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Human Tissue Act
SOP – Withdrawal of consent to use donated tissue for research

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Reviewed:	Signature	Date
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Designation: Designated Individual School of Life Sciences Reviewed: Dr Robert Fowler Designation: Persons Designate School of Life Sciences		01/05/2018
Authorised By: University of Sussex, HTA Coordination Group - Chair	Not sought due to minimal changes	

Version	Date	Reason for Change
2.0		To reflect merger of BSMS and SoLS practices for UoS
3.0	04/08/2017	Changes to reflect update to DI
4.0	01/05/2018	We have changed the wording as what was originally promised or stated conflicted with best practice and other SOPs – mainly that all data will be deleted if someone withdraws consent. This is not possible if their samples have been used in published research. Furthermore, we need to retain at least basic

		information on the samples to retain traceability.
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1. Purpose

This standard operating procedure defines the process that must be followed when a sample donor wishes their sample to be removed from a research programme.

2. Introduction

Donors of banked tissue samples retain the right to withdraw their permission for the tissue samples to be used for research for as long as the tissue remains in the custody of the University of Sussex.

3.0 Procedures

This procedure shall be followed whenever a donor wishes to revoke their consent to the use of donated tissue for research. A donor may indicate that they wish to withdraw consent verbally or in writing, by telephone, face-to-face, in an e-mail, text or letter.

A target completion time for the withdrawal procedure has been set of seven working days after receipt of a signed request for withdrawal.

3.1 Face-to-face withdrawal

- If possible, any donor who wishes to withdraw consent is referred to the individual who obtained consent; it is essential, however, that the donor does not feel that there are any barriers to withdrawal.
- No attempt to change the donor’s mind shall be made if they have decided to withdraw.
- If the person who obtained consent is unavailable, it is acceptable for any trained and competent individual to discuss withdrawal with a donor.
- The donor shall be asked to sign a Consent Withdrawal form. This ensures that the person withdrawing consent is the same person who gave consent.
- The completed form shall be sent to the Person Designate (PD); a copy should also be given to the donor.

3.3 Remote withdrawal

- If withdrawal is requested by telephone, e-mail, letter or fax then “Acknowledgment of withdrawal of consent” letter shown on page 6 of this SOP must be sent to the donor, together with the “Withdrawal of consent form” shown on page 5 of this SOP. This form should be completed by donor and returned to the University of Sussex.
- At the point of request the donor must be told that their samples will be put into Quarantine until the form is received. Samples will be sent for destruction within 7 days of receipt of the form.
- The Person Designate should immediately be notified of the request to withdraw samples and should then ensure that samples are quarantined.
- If the completed form is not received within one month the PD shall destroy the samples as per SOP/HTA/12

- The copy of the consent form held in the donor's 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.

4. The withdrawal procedure

- Within one working day of receipt of the written withdrawal of consent the Person Designate should locate all of the donor's samples and/or their derivatives.
- Samples and derivatives shall be retrieved from storage and destroyed according to SOP/HTA/12.
- Researchers who have received samples from the donor shall be contacted and notified that consent has been withdrawn. They will be asked to destroy any remaining material (see form below on page 4).
- Although the sample will be classed as 'disposed of' on the tissue database, the information for the sample will remain due to the need for tractability in samples.
- The records to be deleted include all personal data as well as sample related data such as sample identifiers, processing data and inventory details. Note that system audit records are not destroyed, as the audit trail must be preserved.

Notification to researcher of donor withdrawal

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

Template - Withdrawal of consent form

This form is used to record your decision to withdraw your consent

I confirm that I have read and understand the letter explaining “Withdrawal of consent” (*insert date and version number*) and have had the opportunity to ask and answer questions. *Please initial*

Participant’s Statement:

Iwish to withdraw permission for my samples to be held or distributed by the University of Sussex. I want my samples to be destroyed so that they are not available for use.

Signed **Date**.....

Print name.....

Template - Letter or email to donor requesting to withdraw consent

Dear (donor),

Thank you for notifying (*insert individual*) that you wish to withdraw consent for your samples and data held at the University of Sussex, for use in research project (*insert project details*).

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 sign the attached withdrawal of consent form and send it back to us at the above address. Until we receive this form your samples will be held in quarantine, and during this period they will not be released for research.

As soon as we receive your signed form your samples will be removed from the Tissue Bank and destroyed and your data and information will be wiped from the research data base. If we do not receive the signed form your samples will be destroyed one month from date of this letter.

Some of your samples and data may have already been distributed to researchers and used in research. If this is the case it will not be possible to retrieve these samples, nor is it possible to withdraw the results of such research or prevent their publication. The University will contact researchers and ask for any unused samples to be destroyed so that they cannot be used in any further research.

Kind Regards