Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-37 **Version: 1.0**

Title: **Acquiring consent for use of human tissue for research purposes**

Purpose: To ensure that consent is obtained for the use of all human tissues acquired for research purposes in a manner compliant with the Human Tissue Act and the Human Tissue Authority's code of practice on consent.

Written By: Alan Harper Date: 12.10.16
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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	None	

1. Introduction:

The Human Tissue Act places the appropriate acquisition of consent of human tissue as a central tenet of all human tissue research. Removing, storing or using human tissue for a scheduled purpose (such as research) without appropriate consent is an offense under the Human Tissue Act (2004).

For consent to be appropriate it must have been given by the correct person as defined by the HTA codes of practice on consent (see below). This will often be the donor themselves. However, in the case of deceased donors, or in children or adults lacking the capacity to provide consent themselves, this may be a nominated representative, or those with a qualifying relationship to the donor. Investigators must ensure that consent is obtained from appropriate individuals prior to acquiring, storing or using any human tissue samples.

Appropriate consent must also be ***valid***. For consent to be valid it must be provided ***voluntarily, by an appropriately informed individual, who has capacity to provide consent***. This process is a sensitive and difficult task and therefore must be performed by an appropriately trained individual.

This Standard Operating Procedure details the procedures that must be followed to ensure that appropriate, valid consent has been obtained for use of human tissue for research purposes.

2. Procedure

2.1 All of the procedures that individual research projects use to obtain consent from their participants should be subject to ethical approval from either an NHS Research Ethics Committee (NHS REC) or one of Keele University's Ethical Review Panels (ERPs). All human tissues must be obtained whilst following the guidelines outlined in the University Hospital of North Staffordshire document Policy No. (C43) Policy and Procedures for Obtaining Consent (including the application of the Mental Capacity Act 2005).

2.2 For human tissue samples that are acquired from sources external to the university, the researcher should seek assurances that appropriate procedures are being used to obtain consent and these have been subjected to scrutiny by an ethical review panel. For non-commercial human tissues, these assurances should be formally documented in a material transfer agreement (MTA), and Keele-based researchers should also seek to obtain documentation of the ethical approval, consent form and information sheets used in the research project. For commercially-sourced tissues, a statement that written informed consent was received should be obtained from the supplier and recorded on the HTA-8 or HTA-9 logbooks.

2.3 Human tissue projects involving transportation of anonymised human tissue samples obtained at Keele to research groups external to the university should use a MTA to provide formal assurance on the appropriate acquisition of consent for use of the research tissue. The MTA should detail what the donors (or their representatives) have consented for the storage, use and disposal of the tissue sample. Evidence of appropriate ethical approvals and example consent forms and project information sheets should also be provided to the institution receiving the tissue.

2.4 Individuals who are being asked to provide consent for the use of a human tissue sample must not be approached about taking part in research until all required ethical and other required governance approvals have been granted.

2.5 All subsequent stages of the consenting process must be performed by a member of the research team who is fully informed of all aspects of the study (including acquisition, storage, use and disposal of the tissue) and is appropriately trained in the taking of informed consent.

2.6 The requisite training for an individual who wishes to take informed consent will be the reading of this SOP, the HTA code of practice on consent, the completion of good clinical practice training through the NIHR clinical research network, as well as appropriate experience of having performed this task previously. For individuals who have not taken consent for research purposes previously, the experience component may be gained

through documented supervision of consent acquisition of the HTA-43 form. Due to the severity of outcome if consent is not obtained appropriately this activity must be classified as a high-risk activity with a minimum of 10 hours of training and supervision allocated to it. This training and supervision must be completed under the observation of either a PI experienced in taking informed consent for research processes (for studies involving healthy volunteers only), or a clinician or experienced research nurse (for all studies). After completion of this training, the HTA-43 a copy of the logbook should be sent to the the human tissue officer for approval. Once formal written approval has been granted, this individual may perform the acquisition of consent independently.

2.7 Potential tissue donors who are eligible to participate in the research project (as defined by the inclusion and exclusion criteria) should have the study explained to them (or their representative). Those being asked to provide consent, and their kin, should have an opportunity to ask any questions about the research project.

2.8 If they are interested in participating they should be provided with a patient information sheet that details all the key information required for the project. For a research project using human tissues, the participant information sheets should provide those providing consent with information on:

i) The aims of the research project

ii) Why the donor has been selected for the study

iii) What the participant will have to do as part of the study

iv) how the tissue will be taken

v) the risks and benefits (if any) of these procedures

vi) how the tissue will be used, stored and disposed of

vii) the scope of the consent that is being requested (e.g. is consent for specific or generic research purposes)

vii) the ***duration*** of the consent that is being requested (how long will the investigators store and use the tissue?).

viii) the procedure for withdrawing consent for the use of the tissue

ix) how the information gained from their sample will be used and how the donor's confidentiality will be maintained

x) if the donor will be informed of any findings arising from these studies, and by what processes this will occur.
xi) the contact details for the principal investigator as well as the Designated Individual
xii) the procedure for reporting concerns or complaints about the conduct of the research teams.

2.9 If the project will involve the analysis of DNA or RNA of the donor's samples, or the xenotransplantation of tissue into animals, these must be ***explicitly*** stated in the information sheet.

2.10 This information sheet provided must be accessible for the participant, and therefore may need to be produced in braille, large print or in other languages as required.

2.11 The project information sheet should be received by the person providing the consent for the use of the tissue as far in advance of the appointment at which written consent will be provided. Unless the study is undertaken in an acute clinical setting where a longer consenting process would be impractical, there should be a minimum of 24 hours delay between the provision of the participant information sheet and the final documentation of consent. This will provide the potential donor with sufficient time to make an informed decision and provide the individual an opportunity to discuss their decision with the research team or other family members or friends.

2.12 Those being asked to give consent should be aware that they are under no obligation to take part in the study. They should also be made aware that they may withdraw at any point prior to the full use or disposal of the tissue as part of the project without the need to provide a reason for their decision.

2.13 Those being asked to provide consent should not be influenced by the offer of incentives or the application of duress. It should be made clear to the individual that refusal to give or subsequent withdrawal of consent should have no impact on the treatment and care provided to themselves or their relative by the research team.

2.14 At the meeting to document consent, the investigator should provide the donor (or their representative) with an opportunity to ask any further questions they have and ensure they have clearly understood how the tissue will be acquired, used, stored and disposed of.

2.15 The investigator should assure themselves that the donor has the capacity to give consent in line with the Mental Capacity Act (2005) code of practice. If there is any doubt about the individual's capacity to give consent, then consent should not be taken.

2.16 If the individual providing consent is happy to proceed then they must complete a written consent form with statements confirming that they have i) read and understood the participant information sheet, ii) that they are willing to participate in the study and iii) they are aware they may withdraw consent at any time prior to the tissue being completely used or disposed of as part of the project. The consent form should also provide clear statements about the duration and scope of the consent to be provided. A template of a generic Keele University consent form may be found on the Research Governance webpages.

2.17 If the project will involve the analysis of DNA or RNA of the donor's samples, or the xenotransplantation of tissue into animals, the consent form must include a section in which the participant ***explicitly*** confirms their consent to these particular procedures.

2.18 Human tissues obtained under consent under Keele University ERP or NHS Research Ethics Committee approval must be logged upon entry and Alan Harper (Guy Hilton Research Centre) or David Furness (Huxley Building) immediately notified and shown the signed consent form. They will provide the relevant HTA-8 or HTA-9 spreadsheet required for logging the acquisition, storage, use and disposal of human tissue samples.

2.19 Consent forms should be stored securely in accordance with our records management policy (HTA-39). Consent forms should be stored securely in a locked filing cabinet only accessible to members of the research team within a licensed Keele Building.

If paper records are removed from secure storage, they should not be left unattended in the absence of a member of the research team. The only exceptions to this would relate to records of donor-related information held by external research partners supplying tissue under the auspices of a material transfer agreement, or those records held by a clinician at the University Hospital of North Midlands Trust. Confidential information relating to the personal information of donors or staff must be stored according to the regulations in Keele University's ***Data Protection*** and ***Confidential Records*** policy documents (see references for links)

2.20 All consent forms must be securely stored in the HTA-licensed premises in which the research is conducted. The only exceptions to this would relate to records of donor-related information held by external research partners supplying tissue under the auspices of a material transfer agreement, or those records held by a clinician at the University Hospital of North Midlands Trust. Written assurances of the storage of these research documents should be obtained and securely stored by the chief investigator.

2.21 A person may withdraw their consent at any time. If this occurs after formal documentation of consent has been taken, then the consent form should be amended by striking through diagonally with a single red line, and a clear statement of "consent withdrawn" marked at the top with the date of the receipt of the request and the signature of the PI. This form must then be held for auditing purposes. The tissues must be disposed of and recorded on the logging sheet. After this has been done a letter should be sent to the donor confirming the receipt of the request and the actions taken to comply with this request. A copy of this acknowledgement letter should be held alongside the amended consent form.

3. References:

ICH Good Clinical Practice Guidelines
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

University Hospital of North Staffordshire document Policy No. (C43) Policy and Procedures for Obtaining Consent (including the application of the Mental Capacity Act

2005).

HTA Cope of Practice: Consent

https://www.hta.gov.uk/sites/default/files/Code_of_practice_1_-_Consent.pdf

Mental Capacity Act (2005) Code of Practice:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf

A generic template for the Project information sheet and consent form can be found on the Keele University Research Ethics Page.

https://www.keele.ac.uk/researchsupport/researchethics/

Keele University data protection policy

https://www.keele.ac.uk/policyzone/viewbyowner/planningandacademicadministration/name,70905,en.php

Keele University Confidential records policy

http://www.keele.ac.uk/policyzone/viewbyowner/planningandacademicadministration/name,70852,en.php