The Sheffield Biorepository

Standard Operating Procedure: Quarantine of Samples in the Biorepository

Document History	
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1. Background

This SOP describes the process for quarantining samples in the biorepository whilst full documentation of its history and consenting are established. It is only to be used a temporary measure and investigators will be given a deadline for completion of documentation. This SOP has been produced in accordance with the Human Tissue Act 2004 (HT Act) and the Codes of Practice issued by the Human Tissue Authority.

2. Acceptance Criteria

Before tissue is accepted into the Biorepository, the Sheffield Biorepository Management Committee must be satisfied that the samples have been collected in an ethically approved manner, that ethics approval is valid, that transfer into the biorepository is appropriate and that all relevant documentation relating to each sample is in place.

Relevant Documentation:

I. Copy of the original ethics application, and where applicable subsequent applications
II. REC approval letter(s) for which the samples were collected.
III. Patient Information Sheets
IV. Blank consent form

If some of the above information is missing then the samples will be placed in quarantine until all documentation is received. If documentation fails to be received within the time scales given then the investigators will be given notice for the destruction of samples in accordance with Biorepository policies

3. Procedure

1. The PI should make initial contact with the Biorepository Manager
2. The Biorepository Manager will carry out an assessment on receipt of the required documentation to ensure that the samples were collected in an appropriate manner using **Checklist.**
3. If documentation is missing the samples will be placed into quarantine until the required documents has been obtained. Discussions with the Research ethics committee may also need to take place to obtain clear guidance on the future use of the tissue.
4. The Biorepository Manager will give the investigator and defined date for which the required information must be return. This will normally be 1 month from the date of receipt.
5. Samples will be logged and placed in the holding freezer in EU17.
6. If required information is received then the samples will be dealt with as per BIO:SOP:29 transferring tissue into the Biorepository
7. 1 week prior to the notice period the biorepository will contact the investigator if information has not been received to remind of deadline.
8. Once the deadline has passed the biorepository will write to the investigator detailing that if information is not received within 7 days the samples will need to be destroyed in accordance with the Biorepository policy

8. Associated Documents

	Document	Document Reference
1	Sample transfer form	BIO:FORM:27
2	Sample Disposal form	BIO:FORM:06
3	Tissue storage & Distribution	BIO:SOP:04
4	HTA code of practice 9: Research	BIO:POLICY:7
5	HTA Code of Practice 1: Consent	BIO:POLICY:21
6	Transfer of samples into the Biorepository	BIO:SOP:29
7		