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 [30 Sep 2024]

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
7. 15/08/2022	4.2	5.0	3 3 4 7	2.5 3.3 6 Appendix 1	Addition of virtual consent materials Delegation log added Inclusion of virtual consent Document retention time updated
8. 30/09/2024	5.0	5.1	4	5.6 Appendix 1	Role of consultee for consent Document retention time updated

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 with a favourable opinion from a Research Ethics Committee)
2.2. Young Person/Childs Patient Information sheet (supplemented with other information media as appropriate and with a favourable opinion from a Research Ethics Committee)
2.3. Consent Form
2.4. Introductory Letter (as required)
2.5. Scripts for telephone/ video consent

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.

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 Group, Campus HTA DI and Persons Designated (PD) and the R&D Departments of GSTT and KCH.
It is advisable for all Lead Investigators to maintain a consent delegation log for each study where relevant material is collected.

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 explain 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. However, there is no standard minimum time period between information provision and seeking consent.
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.
5.6. When a potential participant lacks mental capacity to give informed consent and the study has research ethics approval to recruit these participants, a consultee may be approached. The consultee (as defined in the protocol) must be provided with information and had opportunity to ask questions. The consultee is able to consent on behalf of the participant.

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. When consent is taken remotely, the person taking consent should initial the form and formally note this as a virtual consent process.
6.4. Participants can sign the consent form using digital means, these are considered still to be 'in writing'.
6.5. The participant should be provided with a copy of the consent form and information sheet to retain.

7. Consent Pathway – Record of Consent

7.1. The PI must keep a copy of the completed consent form (either the paper original, scanned copy or digital form). Consent forms should be kept in a secure environment. KCL Schedule of Retention Periods for Research Data should be followed, with consent forms being retained for the same minimum period as the research data (Appendix 1).
7.2. Where further research is anticipated on residual relevant material, 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.

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 investigator's 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 2023)

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Appendix 1: Schedule of Retention Periods for Research Data (2023)

Type of Research Study	Researcher Type	Ethical clearance	Dissemination status of research findings	Minimum period of Retention	Responsibility of retention	Based on
Advanced medical therapy research (ATIMP)	Staff	External Ethical Clearance obtained	Disseminated	Advanced medical therapy research Trial Master Files – 30 years minimum following completion of the trial, plus 2 years after last marketing authorisation (this includes paediatric studies). Source data* & investigator Site File – Completion of trial + 5 years, destroyed only with Sponsor permission.	Researcher	European Medicines Agency guidelines for investigational advanced therapy medicinal products in clinical trials.
NHS clinical trial (CTIMP) 'Clinical trials' includes any studies that involve the investigation of an investigational medicinal product (IMP), including combined IMP/ device studies etc. Refer to Clinical Trials Regulation No 536/2014 for full definitions.	Staff	External Ethical Clearance obtained	Disseminated	Requirements of specific Trusts should also be considered, as well as those of the Sponsor. For marketing authorisation holders, please refer to Section 6 above. Data should be retained for whichever duration is deemed the longest. Where KCL is the Sponsor: • Essential clinical trial documentation will be retained, in accordance with the Medicines for Human Use (Clinical Trials) Regulations, for a minimum period of 25 years following completion of the trial, plus 2 years after last marketing authorisation (this includes paediatric studies), unless a longer retention period is stated in the essential trial documents.	Researcher	Medicines for Human Use (Clinical Trials) Regulations Trust requirements Sponsor requirements

				• Source data* & Investigator Site File – _Completion of trial + 5 years, destroyed only with Sponsor permission.		
Other clinical or social care studies not falling under the above categories, where KCL is the sponsor:	Staff (or student projects with a supervisory CI)	External Ethical Clearance obtained	Disseminated	Requirements of specific Trusts should also be considered, as well as those of the Sponsor. For marketing authorisation holders, please refer to Section 6 above. Data should be retained for whichever duration is deemed the longest. Where KCL is the Sponsor: • Research involving children – _completion of trial + 5 years or 3 years after the youngest subject reaches 18 years of age (whichever is longest) • Research involving those who lack capacity to consent – _25 years Other research study data - Completion of trial + 5 years, unless a longer period has been stipulated by the funder and has been approved by the regulatory bodies.	Researcher	Medicines for Human Use (Clinical Trials) Regulations Trust requirements Sponsor requirements
Commercial clinical trial or health research	Staff	External Ethical Clearance obtained	Disseminated	Refer to Commercial Sponsor requirements.	Researcher	Commercial Sponsor requirements
Other population health studies	Staff	External Ethical Clearance obtained	Disseminated	20 years unless specified otherwise by the funder of the research.	Researcher	As recommended by MRC principles and guidelines for good research practice
Healthy volunteer studies, non-clinical or overseas clinical studies that do not require HRA approval	Staff Student – PhD/ MPhil	KCL CREC, all ethical risk levels including projects where ethical	Disseminated* *	10 years following publication which fundamentally relies on the data, unless specified otherwise by the funder of the research.	Researcher	UKRI Concordat on open research data

		clearance is not required.				
Healthy volunteer studies, non-clinical or overseas clinical studies that do not require HRA approval	Student – Taught Post-graduate/ Undergraduate *without* intention to publish	KCL CREC, all ethical risk levels, including projects where ethical clearance is not required.	N/a	Destroy within 1 month following receipt of award.	Researcher	KCL
Healthy volunteer studies, non-clinical or overseas clinical studies that do not require HRA approval	Student – Taught Post-graduate/ Undergraduate *with* intention to publish	KCL CREC, all ethical risk levels, including projects where ethical clearance is not required.	Disseminated*	**Pre-publication:** Destroy within 1 year following receipt of award. If there is a requirement to retain data for a longer period, this must be discussed and agreed with the Research Governance Office rgo@kcl.ac.uk **Post-publication:** At least 5 years following publication which fundamentally relies on the data, unless specified otherwise by the funder of the research, or by the journal.	Researcher	KCL

*Source Data = All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice-e6r2-step-5_en.pdf
**Where research data is not disseminated following collection or analysis, and dissemination is not intended, sufficient justification must be made for the continued storage of the research data.