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Human Tissue Act
SOP – Consenting Patients and third party donors

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Reviewed	**Signature**	**Date**
Dr Georgios Giamas **Designation:** Designated Individual School of Life Sciences		20/04/2018

Version	Date	Reason for Change
V 2.0	17/07/2017	Change to reflect the update to DI
V 3.0	17/04/2018	Changes to reflect new HTA Codes/Standards. Notably additional information on consent forms.

1. Purpose

This standard operating procedure defines the consent process that must be followed in order to obtain samples for use within research projects covered by HTA license 12119. The overriding principles encompassed in this document should also guide the procurement of tissue samples from healthy volunteers, as documented in separate SOP (HTA/SOP/04).

2. Introduction

University of Sussex aims to collect high quality tissue and data whilst working to the highest ethical standards. Consent received must be voluntary, informed, appropriate and valid. In order to protect the rights of the public and to ensure the integrity and validity of all research that may be carried out on banked tissue samples, appropriate consent must be obtained and recorded. These records must be maintained to ensure that all samples can be linked back to the donor as required. Donors will only be recruited if they have provided written informed consent and this consent has been freely given.

3. Approval of Consent Process

Consent procedures and methodologies must be submitted with an application to a NHS research ethics committee, and a favorable opinion must be granted prior to their use. Research led by the University of Sussex will require formal Sponsorship to be granted from the Sponsorship-Sub Committee before any engagement with the HRA's research governance procedures (http://www.sussex.ac.uk/staff/research/governance/sponsorship). This approval may have been acquired by a third party (e.g. clinician) who is collaborating with the PI or by the supplying Biobank. A copy of the ethical approval must be kept within School of Life Science's records.

Specimens can only be donated as part of an ethically approved project.

4. Training

Any person taking consent must be trained in accordance with HTA standards or equivalent. Anyone taking consent from patients should undertake the NIHR CRN Learn Online Training module available at https://learn.nihr.ac.uk/course/index.php?categoryid=5. Alternatively, face to face GCP training is available at BSUH (bookable via the NIHR system). Certificates of completion and training logs should be kept as evidence. This training should be undertaken every 2 years, with an internal appraisal after 1 year.
A list of staff/student competencies and training log will be maintained. Those seeking consent must also have an adequate understanding of the project they are collecting consent for, and be able to disseminate information relating to the project to the potential patient in a way they can understand and in as much detail as they wish to know. The name of the person taking consent should be listed in the study protocol.

5. Consent procedure (under UoS)

1. Identify individuals suitable to become donors using procedures documented in the protocol for the specific REC-approved research project.
2. Initial approach made according to procedures documented in the protocol for the specific REC-approved research project. Including information relating to the project.
3. Potential donor given approved Patient Information Sheet (PIS) and consent form for specific research study.
4. Ensure the volunteer fully understands the information sheet before consenting. The offer of language translations of the consent documents should be given when appropriate.
5. If it is anticipated that samples acquired as part of such a project will not be used fully during the initial project, researchers may ask participants to consent for the continued storage of specimens and their potential 'secondary use' for broadly defined areas of ethically approved research at a later date.
6. There should be face-to-face discussion between the potential participant and the person taking consent. The potential patient should be able to ask about specifics of the project, including how their sample will be used for this project and for future projects if generic consent is obtained.
7. Once the donor has agreed, they are given the consent form which they read at their leisure and sign. The donor must NOT be pressurized into signing on the spot.

8. Three copies of the consent form should be signed. The donor, person taking consent and the project Principal Investigator (or appropriately trained logged designate), should all sign and date the consent form.
9. The original copy will be securely stored by the Principal Investigator, the donor should receive a copy and, as good practice a copy should be filed in the patient's notes.
10. Where a patient has given consent for the use of their tissue for the purpose of future unspecified research this should be clearly documented in the patient's notes. It would be good practice to adhere a sticker to the front of the notes indicating this and the duration of storage. It should also be stated to the patient how long their sample will be kept for (unless they ask for it to be withdrawn), e.g. for a certain amount of years.
11. The participants should be told about their right to withdraw their sample at any given time, and be told that the process to do this is details in our Withdrawing Samples SOP available online.
12. The consent form is then numbered according to the system employed by the principal investigator and retained securely by the principal investigator.
13. On receipt of the sample the PD should log it onto the Tissue database and assign it with a unique identifier
14. The storage coordinates will be logged into the Tissue database.
15. The consenting pathways are kept current by reporting any necessary change in procedure.

6. Consent Form

An example consent form is below. Other things that should be included on consent forms are:

- Study Title
- PI/Researcher contact details
- Contact details of PI/Researcher
- The appropriate complaints contact (DI: G.Giamas@sussex.ac.uk) See Complaints SOP for more details.
- How and when surplus tissue will be disposed of
- Reference to the Human Tissue Act 2004 and the Human Tissue Authority

Consent Form - Donation of tissue.

	Please tick Yes/No
1. I confirm that I have read and understand the information sheet "Donation of tissue to University of Sussex" (*insert date and version number*) and have had the opportunity to answer questions.	☐☐
2. I consent for my samples to be used within this research project and transfer ownership of the sample and any results obtained hereafter to the University of Sussex	Yes/No ☐☐
3. I understand that I am free to stop participation and have my data and samples withdrawn at any time, without giving any reason and without my medical treatment or legal rights being affected.	Yes/No ☐☐
4. I understand that my medical records and research data collected during the study will be looked at by individuals from the research team and may also be looked at by the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	Yes/No ☐☐
I AGREE THAT surplus material from this project can used for the purpose of research which has been approved by a Research Ethics Committee. I am aware this research may be in collaboration with a commercial company, but that my identity will be kept anonymous.	Yes/No ☐☐

Participant's Statement:

I …… agree that the research project named above has been explained to me to my satisfaction and I agree to donate my tissue to the University of Sussex. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed …… Date……

Print name.....

Investigator's Statement:

I ……confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to this donor.

Signed…… Date……

Print Name.....

Statements that may also need to be included

• I understand that I will not be made aware of my results from this study.

- I agree that [*insert relevant material type*] can be used for genetic research.
- I give permission for responsible NHS contracted individuals to access relevant sections of my medical records.
- I agree that my GP and/or the NHS can be contacted to provide details about my disease if I stop attending the hospital where I was initially treated.
- I am happy to be contacted about participation in future studies.
- I understand that recordings of interviews will be wiped upon transcription.