Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Withdrawal of Consent – Human Tissue**		
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	Name and Position	Signature	Date
Author:	Dr Paula Tighe Research Governance Manager	----------	----------
Reviewed by:	Human Tissue Steering Group	----------	----------
Approved by:	Professor James McElnay, Chair Human Tissue Steering Group	----------	----------

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Version 1.0	10 April 2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	Version 2.0

1. Purpose

This Standard Operating Procedure (SOP) describes the process to be followed if a research participant wishes to withdraw his or her consent for use of human tissue samples donated for research purposes, as defined by the Human Tissue Act 2004 (HT Act).

2. Introduction

The HT Act came into force on the 1 September 2006 and provides a framework for regulation of research involving the removal, storage, use and disposal of human tissue. In order to meet the requirements of the HT Act all relevant material used for research purposes must be stored with appropriate consent stored and entered on the Queen's Online (QOL) Tissue Register to ensure traceability. This SOP should be read in conjunction with the Human Tissue Authority (HTA) Code of Practice and Stnadards E Research and Code of Practice A Guiding Principles and the Fundamental Principle of Consent.

3. Scope

This SOP applies to all members of University staff; both academic and support staff, as defined by Statute 1 and includes honorary staff and students who are involved in the receipt, tracking and storage of relevant material in the areas under the HTA research licences at Queen's University Belfast.

Note: Human tissue samples collected as part of a clinical trial of an investigative medicinal product (CTIMP) or samples acquired and stored within the Northern Ireland Biobank (NIB) will have their own procedures and requirements and should not follow this SOP.

4. Responsibilities

4.1 Designated Individual

The Designated Individual (DI) is responsible for ensuring that appropriate procedures are in place for the withdrawal of consent**.**

4.2 Person Designated

The Person Designated (PD) is responsible for providing advice and guidance on procedures in their area as required.

4.3 Chief Investigator or Custodian

The Chief Investigator (CI) or custodian of the material is responsible for ensuring all procedures are followed regarding withdrawal of consent and that the participant is aware of withdrawal procedures as appropriate.

4.4 Researcher and Support Staff

The researcher and/or other support staff delegated the tasks in relation to withdrawal of consent must ensure those tasks are carried out in accordance with this SOP and that appropriate records are maintained.

5. Procedure

5.1 General - Consent

Consent is the fundamental principle of the HT Act. Appropriate consent must be in place for the removal, storage and use of human tissue for research purposes. Consent is also required for the storage of human tissue (including hair and nails) with the intention of analysing DNA. The Research Governance SOP Informed Consent for Research (QUB-ADRE-004) details the processes for obtaining informed consent.

There are exceptions to the consent requirements under the HT Act. Consent for research is not required if:

(i) The material is an 'existing holding' (ie collected prior to the 1st September 2006);
(ii) The material is imported;
(iii) The material is from a living person and the researcher is unable to identify the person and the specific research project is approved by a recognised Research Ethics Committee (REC) (ie ORECNI or the equivalent statutory ethics committee). A University REC is not considered to be a recognised REC.

It should be noted that although consent is not required for imported material, mechanisms must be in place to provide assurance that the tissue has been obtained with valid consent.

5.2 Withdrawal of Consent

Participants may choose to withdraw consent verbally or in writing.

When seeking consent, it must be made clear to the participants that they can withdraw their consent for the use of their donated samples and that a decision to withdraw will not affect their clinical care. Participants should be made aware of the practicalities of withdrawal of consent and that it may not be possible to withdraw consent for use of human tissue after a certain point, for example, if the samples have already been used and analysed.

It must also be made clear to participants that if they withdraw from a study, they have a choice regarding whether or not they wish to allow samples donated prior to the date of withdrawal to remain available for use in the research study or whether they wish all samples to be disposed of. The notes section of the Tissue Register must be updated to clearly specify if a participant has withdrawn from a study but has consented to the retention of any samples previously donated.

Where a participant withdraws consent for samples to be used for research purposes, the samples cannot be retained. All stored samples and their derivatives must be disposed of in accordance with the SOP Disposal of Human Tissue (QUB-HTA-002). The Tissue Register must be updated to reflect disposal and the reason why (ie participant withdrawal and disposal in accordance with the participant's wishes).

The participant consent form should be retained for audit purposes and clearly marked to indicate that the consent for use of tissue samples has been

withdrawn and signed and dated by the individual recording the withdrawal of consent.

5.3 Acknowledgement for Withdrawal of Consent

Where consent for retention of samples has been withdrawn, researchers should send an acknowledgment to the participant confirming sample disposal. A copy of this acknowledgement must be maintained in the study master file. An example letter is attached as Appendix 1.

6. References

Human Tissue Authority Code of –Practice and Standards E Research
https://www.hta.gov.uk/hta-codes-practice-and-standards
(last access April 2017)

Human Tissue Authority Code of Practice A Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/hta-codes-practice-and-standards (last access April 2017)

Human Tissue Authority definition of relevant material
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm (last accessed April 2017)

7. Appendices

Appendix 1 Letter to confirm donor withdrawal of consent and sample disposal

APPENDIX 1

Letter to confirm donor withdrawal of consent and sample disposal

Queen's University Belfast

Dear (*insert participant name*)

I am writing to inform you that we have acted as per your request to withdraw your consent of use of your tissue samples. All samples donated during the study titled '*insert study title*' have been removed and disposed in accordance with the Human Tissue Act procedures and the samples will not be used for research purposes.

This will not affect your care in any way, now or in the future.

Please do not hesitate to contact me if you have any further queries.

Yours sincerely,

Chief Investigator