The Sheffield Biorepository

Biorepository Policy Document: Human Tissue Related Incidents in Research

Document History	
Document Number	*BIO:POL:27*
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Version	*1.2*
Date	*03/10/2017*
Review Date	*03/10/2018*
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1. Background

This procedure outlines the steps for dealing with incidents involving Human tissue when used in research, incidents involving Human Tissue and covers **ALL** incidents relating to human tissue samples classed as "relevant material", in accordance with the Human Tissue Authority, collected, stored or used for research.

2. Summary of Key Points

- This policy summaries the Trust's policy with regard to incidents relating to human tissue samples collected, used or stored for research.
- This policy applies to all tissue samples classed as Human Tissue Act "relevant material" collected stored or used for research purposes.
- Examples of tissue related incidents can include:
    i. Mislabelled samples
    ii. Equipment malfunction leading to damaged samples
    iii. Lost samples
- If a researcher is unsure whether a something should be classed as an "incident", the Designated Individual (DI) or the Biorepository Manager should be contacted for advice.
- It is the researcher's responsibility to report all tissue related incidents to the Biorepository Manager using the Incident Form
- The DI has ultimate responsibility to decide on the best course of action for any tissue related incident if a solution cannot be found.

3. INTRODUCTION

This policy has been produced in accordance with the requirements of The Human Tissue Act 2004 (HT Act) and the associated Codes of Practice issued by the Human Tissue Authority (HTA).

4. RESPONSIBILITIES

It is the responsibility of individual principal investigators to ensure that all research staff adhere to this SOP.

It is the responsibility of the Designated Individual (DI) for research involving human tissue and his/her Persons Designated to ensure that all relevant research complies with the HT Act and all local SOPs.
It is the responsibility of the Blood/Tissue Bank Coordinator to ensure that the necessary research staff are trained and aware of their responsibility to adhere to the procedures outlined.

It is the responsibility of all research personnel to read and follow the guidance given for incidents relating to human tissue samples in this SOP.

5. Relevant material

This SOP only applies to "relevant material" as mentioned in the Human Tissue Act and Human tissue Authority Codes of practice. This includes any material that contains cells, such as:

- Human bodies and tissue
- Skin and bone
- Bodily waste products
- Parts of blood containing cells
- Stem cells created inside the human body
- Embryonic stem cells
- Non blood derived stem cells
- Umbilical cord stem cells
- Bone marrow
- Primary human cell cultures

The following are not considered "relevant material" and are not subject to the stipulations set out in this SOP. They should comply with any relevant local SOPs relating to this material.

- Cultured cells which have divided outside the human body
- Artificially created embryonic stem cells
- Cell lines
- Extracted DNA
- Plasma extracted DNA
- Plasma and serum

6. Incidents

The following are all classed as "tissue incidents", which should be recorded and reported in accordance with this SOP

- Samples collected without consent (evidence of consent)
- Unlabelled samples
- Mislabelled samples
- Damaged samples (e.g. due to freezer malfunctions)
- Unidentifiable samples
- Lost samples

Any suspected incidents which have not been listed above should be discussed with the DI for research and/or the biorepsotory manager before a decision is made.

7. Reporting Incidents

Researcher's should report human tissue related incidents using the Incident Report (BIO:Form:05).

This form should be sent to the Biorepository manager once it has been completed by the researcher/ technicain.

8. Incident Resolution

The Biorepository Manager and the DI for research will decide on the best course of action for human tissue related incidents.

The DI has ultimate responsibility to decide on a course of action for a tissue related incident if a decision cannot be made.
Failure to comply with this SOP and the legislation detailed in the Human Tissue Act 2004 could result in disciplinary action.

9. Associated Documents

	Document	Document Reference
1	Incident report	BIO:Form:05
2	The Human Tissue Act 2004	www.opsi.gov.uk/acts/acts2004/20040030.htm)
3		