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# Human Tissue Act
# SOP – Consenting Healthy Participants

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| **SOP Reference:** | **SOP/HTA/04** |
| **Version Number V 4.0** | **Date: 17/04/2018** |
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| **Author:** | **Signature** | **Date** |
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| Dr Georgios Giamas<br><br>**Designation:**<br>Designated Individual<br>School of Life Sciences |  | 20/04/2018 |

| Version | Date | Reason for Change |
|---|---|---|
| 2.0 | 30/01/2013 | Addition of form field check box missing in V1 |
| 3.0 | 17/07/2017 | Change to reflect the update to DI |
| 4.0 | 17/04/2018 | Changes made to abide by new codes and standards. Including additional information to be placed 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 are documented in separate SOP/HTA/03, a related document which refers to consenting for samples to be acquired from patients.

## 2. Introduction
University of Sussex aims to collect high quality tissue and data whilst working to the highest ethical standards. 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
All healthy donor Information Sheets and Consent procedures must be submitted with an application to the local research ethics committee, and a favourable opinion must be granted prior to their use. 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 for the donation of Human Tissue 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 human tissue donor 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

1. Donor is approached by trained researcher and given the donation information sheet, the contents of the sheet should be verbally explained to the donor.
2. Ensure the donor fully understands the information sheet before consenting. The offer of language translations of the consent documents should be given when appropriate.
3. There should be face-to-face discussion between the donor and the person taking consent. The donor 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.
4. 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 donors 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. It should also be stated to the donor how long their sample will be kept for (unless they ask for it to be withdrawn), e.g. for a certain amount of years.
5. The donor 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.
6. 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 – a 'cool off' period of 24 hours is recommended between discussing consent and receiving an answer.
7. The consent form is then numbered according to the system employed by the principal investigator and retained securely by the principal investigator.
8. The researcher then takes the sample, logs it onto the Tissue database and assigns a unique identifier
9. The storage coordinates will be logged into the Tissue database.
10. 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
- 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

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# Consent Form - Donation of tissue.

| | Please initial 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 understand that I am free to stop participation and have my data and samples withdrawn at any time, without giving any reason. | Yes/No ☐☐ |
| 3. 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 ☐☐ |
| **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 am happy to be contacted about participation in future studies.
- I understand that recordings of interviews will be wiped upon transcription.

- I am currently of good health and do not know of any reason for my sample to be treated as anything other than a normal health risk