Study Title: Assessing the feasibility of non-contact vital sign monitoring

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Sponsor:	University of Oxford
Funder:	Innovate UK
Chief Investigator Signature:	

Confidentiality Statement

Contents

1. SYNOPSIS

Study Title	Assessing the feasibility of non-contact vital sign monitoring in the clinical setting	
Study Design	Feasibility study	
Study Participants	Adult patients admitted to the intensive care unit following surgery	
Planned Sample Size	50	
Planned Study Period	1 year	
Aim	To establish the feasibility of extended non-contact monitoring of vital signs in an acute clinical setting.	
Research Question	In what proportion of time can data of sufficient quality, to derive vital signs, be measured using non-contact monitoring in an acute clinical setting?	
	Objectives	
Primary Objective	To establish the amount of time when recorded images contain pulse waveforms correlating with those from standard monitoring (photoplethysmography or arterial pressure waveforms).	The duration and proportion of monitoring time when camera derived pulse waveforms correlate with those from photoplethysmography or arterial pressure waveforms.
Secondary Objectives	**1.** To understand the possible clinical failure modes of non-contact vital signs monitoring in an acute clinical setting. **2.** To improve vital sign algorithms from camera data.	**1.** A failure modes and effects analysis will be performed. This will identify the potential modes of failure which could be expected with this novel method of monitoring and to understand the effects that these failures may have on the correct working of the system. **2.** For each vital sign camera derived estimates will be compared to reference data collected from standard ward equipment.
Tertiary Objective	To gain a preliminary understanding of patient and clinical staff perceptions of camera-based non-contact vital signs monitoring in an acute clinical setting.	Questionnaires, supplemented with structured interviews will be conducted with a sample of patients and Clinical staff

Intervention	Non-contact monitoring equipment will record light and thermal images from the patient. Reference tympanic temperature and respiratory rate measurements will be done in duplicate. No other aspect of the patients' usual clinical care will be affected.

2. BACKGROUND AND RATIONALE

Brief background to the study, including scientific justification for the research

Many deaths in hospitals are predictable and potentially preventable [1, 2], as critical illness is often preceded by physiological deterioration. Survival rates after cardiac arrest on hospital general wards are significantly lower than in those occurring in monitored areas and up to 80% of these patients will show signs of physiological deterioration in the hours before their cardiac arrest [3]. It is clear that improved physiological monitoring is needed for early detection of impending deterioration, so that effective preventative treatment can be delivered.

Conventional monitors are not well tolerated by patients. They limit mobility, rehabilitation and are uncomfortable [4]. In a previous study, which aimed to monitor patients for 72 hours, it was found that a significant proportion of patient declined to be monitored for the full duration. For continuous monitoring to be feasible in a ward population it must be more acceptable to patients and staff.

Technology which allows reliable, non-contact collection of cardio-respiratory vital signs, was initially developed in the Oxford University Centre of Excellence for Medical Engineering, funded jointly by the Welcome Trust and EPSRC, and has been further developed by Oxehealth Ltd. The monitor works under any lighting conditions and only requires the digital and thermal cameras to be positioned within 3m of the subject. It is capable of measuring heart rate, respiratory rate, oxygen saturations, temperature and pulse transit time; a surrogate for blood pressure.

This technology could fulfil a critical clinical need for prolonged continuous physiological monitoring in a comfortable, non-invasive manner. While a previous study has collected monitoring data for 4 hours at a time [6], the feasibility of non-contact monitoring for extended periods of time in an acute clinical setting remains untested. In a real clinical environment there is the possibility of video signal quality loss due to noise from flickering lights, clinical staff altering the camera position or physical objects obstructing the field of view. This study will seek to understand the possible failure modes of the technology and to establish the feasibility of using cameras for non-contact monitoring for extended periods of time.

This study aims to assess the feasibility of using the camera-based vital signs system to monitor patients in a clinical setting.

3. OBJECTIVES AND OUTCOME MEASURES

Aim	To establish the feasibility of extended non-contact monitoring of vital signs in an acute clinical setting.	
Research Question	In what proportion of time can data of sufficient quality in order to derive vital signs, be measured using non-contact monitoring in an acute clinical setting?	
	Objectives	
Primary Objective	To establish the amount of time when recorded images contain pulse waveforms correlating with those from standard monitoring (photoplethysmography or arterial pressure waveforms).	The duration and proportion of monitoring time when camera derived pulse waveforms correlate with those from photoplethysmography or arterial pressure waveforms.
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Intervention	Non-contact monitoring equipment will record light and thermal images from the patient. Reference tympanic temperature and respiratory measurements will be done in duplicate. No other aspect of the patients' usual clinical care will be affected.	

4. STUDY DESIGN

An observational study of a novel medical device.

5. PARTICIPANT IDENTIFICATION

5.1 Study Participants

All elective post-surgical patients with a planned post-operative admission to the Oxford Churchill Hospital Intensive Care Unit (CICU) are able to be included within the study. Any patients who are considered high risk for the Churchill Overnight Recovery Unit (CORU)and are possibly going to be admitted to the CICU are also considered candidates for inclusion in this study and may be consented. Any consented CORU patient who goes to the CICU will continue to the data collection phase. Any patient not admitted to the CICU will be excluded.

5.1.1 Inclusion Criteria

The eligibility (inclusion) criteria for the study are:

- Male or female, aged 18 years or older
- Informed Consent given in writing
- Scheduled for elective, post-surgical higher level care in the Churchill Hospital (CICU or CORU)
- Willing and able in the investigators opinion to give informed consent for participation in the study

5.1.2 Exclusion Criteria

The exclusion criteria are:

- Children (those under the age of 18)
- Patients whose anatomy precludes the use of the required monitoring
- Patients who are judged to lack capacity at the time of consent
- Patients who cannot understand written English and for whom no translator could be found.

5.1.3 Staff Inclusion/Exclusion Criteria

A selection of staff that has come into contact with the camera-based contactless vital sign monitoring system will be invited to take part in the study through providing their opinions via a short anonymous

questionnaire. Staff will be selected based on theirs and the Clinical Research Nurse's availability. Questionnaire responses will be supplemented by voluntary semi-structured interviews. Staff who participate in the semi-structured interviews will be recruited from the questionnaire respondents.

6. STUDY PROCEDURES

6.1 Recruitment

The recruitment process will be as follows:

6.1.2 Patient Participants

Patients will be recruited from the Pre Operative assessment clinics servicing the following specialties; Maxillo-facial surgery Gastrointestinal surgery, Hepatobiliary surgery, Renal/Pancreatic Transplant, Urology, and Gynaecology. NHS staff involved in the usual care of patients will screen patients against the study inclusion/exclusion criteria at their preoperative assessment. The care provider will ask eligible patients if a member of the research team can approach them and provide a short patient information sheet. Screening logs will be maintained by the NHS clinical care team to capture the number considered/discounted/approached/recruited, with the reasons for not recruiting where this is available.

A researcher will provide verbal and written information to any patients who agree to discuss the study further. All researchers involved in consenting will be Good Clinical Practice (GCP) trained. Written information will be provided in the form of an Extended Patient Information Sheet. Any queries that the patient may have will be answered. The participant will be allowed as much time as possible to consider the information. They can have the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Some patients may feel happy to provide consent at their preoperative clinic appointment; others may wish to take additional time. These people who have not refused will be approached on their subsequent admission to hospital. Potential participants will be fully aware that even though they are providing consent to take part in the study this may not actually occur for a number of reasons:

- Potential participants' surgery deemed to have been so successful they would not require a CICU admission
- The research equipment is actively being used to record a different participant.
- Surgery in cancelled and rescheduled for an inconvenient date when the study cannot be carried out.

Prior to the post-operative admission to CICU, if any of these situations should arise then the consented participant will be thanked for their interest in the study but will not be assigned a study ID nor included

in the study. Once they are fully informed, all patients agreeing to enter any part of the study will sign a consent form. Informed consent will be taken by the PI or research nurse (both of whom have the experience and qualifications to do so) The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific procedures are performed. Written Informed Consent will be obtained by means of a participant dated signature and a dated signature of the person who presented and obtained the Informed Consent. It will be clear to the patients that they can discontinue all or any part of the study, at any time that they wish without giving any reason for this decision and without any consequences. Patients will be assured that their clinical care will be unaltered whether they are in or out of the study. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

Screening logs will be maintained by the NHS clinical care team to capture the number considered/discounted/approached/recruited, with reasons for not recruiting where this is available.

6.1.3 Staff Participants

Staff participants will only be approached if they have cared for a participant recruited into the study. Staff participants will be recruited on an ad hoc basis when clinical staff members are available to discuss participation. This will be when a GCP trained member of the research team is available to provide information and answer any questions the participants may have. Potential staff participants will be provided with information about the study (staff questionnaire information sheet) and will be given the opportunity to discuss the study with a researcher.

Staff will be given the opportunity to participate in two ways: (i) completion of an anonymous questionnaire, (ii) participation in an interview.

For the questionnaire, completion will be taken as implied consent.

For the interviews, staff will be given at least 24 hours to consider participation. Researchers will approach them after this period to ascertain whether the staff member wishes to participate in an interview. Written consent will be collected from all staff who agrees to participate. A GCP trained member of the research team will take the written consent.

6.2 Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if they consider it necessary for any reason including:

- Decision to palliate

- Discharge from the CICU
- Significant protocol deviation
- Significant non-compliance with study requirements
- Withdrawal of Consent

If a patient withdraws from the study they will be given the option to have their recorded data irreversibly destroyed. If the patient does not require their data to be destroyed, then this data will be included in the analysis. The reason for withdrawal and whether the participant would like all data to be destroyed will be recorded in the CRF.

Staff participants will not be able to withdraw from the study, nor ask for their data to be deleted once they have completed and returned their questionnaires and/or attended the semi structured interview. The reason fo this being that the questionnaires and data collected from the semi structured interviews are anonymous and therfore impossible to determine the correct participants' data.

6.2.1 Loss of participant capacity

We expect that some participants may temporarily lose capacity to revisit consent due to deterioration in their condition while they are being treated on the ICU. It is particularly important to know whether we can monitor people who are unstable, as they may be at the greatest risk. Following discussions with our patient representative and local Clinical Trials and Research Governance representative it has been decided that as the study is wholly non-invasive, we will make it explicitly clear via the patient information sheets and participant consent form, that if a participant loses the capacity to consent, that video data will continue to be collected for the remainder of the study. The participant information sheet and participant consent form will also make it explicitly clear that any participant may withdraw from the study at any point, and request that any data collected is irreversibly destroyed. Therefore participants will be asked to consent to this process from the outset. Continued consent will be assessed verbally over the course of the study. If a patient has an episode where they lose the capacity to consent, consent to continue in the study and to use data already collected will be revalidated verbally once they have regained the capacity to provide consent. This information will be captured and stored on the study Case Report Form (CRF). If a patient is unable to provide revalidation of their consent, because either of either death, or because they do not regain capacity within the hospital admission data will be deleted from the point at which the participant was deemed to have lost capacity.

Screening logs will be maintained by the NHS clinical care team to capture the number considered/discounted/approached/recruited, with reasons for not recruiting where this is available.

6.3 Study Assessments

Figure 1: Study design flowchart

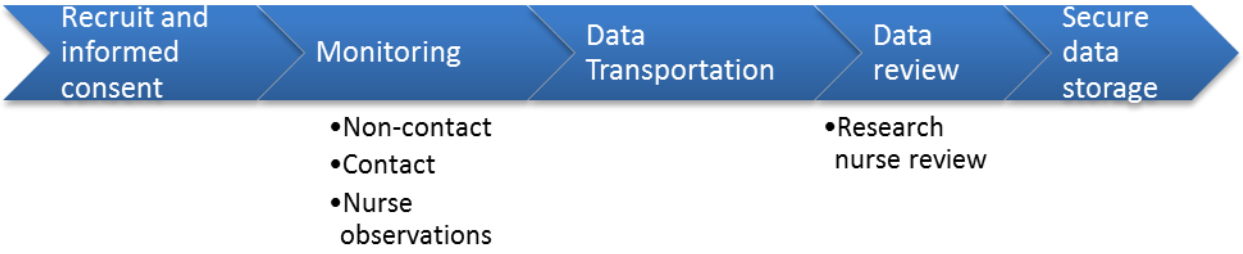

Figure 1 shows the journey from participant recruitment to data storage at study completion.

6.4 Data Collection

6.4.1 Patient participants

All participants consented to the study will have a requirement for higher than standard post-operative ward level care and will have agreed to take part in the study before their surgical procedure has been completed. Post-operatively participants will either; be admitted to the Churchill Overnight Recovery Unit (CORU), or the Churchill Intensive Care Unit (CICU). Those patients, who during this acute post-operative care period are not admitted to the CICU, will be thanked for their interest and will not be included in the study past this point and will not be assigned a study Identifier.

Commencement of non-contact monitoring data collection in participants who do arrive in the Churchill Intensive Care Unit will be initiated as soon as it is practical to do so . This will continue for up to 48 hours or until discharge; whichever is first.

When the Clinical Research Nurse visits the participant they will take additional temperature readings and breathing rate measurement, these will be recorded in the study CRF. These will be measured on an ad hoc basis up to two times per day for the duration the patient is monitored using the contactless vital sign monitor. Temperature measurements will be taken using a traditional tympanic thermometer as is normally used in the ICU patient population. Breathing rates will be visually measured in the standard non touch method. These additional measurements will not be made available to the clinical team caring for the participant and so they will not influence the patients' care in any way.

Relevant data pertaining to a patient's participation in the study will be accessed and captured from both electronic and paper medical records and databases. This data collection will occur both at the start of the study, periodically through the duration of the study and also retrospectively. Data collected manually

by the Clinical Research Nurse will be recorded into the study case report form (CRF). This will include; patient demographics, Fitzpatrick score, past medical history, reason for admission, and other clinical data relevant to any significant deviation in vital signs. Data which can be automatically captured from the participants electronic medical records and associated databases will be exported from NHS databases and then imported into a secure electronic study database at a convenient time for the NHS Clinical staff that will run the queries on these databases.

The non-contact vital signs monitoring equipment will be attached to a trolley positioned at the end of the bed, with a clear view of both the bed and the bedside chair. The trolley will be easily movable, will not affect access to the patient and will not hinder patient care. We wish to capture footage of the patient when they are in the bed and in the chair to test the equipment in both patient locations. This equipment will include an optical video camera, a thermographic camera and an infrared lighting source. This equipment will be collecting data continuously for the duration of the study unless the patient or staff wishes the equipment to be switched off. All equipment will be approved by the Clinical Engineering department of the local NHS Trust.

A poster will be located at the participant's bedside to alert clinical staff, other patients and their visitors, that video recording is taking place and that there is a possibility that they may be included in the footage. It will also state that any data containing identifiable non consented subjects will be removed from the footage prior to analysis.

Usual care monitoring using the standard ward bedside Philips monitor will occur simultaneously. Care decisions will be made by the clinical care team using this data. Parameters normally collected using this type of monitoring include; blood pressure (invasive/noninvasive), heart rate, breathing rate, blood oxygenation levels, and invasive temperature. In addition the clinical care team will use a standard ICU tympanic thermometer to measure noninvasive temperature and also obtain visual respiratory rates. The standard patient monitoring practice carried out by the clinical staff will not be altered by involvement in the study.

Data will be collected from the serial port output of the Philips bedside monitor using a commercially available solution. This allows the collection of 'gold standard' measurements of patient vital signs, against which camera readings can be validated. Data will be saved simultaneously with the video footage and handled with the same levels of security.

Patients who agreed to provide feedback on their experiences and views of vital sign collection and the non-contact monitoring system when signing their consent form will be asked to complete a short questionnaire at the end of the monitoring period.

6.4.2 Staff Participants

Staff members who have cared for patients monitored with the non-contact vital sign monitoring system will be asked to complete a short questionnaire at a time of their convenience.

The semi structured interviews will be guided by the themes seen in questionnaire responses. Staff questionnaires will be anonymous to ensure the opinions they provide cannot be traced back to the member of staff who provided them.

6.4.3 Definition of the End of Study

The study will be declared 'closed' when all data sets have been checked and cleaned for future research uses, as set out in the consent form. Due to a delayed study start this is anticipated to be April 2017. Research data collected from this study will be stored for a minimum of three years (standard Oxford University practice).

7. SAFETY REPORTING

7.1. Electrical Safety

The devices used in the non-contact technology will not be attached to the patient or the patient's bed, and the electrical cabling will be designed to avoid any possible trip hazard. Thus, the non-contact device will present no risk. The OUHT Clinical Engineering Department will conduct an electrical hazard analysis of the set-up to ensure the project is consistent with hospital safety requirements.

7.2. Definition of Serious Adverse Events

The standard definition of a serious adverse event (SAE) is:

A serious adverse event is any untoward medical occurrence that:

- Results in death
- Is life threatening

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe.

- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Other important medical events*

*Other events that may not result in death, are not life threatening, or do not require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above."

It is highly unlikely that this study, which has no intervention, would result in an SAE. Should an event related to the study, of any type, cause patient harm it will be reported to the Chief Investigator who in turn will report to the sponsors and the ethics committee in writing within 15 working days.

8 STATISTICS AND ANALYSIS

8.1. The Number of Participants

Over the duration of the study we intend to continue to recruit patients until we have collected 30 individual patients' data sets where the recording duration is greater than 8 hours per patient. This figure was not calculated to provide statistical significance but is a convenience sample, based on the anticipated constraints of a limited target participant population, funding and time available to complete the study. We also expect to recruit 20 staff members to complete an anonymous questionnaire. A sub set of these 20 staff participants may also consent to participate in further voluntary semi-structured interviews.

8.2. Analysis of Outcome Measures

Summary statistics will be calculated (number of observations, mean, standard deviation, maximum and minimum) for the demographic variables and clinical variables.

The amount of time when recorded images contain pulse waveforms correlating with those from standard monitoring will be presented as a graph of the proportion of active camera time for deciles of cross-correlation coefficient.

The following data will be derived for each patient.

- Total time in the study
- Total monitoring time
- Total camera recording time
- Total time lost (total monitoring time – total camera recording time)
- Percentage of total time lost
- The amount of time when recorded images contain pulse waveforms correlating with those from standard monitoring.
- The amount of time when recorded images contain patient temperature information compatible with those from standard monitoring

8.3. Risk Prediction (Failure Modes and Effects Analysis, FMEA)

We will be performing a Failure Modes and Effects Analysis to predict the ways in which the system

might fail when introduced to the ward. This will allow us to identify those 'failure modes' (scored by likelihood of low, medium and high) and scoring their associated effects upon the clinical workflow and patient safety (scored by severity of low, medium and high). The result will produce a list of ranked failures and associated effects which can be prioritised for correction prior to implementation of the system onto the ward for the study. This will be an iterative process.

8.4. Feedback from Patients and Clinical staff

The tertiary outcome is to gain a preliminary understanding of patient's and clinical staff's perceptions of camera-based vital signs monitoring in an acute clinical setting. This will help to establish a range of opinions on the possible human factors that will influence the popularity of such technology. A questionnaire study with both patients and staff will be conducted. The staff questionnaire will be supplemented with semi structured interviews which will follow the same themes as the questionnaire responses. The aim is not to produce statistically significant results; however it will provide important feedback for designing a future system that will be both usable by clinical staff and popular with patients. The questionnaire will be developed specifically to focus on the issues which have been shown to be of interest and concern in previous interventions regarding vital sign assessment, e.g. time implications, and also those of interest to the project team e.g. patient perception of this novel approach.

9 DATA MANAGEMENT

9.1 Access to Data

Direct access will be granted to authorised representatives from the clinical research team. The level of authorisation each member of the team receives will depend on the position of the data in the data journey. This is discussed in detail in 9.2. Data access is limited at all times during the study to members of the clinical research team. The clinical research nurse and the study participant are the only people who can view the raw, unedited camera data for that individual participant.

Due to the nature of the study it may happen that other people are inadvertently recorded. The camera will be tightly focused on the study participant and so we do not expect this to be a common occurrence. A poster in the clinical area will warn that this maybe the case. The clinical research nurse will, using specifically designed software, prevent access to these periods where identifiable unconsented people appear in the video file. This will ensure that only data from the consenting participant is furthered in the data journey.

9.2 Data Recording and Record Keeping

The data collected from the cameras and the Philips monitor will undergo a rigorous 'journey' from the bedside to where it will be securely stored for analysis. See section 15 (Appendix A) for an outline of the permissions and assigned personnel to conduct each step in the journey, and section 16 (Appendix B) for the state of the data at each step in the journey. The steps are as follows:

9.2.1 Recording by the bedside

Raw video data, stored in a proprietary format that is only readable by the review software, and raw reference vital signs data (from the Philips monitor), are recorded onto a storage device that will be physically secured in the ward. Access to the storage device will be limited to the designated members of the clinical research team using industry standard methods. The images recorded will be a normal camera image and also a thermographic camera image.

9.2.2 Run the review tool

A clinical research nurse will run a bespoke software 'review tool' to check the recorded data. The review software will enable the clinical research nurse to do the following:

- View the footage at higher speed than it was recorded and automatically highlight sections where the scene has changed substantially (e.g. another person has entered the frame).
- Flag video segments containing identifiable staff, non-consented subjects, visitors, or other

unusable data (including sections the participant has asked to be removed) as 'video cannot be used for analysis'.

- Flag video segments as 'query not for analysis' (this can be used as a holding place for queries that research nurses may have).
- Flag a video segment as 'event occurred here'.
- Unflag a video segment previously marked as 'video cannot be used for analysis' (following discussion that footage was in fact acceptable).
- Easily review all the flags that have been set in a recording and allow changes to be made.

Once reviewing is complete, the software locks the data so that only data that can be analysed (consented patients) will now be accessible to researchers' logins. Video that is marked as 'not for analysis' or 'query not for analysis' will be moved to an encrypted secure folder which will not be available to the data analyst.

9.2.3 Data analyst review of the processed data

The data analyst will only have access to video for consented patients. The data analyst reviews the processed data and will discuss any issues with the clinical research nurse. If they agree that some data have been wrongly flagged during the review, it would be possible for the Clinical Research Nurse to revise the flagged sections.

9.2.4 Consented data copied to the server

Consented video segments are transferred to a secure study server in the hospital server room, within the Kadoorie Centre. Non-consented data will not be copied to the study server. The server room is in the secure research area behind two locked doors. Access is by electronic swipe card and is audited.

9.2.5 Hard drive securely erased

The data analyst performs a secure erase of the disks.

9.2.6 Empty storage device returned to the ward

A member of the research team returns the storage device to the ward for use for the next patient.

9.2.7 Quality Assurance Procedures

Regular meetings will be held to monitor data quality. The study may be monitored, or audited in

accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

9.2.8 Case Report Forms

Data relevant to the patient participation in the study will be collected from both paper and electronic medical records and databases. This data will not include any identifiable information. The study database will be the definitive location for storage of these data. Some data (only identified by Study ID) will be collected on case report forms (CRF). These will be transcribed to the study database in a timely fashion. Where feasible, data held in electronic clinical information systems will be exported on an ad hoc basis and imported into a secure electronic study database.

9.2.9 Access to study data/Storage of study data

Access to study paper data and electronic databases will be restricted only to authorized members of the research team. All data collected will be treated as strictly confidential. Paper records will be kept in a secure location in the hospital behind two locked doors. Paper data will be transcribed to secure databases held on secure computer networks in a timely fashion. Electronic data will be kept on a secure server kept behind two locked doors in the research facility located in the hospital. At the end of the study all data will be archived and stored in the secure research facility for a minimum period of 3 years in accordance with local policy.

10. ETHICAL AND REGULATORY CONSIDERATIONS

10.1. Declaration of Helsinki

The Chief Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

10.2. Guidelines for Good Clinical Practice

The Chief Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.

10.3. Approvals

The protocol, informed consent form, and participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), and host institutions for written approval.

The Chief Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

10.4. Data monitoring

Any data collected during the study and the study procedures may be monitored or audited by responsible representatives of Oxford University Hospitals NHS foundation Trust, Oxford University Clinical Trials and Research Governance Group and regulatory authorities. This will ensure compliance with the research protocol within the Department of Health Research Governance Framework for Health and Social Care 2005.

10.5. Participant Confidentiality

Study participants will be assigned a unique study identifier on recruitment. All data collected thereafter will be assigned to this study identifier. The study staff will ensure that the participants' anonymity is maintained. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

10.6. Ethical Considerations

It is conceivable that patients participating in this pilot study may feel beholden to the researchers. To address this, our consent procedure will emphasise that patients are free to withdraw from, or not participate in the study, without giving reasons for their decision. It will be made clear to potential

participants that enrolment in the study, or deciding against it, will not affect their general treatment in any way.

Due to the nature of the data being collected (video) it is impossible to anonymise this data source. Participants will be made fully aware of this fact. There will obviously be privacy concerns and so study procedures, data handling and storage have been scrutinized to ensure that these issues are mitigated.

All data will be kept as strictly confidential. All video data will be stored securely using industry standard methods. During the data collection, the computer will be physically tethered to the equipment trolley to prevent unauthorised removal. The location of the storage device will be monitored at all times.

There is a real possibility that participants may wish not to be recorded for period of time during the study; this could be for example during a dignity compromising situation such as routine hygiene. A privacy blind has been incorporated into the research equipment solution. This allows the participant to request that the camera be covered during these times. The participants care team will all be trained in the use of the privacy blind and can act as a patient advocate and can also cover the camera for periods of time when they feel it is inappropriate for the participant to be recorded.

There may be times when the privacy blind is not activated and as a result the participant is recorded during a period they did not wish to be recorded. Participants will be expressly told that they can request for period of the recording to be deleted. All requests for data to be deleted by the participant will be accepted and acted upon.

There is also a possibility that non consented people might also be inadvertently recorded. Although the camera will be tightly focused on the study participant this risk has been deemed unavoidable. As a result the research team has a robust system in place to ensure that video data is edited where dignity is compromised or a non-consented person is recorded. Prior to the image data being made available for analysis one of the study research nurses will use computer software to delete any sections that include identifiable images of non-consented people or dignity compromising situation making them unavailable for analysis or viewable by anyone else (Please see section 9.2 for full details of this process). This data editing process will take place in a secure location in the Oxford Universities Hospitals NHS Foundation Trust. Only once the data has been fully edited, will the data be transferred to the secure study server. The server will be located in a secure area of the hospital behind two separate locked doors. Access to the data will be restricted to only pre-authorised individuals from the research team.

Subsequent researchers, who will access video data, will only be able to access the pre edited image data which will only contain images of the consented participant.

11 FINANCE AND INSURANCE

11.1. Funding

This project is funded by Innovate UK (File Ref 102110) and Oxehealth Ltd.

11.2. Insurance

The University has a specialist insurance policy in place, which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London).

12 PUBLICATION POLICY

The final results of the study will be documented in technical reports and shared with the whole project team. The results may be submitted to a peer-reviewed journal for publication. Authors will be members of the research team. No identifiable data from individual patients will be published without their specific written permission. Authors shall acknowledge the financial support from Innovate UK, in accordance with Innovate UK guidelines.

13 REFERENCES

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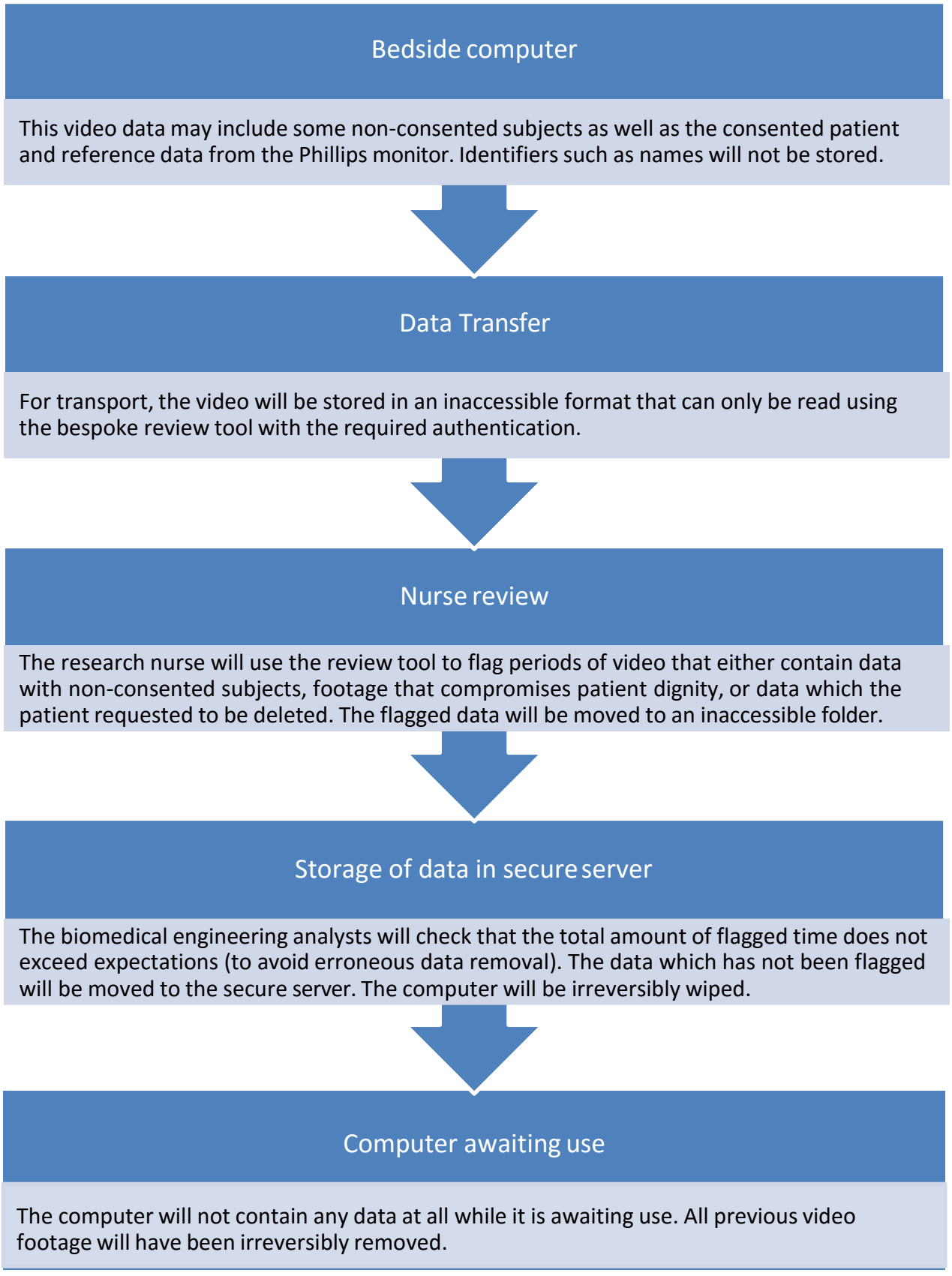
14 APPENDIX A: DATA ACTIVITY DELEGATION LOG

Activity	Ward staff	Research nurses	Non Clinical Researchers
Set up and operate video recording equipment	✗	✓	✓
Set up and operate reference recording equipment	✓	✗	✗
Transport raw data on disk from bedside to study server room	✗	✓	✓
Copy patient data from disk to study server	✗	✗	✓
Scrub (erase) disks for re-use.	✗	✗	✓
Transport empty disks to ward for re-use	✗	✓	✓
View patient identifiers (name etc.)	✓	✓	✗
View medical records	✓	✓ l	✗
View medical annotations relevant to analysis (interventions, medications affecting vital signs)	✗	✓	✓
View video with identifiable, non-consented subjects visible	✗	✓	✗
View video with identifiable patient visible	✗	✓	✓
View de-identified video/signals from patient	✗	✓	✓
View de-identified reference vital signs	✗	✓	✓

15. APPENDIX B: DATA STORAGE PERMISSIONS



16. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
	0.1	8/5/15	Hamish	Initial document
	1.0	9/12/15	David Vallance	REC Submission accepted
1	1.1	25/2/16	David Vallance	Section 10.4 Data Monitoring – Changed to reflect information in PIS and consent forms
2	1.2		Jody Ede	**Section 1 Synopsis** • Respiratory rate added **Section 3**- • Respiratory measurements added **Section 5.1** • Addition of CORU patient inclusion and ability to consent these **Section 6.4.1** • Addition of consenting patients who are booked to CORU • Respiratory measurements added **Section 6.4.3** Study End date-delayed start of study and end of study reflect this delay **Overall document** Date and version of protocol