The Sheffield Biorepository

Standard Operating Procedure: Consent

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The University Of Sheffield.

1. Background

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 at the University of Sheffield.

The University 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.

In addition, staff should be encouraged to attend professional meetings and training events to ensure that they keep abreast of good practices in their area of expertise.

This SOP sets out the requirements relating to the induction and training of staff to ensure compliance with the Human Tissue Act regulations.

2. Approval of Consent process

Consent procedures and methodologies must be submitted with an application to a NHS research ethics committee, and a favourable opinion must be granted prior to their use.

Research Services at the University need to sign off formal Sponsorship and projects will also require registration with Sheffield Teaching Hospitals if their patients are involved.

A copy of the ethical approval must be kept within the site file for the research tissue bank or standalone ethically approved project.

3. Training

Any person taking consent must be trained in accordance with HTA standards or equivalent. Anyone taking consent from patients should undertake either E learning course or alternatively, face to face.
GCP training is also required by all staff involved in Consent process. Certificates of completion and training logs updated and should be kept as evidence.

NIHR offer E learning courses https://learn.nihr.ac.uk/

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 names of staff trained to take consent should be listed in the site file.
Staff should also have an understanding of the Human Tissue act and therefore are required to also complete the MRC HTA course.
https://byglearning.co.uk/mrcrsc-lms/course/index.php?categoryid=1

4. CONSENT PROCEDURE

The consent process should be outlined in the research Tissue Bank protocols.

- Only trained staff should undertake consent.
- The most up to date REC approved Consent form and patient information sheet should be used.
- Informed consent from the donor for must be obtained when tissue is retained specifically for research.
- The signed informed consent forms must be kept in both the ISF (or secure location associated with the tissue bank) and in the medical notes of the patient.
- The Participant Information Sheet should contain sufficient information so that it is clear to the participant, within the description of study procedures, the nature of the tissue sample to be donated.
- ALL sections should be completed in full.
- Initials should be used to indicate approval and not 'ticks'
- Investigator copies of consent forms must be stored in a secure place and the Biorepository informed of their location.

Consent is not required in the following exceptions:

- Tissue was collected before 1st September 2006
- Tissue was taken from a living person and the researcher is not able to identify the donor (Projects must have ethical approval)
- Tissue is imported.

3. Withdrawl of Consent

Where a research participant, the legal representative, or parent/guardian wishes to withdraw consent from a study the withdrawal process and reasons for withdrawal must be fully documented. The sample will be destroyed in accordance with the Disposal SOP.

4. Associated Documents

	Document	Document Reference
1	STH Researcher Informed Consent Policy	A106
2	RTB specific protocols	
3	SOP Disposal	
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