 showed that not many Japanese were aware of stem cells after the ground-breaking news made by Shinya Yamanaka.

> *"When Yamanaka Shinya and Kazutoshi Takahashi in 2006 published their research on iPS cells derived from mice, not many Japanese had heard of stem cells and pluripotency. In 2006, interviewees revealed that most laypeople had not heard of stem cells, though some could relate the subject to the Hwang Woo-Suk scandal…"* (Sleeboom-Faulkner, 2011; p.233)

It can be seen from the quote above that unethical conduct such as Hwang scandal could potentially put the reputation of this area at risk especially

when the public who have not heard of this promising area actually associated the area with scandals that put the lives of people at risk. This could lead to discomfort among the publics, resulting in losing their trust. When there is no public trust, this could consequently affect public funding on which many researchers, especially in the public sector rely.[85]

Therefore, the communication measures suggested above could also be employed to mitigate the awareness issue among the public. Nevertheless, it is noteworthy that the issue is only based on the respondents' account and not based on empirical study and therefore, it could be another potential study in the future. By adopting a similar system to that practiced in the countries mentioned above, it would also enable the public to have access to relevant information, especially given the concerns raised by the respondents over the misleading awareness that may lead to the manipulation by unproven stem cell-based treatment providers in recruiting patients.

In their study on the Korean cloning fraud, Saunders and Savulescu (2008; p. 214) argue and propose six possible ways to improve research ethics practice and among them is the "fostering of public involvement in ethical review and debate through the web." In addition, with a more comprehensive legal framework that governs both public and private sectors and appropriate rules enforcement, this would allow regulators to police private companies better than under the current system.

Also, with the implementation of exhortation technique, action taken against fraudulent companies can be reported through stem cell networks,

[85] This can be seen from the aim of the Advisory Report produced by the Academy Science of Malaysia was to seek government's recognition on hSCR as a priority, and clearly asking for an increment of public funding.

news, and social media. This can be done at the national level to create awareness among the local as well as at the international level, through collaboration with other stem cell networks and medias, which could also contribute towards the global effort in mitigating stem cell tourism.

Apart from mandating the responsibility to the regulatory body alone, other means could also be adopted such as the establishment of a stem cell network, as discussed in Chapter 3. Malaysian stakeholders could benefit from a creation of a similar network for the stem cell community in the country. This would provide a platform for them to communicate with other networks at the global level and work hand-in-hand in strengthening the regulatory standard, as well as creating awareness among the stakeholders.

By working closely with other networks, Malaysian regulators and researchers particularly, would be able to learn from the experience of their counterparts, and at the same time forming collaboration in developing the area both in the research and regulatory aspects. However, it is worth noting that the setting up of a network would involve certain costs in terms of time – a dedicated team would need to be identified, and money – a network would require a significant amount of funding for its operation and activities.

3.5 An Independent Regulatory Body and Public Consultations: Dealing with Contested Ethical Views

As has been established in chapter 1, the area of human embryonic stem cell research in particular, is surrounded by competing and contested ethical views. A range of ethical justifications and arguments informed by a variation of perspectives including of legal, ethical, and religious have been put

forward for debate, but the issues of the use of human embryos and its moral sanctity are still at dispute.

On the one hand, there are individuals, whose views are predominantly informed and based upon strict religious views, drawing on the idea that human life begins at conception. Therefore, the use of human embryos as a means to an end, according to this school of thought, is against the sanctity of human life. Such research activity is regarded as an unethical and should not be allowed. On the other hand, there are people who believe that life begins much later after conception.

For instance, some Islamic scholars argue that ensoulment begins 40 days after conception, or 120 days according to others, and as such, they view human embryos in its early days after conception as a clump of cells. Given the potential benefits from the use of human embryonic stem cell lines, the latter group argues that it is ethically acceptable to use the embryos, particularly surplus embryos from reproductive treatments, to benefit humankind especially when they will no longer be used or kept and they will eventually be destroyed.

In view of the conflicting opinions, it seems unlikely to achieve a consensual understanding and therefore a pragmatic approach i.e. the 14-day rule was introduced as a compromise to respect the sanctity of human embryos and in order to allow research development to benefit humankind. One would question how would Malaysia deal with these competing and contested ethical views and legal issues that arise due to the former. A reference could be made to other countries such as the UK, Australia, and Canada. In dealing with ethical and legal issues, these countries have employed regulatory body and

extensive public consultations, which can be regarded as key measures that play vital functions at the heart of the regulatory system.

As an initial step to regulating human embryonic stem cell research, it is important to ensure that formulated rules would be acceptable and in line with the local context. In so doing, communication-based regulation through public consultations is particularly useful and it is important to ensure that this approach needs to be inclusive even at the early stage of the technological development (Brownsword and Somsen, 2009) by involving the public, key stakeholders, and relevant experts. Such an approach is crucial, particularly when policymakers are facing issues, which are controversial and surrounded by deeply conflicting views.

Referring back to the discussion on the possibility of a policy change in Malaysia with regards to the creation of human embryos for research purposes, as suggested by some respondents, this thesis argues that Malaysian policymakers would need to adopt public consultation with a wider group of stakeholders to determine whether there should be a policy change. The view suggested here is mainly due to the findings reported showing differing views between respondents, whose views may not be representative, given the small sample.

Therefore, to determine whether or not the public would support this policy change, what is needed would be a national wide public consultation, as has been done by other jurisdictions i.e. the UK, Canada, Singapore et cetera, for without the public support; its implementation would not be successful and could stir disputes. As has been argued by Brownsword and Somsen (2009; p.

17), “where a legislative framework is agreed for the application of a new technology, this will usually be preceded by public consultation.”

This would be in line with the practice in other countries as well as to acknowledge the fact that the ‘society’ at the global level has becoming more concerned and engaged with scientific development. For instance, the HFE Act 1990 has undergone a few amendments and this was done with consideration given to the findings obtained from extensive public consultations. (Science and Committee, 2005, Chief Medical Officer's Expert Group ' Stem Cell Research: medical progress with responsibility', 2000)[86]

This thesis further argues that a public consultation could provide evidence whether the derivation of hESCs from created embryos for research would be likely to be a major ethical concern to the wider public, and could inform the decision whether removing the prohibition on embryo creation would be acceptable or not. For instance, in the UK case, a public consultation on hybrid embryos overturned the opposition stated by the former Chief Medical Officer in a report (2000). The outcome of the consultation has led to the permission of human admixed embryo creation by the HFE Act 2008.

Another good example would be the approach taken by Singapore. Prior to the establishment of its national policies on its approach towards the use of

[86] The report by the Chief Medical Officer’s Expert Group, led by Sir Liam Donaldson, mentions that “mixing of human adult (somatic cells) with the live eggs of any animal species should not be permitted.” The Fifth Report in 2004 report shows the view was not universally endorsed. The House of Lords Select Committee for Stem Cell Research argued in favour of the use of hybrid embryos, subject to the same 14-day rule. A public consultation was conducted to find out whether this new advance should be permitted in the UK. In April 2007, a public consultation on Hybrids and Chimeras conducted by the HFEA took place. A draft Bill was published followed by a review and amendment of the HFE Act 1990 to introduce a new Act, the Human Fertilisation and Embryology Act 2008 (hereafter, the HFE Act 2008). The HFE Act 2008 permits the creation of human admixed embryos and thus such research could be licensed provided it adheres to the list of permitted research purposes.

human embryos and hSCR, the Singapore Cabinet appointed its Bioethics Advisory Committee to examine the "scientific, ethical, legal, and social issues arising from biomedical research and development in Singapore." (Kian and Leng, 2005; p.290) In so doing, the committee conducted "an extensive consultation process […] to understand the concerns and sentiments of the local community, the interest groups, the religious and professional organizations." (Kian and Leng, 2005; p.290)

Also, an established independent regulatory body could work hand in hand with institutional bioethics, (Salter and Salter, 2007) which has become an indispensable tool for assuaging public concerns about novel and controversial technologies. It can be argued that besides law and guidelines, institutional bioethics also play an important role in regulating this area. As can be seen in figure 6, many countries have also established what can be regarded as consulting bodies or agencies i.e. advisory councils, bioethics committees. Malaysia could adopt similar approach since it has recently established its own National Bioethics Council.

As has been discussed earlier, a regulatory body plays an important role to monitor and oversee research activities are being conducted according to the rules in place. By ensuring ethical compliance, the body would be able to safeguard and protect human embryos, which to an extent would be able to ease or lessen the tension and concerns among the group with restrictive views. In so doing, such measure can be seen as an assurance that this area is being strictly monitored according to high ethical standards.

4. Strengthening Compliance Measures with Legal Force

As has been argued in Chapters 2 and 3, introducing rules that are backed by legal force alone would not guarantee compliance. Not only does it requires regulators or an enforcing body to enforce the rules, but regulators also need strategies that would enable them to efficiently enforce the rules. In order to achieve optimal regulatory outcome, regulators would need to adopt a combination of different enforcement strategies to ensure compliance.

On the one hand, regulators could adopt a compliance strategy that prioritises conciliation or facilitates compliance in preventing harm or unethical conduct; on the other hand, regulators could resort to a sanctioning strategy to inflict punishment for non-compliance. (Hawkins, 1984, Baldwin, 1997) Whilst the former involves intervention from the beginning as a preventive action, the latter only intervene at the stage when violation to the rules has already taken place. (Hawkins, 1984)

Since hSCR – hESC research in particular, is a controversial and ethically challenging area, it can be argued that it would be ethically appropriate for regulators to adopt both strategies in order to prevent unethical conduct and to have the legal power to carry out sanctions if needed.

The following two sections discuss the practice of some of the existing compliance measures in hSCR regulatory domain to ensure compliance in Malaysia. One could relate some of the measures to the two different enforcement strategies, as described in the preceding chapter; the licensing system and informed consent can be regarded as a compliance strategy

whereas sanctioning or coercive legal actions such as fines and imprisonment is clearly a practice of a sanctioning strategy.

4.1 Licensing System for hSCR

The findings obtained from the interviews expose a number of issues with regards to the implementation of the licensing system in Malaysia and provide a more detailed account with regards to the uncertainty of the role of NSREC sub-committee and MREC in relation to this system, as highlighted in Chapter 3. As has been reported in the empirical chapters; first, unlike other countries, a licensing system is not being implemented for non-clinical research in Malaysia even though it might involve the use of human embryos and embryonic stem cells.

According to a number of respondents who are non-clinical stem cell researchers, they are only required to obtain ethical approval from their institutional ethics committee. This however has resulted in an unsuccessful attempt by one of the respondents to procure embryonic stem cell lines from one of the US top and reputable research universities. The respondent was asked to present much stronger evidence of a measure for safeguarding the stem cell lines requested than that of ethical approval from institutional ethics committee.

Second, notwithstanding the fact that only clinical research involving human subjects i.e. clinical trials will need to get a license from the authority (MREC), as pointed out by respondents, there is an issue of comprehensiveness. The findings show that there is xenotransplantation-based ‘treatment’ being carried out without the MREC’s oversight. This has led to a

few other respondents expressing their concerns and they argued that this 'treatment' should be regarded as clinical trial and licensed by MREC. However, it is worth highlighting that the MREC's remit is only limited to the public sector or only research projects that are affiliated with the ministry.

In view of these findings, one could argue that both non-clinical and clinical stem cell research are currently being carried out within a lax regulatory system. Since the ethical approval is only a practice at the institutional level, how does one ensure that there will be a standard regulatory practice throughout the country and how comprehensive it is – would every stakeholder be required to go through the same approval process?

In addition, if there is no implementation of a central approval or licensing system at the non-clinical research level, one would question as to how the different institutional ethics committees keep track of the research activities in the country: how to control the use of human embryos to avoid unnecessary use and redundancy in research?

With the current system, as pointed out by respondents, how would the relevant bodies – the MREC and NSREC sub-committees, know how the embryos would be used in the private sector and for what purpose? How would the authority ensure that the requirement of using surplus embryos only within a certain period is met? If these questions could not be addressed at the non-clinical research stage, how would then the authority ensure the cells used in clinical trials are sourced ethically, to be in line with the country's aspiration as articulated in the guidelines?

In order to address these questions and concerns; Malaysia might need to legislate and implement a more comprehensive licensing provisions similar to

the UK and Australia, to regulate public and private sectors as well as clinical and non-clinical research activities.[87] It can be seen from the interviews, most of the respondents are in favour of a licensing system and they contended that it should be included in legislation. Such measure would facilitate Malaysian research activities to appear more reputable and this would be of help for the researchers in their collaborative work.

This is simply because unlike a merely ethical approval from institutional ethics committee, a statutorily licensing requirement would require any research work, even those that fall under the category of permitted research, to go through a strict licensing process before being approved by a national regulatory body, and would then be subjected to an oversight system.[88] The adoption of this system would make Malaysian's system in line with the regulatory practice of other countries i.e. UK, Australia, Canada, and would close the regulatory gap for potential collaborations.

Furthermore, this measure might also be useful to facilitate awareness since under this system; an applicant would be in contact with regulatory body prior to carrying out research work. A licensing system, as described earlier, can be regarded as a compliance strategy, whereby it facilitates communication between regulators and the regulated. As has been pointed out, the issue of a lack of awareness in Malaysia, according to the respondents, is due to the lack

[87] As has been shown, licensing system implemented in other countries i.e. the UK, Australia, Canada etc, is embedded in law. Accordingly, the requirement for a licence to be obtained prior to any work involving human embryos and to comply with the terms and conditions of the licence, is automatically applicable to every individuals involved in such work be they from the public or private sector and for clinical or non-clinical research.

[88] As has been shown previously, in other countries with a regime that is based on a licensing system such as the UK and Australia, licence is a 'ticket' without which researchers will not be allowed to enter into this regulated area - to conduct research using human embryos and the cell lines derived thereof.

of access to information and lack of awareness about the existence of a regulatory body. This system, if adopted, would be able to mitigate this issue. Additionally, it will also provide regulators with the authority to prosecute offenders who violate the licence, unlike the current system, which is viewed by most of the respondents as non-binding.

Regulatory awareness is not only a problematic matter exclusive to Malaysian stakeholders. In assessing the lessons that can be learned from the South Korean scandal, as it has been reported that “85% of over 900 biotechnology researchers surveyed in South Korea did not know what the Declaration of Helsinki was, and that 42% did not know about Institutional Review Boards. This study was conducted only in Korea, but may be indicative of an international problem. All research institutions need to assess awareness of ethical standards.” (Cho et al., 2006; p. 614)

4.2 Informed Consent

As with the other jurisdictions, informed consent is also being implemented in Malaysia, and the findings show that all of the respondents believed that it is an important measure, especially to protect research subjects. Unlike the licensing system, which is only being practised for clinical research, the practice of informed consent is more comprehensive, whereby it involves non-clinical research too.

However, there was a concern with regards to the standardisation of its implementation especially between researchers from different backgrounds namely medical practitioners and scientists. It was highlighted that whilst the

former group is given proper training, the latter's exposure in this practice is being questioned by one of the respondents.

Other concerns that have been raised by respondents were regarding the substantiality of the consultation process involved and the absence of a standardised format for drafting informed consent forms, particularly for research work. It was also pointed out that the general public might not be aware of the importance of informed consent. This issue was not only confined within stem cell domain, as it is also occurring in other areas such as organ and blood donation, and biobanking.

Similar to the licensing system as discussed above, if there is no standardisation of informed consent practice, how does the authority ensure the standard of its implementation across the field. It was suggested that proper guidelines on informed consent be introduced and an independent and well-trained expert group be appointed to carry out this practice.

Malaysia does not need to 'reinvent the wheel' to introduce guidelines on informed consent specifically for hSCR field, given that there are existing guidelines on best practice for this measure introduced by the ISSCR, US National Academies of Sciences et cetera. This is also an important measure as a proper practice in obtaining informed consent is necessary to facilitate collaboration. For instance, it would allow sharing of cell lines derived in Malaysia with researchers in other countries, and is also often required for publishing findings in scientific journals.

One can also argue that with standardised implementation of informed consent, regulators would have appropriate guidelines and a platform to create awareness both among researchers and research subjects i.e. donors of

surplus embryos or gametes, through education and advice, and accordingly, would be able to facilitate compliance. In view of its benefits, it is also important to make this measure legally binding.

4.3 Sanctions

Many of the respondents shared the same view on the introduction of sanctions in the system. They believed that sanctions are needed for various purposes. First, they felt that unlike the current non-binding rules, rules enforcement that is backed by sanctions would be able to compel private entities to comply. Second, they viewed legally coercive actions as more effective to ensure compliance, and likely to act as deterrence to discourage anyone who entered into this area from violating the rules in place.

Should Malaysia consider enacting legislation for hSCR, this will inevitably include sanctions since, as shown earlier; legislation is a form of classical regulation, which is based on legally coercive sanctions. Also, it has been shown that such measure is also a common approach in other countries. Nevertheless, it is worth noting that even though the findings might suggest that Malaysian researchers welcome such measures, they could be quite concerned about the level of severity of the sanctions. There was a suggestion of sanctioning that involves suspension of research privileges before opting for more serious terms - imprisonment and fines.

In view of this concern, it is worth pointing out again that this penal style measure can be held as a reserve or a last resort and only be applied as and when needed should the minimum requirement of compliance be breached.

(Gunningham, 1998)[89] This measure would not only give regulators the options to use legal force along with other compliance measures, but it would also result in more comprehensive regulation.

For instance, it was pointed out that unlike scientists, medical practitioners are subject to oversight by a professional body – the Malaysian Medical Council, and the existing law – the Medical Act. This may result in a non-standardised oversight system and punishment for non-compliance. Therefore, one could argue that by having a law specially enacted to govern hSCR underpinned by legal actions, this would result in the same legal requirements and repercussions can be applied to everyone who entered into this sector, whether the person is a medical practitioners or scientist, and in the private or public sector.

Also, it can be seen from the discussion above, as argued by scholars (Hutter, 1997, Morgan and Yeung, 2007), despite the common perception that associates enforcement through law with coercive legal actions, there are other mechanisms that can be adopted within a legal system. These mechanisms are based on education, advice, persuasion, and negotiation, and the two measures discussed above could be associated with this approach. [90]

Many of the respondents in this study believed that legal action is not the only way forward as there are many other approaches that could facilitate regulators to implement rules more efficiently in order to safeguard research

[89] To quote Gunningham and Grabosky again, "certain instruments would be held in reserve, only to be applied as and when other instruments demonstrably fail to meet pre-determined performance benchmarks."

[90] To quote Morgan and Yeung, the common perception towards command-based regulation is the use of legal force, but as pointed out by Hutters, the enforcement of legal action may also involve informal techniques such as education, advice, persuasion, and negotiation.

subjects, the reputation of hSCR, and secure compliance. Nevertheless, they also believed that these approaches require legal force in order to make them binding and more comprehensive. Indeed, as observed by scholars such as Ayres and Braithwaite (1992; p. 21), regulatory agencies would be likely to achieve their desired regulatory goal if they "strike some sort of sophisticated balance between the two models."

5. Legal Transplant: Possibilities and Challenges

Many respondents contended that there is a need for legislation to regulate hSCR in Malaysia. Given that legal transplant is a rather common practice in Malaysian jurisdictional system, as shown in Chapter 3, it seems that it would be possible for policymakers to import some rules or law from other countries.

Another reason as to why legal transplant would be a favourable option is that, as identified in this study, there are concerns among the respondents with regards to the time that it might take to establish an entirely new law for this field. Among of all the commonwealth countries in this study, the UK regulatory system for hSCR can be said more established and therefore, it would be beneficial for Malaysian policymakers to look at the UK.

Nevertheless, it could be challenging for the policymakers to simply transplant UK's rules into Malaysian system, as not all rules would be suitable for the Malaysian context, due to its multi-faith and multi-cultural society. For instance, on the one hand, the UK allows the creation of human embryos for research purposes, but on the other hand, this is currently not allowed in Malaysia.

As explained earlier, the prohibition is largely influenced by religious views, as stipulated in the national fatwa.[91] Even though the fatwa is commonly known as the legally binding rules that can only be imposed on the majority Muslim community, it is worth noting that its promulgation particularly for this contentious field, also heavily considered views from other religious groups.

If the transplantation of rules would not be a feasible option, Malaysia could follow the Singapore's step in using UK's law as a model to promulgate their own rules. Certainly, this would require extensive public consultations with relevant stakeholders. (Kian and Leng, 2005) In addition, Malaysia could also take a similar approach, as has been done by Australia, whereby their government has recently changed its regulatory system by adopting UK's licensing system.

The most relevant feature of the UK's licensing system would be the model of an independent regulatory body - the HFEA, the arm's length body, which is the key strategy underpinning the UK's regulatory system. Another example could be the Human Tissue Authority (HTA), which is also an arm's length statutory body using a licensing system in its operation. This would benefit the Malaysian system, particularly in addressing the lack of regulatory oversight and awareness.

Furthermore, not only does Malaysia's current system have issues with regulatory oversight, but it has also been shown that there is concern about the allocation of funding, hence, the suggestion for a coordinative council be established in Malaysia. In so doing, Malaysia could learn from the Canadian

[91] Note that the fatwa on human stem cell research in fully incorporated into the National Guidelines.

system – the Tri-Agency Council. This would be possible since a similar system is already in practice for cancer research.

By adopting this system, different funding bodies could come together in administering federal funding, a system practised by the Canadian Tri-Agency Council. This approach could also ensure ethical conduct whereby the approval for funding is dependent on ethical approval and compliance to national guidelines. This technique can be regarded as a form of an incentive-based regulation, whereby regulators deploy public wealth as incentives in obtaining compliance. (Daintith, 1994; p.470, Ogus, 1999; p.419, Driesen, 2010; p.668)

6. Overall Conclusions

This thesis has examined the features of regulatory instruments and techniques employed to regulate hSCR in a number of countries. The examination was carried out with the primary aim of providing a comparative analysis for a more fitting and improved regulatory framework for Malaysia. It has focused on the functions of regulation to address issues surrounding hSCR.

Also, it considered how Malaysian policymakers could establish a framework that could ensure compliance, provide adequate protection for human embryos and research subjects, as well as facilitate the development of this area. This chapter has concluded this thesis as a whole and demonstrated how the research question is linked to the findings reported. It has also considered additional research questions that arose during this study as well as potential future work.

6.1 Concluding Remarks

Based on the findings obtained from the interviews and the comparison with other jurisdictions' regulatory practice, this thesis concludes that Malaysia lacks some of the key regulatory elements that are essential to ensure ethical conduct and to secure compliance in hSCR. This explains why there are shared concerns among the respondents about the possibility of unethical conduct that may put the reputation of this field as well as public safety at risk.

This concern is largely due to the current framework that lacks legal effect in the implementation of the rules and the regulatory oversight. In view of this situation, it can be said that hSCR activities in the public sector are being under-regulated, and non-clinical hSCR activities are being carried out in a regulatory vacuum. Therefore, this may in the near future, stimulate or facilitate non-compliance with the rules in place if the current framework is not strengthened.

6.1.1 Hybrid Regulation: Malaysian Potential Regulatory Approach

Based on this study, it can be said that to develop this area ethically, Malaysia will need to establish and maintain a regulatory framework that is designed from a combination of different regulatory instruments and enforcement techniques. This framework requires a system equipped with measures that are capable of securing and facilitating compliance. With such a framework, not only would researchers be able to further explore this medically promising technology with a clear and proper guidance, it could also provide protection both for research subjects and the field itself.

The optimal means of improving and strengthening Malaysia's framework would be through a variety of measures, including: (i) the introduction of legislation (command-and-control regulation); (ii) revisiting the prohibition on human embryos creation and the introduction of requirement to provide qualifications or justifications to ensure that any use of human embryos in research is for necessary purposes, that cannot be achieved using other means; (iii) the establishment of an independent regulatory body, which could implement communication-based regulation and enforced self-regulation; and (iv) the standardisation and a reinforcement of the rules enforcement techniques. It is also important to consider the possibility and challenges in transplanting rules or adopting legal system from other countries.

By adopting hybrid regulation, Malaysian regulators will have options that they can employ, depending on the situations and suitability, in order to achieve their desired regulatory goals, given different regulatory techniques have their own strengths and weaknesses. As has been pointed out earlier, by implementing command-and-control regulation, this technique will provide Malaysian framework and all regulatory measures that are necessary in this field with legal effects. Such regime would also be able to close the regulatory gap by providing more comprehensive framework. For instance, research activities involving the use of human embryos that are governed by law will have legal effects both in public and private sectors and regardless whether or not the activities take place for non-clinical or clinical purposes.

With law in place, the framework will provide Malaysian regulators with legal power; however, they would also benefit from other regulatory techniques such as enforced self-regulation through independent regulatory body at the

national and institutional levels. As has been highlighted in the preceding discussion, even though statutory rules are backed by legal force, they are not self-enforcing and therefore, such body is crucial for rules implementation and enforcement. In addition, legal rules are also not self-explanatory and therefore, by having such body, awareness and compliance with the rules could be secured through communication with the regulated parties.

In times of the rapid development of hSCR, this thesis argues that an independent regulatory body functions at the heart of a regulatory system. Not only that the body's involvement in enforcing rules, monitoring, and overseeing compliance from the beginning could lead to an optimal regulatory outcome, but it would also expedite continual communication between regulators and the regulated. This would result in the regulators being informed of the latest development of the state of the art of this field. It is also important for regulators to get involved in the beginning by educating and giving advice to the regulated instead of relying on legal sanctions and only intervene when legal rules have been breached, particularly for ethically challenging and controversial technology such as human embryonic stem cell research.

Based on this research, this thesis can conclude that what Malaysia needs is an improved regulatory framework that is designed based on a combination of different regulatory techniques and compliance strategies, appropriate to the Malaysian context. Such approach would facilitate Malaysia to ensure ethically acceptable hSCR activities and offer assurance for patients' safety.

6.1.2 Determining the 'appropriateness' of an Improved Regulatory Framework

Section 2.2 and section 6.1.1 of this concluding chapter have drawn together the possible means that could be employed to improve the current regulatory framework and highlighted the key aspects and regulatory targets respectively. Nevertheless, it is important to note that an extensive public consultation would be needed to determine whether or not these possible approaches are appropriate to the Malaysian context.

One would question what are the key criteria that can be relied upon in order to define the 'appropriateness' of an improved regulatory framework. Based on the discussion earlier, it can be said that possible key criteria that can be derived from this thesis and that can be considered by Malaysian policymakers would be (i) the established rules and system can be accepted by the key stakeholders and in harmony with the societal context and customary setting to ensure its acceptability and legitimacy; (ii) the promulgation of the rules and enforcement approaches satisfy democratic mandate. One way to achieve (i) and (ii) would be through an extensive public consultation, a practice of which has been discussed in section 3.5; (iii) there is a clarity in the established rules and system, as pointed out in section 1.4; (iv) the framework provides inclusive rules and comprehensive enforcement, as discussed in section 1.3 and 3.1, without impeding research development; and (v) the rules and regulatory system able to stay in connect with the research development to ensure its sustainability, as discussed in section 1.4.

6.2 The Way Forward and Potential Future Work

This thesis acknowledges that the options discussed above do not represent a final determination and definitive solution. However, by producing the options, this thesis lays down the path for future scholarly work and for policymakers to consider as to how they would proceed in resolving the issues reported in this thesis. To further rectify whether or not the options are practical and applicable to Malaysian context, Malaysian policymakers would need to engage in a campaign of consultations with various relevant stakeholders. In so doing, they could use the issues and findings reported as guideposts. The outcome of the consultations can then be further analysed by relevant expertise such as the National Bioethics Council.

In addition, as has been mentioned earlier, there were research questions identified in this thesis of which could potentially lead to another scholarly work; (i) international prospect - the creation of a regulatory database among Commonwealth countries, and (ii) national prospect - an investigation of the levels of awareness among the Malaysian public on stem cell research and therapy.

6.2.1 The International Prospect

Chapter 2 has considered a few databases on stem cell policy across the globe. In addition, there is also a website, EuroStemCell, created to host a database that provides information on the regulatory system among the European Member States. (EuroStemCell, 2011) Given there are a few Commonwealth countries that are well established in this field, and the fact that there are still a significant number of other Commonwealth countries that have

not yet established regulatory systems in this field, it would be beneficial to create one database specifically for Commonwealth countries.

6.2.2 The National Prospect

As stated previously, the discussion on the public awareness regarding hSCR in Malaysia is only based on the opinions of the respondents of this thesis. There are a number of empirical studies conducted on this subject to show the level of public awareness in other countries but it seems there is no study on the Malaysian public so far. Therefore, there is no indication as to how well versed the Malaysian public is, in terms of hSCR, especially the use of human embryos, and human-animal hybrids. Also, it would be desirable to investigate the scale of stem cell tourism and the private sector or even whether people have used, or considered using unproven stem cell-based therapy offered by private clinics.

It is hoped that this thesis will contribute to the literature and enhance further understanding of legal issues surrounding hSCR in Malaysia.

Appendix 1: Methodology

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This appendix explains the methodology employed for this thesis project. It describes the issues of research ethics involved, the sampling justification, the questionnaire structure, the methods used for data collection and analysis of the empirical findings.

1. Empirical Methods: Qualitative Interviews

This research project considered qualitative interviewing as the most suitable and flexible approach to data collection for this project, since it requires in-depth information. (Punch, 2013, Silverman, 2011) Since there is limited information (from websites or academic papers) on the current practice in Malaysia available for public access except the guidelines, it is therefore not clear how strict the compliance enforcement is and whether or not ethical procedures are being followed. This method is also chosen because it would enable the interviewer to deeply probe “more of an insight into the meaning and significance of what is happening.” (Wilkinson and Birmingham, 2003; p. 44)

The required first hand information able to be obtained through interviews. This method allowed the respondents to express their differing ideas and opinions of what type of regulatory approach would work for Malaysia. The interview also provided a platform to engage with the respondents. To ensure that the findings of the interviews would be at least representative of different relevant expertise groups if not the overall stakeholders in the domain of hSCR, the respondents targeted for these interviews are among the key stakeholders. More details of the targeted sampling for this research are explained in section 3.

Other methods such as focus groups and a fixed survey instrument were also considered. Nevertheless, they were rejected for a number of reasons. Unlike one-to-one interviews, it would be unlikely for respondents to be open in a group discussion due to the sensitivity of this field. Many of the respondents hold more than one role, as some of them who are researchers are also a member of ethics committee at institutional level and/or national level. Therefore, some of them might find it uncomfortable to be open with their experience and thoughts. For instance, respondents who are in an ethics committee might not want to share his or her views on the current system in front of researchers who may be their colleagues. Also, it would be difficult to ensure confidentiality and anonymity especially among regulators and researchers if focus group methods were used.

As for the survey method, it was rejected simply due to the fact that respondents would not have the platform to express opinions and elaborate further, as they would be restricted to the format of the survey. Furthermore, there would not be any opportunity to diversify the direction of the interview

based on the experience of the respondents. This is particularly important because the respondents of this research are from different backgrounds and have different expertise, and therefore, during the interviews, some respondents were prone to discuss more on certain areas and only able to provide brief views on other areas.

2. Questionnaire

The questions for the interviews were designed as a topic guide for discussion with the respondents, to probe more into the regulatory domain of hSCR in Malaysia. The aim is to obtain respondents' views on (i) their awareness on the regulation of hSCR in general; (ii) the regulatory approach in Malaysia; (iii) a more focussed discussion on the national guidelines; (iv) the measures specifically adopted to provide for protection of human embryos and research subjects; (v) the overall research governance for hSCR.

Semi-structured interviews with open-ended questions were chosen because this format allowed sufficient flexibility during the interviews and encouraged respondents to provide more information than that of closed questions with structured model. (Wilkinson and Birmingham, 2003; p. 45) Before the interviews were carried out, a pilot study was conducted to ensure the interview questions and the structures of the questions are appropriate. It was important to ensure that the questions were clear and easy to understand. (Wilkinson and Birmingham, 2003; p. 52) By conducting the pilot study, useful feedback was obtained for the improvement of the interview questions in order to ensure their relevance and clarity.

All respondents were asked the same set of open questions although in some interviews, certain questions were given more emphasis and expansion. For instance, the discussion with respondents who are not really familiar with the current national guidelines were brief and more emphasis were given on their views about the protection for human embryos and research subjects.

3. Targeted Sampling

The respondents of the interviews were identified as being the stakeholders of this field in different areas of expertise, namely stem cell scientists; religious scholars/group leaders; ethicists or bioethicists; government officials, policymakers, research sponsors, collaborators, and NGOs or advocacy group leaders. Originally, it was anticipated to interview government officials from relevant Ministries. However, this plan was abandoned due to some difficulties in getting candidates with suitable availability and additional ethical approval was required, which in itself was rather difficult to obtain in a limited period of time. Nevertheless, some of the researchers took part in this project can also be considered as government officials.[92]

The interviews were first carried out with established personal contacts (known from the past at relevant conferences) and some were identified through the internet, in particular, through the websites of Ministries, research universities, and research institutions. Another method of identification used was a 'snowball' sampling technique, (Bryman, 2012) whereby at the end of

[92] It is common in Malaysia for researchers from research or academic institutions to be also part of Ministries. They can be actively involved in research activities as well as in regulating research.

each interview, a respondent was asked to suggest other potential candidates whom he or she thought would be relevant to be interviewed. Many of the respondents in this project were identified through this method.

The invitation to take part in this project was first initiated via email, and some phone calls were also made due to lack of response. This was anticipated since most of the respondents are key stakeholders and have multiple roles, and therefore they were expected to be extremely busy. A record was kept of all respondents who agreed to be interviewed. Once they expressed their interest, they were given an invitation letter (see Appendix 2.2), information sheet (see Appendix 2.1), questions guide (see Appendix 2.3, and informed consent form (see Appendix 2.4). Prior to each interview, the respondent was asked if they have any further questions and to give informed consent to their participation.

Initially, the target was to interview 30 respondents, however, in total only 26 interviews were conducted. The number can be considered appropriate considering that this area is not vastly developed in Malaysia and most of the respondents interviewed are among the key stakeholders. Also, it was felt that the number is sufficient as the data obtained from the interviews have reached saturation; all the issues and opinions given by the respondents are consistent across all interviews. However, there were some degrees of disagreement in some issues, and this has been highlighted in the empirical chapters 4, 5 and 6, and further analysed in Chapter 7.

4. Research Ethics

This thesis project explored the regulatory practice in the area of human stem cell research in Malaysia and a number of interviews were conducted with relevant stakeholders. As a result, this project had to undergo the process of ethical approval through Medical Sciences Inter Divisional Research Ethics Committee (MSD-IDREC). In order to obtain the ethics approval, a number of documents were submitted; information sheet, interview invitation letter, informed consent form, interview questions / topic guides. These documents are also attached as appendixes. By obtaining this ethical approval, this project complied with the University of Oxford ethics committee requirements.

The ethical approval for this project was rather straight forward, as it did not require any intensive approval process from different ethics committees, as for instance, if this project were to involve UK's NHS patients or employees.[93] Through the approval process, a number of ethical issues were considered and verified by the ethics committee namely confidentiality and informed consent. Both of these ethical matters were clearly addressed in separate documents (also attached as appendix in this thesis).

4.1 Confidentiality and Informed Consent

Confidentiality and anonymity were given a strong emphasis throughout this research project. Respondents of the interviews were recruited or invited to take part on the basis of the understanding that their anonymity would be guaranteed. The promise of anonymity was stressed prior to each interview to

[93] Central University Research Ethics Committee (CUREC) https://www.admin.ox.ac.uk/curec/

ensure that respondent remained comfortable and able to be as open as possible during the interview process. It was also stressed that the interviews were conducted not to record their personal practice but to capture their experience and opinions about the regulatory system in Malaysia.

Given the population of the key stakeholders in stem cell research in Malaysia – the targeted respondents for this project, is relatively small, the probability of indirect identification is rather high, as most of them know each other in one way or another. For instance, some of the respondents are researchers who are working closely with each other and within the same group, some are also members of ethics committee and aware of whom is doing which research work in the country. As a result, significant consideration was given to ensure the confidentiality is preserved the best way possible.

In order to preserve the confidentiality of the respondents, it was important and necessary to anonymise all interviews. In so doing, there is no direct identification of their personal information and affiliated institution in the reporting of the findings of the interviews and in the analysis of the findings. All of the respondents were only identified as 'respondent' and their expertise i.e. 'respondent 16: … [embryologist]. Given the small population (as explained above) and the fact that many of the key stakeholders know each other, it was also essential to avoid the identification of respondents' gender i.e. "'respondent 3' further argued" is used instead of typing "'she/he' further argued" throughout this thesis.

In addition, informed consent was also emphasised during the recruitment and obtained prior to interviews. The informed consent is important as an indication that the respondents understand the risks of participating in the

research and the purposes for which this research is carried out. Also, to demonstrate that having such understanding, they agree to take part in this research, on their own volition and without being coerced or deceived into participating.

5. Methods of Data Collection and Qualitative Analysis

5.1 Approach to Data Collection

The interviews were conducted on a one-to-one and face-to-face basis in Malaysia, in the year 2012 for three months from January until March. The Nuffield Department of Population Health, University of Oxford funded the cost for the expenditure of this research in Malaysia. The extra time travelling to and within Malaysia for the interviews and the costs incurred can be considered worthwhile for the candidate able to meet respondents in a face-to-face setting and have an open discussion. The expected time for each interview was one hour, however, most of the interviews lasted for about one hour and a half, somewhat longer than the expected time.

As for the area where the interviews took place, all of the interviewees were not significantly geographically diverse, only concentrated in the area of Kuala Lumpur, Selangor and nearby distircts, Bangi and Putrajaya. This is because most of the research Universities and relevant institutions are based in Kuala Lumpur, Selangor, and Bangi. Moreover, most of the government agencies, especially the main government offices i.e. Ministries are located in Putrajaya. It can be seen during the course of the interviews process that almost every respondent expressed interest in the subject of this research project, and as a result were keen to participate, and were interested to know

the outcome. They also encouraged the researcher to further develop on the outcome of this project and become actively involved in the effort to improve the current regulatory framework.

With permission from the respondents, as indicated through the informed consent obtained, the interviews were recorded using a digital voice recorder. As per ethics requirement, the recording files are downloaded and kept in the researcher's personal computer and backed-up as well as secured with a password. Based on the discussion with supervisors, it was felt that it would be beneficial to transcribe each recording after each interview. All of the interviews were transcribed into a Microsoft Word document and produced without hiring a professional transcriber. The transcripts were then checked for accuracy. This has been a useful approach, as it enables the candidate to be fully aware of and have an in-depth understanding of individual accounts.

5.2 Approach to Coding Framework and Data Analysis

The transcripts were analysed using thematic analysis based on the modified grounded theory, a widely used approach in qualitative research. (Bryman, 2012, Punch, 2013) The candidate went through the first few transcripts, examined and scrutinised the data to identify suitable codes. To ensure consistency in the analysis, the transcripts were read a number of times; relevant texts were broken down and labelled with codes on the right margin of the transcript soon after each interview. As the interviews progressed, new codes were generated and constantly compared with the generated ones and modified to ensure their suitability.

At the end of the interviews, a large number of codes were produced, which were then revisited a number of times to make them more concise and defined. The identified quotations were edited for reporting by removing extraneous filler words i.e. ‘um’, ‘er’, and ‘you know’ and repeated words. Nonetheless, some repeated words are kept (verbatim) because they were repeated for emphasis.

By using the ‘one sheet of paper’ (OSOP) approach, all of the codes produced were then written down on a piece of paper. This approach was introduced during a workshop for qualitative interviews organised by the Health Experiences Research Group, University of Oxford. The codes were compared and their relationship were analysed and considered. From this analysis, the codes were linked to generate overarching categories or themes in the context of the research question of this project, allowing the candidate to best set out relevant data to provide answer to the research question.

The generated categories were critically evaluated and reconsidered before being used as the basis or structure for analysis and reporting the findings in the empirical chapters. The development of the coding framework and analysis of the codes generated were accomplished without recourse to NVIVO or other qualitative data analysis software. This method may not be as convenient as if the mentioned software were used, however, it helped the candidate to recollect the data obtained clearly.

6. Limitations of this Approach

Throughout the analysis process, it was discovered that there are a few uncertainties with regards to the actual practice of the regulatory measures i.e. informed consent and ethical approval process. Qualitative interviews are useful to explore and obtain opinions of the stakeholders in the Malaysian hSCR field but it only allows this thesis to report their views and attitudes towards the current system. The method, however, does not reveal the actual practice. To do so, it might require another method of which could be an observation and record of the actual practice i.e. the process of obtaining informed consent from research participants or tissue donors.

Appendix 2: Ethics Committee Documents

This appendix presents documents that are required by the Central University for Research Ethics Committee (CUREC) for ethics approval. The documents are (i) the letter of invitation to interviewees and (ii) the information sheet provided to the respondents of this thesis project. Note that the title in the documents is ‘What should be the future governance framework for human stem cell research in Malaysia?’ It was subsequently changed to the current title of this thesis.

Appendix 2.1: Information Sheet



What should be the future governance framework for human stem cell research in Malaysia?

Information Sheet

You are kindly invited to take part in an interview as part of the above research study. Before deciding whether or not to take part in this study, it is important for you to read this information sheet carefully. It provides you an overview of the purpose of the interview as well as other aspects of the research study.

About the study

I am conducting a comparative study on an interdisciplinary area, the governance of human stem cell research. The UK is widely known, as the leading nation in this field and Singapore is famously perceived as the new upcoming nation, which is rapidly advancing its stem cell research, competing at the global level. In terms of the jurisdiction policy that governs this area, the UK has constantly adopted permissive approach, which is recently embraced by Singapore as its basic model approach.

Notably, nations that adopt permissive policy are the ones at the forefront of the realm of stem cell research environment. Permissive policy is claimed, able to attract world-renowned stem cell scientists and facilitate the progress of this field. Malaysia's current guiding policy is less permissive than that of the mentioned countries and arguably, may not be able to compete at the global level. Therefore, it is important to find out whether or not Malaysia would revisit its guiding policy before enacting a binding one.

To date, there is no embryo use for research has been reported in Malaysia, whilst some world-renowned scientists perceive that this research is crucial to advance towards stem cell treatment. However, it is worth noting of the new discovery of research techniques, which do not necessitate the controversial use of human embryos, and the emergence of global initiative of stem cells bank, which functions to supply established stem cells to its member states. Arguably, this suggests that the use of human embryo for research purposes may cease in the future. Will these developments influence the future binding policy of Malaysia?

Purpose of the study

One of the aims of this research study is to find out, what Malaysia can learn from the experience of the UK and Singapore in establishing their policy through which

ethical concerns are addressed without impeding the progress of stem cell research activities. It is anticipated that from the interview with some Malaysian experts, it would give an idea of the actual setting and development in Malaysia. I hope that from the interview, I would be able to get some information, views and thoughts that would assist the construction of policy recommendations for Malaysia's future governance framework to regulate this area. This research will also add to the relatively few socio-policy studies that explore the ethics and policy dimensions of human stem cell research in Malaysia.

Sponsor of the study

This research study is fully sponsored by the Ministry of Higher Education of Malaysia through an affiliation as a fellow at the Faculty of Law, University of Malaya, Malaysia.

Researcher of the study

I am currently a DPhil candidate based at the Centre of Law, Health and Emerging Technologies (HeLEX), Department of Public Health at the University of Oxford. Dr. Jane Kaye, the Director of the Centre is the supervisor of this research study. This research study is crucial as part of the completion of my doctoral degree. I graduated from University of Malaya with Bachelor of Science major in Genetics and Molecular Biology in 2007. I worked as a Special Project Officer at the International and Corporate Relations Office, Vice-Chancellor's office of the University of Malaya for about one year and a half, from 2007-2009. I then pursued a Master Degree in Biotechnological Law and Ethics at the University of Sheffield in 2011. After graduated from Sheffield, I worked for a few months at the Ministry of Science, Technology and Innovation of Malaysia, as a Special Officer to the Deputy Secretary General (Policy) before coming to Oxford later in 2011.

Participants of the study

Since the study involves an interdisciplinary area, I am looking for experts from various backgrounds such as ethicists, policy makers, stem cell scientists, and relevant stakeholders such as leaders of religious group, NGOs, and collaborators. Your expertise should fall within one of these groups. You could be involved directly or indirectly with the activities of stem cell research. Your views and thoughts are highly needed and would give an impact on the accuracy of the policy recommendations. Your involvement in this research study will do a great contribution and highly appreciated. There would be approximately 30 participants expected.

Voluntary participation

Please be rest assured that the participation is absolutely voluntary. You have no obligations whatsoever towards this study if you accept to take part. You have every right to refrain from answering any questions during the interview or disclosing any information, if you wish to. If you decide to withdraw, you can do so at any stage without having to provide a reason of your decision.

Process of participation

The interview will last for one hour to one hour and a half, and assuredly will not exceed more than two hours. Before the interview takes place, you will be

informed that the interview will involve audio recording using a digital recorder. You may declare your permission for the audio recording by signing the *Consent Form*. This is to ensure the accuracy of information gained from the interview for the purpose of data analysis at a later stage. The recorded conversations will be transcribed and analysed. Please take note that some of your lines would be used and quoted in the thesis. The questions that I will ask are as outlined in the *Interview Questions Guide*. But if in any situations, there are other relevant questions need to be addressed, which are not mentioned in the *Interview Questions Guide*, you may choose not to answer.

Confidentiality and anonymity

This research is confidential and anonymous. The Data Protection Act of two jurisdictions, Malaysia and the UK, and ethically approved research protocol will be strictly complied. This research should be ethically approved by the University of Oxford Central University Research Ethics Committee before the interview takes place. All the recorded and transcribed information will be kept in password-protected computers and files. Information in a form of hard copies will be stored in locked filing cabinets. You will not be named; instead, all participants will be coded to ensure that they remain anonymous.

Some of the information that you provide may be used for thesis writing. Once the thesis is successfully submitted, it would be deposited in a form of hard and soft copies in the University of Oxford archives. The thesis will be published on the Internet and could be accessed by everyone, particularly, among the academic community. This is to facilitate further research and impact on the outcome of this research study. Should there be any high risks of which concerns your personal identification through the information that need to be used in the thesis writing, you will be contacted to seek for your further consent.

Outcome of the study

This research study will eventually result in a Doctoral thesis of which will be held at the University of Oxford Bodleian Library. A few articles and papers may be written based on the analysed data of the interview, which may be published and presented. Therefore, it might reach a wider community of stem cell research environment outside of Malaysia. The most awaited outcome of this study is the policy recommendations for law and policy makers that would be based on the entire research study. Hence, the anticipated information and views from interview participants are very crucial to ensure the success of the study.

Reassurances of the study

University of Oxford is famously known as one of the prestigious universities in the world. Therefore, this research will be conducted according to a high standard. A responsible and very experienced supervisor will review this study, as well as other relevant authorised persons or organisations that involved directly or indirectly. Should there be anything that goes wrong during the research, the University of Oxford will take full responsibility and you may take any necessary actions against the university. Should you have any formal complaints to be made with regards to this study, you may do so by contacting the supervisor, Dr. Jane

Kaye, who is also the Director of HeLEX and Professor Ray Fitzpatrick, the Head of the Department of Public Health.

Last but not least, should you have any queries or concerns about the study, please do not hesitate to ask for further explanation and clarification. I can be contacted at the details given at the bottom of this information sheet.

Thank you.

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Appendix 2.2: Interview Invitation Letter

Address

Date

Dear Someone,

An invitation to take part in an interview for a DPhil study

I am writing to invite you to participate in my research project by taking part in an interview. I am a DPhil candidate at the Department of Public Health, University of Oxford, carrying out a comparative study on the regulation of human stem cell research.For your kind information, this interview is part of my DPhil (doctoral degree) study, which is funded by the Ministry of Higher Education of Malaysia through a fellowship affiliation at the University of Malaya, Malaysia.

This study will involve experts from various backgrounds related to human stem cell research. Through this study, I hope to be able to contribute in academic literature resource highlighting the Malaysians' perspectives on human stem cell research and to explore the actual setting of research activities and its regulation. Also, I hope the information/views/comments that you will share during the interview would help me to come out with a proposal of policy recommendations for the future governance framework to regulate this area in Malaysia.

If you are taking part in the interview, please be rest assured that the study will be conducted with high confidential standard according to Data Protection Act of both jurisdictions; Malaysia and the UK. The interviews will only take place after this study has received ethical approval. All information and data will be stored in locked filing cabinet and password-protected computers and files. They will not be disclosed to anyone. Only my supervisor and I will have an access to the information. I would also like to stress that the nature of your participation is completely voluntarily. This means that you can withdraw from this project at any stage including after the interview, if you wish so, without being obligated to give any reasons.

Please find attached are the information sheet, interview questions guide, and consent form. If you would like to take part, please read the information sheet carefully and sign on the consent form. Should you have any queries, please contact me at the details below:

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Website: www.dph.ox.ac.uk/helex

Please accept my greatest appreciation for your kind consideration to accept this invitation. Thank you.

Yours sincerely,

Mohammad Firdaus Abdul Aziz

Appendix 2.3: Interview Questions / Topic Guide

Prior to Interview:

- Information Sheet
- Interview Questions – any questions about the thesis project?
- Informed Consent Form
- Permission for audio recording
- Explanation about the thesis project and why the interview is relevant to the project
- Brief introduction about the organisation (respondent's)

Introduction

- Can you tell me what you do?
- Are you aware of the different regulatory approaches towards human stem cell research in the world?

Regulatory approach

- What do you think of the regulatory approach adopted by Malaysia?
  - Create challenges? What are they?
  - Able to advance research development?
  - Able to ensure ethical conduct?
  - Singapore is known as the "haven" of stem cell research due to its liberal policy and a massive investment made by the government. Do you think Malaysia should do the same?
  - Any suggestions?

National Guidelines

- Is the prohibition of creating human embryos to derive its stem cells based on religious ruling only?
  - Any public and expert consultations?
  - Adequate to safeguard ethical conduct?

- In your own views, do you think the current guidelines can secure ethical compliance, especially to protect research subjects involved?
- Malaysia needs to legislate law? Why?
- Any suggestions?

Protection for human embryos and research subjects

- As for the human embryonic stem cell research, do you think there is an adequate protection for human embryo in place?
  - What do you think of the 14-day rule?
  - Adequate to be applied by itself or justification is also needed?
  - Any thoughts or suggestions?
- How important do you think informed consent is in this area?
  - What is the current practice? Checking off boxes and sign only?
  - Difficult to follow? Why?
  - How do you ensure the participant is informed?
  - Should voluntarily informed be emphasised/stipulated in regulatory framework?
  - Any other suggestions?

Research governance

- Who's the governing body?
  - What is the current practice in granting licence/ethical approval?
  - Any obstacles/difficulties?
  - Independent/Non-Independent authorised body? Multidisciplinary members?
  - Monitoring system? Registry institution?
  - Things that should be improved? Any suggestions?

- A few kinds of sanctions are being introduced in other jurisdictions but not in Malaysia. Is it not needed in Malaysia?
  - What is appropriate? Imprisonment/civil fine/malpractice & liability?
  - The degree of severity? How many years/how much fine?
  - Suggestions?

- What do you think of the requirement of peer review in order to approve a research?
  - Is it being practiced in Malaysia?
  - Any other suggestions?

- Do you think it is important for Malaysia to be actively involved on the world stage discoursing government policies in this area?
  - Match and equalise ethical standard to facilitate good scientific collaboration?
  - Any particular country you would like to establish collaboration with? And why?
  - Collaboration between malaysian researchers themselves? Private & Public
  - Does the public need awareness? What kind of awareness?
  - Who should do this?

Appendix 2.4: Informed Consent



What should be the future governance framework for human stem cell research in Malaysia?

Consent Form for Participating in an Interview

Purpose of the study:
Malaysia aspires to advance its human stem cell (HSC) research and to ensure that the advancement progresses in an ethical way. However, it is not evident that the current regulation able to facilitate the nation to realize its aspiration. This socio-legal study, therefore, aims to develop some policy recommendations or points to consider, which could help Malaysia revising its regulatory framework to realise its aspiration.

Researcher of the study:
This study will be carried out by Mohammad Firdaus Bin Abdul Aziz, a DPhil candidate based at the Centre of Health, Law and Emerging Technologies (HeLEX), Department of Public Health at the University of Oxford. The researcher can be contacted at the details given at the bottom page of this form.

Please indicate your consent to take part in this research project, by ticking the boxes below. Also, please print and sign your name, and date the form in the spaces provided.

Declarations by participant:

1. I confirm that I have read the *Information Sheet* thoroughly and I understand the purpose of this interview and the research study above. [ ]

2. I confirm that I have given the opportunity to raise some questions and concerns about the study and they were satisfactorily answered and explained by the researcher. [ ]

3. I understand that the nature of my participation is completely voluntarily. Therefore, I retain the right to refrain from answering any questions, I can withdraw from the study without penalty by advising the researcher of my decision at any time, and I am not obliged to give any reason. [ ]

4. I understand that this study has been reviewed and received ethics clearance through the University of Oxford Central University Research Ethics Committee. [ ]

5. I understand who will have access to the data provided, how the data will be used and what will happen to the data at the end of this study as mentioned in the information sheet. [ ]

6. I understand that any information that can relate to my identity will not be disclosed in any means by the researcher without my permission. [ ]

7. I understand that information gained from the interview would be used and included in a thesis, which will be deposited in Oxford University archives, as well as in publication arising from the study. The thesis can be then accessed by anyone on the Internet. [ ]

8. I agree to participate in this study. [ ]

9. I understand how to raise a concern and make a complaint and I have been provided with the contact details. [ ]

Participant's name:
Signature: Date:

Researcher's name:
Signature: Date:

Appendix 2.5: List of Interviewees

Interviewees	Profession / Expertise
Respondent 1	Medical Practitioner, Stem Cell Scientist, Stem Cell Policy Panelist
Respondent 2	Lawyer, Advisory Council
Respondent 3	Scientist, Ministry Official, Advisory Council
Respondent 4	Stem Cell Scientist, Stem Cell Policy Panelist, Advisory Council
Respondent 5	Stem Cell Scientist
***Respondent 6**	Religious Authority
Respondent 7	Lawyer, Religious Authority, Advisory Council
Respondent 8	Science Agency, Advisory Council
Respondent 9	Ethics Committee Member
Respondent 10	Medical Practitioner, Stem Cell Scientist Advisory Council
Respondent 11	Lawyer, Stem Cell Policy Panelist
Respondent 12	Stem Cell Scientist
Respondent 13	Stem Cell Scientist, Embryologist
Respondent 14	Medical Practitioner, Stem Cell Provider
Respondent 15	Stem Cell Consultant, Former Ministry Official
Respondent 16	Embryologist
Respondent 17	Non Governmental Organisation
Respondent 18	Stem Cell Scientist, Advisory Council
Respondent 19	Stem Cell Scientist
Respondent 20	Scientist, Stem Cell Policy Panelist
Respondent 21	Ethics Committee Member

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