King's College London
Human Tissue Authority Licensed Laboratories

Standard Operating Procedure

Title: Seeking Consent for the Removal, Storage & Use of Relevant Material for Research Purposes

Purpose
The purpose of this SOP is to describe the procedure for providing information and seeking consent from participants of research studies where tissues or cells are to be procured (as defined by the Human Tissue Act 2004).

Scope
The scope of this SOP is to describe the training requirements for anyone wishing to take consent. It also covers the fundamental requirements to ensure potential participants are fully informed and have time to consider if they wish to participate. It describes how the participants wishes are recorded and the process in place to ensure these are adhered to.

Document Detail	
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Approved By	KCL HTA Governance Group [20 Nov 2019]

Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 14/5/09	1.0	2.0	4	7	Storage of consent forms & research related records
2. 17/6/10	Review Only				No Changes
3. 28/5/13	2.1	3.0	3	3.3	Expansion of who can view training records
4. 8/6/15	3.0	4.0	4	7.5	Change in research record retention period
5. 22/9/17	4.0	4.1	4 5	5.1 10.21 11.2, 11.3	Role of GSTT R&D updated Updated COP reference Updated COP reference
6. 18/11/2019	4.1	4.2	4	5.1	Change in REC and R&D terminology

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1. Responsibilities

It is the responsibility of all staff to ensure that:

1.1. They adhere to the procedure outlined in this SOP.

1.2. They inform the Designated Individual or Person Designated of difficulties in the process of obtaining and recording consent

2. Materials

2.1. Adult Patient Information sheet (supplemented with other information media as appropriate and agreed by an accredited Ethical Committee)
2.2. Young Person Patient Information sheet (supplemented with other information media as appropriate and agreed by an accredited Ethical Committee)
2.3. Consent Form
2.4. Introductory Letter (as required)

3. Who can take consent?

3.1. Training

KCL staff/students and other personnel who wish to take consent for research studies operating under a KCL HTA licence, must have received formal training in taking consent for either a surgical procedure, treatment, clinical trial, tissue banking or research. Individuals with previous experience in taking consent may, at the discretion of the campus HTA Designated Individual (DI), be exempt from formal training. KCL staff and students must undertake refresher consent training at three yearly intervals

3.2. Knowledge

An individual who takes consent to remove, store or use Human Tissue Authority defined relative material must have a basic knowledge of the Human Tissue Act 2004, Human Tissue Authority and type of research undertaken with the tissues and data.

3.3. Evidence

Staff/students who complete a consent training programme should retain evidence of completion. A central register will be kept of current staff/students who have successfully completed either the in-house or DI approved external consent training programme. This record will be available to members of the HTA Governance Committee, Campus HTA DI and Persons Designated (PD) and the R&D Departments of GSTT and KCH.

4. Information sheets and Consent forms

4.1. Information sheets (or other suitable media) should provide sufficient information for a participant to understand why the study is being undertaken, what material is to be sampled and how this will be obtained, any risks associated with the sampling procedure, what personal information is required and how this will be collected and the impact of research results on an individual. It should be made clear that participants have the right to withdraw and revoke consent at any time during the study
4.2. Information sheets must include contact details of the investigator or other nominated person.

4.3. KCL actively encourages the retention of surplus relevant material and derivatives for future research when the initial study is complete. The information sheet should refer to the value in retaining surplus material and that this is for future, as yet unspecified, research, which may be in collaboration with commercial companies.
4.4. Information sheets must also state how any surplus material will be disposed of at the end of the study.
4.5. For some studies, it is appropriate that the information sheet and consent form are available in different languages, large format or Braille.

5. Consent Pathway – Providing Information

5.1. Recruitment can only be initiated once a Research Ethics Committee favourable opinion has been received. If NHS patient material or data are being used, then the Trusts R&D Office will assess if the Trust has the capacity and capability to support the research .
5.2. Individuals who meet the study inclusion criteria should be invited to participate either verbally, by introductory letter or by other media. Individuals who consider participating should be provided with information (as approved by the ethics committee).
5.3. Potential participants MUST be given an opportunity to read, watch or listen to information. The environment and timescale must be such that participants are able to comprehend the information they have been provided with and if required discuss with family/friends.
5.4. Where appropriate translators should be available for participants. The use of family members/friends to translate should be avoided wherever possible
5.5. Potential participants must be given an opportunity to ask questions about the study and their involvement.

6. Consent Pathway – Taking Consent

6.1. Individuals taking consent must confirm that the participant has understood why they have been asked to participate and the impact this will have on them.
6.2. If the participant agrees to proceed, they must initial the relevant statements on the consent form, sign and date. The person taking consent should confirm that it has been given freely by also signing the form.
6.3. The participant should retain a copy of the consent form and information sheet.

7. Consent Pathway – Record of Consent

7.1. The PI must keep a copy of the completed consent form (either the original or a scanned copy). Consent forms should be kept in a secure environment for a minimum of 10 years after the research has been completed, the data analysed and final publication of findings has been made.
7.2. Where further research is anticipated on residual relevant material, then consent forms should be kept as long as a need may exist.
7.3. Forms should be stored in such a way that they are accessible for audit and review.
7.4. If the PI leaves, consent forms should either be handed over to another senior researcher if the study is ongoing or archived in accordance with College policy for retention of academic research records.
7.5. All working records and research data relating to relevant material must be retained for a minimum of 7 years after completion of the study. Wherever possible these records should not include participant identifiable data, unless consent for such retention has been obtained. Retention of records and data must follow the College Research Data Management policy.

8. Participant Consent for Material Received from other Establishments for Research at KCL

8.1. The principle of informed consent applies to materials obtained from participants both within the UK and imported from overseas.
8.2. All material transferred to KCL from outside of the organisation for the purposes of research must either be referred to in the Research Ethics Committee approved study protocol or, be accompanied by a material transfer agreement (MTA). The MTA must specifically refer to the process of obtaining consent and confirm that all participants have given informed consent. A copy of individual consent forms is not required provided details are adequately covered in the MTA.

9. Participant Consent for Material Collected at KCL and sent to other Establishments

9.1. Material transferred from KCL to other organisation for the purposes of research must either be referred to in the Research Ethics Committee approved study protocol or, be accompanied by a material transfer agreement (MTA). The MTA must confirm that all participants have given informed consent.
9.2. Other establishments may request copies of information provided and a blank consent form. Completed consent forms can only be supplied to other establishments if the participant has consented to this.

10. Revoking Consent

10.1. Participants who wish to revoke consent must do so in writing to the investigator named on the information sheet, the DI or PD.
10.2. If consent is revoked the DI and appropriate PD must be informed and ensure that:
- 10.2.1. Relevant material and derivatives held in storage are destroyed in accordance with HTA Code of Practice E (Research).
- 10.2.2. Details are added to the investigators relevant material disposal log
- 10.2.3. Data are deleted from Research database
- 10.2.4. No further data are collected on the individual
- 10.2.5. A copy of the letter revoking consent should be appended to the original consent form and a note made on the consent form itself of the fact it has been revoked, the date it was revoked, and details of the investigator updating the form.

10.3. The DI or nominated person will write to the individual confirming that the request has been received and action taken to destroy stored tissue and data.
10.4. When material and data have been sent to other investigators, the DI or those under the direction of the DI will contact the investigator. Any unused sample, including derivatives, should be disposed of (in accordance with the HTA Code of Practice E). The KCL investigator must update the relevant material disposal log.

11. References

11.1. The Human Tissue Act 2004 (Statutory Instrument 2005 No.919)
11.2. Human Tissue Authority Code of Practice A: Guiding principles and the fundamental principle of consent
11.3. Human Tissue Authority Code of Practice E: Research
11.4. Health Research Authority, Consent and participant information sheet preparation guidance (www.hra-decisiontools.org.uk/consent/)
11.5. KCL HTA Policy Consent
11.6. KCL HTA101/Disposal SOP– Disposal of human material
11.7. King's College London Records and Data Retention Schedule – Research Records (September 2011)