

STANDARD OPERATING PROCEDURE NUMBER:		Newcastle University research sector HTA licence (Ref. 12534) Uteroplacental Tissue Bank UCS15.version 4	
NEWCASTLE BIOMEDICINE BIOBANKS			
TITLE	Management of Standard Operating Procedures in the Uteroplacental Tissue Bank (creation, retention, amendment and removal)		
AUTHOR	Julie Taggart HTA coordinator		
APPROVAL	Professor Michael Taggart, Person Designate		
EFFECTIVE DATE:	31.10.18	REVIEW DATE:	30.10.20

## Distribution

This SOP should be followed by all those obtaining, using and storing human tissue samples within the Uteroplacental Tissue Bank.

This document will be approved by Prof M J Taggart. It will be retained electronically in ntissue (\\campus\rdw\ICMr2\icmresearch) (V:). Printed copies will be available within each laboratory for immediate referral but it should be noted that this document is controlled and may be updated electronically. Researchers should always refer to the electronic version.

Any changes to this SOP will be notified to researchers at the bi-monthly HTA meeting of the Uteroplacental Tissue Bank group. Minutes of this meeting will be circulated and researchers are required to confirm receipt and reading of the information contained in the minutes.

## Change control

To request any changes to this document please contact Prof Michael Taggart, PD or Julie Taggart.

## Revision Category

<b>Category 1</b>	This is a new/revised document. All personnel required to follow content must read this version and complete training	
<b>Category 2</b>	This is a revised document in which only the area of applicability has changed. All newly impacted personnel required to follow content must read this version and complete training	
<b>Category 3</b>	This is a new/revised document. All personnel required to follow content must read this version	
<b>Category 4</b>	No significant change to document content – no requirement to read or train	✓

**Note:** As applicable, documentation of reading and/or training must be completed prior to performing the procedure.

## 1. BACKGROUND

The Human Tissue Act (HTA) is a legal framework which regulates the “removal, storage, use and disposal of human bodies, organs and tissues”. The Act came into effect on the 1<sup>st</sup> September 2006 and applies to England Wales and Northern Ireland. Newcastle University holds a Research Human Tissue Act licence (Ref. 12534) which licenses the storage of human tissue for research. The Uteroplacental Tissue Bank operates as part of the Newcastle Biomedicine Biobank under this research HTA licence..

Under the terms of The Human Tissue Act, it is essential that clear and unambiguous policies and procedures are in place covering all licensable activities, and that there is a systematic and planned approach to the management of records.

To meet governance and quality systems standards, it is therefore essential that:

- A document control system covering all documented policies and standard operating procedures (SOPs) exists
- There are documented procedures for the creation, amendment, retention and destruction of records
- There is a regular audit of record content to check for completeness, legibility and accuracy.
- Systems ensure data protection and confidentiality

This SOP provides information on management of SOPs within the Uteroplacental Tissue Bank. It describes the procedures that must be followed by all researchers who are using and storing tissues obtained within the Uteroplacental Tissue Bank.

## 2. SCOPE

This SOP applies to all individuals working with tissue stored or obtained under the Uteroplacental Tissue Bank Ethics approval (Newcastle and North Tyneside Research Ethics Committee 1 (Ref: 16/NE/0167)).

## 3. DEFINITIONS

<b>HTA</b>	Human Tissue Act
<b>NBB</b>	Newcastle Biomedicine Biobanks
<b>PD</b>	Person Designate
<b>QA</b>	Quality Assurance
<b>SOP</b>	Standard Operating Procedure

## 4. PROCEDURE

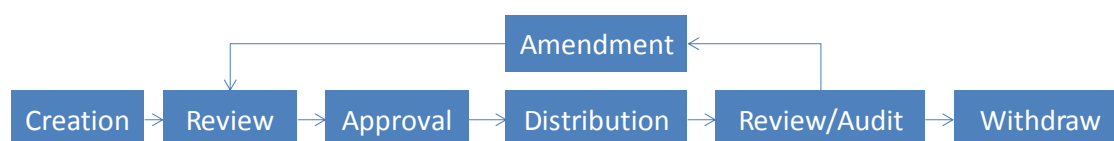
### Document Control System

All SOPs are controlled documents. They are stored electronically in ntissue (\\campus\rdw\ICMr2\icmresearch) (V:).

Printed copies will be available within each laboratory for immediate referral but it should be noted that this document is controlled and may be updated electronically. Researchers should always refer to the electronic version.

### Life-cycle of SOPs

These key steps are in place for managing SOPs within the Uteroplacental Tissue Bank.



### Creating a new SOP

If a new topic is identified that needs to be controlled by a formal Standard Operating Procedure, it should be considered whether a new SOP is required, or whether the topic can be incorporated into an existing SOP.

If the topic can be incorporated into an existing SOP, the author of the SOP should be approached to discuss the topic and amend the existing.

If a new SOP is required the NBB SOP template should be used to create all new SOPs. As SOPs are modified, they should be migrated onto the NBB SOP template when practical.

### Reviewing SOPs

A copy of the draft SOP should be sent to all individuals required to review the SOP. This must include the individuals named as approvers of the SOP.

The author of an SOP cannot approve an SOP that they have written; another person must review and approve the document. This person should be suitably qualified, and preferably in an equivalent or more senior role than the author (e.g. senior management, QA Manager, or suitably qualified member of staff).

Following the receipt of comments, the SOP should be updated where required. Where major changes have occurred, it should be considered if the revised document requires a further cycle of review. Once all changes have been agreed, the SOP must be taken for approval.

### Approval of SOPs

Once all approvers have accepted the draft document the document will be signed as approved. The effective date of the document will be added to SOPs and a revision date set to 2 years (minimum).

All SOPs within the Uteroplacental Tissue Bank will be approved by the Person Designate (PD) or nominated individual.

Signed wet-ink versions of SOPs will be retained in the PD's office in a locked cabinet. Scanned copies are available electronically as PDF files in ntissue (\\campus\rdw\ICMr2\icmresearch) (V:).

## **Distribution**

The availability of new approved SOPs will be notified to all users of the Uteroplacental Tissue Bank by e-mail and also in person at the bi-monthly HTA meeting of the Uteroplacental Tissue Bank group. Minutes of this meeting will be circulated and researchers are required to confirm receipt and reading of the information contained in the minutes.

Printed copies of SOPs will be available within each laboratory for immediate referral but researchers will be notified within the SOP file these documents are controlled and may be updated electronically. Researchers will be referred to the electronic version.

When an SOP is updated or reviewed, old printed copies will be removed from the laboratory files and replaced with updated versions. The electronic versions will be removed from the current SOP folder on ntissue (\\campus\rdw\ICMr2\icmresearch) (V:) and stored securely in a separate folder on the drive.

## **Audit/Review**

There will be regular audit of SOP content to check for completeness, legibility and accuracy. All SOPs will be audited every 2 years, at minimum.

Changes can be requested at any time by notifying the author and approver of the SOP. This can be done in writing, by e-mail or in person.

## **Amending SOPs**

Where changes are required the current version of the SOP will be reviewed and changed made. The changes made will be documented and described within the revised document. Any actions required by staff following the revision of the SOP will be detailed in the "revision category" on the cover page.

Once all changes have been incorporated, the SOP edition number will be updated to the next sequential number and the SOP submitted for review as described above.

### **4.2.7 Withdrawal of SOP**

If at any time a SOP is to be withdrawn this will be considered by the author and approver. All distributed copies of the SOP will be removed. Where new editions of the SOP are to be added, these will replace the withdrawn SOP.

Archived SOPs will be retained electronically on a secure computer. Original signed "wet-ink" SOPs will be retained in the PD's office in a locked cabinet for 7 years.

## 5. DOCUMENT REVISION HISTORY

Section affected	Description of changes	Reason for change
4	This revised document documents reference to the use of a new shared drive address	A new shared drive address was required due to Institutional changes
All	This revised document documents the change of PD to Professor Michael Taggart	Professor Michael Taggart became PD when the previous PD retired

## 6. APPENDICES

### See also

Newcastle Biomedicine Biobanks HTA-SOP-1  
Document Management – The creation, amendment, retention and destruction of records under the Newcastle University research sector HTA licence (Ref. 12534)

Central SOPs: Several generic SOPs are produced under the Newcastle University research sector HTA licence (Ref. 12534). These should be followed and read in conjunction with SOPs produced locally within the Uteroplacental Tissue Bank.

Information for the Newcastle University research sector HTA licence (Ref. 12534) is also available on the Newcastle Joint Research Office Website: <http://www.newcastlejro.org.uk/>