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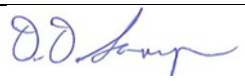
Written By:	Ferdousi Chowdhury	Head of RIGO		17.12.2019
Approved By:	David Sampson	DI		08.01.2020
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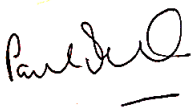
Revised by:	Linda McLatchie	Hub PD (acting)		03.06.2023
RIGO approval:	Gill Fairbairn	Interim Director R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

Consent is essential for good and ethical research practice where human participants are involved. According to the NHS Health Research Authority : '*Consent is always required under the common law (and the Mental Capacity Act 2005) to remove human tissue from the living. However, consent from the living may be given for diagnostic or therapeutic purposes. If it is also intended to store and use part of the human tissue for research, consent is required, and it is good practice to seek specific consent for research at the same time.'*

When collecting, using, and storing human tissue for research, there are specific ethical and legal requirements that must be considered during the consent process. Consent is the fundamental principle of the Human Tissue Act 2004 (England, Wales and Northern Ireland) and it lists the purposes for which consent is required. The Human Tissue Authority (HTA) has produced a Code of Practice: Code A: Guiding Principles and the fundamental principle of consent which has been used as the basis of this standard operating procedure (SOP) and should be referred to for further guidance on the process of consent.

This SOP describes the essential elements that should be followed to ensure appropriate and valid consent is obtained from donors before using their samples for research purposes.

2. SCOPE

This SOP applies to all individuals intending to use any type of human material whether relevant or non-relevant as defined by the Human Tissue Act, including tissue obtained under NHS REC approval and purchased from commercial suppliers and human DNA, RNA and any human biological fluids.

This SOP does not apply if you are receiving established cell lines from a source that can be verified (e.g., from a reputable commercial supplier or collaborator where the provenance of the cell lines can be demonstrated to be in line with the original consent of the primary material) but does apply if you are generating cell lines directly from a primary source.

3. RESPONSIBILITIES

3.1. The Designated individual (DI) has *a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place.* This includes ensuring that all samples being held under the authority of the HTA licence have appropriate valid, informed consent.

3.2. The Persons designate (PD) are responsible for *assisting the DI in ensuring compliance with HTA standards.* There is a PD for each of the areas; Stag Hill (Hub PD and FEPS PD), Leggett, VSM, VSP and Surrey CRB. They are responsible for assisting the DI in checking that all samples stored have appropriate valid, informed consent and that in any case where consent to store/use samples has been withdrawn all samples have been removed and destroyed.

3.3. The Research Integrity and Governance Office (RIGO) is responsible for co-ordinating the ethics and governance review of the research projects to ensure the consent process being used by the researcher complies with ethical and regulatory standards. Where samples have been collected elsewhere, they are responsible for checking that the consent permits their storage and use at the University of Surrey.

3.4. The principal (or lead) investigator (PI) is responsible for ensuring that they have appropriate consent for all of the samples they hold, whether these are under the HTA licence or have NHS REC or other REC approval, in accordance with this SOP, and any ethical and legal requirements. They are also responsible for ensuring persons taking consent are trained and that consent records are stored securely, in a documented location. For student projects, the PI responsibility falls on their supervisor.

3.5. All individuals, whether staff, student or visitor, conducting/supporting research activities with human material under the auspices of the University of Surrey must comply with this SOP, complete the required training, and adhere to all associated regulations, policies and procedures.

4. PROCESS

4.1. Training requirements

All individuals involved in taking consent for obtaining human samples for research purposes must first complete the additional mandatory training as detailed in UOS_HT_SOP_03.

4.2. Consent procedure

4.2.1. The procedure being used to obtain appropriate and valid consent should be included in the study protocol (sometimes referred to as the research plan) and include details on:

- recruitment such as how participants will be identified and contacted, including recruitment material such as flyers or social media posts
- how information will be provided to the potential participant (e.g., verbal, written)
- how long participants will be given to consider the invitation to participate
- how the opportunity to ask questions will be given
- who will take consent and their suitability
- how consent will be assessed as being valid (i.e., understood by the potential participant)
- how consent will be recorded, including the requirement for boxes to be initialled or signed rather than just ticked
- the process for withdrawing consent and whether this will include any samples/data already processed/obtained or only samples not yet used and what the process for disposing of such samples will be.

4.2.2. Participant-facing documentation including the information sheet, the consent form, and any recruitment material for a new study should be prepared in line with the guidance and templates found on the RIGO webpagehttps://surreynet.surrey.ac.uk/academic-services/research-and-innovation-services/research-integrity-and-governance-office and follow the University ethics policy (https://www.surrey.ac.uk/research/excellence/ethics). If the study is ongoing or joint with another institution alternative formats are acceptable as long as they meet the same requirements.

4.2.3. The study protocol and all study documentation must be submitted for review and approval by an ethics committee before beginning any research.

4.2.4. Once approved, the study documents and the agreed consent procedure must be adhered to and any changes or amendments must first receive ethics approval before being implemented.

4.3. Obtaining consent from colleagues, other staff members or students.

When staff and students, are being asked to give 'healthy volunteer' samples, they must not be made to feel pressured or coerced to donate. Personal relationships and friendships should never be used to encourage colleagues to donate samples and no one should be asked directly on a one-to-one basis to donate. Instead, requests should be made to groups of two or more people at once or via more general advertising material. The following additional measures should also be followed:

- Use of a confidential coding system, so that donors aren't readily identifiable;
- Clear and easy ways to withdraw consent at any time, without needing to give a reason, and without any negative impact on work relationships or conditions of employment or enrolment;
- Care that there is no unfair targeting of potential donors with specific desirable biological characteristics;
- Careful monitoring of donation quantities with clear maximums set;
- When being asked on more than one occasion consent should be sought afresh for each donation or at least reconfirmed, and any changes in lifestyle or medical history reviewed to check for continued suitability and infection risk.

4.4. Participant information

4.4.1. Information on a research project should be provided to potential participants using participant information sheets, but other media/formats can be used, to help them understand and decide whether to take part.

4.4.2. The information must be provided in a proportionate manner, i.e., concise, relevant and using non-technical language, that allows the participant to fully understand and make an informed decision. Further guidance on writing a participant information sheet (PIS) and a PIS template is available on the RIGO webpage.

4.4.3. With regards to taking human samples for research, the following information should be provided in the PIS in relation to the samples:

- Why do you need to take the samples
- What type of samples will you need to take, how many, how much per sample and how often
- How will you take the samples
- Are there any risks or discomfort to the subject that will be experienced when taking the samples
- Will you need to take any personal information or health details. If so, how will this information be obtained, recorded and used (consider Data Protection requirements as per PIS template available on the RIGO webpage)
- Where will samples be stored and who will have access to them
- How long will samples be stored
- Will samples be stored pseudonymously? If so, who will have access to the code and where will this code be stored?

- Will you share the samples with anyone? If so, for what purpose and will you share the samples anonymously
- Will there be any samples left at the end of the study and if so, what will happen to them
- How will samples be disposed of
- Whether you will request consent to use the samples for future research (see section 4.8)
- How will you report incidental findings of medical significance to the participant
- How can participants find out about the results of the research
- Contact details of the PI or research team should be included.

4.5 Consent form

4.5.1. When seeking consent for the use of samples in research, this should be recorded using a consent form. A detailed template is available on the RIGO webpage.

4.5.2. It is important to ensure the participant has understood the reasons for which they have been asked to participate and what it involves before they sign the consent form.

4.5.3. Each statement that they agree with should be **initialled or signed** and not just ticked so that there is no ambiguity that they have consented to that point.

4.5.4. The person taking consent should not in any way exert influence or pressure on the participant and should take care that this does not occur inadvertently.

4.5.5. Both the consent taker and the participant should sign and date the consent form.

4.5.6. A copy of the signed consent form and the information sheet should be provided to the participant to retain as a record.

4.5.7. If the person giving consent is unable to write, this should be clearly recorded, including when consent was given and for what purposes. In this case, consent should be witnessed, signed by the witness, and kept for future reference.

4.6. Ethics

To safeguard participants, any research involving human samples must undergo independent ethical review of the proposed study. The PI (or student supervisor) is responsible for ensuring that no research with human samples begins until approval is granted in accordance with UOS_HT_SOP_02 Applying to use human tissue in research.
Any deviations from the consent procedure that was approved by an ethics committee must be reported to RIGO via rigo@surrey.ac.uk.

4.7. Valid and appropriate consent

Consent is only considered valid and appropriate if it has been given voluntarily, by an appropriately informed person who has the capacity to understand, who is able to assess the risks and decide on whether to agree to donate samples for research. It may be given by the donor, their nominated representative or a person in a qualifying relationship with the donor if

they are currently incapacitated (e.g., unconscious). Parental consent is required for donors under 16 years of age. The young person should also be given age-appropriate information and asked to give their assent to the donation of samples.

4.8. Generic consent for future use

4.8.1 When obtaining consent for use of samples in research, the researcher should consider the potential value of those samples for future research. The Human Tissue Authority (HTA), the Health Research Authority (HRA), and UK research funders, such as the Medical Research Council, recommend that broad and enduring consent (also known as generic consent) – that is consent which is broad in both scope and time – should be sought whenever possible.

4.8.2 Any researcher wishing to store samples following completion of the original project for potential future research should include a specific statement on the consent form. This should be optional and not exclude participants from taking part in the original planned research project.

4.8.3 The participant information sheet should explain the value of holding surplus samples for future research and provide assurances on how the samples will be stored and approved for future research. Explain who will have access to the samples, the possibility of sharing the samples outside of the research team, and whether this will be done without sharing personal identifiers.

4.8.4 The participant information sheet must explain to the donor how they can withdraw their samples in the future if they change their mind. The process for managing a withdrawal request and destroying samples should be described in the study protocol.

4.8.5 Participants should be given the opportunity to express objections to certain types of research. If these wishes cannot be guaranteed, the sample should not be retained for future use.

4.8.6 It is an offence to proceed if a condition placed on consent by the donor cannot be met, as valid consent would not be in place.

4.9. Records of consent

4.9.1 Consent records must be held by the PI in a secure, controlled access location.

4.9.2 The location must be declared on the Human Tissue Governance Application Form (UOS_RIGO_Template_010) when applying for approval to use human tissue for research and should be known by all members of the research group.

4.9.3 The consent form should be linked to the samples via a study/participant code noted on the consent form. Access to the code must be controlled in accordance with the study protocol and PIS.

4.9.4 When a PI leaves the University, before leaving they must inform RIGO so that consent records can be transferred to an appropriate responsible person.

4.10. Withdrawing consent

Research participants must be allowed to withdraw from research without providing a reason. In the case of withdrawing consent to store/use samples, this must be respected. The process for withdrawing consent must be clearly explained to the participant so that they are able to request this. It is also important to clarify in the participant information sheet if there is a point at which it will no longer be possible to withdraw data from the study from any samples already processed even if consent is subsequently withdrawn.

4.11. Samples from third parties

4.11.1. If a researcher wishes to receive samples from a third parties these must be declared through completion and submission of the Human Tissue Governance Application Form to rigo@surrey.ac.uk. Evidence of valid consent must be provided with the application form as detailed below:

- Information that the third parties have collected the samples with appropriate and valid consent (study protocol including how consent was taken)
- That this consent form includes a statement that gives permission for their use at other institutions including institutions in England if not originating here for research purposed that include the intended research (blank consent form, translated if necessary).
- Validated documentation to indicate that all participants whose samples will be sent to the University of Surrey have given this consent.
- In the event that a consent form has been ticked rather than initialled or signed then it is at the discretion of the organisation taking responsibility of consent to determine whether they are confident that consent has been given and if there is any doubt it should be assumed that it has not.

4.11.2. Where having ethical approval is specified as a condition of consent this must have been granted before any samples arrive. However, if ethical approval is not specified samples may arrive whilst it is being sought but, in this case, will be placed in quarantine on arrival until ethical approval is granted.

4.11.3. A material transfer agreement (MTA) or equivalent document is required (UOS_HT_SOP_07), which must include a statement detailing which party is taking responsibility for consent.

4.11.4. When wishing to acquire tissue from areas outside those covered by the Human Tissue Act, namely; England, Wales and Northern Ireland (import), although there is no legal requirement to have sought consent the HTA still asks researchers to consider that it might be ethically appropriate to have done so. The University of Surrey will therefore only accept imported samples where there is evidence that consent has been obtained in a culturally sensitive manner, and in accordance with local ethical and legal requirements and covers the proposed use and transfer to England.

4.11.5. If a researcher wishes to obtain samples form a commercial supplier or licenced tissue bank it is their responsibility to ensure that the supplier used has obtained appropriate informed consent for their proposed use and storage.

4.12. Samples transferred to third parties.

4.12.1 It is the responsibility of all researchers to ensure any samples being sent to third parties have appropriate and valid consent in place and that they are being sent for a purpose for which consent has been given.

4.12.2 An MTA or equivalent document is required (UOS_HT_SOP_07) and must include details of which party is taking responsibility for consent.

5. ASSOCIATED DOCUMENTS

UOS_RIGO_Guidance_001: Guidance notes for the preparation of Participant Information Sheets and Consent Forms
UOS_RIGO_template_005: RIGO Generic Participant Information Sheet for Research
UOS_RIGO_template_006: RIGO Generic Consent Form for Research Participants
UOS_RIGO_template_010: Human Tissue Governance Application Form (HTGov AF)
UOS_HT_SOP_02: Applying to use human tissue in research
UOS_HT_SOP_03: Training requirements for using human tissue.
UOS_HT_SOP_07: Transfer of human tissue into or out of the University including import and Export.

6. REFERENCES

Health Research Authority (HRA)
Human Tissue Act 2004
Human Tissue Authority (HTA)
HTA Code of Practice: Code A: Guiding Principles and the fundamental principle of consent

7. TRAINING

Before commencing any work with human tissue samples anyone wishing to do so must have completed all the training detailed in UOS_HT_SOP_03, including CGP training and the Global Health Training Centre's introduction to informed consent if they will be taking consent.

8. USEFUL ABREVIATIONS

HTA – Human tissue authority
HRA – Human Research Authority
HT Act – Human Tissue Act
LH - Licence holder
DI- Designated individual
RIGO – Research Integrity and Governance Office
HTROG – Human Tissue Research Operations Group
PD- Person Designate
SOP-Standard Operating procedure
AE/I - Adverse event or incident
GCP – Good Clinical practice
MTA– Material Transfer Agreement
REC – Research Ethics Committee
UEC – University ethics committee

9. REVISION HISTORY

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1.0	New Document	Ferdousi Chowdhury	17.12.2019
2.0	Major revision	Linda McLatchie	03.06.2023