

The value of sharing genomic findings with research ethics committees

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Abstract:	The role of ethics committees is to protect and safeguard the rights and welfare of participants, and promote good research by providing ethical guidance to researchers. In order for ethics committees to fulfil their role and obligations, they need to have adequate understanding of the science and scientific methods used in research. Genomics is a novel and rapidly evolving research field, and identifying the ethical issues raised by it is not straightforward. Limited understanding of, and expertise in reviewing genomic research may lead to ethics committees either inappropriately applying the precautionary principle and hampering novel research, or overlooking important ethical problems. Researchers are in the best position to assist ethics committees in their efforts to remain informed about scientific advancements.

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The role of research ethics committees has been described and debated extensively in the literature (Aulisio and Arnold, 2008; Garrard and Dawson, 2005; Coleman and Bouesseau, 2008; Siegler, 1986; Tinker and Coomber, 2004; World Health Organization, 2011; World Medical Association, 2013). This role is generally considered to be twofold: first to protect and safeguard the rights and welfare of research participants, and second to provide ethical guidance to researchers. In order for ethics committees to fulfil their obligations to participants and researchers, an adequate understanding of the science and scientific methods used in biomedical research is required (Ashcroft, 2003; Dawson and Yentis, 2007). Although ethics committees do not replace scientific review boards, being able to ascertain whether a research project is using the appropriate method to address its aims, and also how scientific methods translate practically in the field, is of ethical relevance. For example, an inappropriate scientific method or a statistically underpowered research study will render any risk or harm imposed on participants ethically unjustifiable.

Biomedical research is a diverse and rapidly evolving field that constantly seeks to develop and utilise new knowledge and methods in the quest for novel medicines and therapeutics. As an example, genomic research¹, despite having existed for many decades as a field in biology, has in the past 15 years emerged as a promising tool of biomedical research, making it an important and rapidly expanding field of research (Pohlhaus and Cook-Deegan, 2008; WHO, 2011). Recently, the decreasing cost of sequencing, the increasing ability to

¹ By genomic research, I mean any type of research that either uses genomics data or creates genomics data. I am using genomic research as a case study here, but the conclusions could easily apply to other types of research that involve sharable data sets.

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3 analyse and store data, and the development of data-sharing and open access policies have
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5 contributed to the growing use of genomics in many areas of clinical research, such as
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7 epidemiology, cardiovascular diseases and cancer research. This means that the number of
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9 genomics research protocols submitted to ethics review committees has been also steadily
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11 increasing. Appropriate review requires both an appreciation of the potential risks that this
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13 type of research entails for participants and communities, and the ability to suggest suitable
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15 ways to minimise these. Yet, limited understanding of genomic research could lead to
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17 suboptimal or inappropriate results, such as hampering novel and promising research, or
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19 approving unethical practices. As Benatar notes, knowledge and expertise are necessary for
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21 the promotion of good research (Benatar, 2002).
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27 International guidelines recommend that ethics committees include a range of scientific and
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29 ethical expertise in their composition to ensure the appropriate and effective review of
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31 protocols and to inspire trust in the ethics review process (CE, 2012; WHO, 2000). However,
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33 having representatives from *all* research fields in an ethics committee might not be practical
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35 or efficient, and decisions will have to be made in order to keep the size of the committee at
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37 a functional level (Rothwell, 2015). Ethics committees could endeavour to include experts of
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39 research fields that are commonly represented in the protocols they review. How common a
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41 research field would have to be to warrant the inclusion of an expert would be debateable,
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43 however, and ethics committees therefore risk inappropriately under-representing certain
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45 fields if an area of expertise did not reach the inclusion threshold. Furthermore, even when
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47 there is a clear need for the inclusion of an expert, it might be the case that ethics
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49 committees do not have access to representatives of niche scientific fields like genomics. A
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51 lot of genomic research is taking place in areas of the world where local capacity in
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53 genomics is minimal or lacking, and this has been recognised as a problem for the
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appropriate assessment and governance of research (Ramsay et al., 2014; Wekesa, 2015). It is, therefore, important to consider alternative ways of ensuring the appropriate review of research protocols, and for enabling members to keep up-to-date with new technological and scientific advancements. I argue that researchers could play a more active role in facilitating the continuous education of ethics committees. Similarly, ethics committees, with the support of the hosting institutions, could be more proactive in seeking out and creating opportunities to enhance their knowledge and expertise.

It has been argued that researchers have an obligation to share the findings of their research and newly acquired knowledge with relevant stakeholders, as a way of increasing shared understanding of science (Kerasidou, 2014). Ethics committees are one of the stakeholders that play a crucial role in supporting and promoting good research. This has led to the development of specialised training resources for ethics committees, and of policies and guidelines to support best practices (Introduction to Reviewing Genomic Research: Ethics online training). Notwithstanding the value of such courses and policies in supporting ethics committees, having the opportunity to be updated and informed about scientific advancements in a fast-moving research field is still necessary to maintain adequate expertise. Given their expertise and knowledge, researchers are in the best position to assist ethics committees in their endeavours.

While knowledge sharing is essential for all types of research there is a further reason that makes facilitating and promoting ethics committees' understanding of genomic research particularly urgent. This is the requirement for open sharing of genomics data. Genomic data can be used for a wide range of studies, and therefore data sharing has been identified as a useful way to accelerate research, avoid waste and minimise harm to participants

(Chokshi et al., 2006; Walport and Brest, 2011; Birney et al., 2009). As the number of biobanks and data repositories is increasing, it is reasonable to expect an increased number of research projects that would seek to utilise shared data collected under a different research protocol (commonly termed secondary use of data). In anticipation of this secondary use of genomics data, and in recognition that identifying and re-consenting participants might be both ethically problematic and logistically difficult, many projects are already seeking broad consent from participants (de Vries and Tindana, 2016). The safeguard for broad consent is that secondary use of data will be allowed only if the research is authorised by the relevant ethics committee. In the absence of individual consent, the sole responsibility of assessing the appropriateness of a research project is entrusted to ethics committees. For this reason finding ways to support ethics committees in acquiring and maintaining adequate knowledge of genomics is crucially important.

There are a number of mechanisms by which knowledge can be shared with research ethics committees. This could be achieved through a short summary of findings written in a lay language that can be submitted to the committee alongside annual reports and end-of-study reports. This lay summary could then be distributed to all committee members for consideration, and time for discussion could be allocated during regular meetings. Better still, sharing of knowledge could be achieved through seminars and presentations, where scientists and ethics committee members can engage and ask questions. Seminars could be organised by the committee sufficiently regularly to address their needs, but without being overburdening (e.g. biannually), and members could be required to attend as part of their continuous training (DoH, 2011: 25; WHO, 2009: 14-15). The committee's institution would provide the appropriate facilities. In recent years, some ethics committees have started introducing fees, payable by the applicants, to cover administrative costs. In cases where

institutions are unable to cover the costs of seminars, such fees could help with meeting this need.

An objection to sharing findings with research ethics committees, at least in the manner suggested here, is that it might compromise the committee’s independence and introduce biases –positive or negative– towards specific projects or people. Closer relationships and more frequent interactions entail such risks. Committee members and scientists should be mindful of these risks and try to minimise them. Yet, given the importance continuous education of ethics committees can play in ensuring the appropriate review of protocols, learning about complex new science would not be possible without, at least, some interaction with, and input from, the scientists themselves.

Ethics review committees have an obligation to develop capacity in the review of genomic research to ensure that they can appropriately evaluate and assess protocols, and protect both researchers and participants. Similarly researchers have an obligation to share developing scientific knowledge with research stakeholders, including ethics review committees. Routinely sharing findings and knowledge in this manner can help to ensure appropriate review of protocols and to reveal important points of ethical focus, leading to the promotion of good research.

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