Standard Operating Procedure:

Name of procedure:

Taking Informed Consent

SOP Number: SOP07/UoE/HTA (includes Adverse Events Reporting Form) **Version Number & Date: V5 16/01/2017** **Superseded Version Number & Date (if applicable): V4 13/09/2016**	**Review Date: Annually**

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BACKGROUND
The Human Tissue Act 2004 (HT Act) came fully into force on 1 September 2006. The HT Act (2004) makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons.

RATIONALE
To describe the procedures for obtaining valid consent from legally competent individuals to enter research studies, in order to ensure a correct and uniform approach to obtaining consent from research participants.

NB: This Standard Operating Procedure (SOP) does not address procedures for the consent of 'vulnerable' subjects into studies.

LOCATION
University of Exeter, St Lukes, Streatham and Penryn Campuses.

SKILL LEVEL
It is mandatory that all personnel taking informed consent have received documented, informed consent training.

Additionally all individuals taking informed consent should have an in depth awareness of the study to allow informed discussion with the potential participant. (See below for more detailed description).

SCOPE

This SOP applies to all individuals involved in obtaining informed consent for research procedures at the University of Exeter, St Luke's, Streatham and Penryn Campuses.

RESPONSIBILITIES

It is the responsibility of all researchers to read and use this SOP prior to obtaining informed consent from research participants. This SOP must be used in conjunction with the HTA Codes of Practice and all other relevant University policies and SOPs including the University of Exeter HTA Management Handbook.

POLICY

In accordance with the principles of the GCP (Good Clinical Practice) all the subjects participating in the research studies must be fully informed about the study that have been asked to participate in. A written consent form must be obtained before any procedures are carried out. The patient information sheets, consent form and the protocol must receive ethical approval.

Whilst performing research involving human subjects it is important to ensure that the research is not contrary to the individual's interest. It is also important that the participant understands that the study is research and it is not possible to predict with absolute assurance the effect or reactions caused by the study.

Requirement for Informed Consent

Tissue from the Living

Under the HT Act 2004 tissue from the living may be stored for use and/or used without consent for research purposes, provided that:

- the research is ethically approved by a recognised research ethics authority, **and**
- the tissue is anonymised such that the researcher is not in possession of the information identifying the person from whose body the material has come and is not likely to come into possession of it (this does not mean that samples must be permanently and irrevocably unlinked).

In **all** other circumstances informed consent is required before tissue from the living may be stored or used for research and teaching purposes. In addition, consent is required to process information in the donor's health records which identify the donor.

Tissue from the Deceased

Consent is needed for the removal, storage and use of human samples for research purposes, unless it is part of an investigation under the authority of the coroner or in connection with a criminal investigation or following a criminal conviction.

Who Has Authority to Give Consent?

Tissue from the Living – Competent Adults

If an adult is competent, only they are permitted to give consent. From October 2007 the Mental Capacity Act 2005 requires that there is a presumption that persons aged 18 have capacity to give consent, unless it is established otherwise.

Tissue from the Living – Children
Children may consent to the storage and use of their tissue if they are competent to do so. A child who has sufficient intelligence and understanding to enable them fully to understand what is involved is considered to be competent to give consent.

It is recommended as good practice that parents of children who are competent to give consent in their own right are still involved in a supportive role in the decision-making process. Where a child is not competent to give consent a person with parental responsibility (as defined in the Children Act 1989 as amended) may give consent on his/her behalf.

Foetal tissue
The law does not distinguish between foetal tissue and other tissue from the living – foetal tissue is regarded as the mother's tissue.

Tissue from the Living – Adults Lacking Capacity
This SOP does not cover taking consent from adults lacking capacity – see the Human Tissue Authority Code of Practice on Consent for further information

Tissue from the deceased
This SOP does not cover taking consent for removal of tissue from deceased individuals – see the Human Tissue Authority Code of Practice on Consent for further information

PROCEDURE

Who can take consent at the University of Exeter?
- Any individual taking consent for the lawful storage and use of human samples must have completed an appropriate training course.
- Records of such training should be kept in the study file.
- Individuals seeking consent should read this Standard Operating Procedure ((SOP 07/UOE/HTA) and sign to confirm.
- Individuals seeking consent should have a good understanding of the activities they are seeking consent for. They should also be in a position to answer questions that participants or their families may ask. In particular, they should know enough about the proposed procedure, the intended use of the tissue and the risks involved, for the subject to make an informed decision.

How can Informed Consent be Obtained?

Informed consent consists of two parts: the Participant Information Sheet (PIS) and the Informed Consent Form (ICF).

1. The PIS should be written in layman's terms and provides the participant with comprehensive information about the study. The participant must be given adequate time to consider the contents of the PIS, ask questions of the researcher and talk to friends/family as required, prior to signing the ICF. The information sheet must include:
    - The possible benefits and risks involved
    - The unproven nature of the research
    - Confirmation that the research committee has approved the research
    - Freedom to withdraw from the study without repercussion
    - Informing the participant that they may not get any personal benefit from the research
    - Details about the remuneration, if any, given

- Name of Principal Investigator
- Name of Organisation
- Name of study
- Version number and date i.e. be version controlled.

2. The ICF documents that informed consent, has been taken, when and by whom. The ICF should:
   - Record the date and version number of the PIS given to the subject
   - Record the participant's ID code – the ID code should be unique to the study
   - Provide a series of paragraphs separately describing each requirement that the participant can agree to for participation in the study
   - Provide boxes in which the participant must initial next to each paragraph of the consent form. These allow participants to agree to each paragraph independently
   - Provide space to ensure that both researcher (taking consent) and participant print their names and provide a signature and date (of signature) at the time of consent
   - Include a paragraph for the participant to give their agreement to their tissue being sent to other labs in the UK and overseas for analysis (if appropriate)
   - Include a paragraph for the participant to give their agreement to any surplus tissue samples being retained for future studies - subject to further Ethical Approval, and in accordance with any restrictions expressed by the donor.

It should also record:
- Name of Principal Investigator
- Name of Organisation
- Name of study
- Version number and date i.e. be version controlled.

PIS and ICFs must be approved by a Research Ethics Committee prior to commencement of the research and the most recent version receiving approval should be used for obtaining informed consent.

For prospective minority ethnic subjects who cannot read English, every effort must be made to make material available in the potential subjects' first language, or a translator independent to the study team should be used to read the information sheet. The use of family members as translators should be avoided where possible.

Providing Information to the Potential Participants:

- Initial contact with the participant should ideally be in person

- Briefly state who you are and explain that you are inviting the participant to participate in the research you are doing. Say why that individual has been approached and give them the PIS.

- Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not.

- Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

- The participant must be given adequate time to consider the contents of the PIS, ask questions of the researcher and talk to friends/family as required, prior to signing the consent form (ideally at least 24 hours).

Researchers may find it helpful to refer to the standardised Participant Information Sheet and Consent Form formats in the University of Exeter HTA Management Handbook.

When can Informed Consent be Obtained?

- Once a potential participant has been given the PIS and had an opportunity to consider participation in the study then researcher obtaining informed consent must assess the subject's understanding of what they are agreeing to and fully understand the complications involved.

- If there is a doubt as to the subject's understanding the individual should not be recruited.

- The researchers should not put any pressure on the subjects to take part in the study.

- Ask participants to read each statement on the consent form carefully and initial in the box next to each statement if they agree with the statement.

- The subjects' name and study title should be checked to ensure that they are given the version agreed by the Ethics Committee and also check that the subject has received the relevant documentation.

- The ICF has to be signed and dated by the subject and the person obtaining the informed consent as witness, this must be done in each other's physical presence.

For subjects/representatives who cannot read an impartial witness should be present and should sign and date the consent form to attest that the information provided was explained and understood by the subject/representative.

Storing Informed Consent:

- The completed original consent form should be filed in the study file. If the subject is participating in an interventional trial a copy of this (or a second signed copy) of this consent should be filed in their medical records. The participant subject should be given a copy of their consent form as a record of what they have consented for.

- Forms should record the unique patient ID code, must be kept in the study file and linked (in the study specific database) to any samples that have been collected.

- All relevant, updated and new information regarding the study must be relayed to the study subject and where necessary the subject must be re-consented.

Audit

Appropriate completion and storage of the ICFs will be subject to regular audit.

Brief overview of the informed consent process

1. Seek ethical approval from the relevant Ethics Committee.

2. Identify potential participants.

3. Approach potential participants, invite them to discuss study and provide a PIS.

4. Give the potential participant time to consider the information they have received and discuss the project with family and friends (ideally at least 24 hours).

5. Invite the participant to return to ask any questions they may have and to go through and sign the consent form if they wish to take part in the study.

6. Both the participant and researcher should retain a copy of the signed consent form. The researcher should note the participant's unique study ID on the form and then file it in the study file.

7. Provide study file for consent form audit within 6 months of start of study.

Where to go for more information
Chair of your Research Ethics Committee

University of Exeter HTA Designated Individual

University of Exeter HTA Management Handbook

Relevant UoE HTA Standard Operating Procedure (SOP 07/UOE/HTA)

HTA Consent Code of Practice: https://www.hta.gov.uk/sites/default/files/files/Code%20A.pdf

Health research authority:
http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent -and-participant-information/