Biobank SOP

Depositing samples in the biobank.

Samples are processed for storage only from patients with informed and signed consent of either the patients, or their legal guardian in cases where an individual is considered unable to give consent. In addition, a referral form signed by the referring clinician should accompany each sample and include at least the minimum shared data set including patient's or donor's personal details such as name, date of birth, gender, phenotype, ambulant status, presence of consanguinity, genetic results and confirmed or suspected diagnosis. It is essential to declare if the sample is deemed 'high risk' due to infection by blood-borne viruses or prions. The biobank cannot accept and process 'high risk' samples.

Researchers who wish to prospectively collect and bank a large volume of samples as part of their project should discuss this in advance with the biobank coordinator since additional resources are required to process and bank large volume requests which must be costed for upfront in the grant application.

Unless otherwise agreed with the biobank coordinator, surplus samples deposited in the biobank for a particular research study, can also be made available to other research studies (providing they have met the requirements of the study).

Accessing samples from the biobank.

Collected samples with a confirmed diagnosis are available to users via EuroBioBank catalogue (http://www.eurobiobank.org/sample-catalogue/). The catalogue lists the samples available by type of biomaterial and can be filtered by disease or by bank contact. Once a sample has been located in the catalogue, it can be requested from the MRC CNMD Biobank London.

Access to the samples is available to research groups based in the UK and elsewhere around the world, and is on a cost-recovery basis. The biobank does not benefit financially from supplying samples to researchers, but does make a charge per sample to recoup the costs of collecting, processing and storing the samples (this will also include a contribution towards the salary of the biobank coordinator).

Applicants should be employees of a recognised academic, research or clinical institution; or employed or contracted by a commercial organisation working towards developing diagnosis and treatment for neuromuscular or other rare disorders. Samples can also be accessible to scientists who are interested in basic science research i.e. in research of muscle structure and function. Researchers who wish to access the collection should initially contact the biobank coordinator directly.

Once verified that the required materials are available the following documentation is required:

1. A copy of the ethical approval for the project, in English

2. A copy of the protocol, in English
3. The completed sample request form. (An “Application for use of samples for research” form provided by the biobank should be completed by applicants, giving a brief outline of the proposed study and for what purpose the samples will be used, followed by the number and type of samples required)

(N.B. Ethical approval is required for human cells, as well as tissues, to be provided by the biobank).

Two members of the 3-member Access Committee will assess the suitability of the application.
They will consider the following:
Consent is in place
Ethical Approval
Sufficient cells or tissue is available
The samples are available for general use (i.e. are not being stored in the biobank for use of a designated project).

The biobank coordinator or relevant biobank member of staff will respond to the applicant. Upon approval of the application form, the applicant will be required to complete an MTA form and agree to the conditions of access set out in the MTA and return a signed e-copy to the Intellectual Property and Legal Services Department at UCL. Samples supplied to the applicant from the biobank collection are only allowed be used for the purposes stated in the application form that were accepted by the Access Committee and described in the MTA.

Timeframes

The Biobank Review Committee aims to provide a decision within **1 month** of receiving a full application.

The Biobank aims to release requested samples within **6 weeks** of receipt of full documentation. This is subject to the full authorisation of the MTA which may delay shipment.

The prospective approval expires **one year** after the request was approved by the Biobank Review Committee OR when the maximum number of samples approved in the request have been released, whichever is soonest.

Disposal of samples

All unused relevant materials must be returned to the Biobank on completion of the project or expiry of ethics (whichever the sooner). Material not considered relevant for the purposes of the Human Tissue Act should be disposed for incineration.

Sample distribution

Samples may be transferred to collaborators or for outsourcing of lab work only by permission of the Biobank. A MTA or Service Level Agreement must be established prior to transfer of samples.

When applying locally for studies that will require either use of biobank samples, or storage of your samples in the biobank.

Send the biobank the following details:

1. Project title
2. Name of PI
3. Start and end dates of your project

a) Use of biobank samples.

- Contact the biobank at an early stage in the planning of your project - ensure that the cells or tissues that you require are available.
- Cost for shipping of samples.

b) Storage of samples in the biobank.

Contact the biobank at the planning stage of your project with the details above and also:

4. How long you will require your samples to be stored in the biobank
5. What types of sample will you need to be stored: types of cell (fibroblast, myoblast etc.) blood, serum, plasma, DNA, RNA
6. How many patients will be collected a week
7. How many and what samples will be collected from each patient
8. What is the total number of samples that need to be stored
9. How long it will take to process each sample
10. Will you require the samples to be processed by the biobank or will you be processing them yourself*?

* **Remember, samples will incur a technical charge for collecting, processing and storage and you must cost for this upfront in your grant application. Potential applicants must discuss and agree with the biobank any additional things they may have to cost for – fridges, freezers, nitrogen, consumables, shipping costs, a proportion of the biobank coordinator's costs, etc.**

11. What kind of storage do you require – liquid nitrogen, -80, -20, 4°C?
12. What volume of storage space in each area will you require (you will need to contribute to the costs of a fridge/freezer, nitrogen etc. – to be included in your grant application).
13. What reagents/equipment will be required for storage of these materials? e.g. DNA extraction kits, tips, Blood collection tubes (you will need to cost for these in your grant application).

Also remember:

- Obtain ethical approval for your project in advance
- You may need to arrange to collect and bring samples to the biobank yourself (cost for staff, transport costs etc. on your grant application).
- Only deposit samples on the dates and times previously agreed with the biobank.
- The biobank may not be able to fully process your samples (e.g. prepare RNA, DNA from cells/tissues). This will be by agreement only and if it has been costed for.

- You must put in a new request on each occasion that you request tissue (even if it is for more of the same sample).