The Sheffield Biorepository

Standard Operating Procedure: Transfer of Existing Collections into the Biorepository and Tissue Quarantining

Document History	
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The University Of Sheffield.

1. Background

This SOP describes the process of:
1) Transferring existing collections of human biological samples into the Sheffield Biorepository.
2) Quarantining human tissue samples in the Biorepository as a temporary measure, until the legitimacy of storage for future use is demonstrated.

This SOP has been produced in accordance with the Human Tissue Act 2004 and the Codes of Practice issued by the Human Tissue Authority. This SOP covers tissue collected both before and since 1st September 2006, when the Human Tissue Act 2004 came into legislation.
Human tissue that is part of an existing holding must be held under one of the following two criteria:

1. For use in a currently active NHS REC approved specific research study.
2. In a HTA Licensed Tissue Bank i.e. the Sheffield Biorepository.

If an NHS REC approved study has finished or the REC approval has lapsed, then any residual tissue collected as part of this study becomes licensable under the Human Tissue Act and must be moved to one of the licensed areas within STH and the University of Sheffield. The Sheffield Biorepository rooms are the only licensed areas in STH and the University of Sheffield for the storage of human tissue samples used for research.

2. Acceptance Criteria

2.1 In order for tissue samples to be accepted into the Biorepository, the Sheffield Biorepository Management Committee must be satisfied that:

1. The samples have been collected in an ethically approved manner.
2. REC approval does not preclude storage of samples for future unspecified research.
3. Donor consent did not preclude use of samples in future unspecified research
4. Documentation demonstrating REC approval and consent for each sample is available for review.

2.2 If the documentation provided with the samples **does not clearly demonstrate** that the tissue can be stored for future use in unspecified research then the tissue will be quarantined, prior to applying for approval from an NHS Research Ethics Committee to store the tissue for research purposes.

Relevant Documentation:
Checklist A: Documentation for tissue collected **without** consent:

I. Copy of the original REC application or study protocol with any subsequent revisions/amendments
II. Copies of the REC approval letter(s) covering the project for which the samples were collected.

Checklist B: Documentation for tissue collected **with** consent:

I. Copy of the original REC application or study protocol with any subsequent revisions/amendments.
II. Copies of the REC approval letter(s) covering the project for which the samples were collected.
III. Copy of the Patient Information Sheet(s).
IV. Copy of the Consent Form(s).
V. Signed and dated statement from PI that each tissue sample has signed consent forms associated with it.

2.3 If the Principal Investigator (PI) is **already in the process of applying for renewal** of a previous ethically approved study which has lapsed, a copy of the documents in Checklist C should be submitted to the Biorepository for review.

Checklist C: Documentation for a new REC application

I. NHS REC Form (Generated from IRAS)
II. Protocol
III. Participant Information Sheet
IV. Consent form
V. Letter from REC confirming that the application is valid

3. Procedure

3.1 The Principal Investigator provides the Biorepository Manager or Deputy with the required documentation using Checklist A or B. or see 2.2

3.2 The Biorepository Manager or Deputy will log the samples on to the Biorepository Database and temporarily store them in room E150 of the Royal Hallamshire Hospital or in room 50 of the Biorepository NGH.

3.3 The Biorepository Manager or Deputy will carry out an assessment of the tissue and documentation to ensure that the tissue samples were:

i. collected and retained in an appropriate manner
ii. that there is nothing in the consent / collection provisions that precludes the tissue from future storage or use.

The assessment will be based on Checklist A or B, and a response emailed within 10 working days, cc Biorepository Director and nana.theodorou@sth.nhs.uk in the STH Research Department.

3.4 **If the required documentation as per the checklists above is in place** the Biorepository Manager or Deputy will transfer the sample to the Biorepository.

3.4.1 The PI will submit details of the samples using the Sample Transfer Form (BIO: FORM: 27) including details on the date sample was collected, user sample id, donor date of birth, donor sex, sample type and quantity; REC approval, PIS, and consent. No patient indentifying information should be provided to the Biorepository.

3.4.2 Upon receipt of the sample, the Biorepository Manager, or Deputy will

i. cross check the labelled sample with the sample transfer form,.
ii. allocate a Biorepository reference number to each tissue sample
iii. add the information on each sample to the biorepository database.
iv. file paper work relating to the tissue samples in secure filing cabinets in the sample processing room of the Biorespository.
v. store the sample in the appropriate holding location or storage location proper.

3.5 **If any required documentation as per the checklist A or B is missing**, (see section 2.2) or the legitimacy of storage for future use is in doubt, the tissue samples will be placed into quarantine in the Sheffield Biorepository until the required documents have been submitted to the Biorepository Manager or Deputy.

3.5.1 The Biorepository Manager or Deputy will email this SOP to the Principal Investigator.

3.5.2 The Biorepository Manager or Deputy will give the Principal Investigator a defined date, 6 weeks from the start of quarantine, by which time:

i. The Principal Investigator will have submitted to the Biorepository any missing documentation for scrutiny by the Biorepository Manager or Deputy allowing the tissue to be moved into the Biorepository proper.

or

ii. The Principal Investigator will have submitted to the Biorepository a letter stating that a valid application has been received by an NHS REC to establish the legitimacy of storage or use of the tissue samples. This letter will also be submitted to Jemima.Clarke@sth.nhs.uk STH Research Department.

3.5.2 If the Principal Investigator provides the Biorepository Manager or Deputy the required missing documentation, and satisfies that:

i. the tissue was collected and retained in an appropriate manner
ii. that there is nothing in the consent / collection provisions that precludes the tissue from future storage or use.
iii. the samples will be transferred into the Biorepository in accordance with step 3.4 of this SOP

3.5.4 If the Principal Investigator provides the Biorepository Manager or Deputy and Jemima.Clarke@sth.nhs.uk STH R&D with a letter from a REC stating that a valid application has been received to establish the legitimacy of storage or use of the tissue, then:

i. If the REC gives approval for continued storage or use of the tissue samples; the tissue will be transferred into the Biorepository in accordance with step 3.4 of this SOP.
ii. If the REC rejects the continued storage or use of the tissue; the tissue will be destroyed in accordance with SOP BIO:FORM:06

3.5.5 If the Principal Investigator **does not** provide missing documentation or evidence of a valid REC application by the date agreed in step 3.5.2 of this SOP, the tissue will be destroyed in accordance with SOP BIO:FORM:06.

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