BRISTOL BIORESOURCE LABORATORIES CONDITIONS OF SERVICE: PROCESSING AND/OR BIOBANKING OF SAMPLES

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Contents

Introduction

This document sets out the requirements of the Bristol Bioresource Laboratories (BBL) when using the facility to process and/or store biological samples for cohort studies. As individual studies may have specific requirements not within the scope of this document it is important that you contact BBL as soon as possible to discuss the service you need.

Initial evaluation

In order for BBL to assess whether they are able to provide a service for your study and to give you accurate costings one of the documents below MUST be completed online

1) Processing and Biobanking of Sample Collections, accessed here

or

2) Biobanking of Sample Collections, accessed here

Biological risk assessment

A biological samples risk assessment form will need to be completed for all samples to be sent to BBL for either processing and/or biobanking, accessed here. This is required to assess the potential risk with respect to associated infectious agents for the sample type, also taking into consideration the participant group. Samples will not be received by BBL without the information to assess this risk.

BBL will not process or store samples that have been collected from individuals thought to be at a high risk of an infectious agent. These include, but are not limited to, Hepatitis B, Hepatitis C, HIV or MRSA. If samples are from a high-risk group BBL *may* be able to receive samples if the infectious agent has already been neutralised, or processed in a way that reduces the risk. If your study is collecting samples from a high-risk group please discuss with BBL as soon as possible. Please note that the circulating levels of a particular infectious agent at the time of sample collection could affect whether the sample type and/or participant group is classified as a high risk.

A new risk assessment may need to be submitted and approved by the University of Bristol's Biological and Genetic Modification Safety Committee before samples can be accepted.

BBL will not store cell lines that are contaminated with mycoplasma.

Please see 'Data manifests' section for additional information that is required before BBL will receive samples that have been processed/stored externally to BBL.

Research Governance

To ensure that your study has the correct ethical approval and consent in place to specifically process and/or biobank biological samples the BBL MUST be provided with the following documentation

1. a copy of the participant information sheet (PIS)
2. a copy of the consent form
3. a copy of the ethical approval
4. a copy of the study protocol which must include details of the consent process and how consent for samples collected will be/is verified

If your study has yet to go through ethical approval it is advisable that the BBL reviews the PIS and consent form. This will identify if any changes need to be made so that samples have the correct approval to be processed and stored. If the PIS and consent form have gone through ethics and do not contain the necessary information then an ethics amendment will have to be made before the BBL will receive any samples.

BBL will not process or store existing samples if the correct consent has not been obtained.

Contract

A contract or material transfer agreement (MTA) will need to be set up between the study and the BBL. Completion of contract/MTA must be factored into project timescales. Samples will not be accepted until all contractual agreements and finance arrangements are in place.

Consent

It is the responsibility of the study to ensure that consent is in place for all samples sent to BBL. The responsibility for confirming consent will be included in the contract with BBL.

Samples delivered directly to BBL once collected

The process for checking consents must be confirmed with BBL before any samples can be received. A report will be sent by BBL, at a frequency agreed with the study, containing a list of participants IDs and the associated samples which have been received. BBL will require evidence that consent for the processing and storage of all samples has been audited and verified by the study. BBL cannot hold samples that do not have the appropriate consent therefore samples without this will be destroyed.

For studies where samples will be delivered straight to BBL but not processed immediately a report will be sent by BBL with a list of participants IDs and their associated samples to the study. Consent for the processing and storage of all samples MUST be verified by the study. Samples that do not have the correct consent will not be processed and will be destroyed.

It is the responsibility of the study to check whether the samples which have been collected correspond to the samples BBL have received (i.e. if samples have been lost in transit).

Samples to be biobanked that have been processed elsewhere

For studies where samples have been processed in another laboratory and the BBL will be biobanking the samples documentation MUST be provided confirming all samples were collected with the appropriate consent. The BBL will not receive any samples without this document.

Please note that individual level consent forms for samples covered by the Human Tissue Act may be requested by the Human Tissue Authority. Therefore, studies must have a mechanism in place for providing these to BBL.

Sample and box/racking labelling

For studies where samples will be processed and/or biobanked by the BBL the following conditions for labelling must be adhered to

- All labels must be resilient to long term cold storage
- All information must be printed on labels able to withstand freezing, using ink that is not water soluble
- All samples must be barcoded
- Labels must not contain any personal identifiable data

Samples may be destroyed if the above is not followed and they cannot be identified. If you have historical samples that do not have barcoded labels please contact us to discuss.

Barcoding

Barcodes must be one- or two-dimensional and contain a unique identifier for the sample. This should be the sample ID, unless specifically agreed beforehand with BBL.

Data manifests

For studies requiring a biobanking service or processing service where samples have initially been stored externally data manifests containing information on how the samples are stored and the date

samples were collected must be received by the BBL before samples can be accepted. The minimum information required by BBL for each sample is

- sample ID
    - To be labelled as 'sample_id'
    - This is the sample identifier and must be a unique value within the study
    - This should be the value of the scannable barcode on the sample
- box ID
    - To be labelled as 'box_id'
    - This is the box identifier and must be unique
- well
    - This is the location of the sample in a box (e.g. 'A01').
    - This should be capitalised with placeholder zeros (e.g. the '0' in 'A01')
    - There must be a row/column indexing system (e.g. left-to-right, front-to-back)
- date
    - This is the date the sample was collected
    - To be formatted in separate columns as
        - 'day_taken' (2 digit number e.g. 01)
        - 'month_taken' (2 digit number e.g. 01)
        - 'year_taken' (4 digit number e.g. 2001)

    Samples without date information may not be accepted by BBL. It is important that BBL hold the date samples were taken for analytical and health and safety reasons. Please contact BBL if there could be any issues with providing this information.

Further information may be required, and this will be agreed upon on a case by case basis.

Data formatting

All fields must be provided with a field name in a practical machine readable format

- all lowercase
- no non-alphanumeric characters other than _ (underscore)
- e.g. date_received_consent

Additional metadata can be included in the manifest but must adhere to the requested format. No more than 10 metadata fields will be accepted.

Data files

- Data should be provided in .csv format, with the field names as a header row
- Each box for biobanking must have a separate manifest. The filename should be the 'box_id' (see key fields above)
- Alternatively, data can be provided as a single file, with the addition of a 'box_id' column
- Manifests must be sent via email as AES256 encrypted zip files, with a password exchanged via telephone or an alternative email address. Please contact BBL if there will be difficulties in doing this.

Manifest receipt

- Shipping dates will only be agreed upon once all sample manifests have been received and approved
- Samples will not be accepted until all sample manifests have been received and approved
- If data cannot be provided in the above requested format please contact the BBL to discuss

BBL will confirm receipt of manifests and if they meet the specification requirements.

Timeframe

At least 2 months before the proposed sample receipt date the BBL MUST have information on all samples to be processed and/or biobanked including any associated data to be stored. Depending on the study additional time may be required to set up the necessary systems.

Reporting

Transfer of data from the BBL to the study and any reporting requirements must be agreed at least 1 month in advance of BBL receiving any samples.

Sample selection

If a study requires biobanked samples to be selected for analysis the following criteria must be met

- Completion of the BBL sample selection form
- Confirmation that the appropriate consent and ethical approval is in place for the planned analysis
- Confirmation that the analysis and release of samples has been approved by the study
- Sample selection manifest received in the correct format (as discussed above)
- Study ensures an MTA is in place between the study institute and the sample recipient institute and provides a copy to BBL

The picking and shipping of samples by BBL will incur a cost which will be dependent on sample number, sample type, the destination of samples and whether any specific preparation is required. A date for shipping will be agreed once the BBL has all the required information. Samples will not be shipped until all invoices have been paid and a copy of the appropriate MTA has been received.

General

As each study has different requirements it is essential that the BBL is notified of any changes to the study which will affect the service that the BBL provides. The BBL will not be held accountable for any delays if they have not received all the necessary information and if the conditions set out in this document have not been met. Where additional work has had to be undertaken by BBL as the conditions of service were not met, further costs may be incurred.

Please note that the BBL is not a clinical service and is unable to provide advice on clinical matters or how to feedback to participants concerning lab activities.

Please email any queries to ‘BBL-info@bristol.ac.uk’