Standard Operating Procedure CBE/HTA-PR-SOP012

Title: Obtaining Informed Consent from Human Participants

Location: CBE Laboratories

1. PURPOSE

The purpose of this SOP is to set out procedures for obtaining informed consent for the acquisition of human tissue for research.

2. SCOPE

This SOP applies to ALLCBE staff / students whose research studies require the recruitment of human participants with the intention of acquiring human tissue samples.

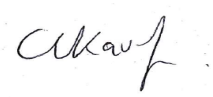
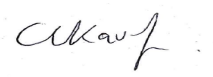
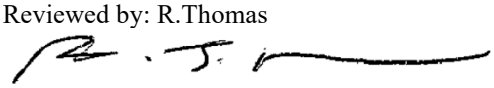
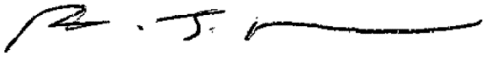
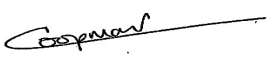
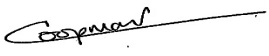
Consent from the living under the Human Tissue Act relates to the purposes for which material might be removed, stored or used. These purposes are listed in detail in schedule 1 (Paragraph 81) of the Human Tissue Act and are referred to as scheduled purposes. The scheduled purpose of "Storing and using relevant material from the living" takes place within laboratories within the CBE , as such ANYONE removing, storing or using material for which the Human Tissue Act requires consent, must ensure that consent is in place.

3. RESPONSIBILITES

ONLY TRAINED PERSONNEL CAN TAKE CONSENT

3.1 Principal investigators and Associated Staff and Postgraduate Research Students.

- CBE staff and students (research) are responsible for obtaining informed consent from research participants for the use of their tissue(s) for research.
- The researchers also have a responsibility to follow the procedures defined by the SOP for obtaining consent and if applicable, the procedures defined by the 'Withdrawal of consent process'. Researchers must ensure that all associated documentation and amendments are completed.

Written by: C.Kavanagh Date: 27/04/2021  Reviewed by:C.Kavanagh  Date: 04/12/2023	Reviewed by: R.Thomas  Date: 22/06/2021 Reviewed by:R.Thomas  Date:13/12/2023	Approved by: K.Coopman  Date: 22/06/2021 Reviewed by:K.Coopman  Date: 13/12/2023

- Principal Investigators are responsible for ensuring staff and students comply to all consent procedures and undertake the necessary training.
- Staff and students must ensure they attend all consent training.

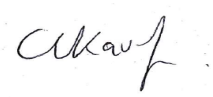
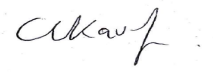
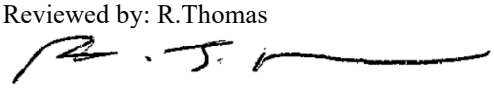
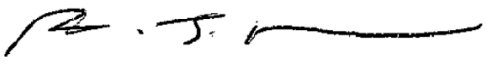
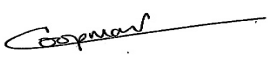
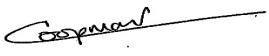
3.2 The Regulatory Compliance Officer
Is responsible for ensuring all staff and principal investigators and postgraduate students carrying out or overseeing Human Tissue Authority (HTA) related activities have received the appropriate training and are aware of their responsibilities within the scope of the Human Tissue Act.

3.3 The University Quality Manager
The University Quality manager, in conjunction with the Department Quality Managers, is responsible for the management of the Quality Management System documentation to ensure that any local documents comply with the quality management system.

3.4 The Departmental Quality Manager
The Departmental Quality Manager or their representatives are responsible for carrying out internal consent competency audits of activities carried out under the University HTA licence; including the consent process.

4. REFERENCES

- HTA Code of Practice A, Guiding Principles and the Fundamental Principle of Consent,
- The University HTA Quality Manual
- CBE Quality Manual
- HTA-PR-SOP013 Withdrawal of consent to use tissue donated for research.

Written by: C.Kavanagh Date: 27/04/2021  Reviewed by:C.Kavanagh  Date: 04/12/2023	Reviewed by: R.Thomas  Date: 22/06/2021 Reviewed by:R.Thomas  Date:13/12/2023	Approved by: K.Coopman  Date: 22/06/2021 Reviewed by:K.Coopman  Date: 13/12/2023

5. PROCEDURE

5.1 Valid Appropriate informed Consent from the living

5.1.1 Valid consent constitutes consent which has been obtained voluntarily. Consent must be sought from an appropriately informed person who not only has the mental capacity to understand what the study involves and their involvement within it, but also the capacity to agree to participate in the study.

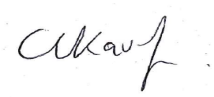
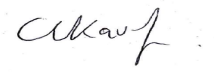
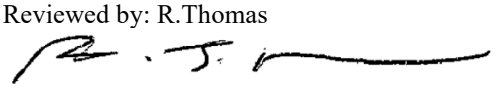
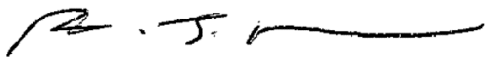
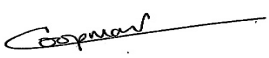
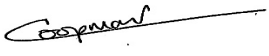
5.1.2 There are various ways in which consent can be expressed, although best practice advises that consent is sought in writing. This does NOT mean however that a signature on a form constitutes consent. Consent is a process, and is only valid if given by an appropriately informed person who has the capacity to understand the information given and freely make a decision regarding their intent to consent to donating their tissue for research. This includes ensuring that the potential donor has had time to discuss the issue fully, ask questions and make an informed choice.

5.1.3 For consent to be valid, the participant/ tissue donor should understand what the study/ activity involves, and what the associated risks (of participation) are.

5.1.4 When seeking consent, suitably experienced people should ensure that it is appropriate for the intended purpose. For example, for research where several areas of specialist knowledge are involved participants should be offered access to specialists if they require additional information to enable them to make a fully informed choice.

5.1.5 It is expected that a written Participant Information Sheet (PIS) will be used to support the process of gaining consent. This can be, and is often sent out in advance of the consent session.

5.1.6 It is expected that consent will be confirmed in writing via a consent form being signed and dated by the Participant and the person seeking consent. To decrease the risk of the participant not fully taking in

Written by: C.Kavanagh Date: 27/04/2021  Reviewed by:C.Kavanagh  Date: 04/12/2023	Reviewed by: R.Thomas  Date: 22/06/2021 Reviewed by:R.Thomas  Date:13/12/2023	Approved by: K.Coopman  Date: 22/06/2021 Reviewed by:K.Coopman  Date: 13/12/2023

what they have been asked to do, the consent form has been updated in line with NHS good practise such that each point needs to be initialled.

5.1.7 Two copies of the consent form should be signed and dated by both the Participant and the investigator. One copy of the consent form should be given to the participant and the other copy of the consent form should be placed in the participant's research record. The latter should be held in a secure location in the investigator's office or laboratory.

5.1.8 Consent for research may be generic or specific. It is good practice to request generic consent, thereby avoiding the need to obtain further consent in the future. For example, on the Loughborough University consent forms there is an initialled requesting permission for participants samples to be used in further research.

5.1.9 Consent may be withdrawn at any time whether it is generic or specific. Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent should be made clear. Participants must be made aware that they can withdraw consent at ANY time during sample acquisition, or any procedures involving interventions (e.g. exercise testing) or investigations prior to sample acquisition. However, the limitations of consent withdrawal MUST be made clear. For example, if consent is withdrawn by the participant, but their samples have already been used in a research project, withdrawal of consent cannot be as effective once the data has been collated and figures published for example. Guidance on managing withdrawal of consent is outlined in CBE-HTA-PR-SOP013"Withdrawal of consent to use tissue donated for research"

5.1.10 It is unlikely that non-written consent will be taken at Loughborough University; however, if an instance arises whereby consent has to be taken verbally, or via a phone conversation, say for someone with a sight limitation, then please contact the research office for further advice.

5.1.11. Consent is only valid if appropriate and legitimate communication has taken place. In instances where the participant's first language is NOT English and their standard of English inhibits their ability to understand and question the information given to them, then provision for a translator must be made. Provision for translators can be organised via the University Research Office.

5.1.12. Consent for Vulnerable groups
If you intend to obtain consent from vulnerable groups, which include;

- Children under 18 years of age
- Adults without capacity to give consent
- Prisoners and Young Offenders
- A participant who is a dependant of the investigator

It is important that all relevant legislation and requirements be considered when developing the consent process and associated documentation. Please consult the departmental quality manager/ technical resources manager/ officer for advice.

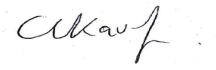
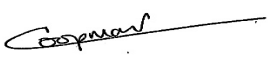
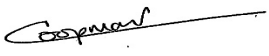
6. OBTAINING INFORMED CONSENT

6.1 Attend consent training, get in contact with the Regulatory Compliance Officer via regulatory@lboro.ac.uk **THIS IS MANDATORY .** You must complete the training before you can begin the consent process.

6.2 Prepare the Participant Information sheet (s) and Informed Consent Form (s). Templates are available to download through **LEON (Loughborough Ethics OnLine via the 'Help' section)**
Loughborough University Ethics Online | Research ethics and integrity | Loughborough University

6.3 Go onto the LEON Portal and select help tab at the top, scroll down to templates to download which one you need. Remember to remove the 'suggested texts' and make specific for your study. Always use a new form for each study as the template could change.

6.4 Fill out an ethics checklist and research proposal form and associated risk assessments and submit these through LEON. Follow any and all feedback given by the Regulatory Compliance Officer/, Technical

Written by: C.Kavanagh Date: 27/04/2021  Reviewed by:C.Kavanagh  Date: 04/12/2023	Reviewed by: R.Thomas  Date: 22/06/2021 Reviewed by:R.Thomas  Date:13/12/2023	Approved by: K.Coopman  Date: 22/06/2021 Reviewed by:K.Coopman  Date: 13/12/2023

Resources Manager / research administrative support. Otherwise await clearance for your study. This is usually received within 2 weeks of the ethics committee meeting date.
On receiving clearance for your study you can start recruiting participants.

6.5 Provide the Participant Information Sheet to potential donors in advance.This should be given at least 24hrs in advance but ideally 1-2 weeks. Allow the potential participant time to decide if they wish to participate in the study and ensure that yourself or another individual with specialist knowledge of the study is available to answer any further questions that the potential participant has. Let them take the participation sheet away with them to reflect or discuss with a friend.

6.6 Arrange a meeting to discuss the consent process. Make sure this meeting is relaxed with no interruptions. The Participant can bring a close friend or relative if they wish. Let the participant ask any questions they might have and equally ask your own questions to ascertain their level of understanding to reinforce information but be careful not to use jargon. Do they understand the time commitment?. Do you think they meet the criteria?.Make it clear to them that they do NOT have to participate and do NOT have to give a reason why they do not wish to participate. Do not Coherce. This meeting can take place face to face in a quiet area or potentially through a virtual means as long as you can ensure clear communication and understanding. You could sign in real time during the virtual meeting and E-mailed after.

6.7 If the potential participant is willing to give consent, confirm the consent by signing and dating two copies of the Informed Consent Form you have created. Ensure the form is specific to your study. (Please note that investigator and participant signatures and dates are required).

6.8 Give one copy of the consent form to the participant and file one copy of the consent form in the participant's research record which should be held in a secure location.

Commercial Suppliers

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Even if we are obtaining HTA Relevant material from commercial suppliers (in which case they will have obtained the consent) we have a duty of care to ensure that ethical informed consent has been obtained for the use of the tissue from these commercial suppliers. A blank consent from should be sought and placed in study file.

7 DOCUMENTATION

The following records are outputs of this SOP:

7.1 Participant Information sheet

7.2Informed Consent Form

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SOP Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
001	6th December 2021 by C.Kavanagh	N/A	No amendments required.	N/A
001	4th December 2023 by C.Kavanagh	N/A	No amendments required. New revision date only.	N/A

SOP Withdrawal Date:	

Document Control

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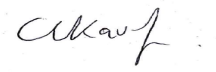
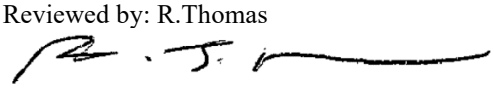
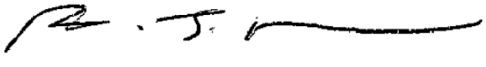
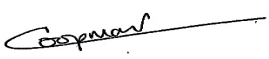
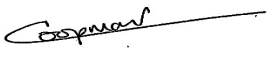
Written by: C.Kavanagh Date: 27/04/2021  Reviewed by:C.Kavanagh  Date: 04/12/2023	Reviewed by: R.Thomas  Date: 22/06/2021 Reviewed by:R.Thomas  Date:13/12/2023	Approved by: K.Coopman  Date: 22/06/2021 Reviewed by:K.Coopman  Date: 13/12/2023

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Security Statement

This SOP is the intellectual property of the CBE within Loughborough University, and as such, must not be circulated outside of the University without the written approval from the dQM and the author.

Acknowledgements

<include if appropriate>

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