



Standard Operating Procedure: Tissue Storage & Distribution

Document History

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<i>Created By</i>	<i>Kevin Corke</i>
<i>SUPERSEDED</i>	<i>Steven Haynes</i>
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<i>Approved by</i>	<i>Franco di Giovine</i>



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1. Background

This is an SOP for the UOS & Trust users of the Biorepository to store tissue in a licensed tissue bank and to distribute tissue for use in ethically approved research. This SOP is written in accordance with the Human Tissue Act 2004 and the Codes of Practice of the Human Tissue Authority.

2. Procedure

- The researcher contacts the Biorepository manager regarding the storage of tissue samples in the Biorepository.
- The Biorepository Manager informs the researcher that they must complete a data sheet (Appendix No 1) on the nature of the tissue samples to be transferred into the Biorepository.

Next the researcher should obtain a copy of the latest 'Project Costing Form', either downloaded from the Sheffield Biorepository website or by requesting one directly from a member of biorepository staff. Once submitted the full storage costs will be confirmed by the Biorepository manager, and any necessary adjustments made by mutual agreement. The researcher must ensure funding will be in place to meet these costs at an agreed future date.

- The Biorepository manager enters the information from the data sheets entered onto the Biorepository database CloudLIMS, which is a secure online LIMS system. Access to the database is restricted to authorised personnel.
- The Biorepository manager will enter all information provided on a tissue sample by a researcher to the Biorepository database. This will include details of the nature of the tissue sample, quantity and its location in the Biorepository. This information will be updated as required, for example in the event of the tissue being removed from the Biorepository. Removal and disposal of tissue samples must be recorded appropriately on either a dispensation form or disposal form.
- If someone requests tissue from the Biorepository which was collected surplus to diagnostic requirements, for further diagnostic purposes the tissue is to be sent to the person requesting the tissue as soon as is practically possible as long as they can prove they are dealing with the patient diagnosis. The database must be amended to show that this has occurred and the new amount of

tissue (If any is left) to be entered on the database. A sample disposal form should be completed.

- An internal material transfer agreement will be completed and signed by the Biorepository manager for all material dispensed from the Biorepository. For tissue transferred to another institution an appropriate MTA (STH or University) will be completed.
- In the event of tissue being requested by a trial which has been collecting tissue solely for their own purpose (e.g. UKCCSG) the tissue can be supplied as soon as is practically possible and the database records adjusted to reflect this event. The datasheet and the database will both have a note for these samples that the tissue is to be for the sole use of that trial and should not be distributed to any other researcher. A record of their project details including REC approval, appropriate consent as well as R&D approval will already have been obtained when the collection was agreed.
- If a researcher requests tissue from the Biorepository for a new study then they must complete the appropriate dispensation form and supply details of the type of tissue sample they require to the Director of the Biorepository, BRU or Brain Bank as appropriate and these details must be accompanied by details of Research Ethics Committee (REC) approval, appropriate consent and R&D approval, if applicable, for the study and details of the study protocol. The final decision as to whether the requested tissue may be released lies with the appropriate tissue bank Director. REC approval does not automatically mean the tissue will be released to a researcher.
- Once permission to have a tissue sample has been granted, the Biorepository database will be queried to locate any suitable tissue sample. Unless there has been a specific consent sought from a REC to provide additional details relating to a tissue sample, then the tissue will be supplied to the researcher with just the bank number and no further detail. In this way the tissue remains anonymous to the researcher but can be traced by authorised personnel should the need arise.
- Tissue dispensed from the Histopathology bank will always be dispensed anonymously as per the terms of its collection.
- Sample dispensation will be recorded on CloudLIMS and a follow up date entered.

- At the time of follow up the Biorepository will contact the investigator and request that any tissue supplied that has not been exhausted either be returned to Biorepository or disposed of appropriately by the researcher. The project proposal should include a plan for this with proposed starting and end dates.
- If any tissue sample is exhausted then this is recorded on the database by the Biorepository manager and neither the reference number nor the location is reused for another sample.

8. Associated Documents

	Document	Document Reference
1	Sample Disposal form	BIO:FORM:06
2	Dispensation form	BIO:FORM:07
3	SOP dispensation form	BIO:SOP:09
4	Internal material transfer agreement	BIO:FORM:11
5	MTA	BIO:FORM:12
6	Transfer of existing samples into the Biorepository & quarantine	BIO:SOP:29
7	Sample flowchart: Collection	
8	Sample flowchart: Dispensation	