Standard Operating Procedure **CBE/HTA-PR-SOP-013**

Title: Withdrawal of consent to use tissue donated for research (HTA)

Jurisdiction: CBE Laboratories

1. PURPOSE

To outline the process that must be followed when a sample donor expresses a wish to withdraw consent for their donated tissue to be used in research. Note that withdrawal of consent MUST be discussed at the outset when consent is being sought. The practicalities of withdrawing consent, the withdrawal process, its limitations and implications must be made clear from the beginning.

Consent can be removed for;

- Subject participation
- Collection and/ or use of tissues
- Use of data collected from the participants tissues

2. SCOPE

This procedure is applicable to any and all CBE researchers working for Loughborough University who are collecting samples from human participants.

3. RESPONSIBILITES

. **3.1 Principle Investigators and Associated Staff and Students**

3.1.1. Have a responsibility to honour the withdrawal of consent. The participant does not have to give a reason or justify why consent has been removed, (however it is helpful to ask why, and see if they are willing to volunteer feedback). If consent has been withdrawn for sample collection and

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use, ensure that all samples associated with the donor who has withdrawn consent are disposed of appropriately.

3.1.2 The researchers also have a responsibility to follow the procedures defined by the 'withdrawal of consent process' and ensure that all associated documentation and amendments are completed.

3.2 Persons Designate

3.2.1 To oversee the withdrawal of consent and ensure all processes relating to the withdrawal of consent for tissues to be used in HTA related activities are carried out in accordance with the Act as outlined in this SOP.

3.2.2 The PD is responsible for ensuring all staff and principal investigators and postgraduate students carrying out or overseeing HTA related activities have received the appropriate training and are aware of their responsibilities within the scope of the act.

3.3 University Quality Manager

3.3.1 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 Departmental Quality Manager (DQM)

3.4.1 DQM or their representative are responsible for carrying out internal audits of activities carried out under the University HTA licence, including auditing the consent process.

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4. REFERENCES

- The University HTA Quality Manual
- CBE Quality Manual
- HTA-PR-SOP012 Obtaining Informal Consent from human Participants
- See the Human Tissue Authority Website for more information, http://www.hta.gov.uk/

5. PROCEDURE

This procedure shall be followed whenever a donor revokes consent for their donated tissue to be used in research. Means by which a donor may express their wish to revoke consent can comprise the

following; verbal withdrawal of consent or in writing, by telephone, face-to-face, virtual meeting, via e-mail, text or a formal letter.

5.1 Face-to-Face Withdrawal of Consent

5.1.1 It is ESSENTIAL that the donor does not feel that there are any barriers to withdrawal.

5.1.2 If a donor has decided that they wish to withdraw consent, NO attempt to change their mind must be made. Their wishes MUST be fully respected and actioned.

5.1.3 If possible, any donor who wishes to withdraw consent is referred to the individual that obtained consent.

5.1.4 If the person who obtained consent is unavailable, it is perfectly acceptable for any trained and competent individual to discuss withdrawal with a donor.

5.1.5 The donor shall be asked to sign a Consent Withdrawal form. This ensures that the person withdrawing consent is the same person who originally obtained consent.

5.1.6 The completed form shall be sent to the secretary of the HTAL sub-committee who is based in the Research Office a copy shall also be given to the donor.

5.2 Remote Withdrawal

5.2.1 If withdrawal is requested by telephone, e-mail, letter or fax then the "Acknowledgment of withdrawal of consent" letter in section 6 of this SOP must be sent to the donor to complete, in addition to the withdrawal of consent form (in section 6 of this SOP). Both forms need to be signed by the donor and then returned to Loughborough University In the first instance the form for the withdrawal of consent should be sent to the principal investigator of the study (or his/her representative) to provide confirmation that the correct person is withdrawing consent and match these with the samples in Procuro.

5.2.2 At the point of request the donor must be told (by the principal investigator or a senior laboratory representative) that the samples will be put into quarantine until the withdrawal of consent form is received. Upon receipt of the withdrawal of consent form, samples must be destroyed within 7 days.

5.2.3 The person designate should immediately be notified of the donors request to withdraw samples and should then ensure that the samples and data are quarantined.

5.2.4 If the completed withdrawal of consent form is not received within one month the PD should ensure the samples are destroyed and disposed of in accordance with the guidance set out in CBE-HTA-PR-SOP007 Disposal of HTA licensable material.

5.2.5 Once the withdrawal of consent form has passed through this level of control it must be sent to the secretary of the HTAL subcommittee Jacqueline Green in the research office.

5.2.5 The copy of the consent form held in the Donors case notes shall be scored through with a single line, "WITHDRAWN" written and the form dated and signed. Copies of the amended consent form shall be sent to everyone who received copies of the original.

5.3 <u>The Procedure for the Withdrawal of Consent</u>

5.3.1 Within one day of receipt of withdrawal of consent the principal investigator for the research group or their representative should locate all of the donor samples and any associated derivatives/ laboratory products from such.

5.3.2 Samples and derivatives shall be sought out and disposed of as per CBE-HTA-PR-SOP007 Disposal of HTA licensable material.

5.3.3 Researchers who have received samples from the donor shall be contacted and notified that consent has been withdrawn.

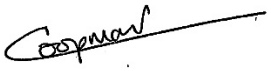
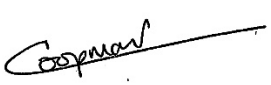
5.3.4 Researchers will be asked to remove the samples from quarantine and update any relevant sample records on Procuro.

5.3.5 The system audit trail must be preserved, so even though the donors' data is logged in the system, any and all sample identifiers, processing data and inventory details must be noted as deleted.

6. DOCUMENTATION

The Following documents are products of this SOP:

6.1 Notification to researcher of donor withdrawal.
6.2 Template withdrawal of consent form.
6.3 Template letter or e-mail to the donor requesting to withdraw consent.

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 C.Kavanagh  Date:13/12/2023

7.1 Notification to researcher of donor withdrawal

Date; 00 Month Year

To; (Researcher)

The donor of the samples identified below has withdrawn consent for their use by researchers. Please destroy all unused samples and delete any data held.

Sample Type	Sample Identifier	Date Destroyed

Yours sincerely

Sender's name

Title

Encs

cc

7.2 Template- Withdrawal of Consent form

This form is used to record your decision to withdraw consent for the use of your samples in research.

I confirm that I have read and understood the letter explaining "Withdrawal of consent" (*insert date and study reference*) and have had the opportunity to ask questions and discuss my wishes.

Signed……..

Participant's Statement;

I ……wish to withdraw permission for my samples and data to be held or used for research purposes by Loughborough University. I would like my samples to be destroyed and data deleted such that they are no longer available for use.

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Signed…….

Date……..

Print Name……...

7.3 Template-Letter or E-mail to the donor requesting to withdraw consent

Addressee's name
Street address
POST TOWN
County
Postcode

Direct Line:
Fax:
E-mail:
http://

Date

Dear (donor),

Thank you for notifying (insert individual) that you wish to withdraw consent for your samples and associated data held for research purposes at Loughborough University.

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Title: Withdrawal of Consent for using human material for research

Location: CBE Laboratories

(Insert project details; title, reference number).

Before we destroy samples and data we normally ask the donor to sign a form to confirm their wishes in writing. This is to ensure that the person withdrawing consent is the same person who gave consent.

We would therefore be grateful if you could use the attached withdrawal of consent form and send it back to us at the following address, ……..

Your samples will be held in quarantine until the withdrawal of consent form is received. During this time, any samples that you donated to Loughborough University will not be used for research.

Upon receipt of the notice for the withdrawal of consent the samples donated by yourself will be removed from quarantine and destroyed. Your personal information will be removed from the research database. If the signed “withdrawal of consent” letter is not received within one month of your initial communication to revoke consent, your samples will be destroyed.

Some of your samples may have already been used to generate experimental data. If this is the case it will not be possible to retrieve these samples, nor is it possible to withdraw the results of the research or prevent their publication.

Yours sincerely

Sender’s name
Title

Encs

cc

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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

The Master Copy of all SOPs is filed by the dQM. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network. If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of the dQM or their Supervisor immediately.

Security Statement

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Acknowledgements

<include if appropriate>

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