

<b>STANDARD OPERATING PROCEDURE NUMBER:</b>		Newcastle University research sector HTA licence (Ref. 12534) Uteroplacental Tissue Bank UCS16.version 4	
<b>HUMAN TISSUE ACT – RESEARCH SECTOR</b>			
<b>TITLE</b>	<b>Procedure for rejection of tissue received in the Uteroplacental Tissue Bank</b>		
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<b>APPROVAL</b>	Professor Michael Taggart, Person Designate		
<b>EFFECTIVE DATE:</b>	31.10.18	<b>REVIEW DATE:</b>	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 Professor Michael Taggart, PD. It will be retained electronically in the shared drive ([\\campus\rdw\ICMr2\icmresearch\ntissue](#)) (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.

The majority of samples that are received in the Uteroplacental Tissue Bank are of acceptable quality for receipt into the Tissue Bank. Rare samples are not of sufficient quality to be accepted into the Tissue Bank as they are deemed to be not useful for any applications currently in use by researchers or likely to be in use in the future.

This situation may occur if the sample is too small to be used or if there has been a delay in receiving the sample. In rare situations consent has been obtained for a sample which is not suitable to be accepted into the Tissue Bank eg if the patient is taking a hormone treatment that would affect the results of experiments.

This SOP details the action to be taken in the rare situations when samples are received that are not suitable for banking 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

## 4. PROCEDURE

Samples obtained with informed written consent are received in the department and booked in as per SOP UCS12. The sample must be given a Biobank number as detailed in SOP UCS12.

If a sample is considered too small for storage or a sample has been delayed in transport to the laboratory, a decision may be taken not to store the sample.

There are specific situations when myometrial samples may be unsuitable for storage within the Uteroplacental tissue Bank. These should be assessed as described below.

Each myometrial sample should be rinsed in tissue collection buffer (modified physiological salt solution) and placed in a glass dissecting dish for examination.

Samples should be observed under a light dissecting microscope and assessed as to the viability of the tissue, specifically in terms of the micro-architecture for micro-dissection of thin myometrial strips and intramuscular arteries.

Myometrial samples can be rejected for any of the following reasons:

1. The biopsy is of tissue type other than myometrial (endometrial and fibrous material)
2. Biopsy is too small (micro-dissection of viable tissue is not possible)
3. Biopsy is too bloody (tissue viability is compromised by proteolytic degradation)

Once a decision has been taken that the sample is not suitable for storage, it should be disposed of as detailed in SOP UCS03a and UCS03b.

Information that the sample has been rejected as unsuitable for inclusion in the Uteroplacental Tissue Bank should be recorded on the back of the sample collection sheet and then on the Achiever sample tracking system (SOP UCS18) and the reason for the rejection of the sample should be clearly stated.

## 5. DOCUMENT REVISION HISTORY

Section affected	Description of changes	Reason for change
All	This revised document updates the post of PD to Professor Michael Taggart	Professor Michael Taggart undertook the role of PD when the previous PD retired
4	Use of the new Achiever sample tracking system is documented	A new sample tracking system was implemented which is compulsory to use

## 6. APPENDICES

NBB-SOP-03 Adverse Event Reporting for Research Groups covered by the Newcastle University research sector HTA licence (Ref. 12534)

SOP 03a Disposal of Tissues and Fixatives (placental group)

SOP 03b Disposal of Tissues and Fixatives (myometrial group)

SOP 12 Receipt and coding of Uteroplacental tissue bank specimens

SOP 13 Use of UCS Tissue Bank database

