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| STANDARD OPERATING PROCEDURE NUMBER: | | Uteroplacental Tissue Bank UCS14.version 4 | |
| NEWCASTLE BIOMEDICINE BIOBANKS | | | |
| TITLE | Local Reporting of Adverse Events in the Newcastle Uteroplacental Tissue Bank | | |
| AUTHOR | Julie Taggart HTA Coordinator | | |
| APPROVAL | Professor Michael Taggart, Chair of Reproductive Sciences | | |
| 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 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 M Taggart, PD or Julie Taggart

Revision Category

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|-------------------|--|---|
| Category 1 | This is a new/revised document. All personnel required to follow content must read this version and complete training | |
| Category 2 | 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 | |
| Category 3 | This is a new/revised document. All personnel required to follow content must read this version | |
| Category 4 | 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 Uteroplacental Tissue Bank is part of the Newcastle Biomedicine Biobank (NBB) and houses a range of biological materials, including both relevant and non-relevant material under the Human Tissue Act 2004 (HTA).

As Newcastle University holds a Research HTA licence (Ref. 12534) it is a licensing requirement to have a system in place to ensure that all adverse events associated with the procurement, testing, processing, storage and distribution of human tissue and cells are investigated promptly and corrective and preventative actions taken where required (GQ8).

The purpose of this SOP is to inform local researchers within the Uteroplacental Tissue Bank of action to be taken in the event of any adverse incident. This SOP is intended to provide an initial framework for the managing and reporting of adverse events relating to the receipt and storage of human tissue.

The Person Designate or Tissue Bank Manager will then report the incident to the NBB or escalate as required.

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)).

Adverse incidents should initially be reported to:

Dr Paul Ayuk, Tissue Bank Manager
Prof M Taggart, Person Designate
Julie Taggart, HTA coordinator

3. DEFINITIONS

| | |
|---|---|
| Adverse Event (AE) | Any untoward occurrence associated with the procurement, testing, processing, storage and distribution of human tissue, cells or other human materials within the Uteroplacental Tissue Bank that leads to or has the potential to lead to: <ul style="list-style-type: none">• loss or damage of stored human tissue• harm to staff or visitors• a breach of security of the premises and the contents contained therein• a breach of the Human Tissue Act or the Code of Practice• the need for an internal inquiry |
| Adverse Event Report (AER) | The system used to report adverse events at the University |
| Corrective Action/ Preventative Action (CAPA) | Actions that are identified during the investigation into the adverse event that either act to: <ul style="list-style-type: none">• Correct the current issue through remedial action, or• Prevent the event occurring again |
| HTA | Human Tissue Act |

4. PROCEDURE

What is an Adverse Event?

There are many different possibilities that may give rise to an adverse event. Any adverse events should be quickly identified as all samples are collected by laboratory staff. Examples of adverse events that may occur within the Uteroplacental Tissue Bank are listed below.

| TYPE OF INCIDENT |
|---|
| Consent |
| <ul style="list-style-type: none"> Human tissue removed from patient without appropriate consent Human tissue stored without appropriate consent Human tissue used without appropriate consent Human tissue used for research project that has not been REC approved Staff member seeking consent is not appropriately trained |
| Governance and quality |
| <ul style="list-style-type: none"> Conduct of non-licensed activities Wrong version of SOP in use/failure of change control mechanisms Breach of data protection/confidentiality (e.g. sample bearing patient identifiers) Research material sent off site without a Material Transfer Agreement (MTA) |
| Sample taking |
| <ul style="list-style-type: none"> Wrong type of specimen Incorrectly labelled specimen Specimen from wrong patient Specimen in wrong format |
| Tracking |
| <ul style="list-style-type: none"> Labelling error No record of stored sample on tissue database Sample logged on tissue database but not in correct location Incomplete audit trail resulting in failure to trace sample Tissue database failure |
| Storage |
| <ul style="list-style-type: none"> Short term cold storage failure Alarm failure Cold storage failure and alarm failure resulting in material loss Any other event which compromises tissue integrity |
| Transportation |
| <ul style="list-style-type: none"> Sample lost in transport Sample integrity compromised in transport |
| Disposal |
| <ul style="list-style-type: none"> Failure to dispose of material appropriately Incorrect labelling of human tissue waste Failure to document reason for sample disposal |

All adverse events MUST be promptly reported so that prompt action can be taken. Research staff should always be aware of which samples are expected on a given day.

- If a sample is taken in error, this will quickly be picked up. The surgeon responsible, the person who obtained consent from that patient, the PI and the Tissue Bank Manager must be informed immediately so that further action and investigation of the incident can occur without delay.

- If a patient has been consented for a research sample but no sample is taken, this should be established with the operating theatre/delivery suite staff and noted on the request form as a clinical decision.
- Samples which are sent to the wrong location, eg the Cellular Pathology laboratories, need to be located and if practical should be retrieved promptly and used. If a sample cannot be used because of a delay in retrieving the sample, this must be reported as an Adverse Event. It is essential that if a sample is expected on a given day it should not be presumed that if the sample is missing then it has not been taken. The sample should always be traced or it should be established with certainty that the sample was not taken. Prompt retrieval of a sample that has been sent to the incorrect location may avoid an Adverse Event if the sample is retrieved sufficiently quickly to be useful.
- All Adverse Events must initially be reported to

Dr Paul Ayuk, Tissue Bank Manager
Professor Michael Taggart, Person Designate
Julie Taggart, HTA coordinator
- All members of the group will be informed of any Adverse Events at the Uteroplacental HTA meeting held every other month.

5. DOCUMENT REVISION HISTORY

| Section affected | Description of changes | Reason for change |
|------------------|---|---|
| 2 | This revised document updates the post of PD to Professor Michael Taggart | Tissue bank management changed |
| 4 | This revised document updates the post of PD to Professor Michael Taggart | Tissue bank management changed |
| Distribution | This documents the change in shared drive address | A new shared drive address was needed due to Institutional change |

6. APPENDICES

Refer to Newcastle Biomedicine Biobanks NBB-SOP-03
Adverse Event Reporting for Research Groups covered by the Newcastle University HTA licence (12534)