

## **ACCESS POLICY**

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## 1. Introduction

The Northern Ireland Biobank operates under the guiding principles applicable to the management and operation of a human biosample resource/bank in the ethical and legal framework of the UK from 2006 onwards. These guiding principles underpin the National Cancer Research Institute's (NCRI) Confederation of Cancer Biobanks (CCB). These guiding principles can be viewed at [www.ncri.org.uk.ccb](http://www.ncri.org.uk.ccb)

## 2. Access

### a. Types of sample

The following samples may be collected from each prospectively consented patient:

1. Frozen normal<sup>1</sup>
2. Frozen tumour
3. FFPE fixed normal<sup>2</sup>
4. FFPE fixed tumour
5. Blood<sup>3</sup>
6. Urine
7. Saliva

1. Frozen samples can be distributed as frozen sections or as aliquots of extracted DNA or RNA
2. Fixed samples will be issued as paraffin sections or as aliquots of DNA or RNA
3. Blood samples will be available as 1ml whole blood, serum, buffy coat and/or plasma aliquots.

Applications for fresh tissue samples for in vitro cell culture projects are also encouraged and will be assessed on a project by project basis dependent on project logistics and Biobank resources.

The Northern Ireland Biobank can also access formalin-fixed, paraffin-embedded tissue blocks from the Tissue Pathology archive within the Belfast Health & Social Care Trust (BHSCT). For access to this type of sample researchers must identify the specific set of blocks required for the project<sup>1</sup>. The NIB will then administer the collection and distribution of paraffin sections or aliquots of DNA or RNA from the samples.

1. Researcher must collaborate with an appropriate Consultant Histopathologist from the BHSCT to identify the sample cohort required for the study.

### b. Who can access samples?

Researchers accessing samples from the NIB will be classified in one of 3 groups

- a) NI-based researchers, from academia and healthcare
- b) Researchers external to NI, from academia and healthcare
- c) Commercial

All requests for samples must first submit a preliminary application form with details of the number and type of samples required. Following an NIB internal review of the preliminary application and, upon request, the researcher will be asked to complete a full application and submit it with a detailed scientific protocol. Where there is

competition for the same set of samples the NIB will work to ensure the most efficient use of samples.

### **c. Charges**

The NIB will make a charge per prospective sample to cover costs over and above those incurred by standard processing, storage and distribution. The NIB also seeks to facilitate the recovery of costs for any work carried out on the samples by the Northern Ireland Molecular Pathology Laboratory (NI-MPL).

Researchers who wish to access samples from the BHSCT pathology archive must also meet costs associated with retrieval of tissue blocks from storage.

### **d. Tissue Microarrays (TMAs)**

The NIB can provide tissue sections from TMAs which have been constructed and are held within NIB.

In collaboration with the NI-MPL in QUB, the NIB can also construct new TMAs on a project-per-project basis. There will be a flat hourly rate for the construction of the TMAs the costs of which must be met by the research project.

**NB** All TMA blocks constructed through the NI-MPL/NIB will remain in the Biobank as a resource for future applicants. Sections will be released for individual projects rather than whole TMA blocks. The original project, for which the TMA was constructed, will take precedence until the project has been completed.

### **e. Data**

Anonymised clinical and pathological information required with samples must be described on the preliminary application form. When requesting samples from the BHSCT Tissue Pathology Archive, researchers must have an appropriate clinician or pathologist as a named co-investigator who has permission to access the required clinical and pathological information.

## **3. Process of Application for Samples**

All researchers (academic or commercial) wishing to access samples from the NIB must first complete a preliminary application form which is available from the NIB website or via the NIB Administrator ([nibiobank@qub.ac.uk](mailto:nibiobank@qub.ac.uk)). Researchers must comply with the Terms and Conditions as listed in the preliminary application form. In doing this, researchers will be agreeing to acknowledge the NIB on any publications or conference proceedings arising from the use of the samples and will provide NIB with copies of any such publication.

The application process may be preceded by e-mail or discussions with the NIB Administrator, Scientific Director or Deputy Scientific Director to ascertain the feasibility of the proposal. The main purpose of the preliminary application is to determine the following:

- The request for tissue samples is hypothesis-driven and describes a finite set of experiments with specific goals
- All named co-investigators have confirmed their participation in the study
- The required sample set is available within a realistic time-frame.
- There is evidence of sufficient funding to carry out the research for which the tissue or fluid samples are requested.

Based on the preliminary application the NIB Scientific Director or Deputy Scientific Director will decide if the project can proceed to submission of a full application. Completed full application forms must be accompanied by a comprehensive scientific protocol. The NIB Administrator will invite the researcher to complete a form for electronic submission. Completed forms must be returned to the NIB Administrator. If the specific tissue based work contained within the NIB application has already been subject to peer-review by recognised external fund providers the NIB may decide to approve the project without the need for external peer review.

#### **a. Ethics Approval and Consent**

The NIB has generic and enduring ethics approval which enables researchers to use samples from the NIB as long as the research falls within the remit of the NIB ethics approval. The ethics covers a wide variety of research areas and tests. However, the use of human tissue samples in animal models is not permitted under current NIB ethics.

Where the NIB is being approached to facilitate a research project or clinical trial which already has separate ethics approval, this should be clearly stated in the biobank application form and a copy of the original ethics application should be submitted as a supporting document where appropriate.

NB Prospectively collected NIB samples are only eligible for use in cancer-related research projects. Applications for non-cancer research projects will not be accepted.

#### **b. Withdrawal of Consent**

Unless patients have been specifically consented for cell culture based experimental procedures, prospectively collected patient samples will not be made available to researchers until 4 months after collection. Patients are made aware, at the time of consent that, if they withdraw consent after this four-month period, their samples may have already been released to researchers. If consent is withdrawn the NIB will dispose of any remaining tissue samples and inform the patient according to standard operating procedures.

#### **c. Receipt of Applications**

The researcher will be sent an email to acknowledge receipt of their preliminary application form. The application will be assigned a unique reference number. For those applications without peer-reviewed funding in place, expert scientific opinion of their proposal will be made within 30 working days.

## 4. Reviewing Applications

### a. Who will review Applications?

Applications for use of samples will be reviewed by 2 reviewers selected from the NIB Scientific Review Committee which comprises Consultant Histopathologists, Clinicians, Surgeons and Basic Scientists.

Reviewers will complete a scientific review form which considers distinct aspects of the proposal:

- Novelty
- Significance
- Study Design
- Research team and facilities
- Value for money

The reviewer will be asked to recommend the project as:

- Appropriate and should be supported in full
- Requires minor amendments
- Resubmission by the researcher will be subject to Chairman's action by the Scientific Director and does not require further peer review
- Is inappropriate and should not proceed.

Based on the recommendations of the reviewers and any other project logistics and operational issues, the NIB Scientific Director will either approve or reject the application. In the event of conflicting reviewers' recommendations, the opinion of a third referee will be sought.

The applicant will receive an e-mail informing them of the decision. If the proposal has not been approved, clear reasons will be given.

If the application is approved the applicant will receive an e-mail informing them of the approval accompanied by an Invoicing Request Form and the relevant Material Transfer Agreement for completion. These must be completed and the MTA signed before release of samples.

### b. Appeals

Appeals for rejected projects will be considered on a case by case basis by the NIB Steering Committee.

### c. Amendments

Researchers wishing to submit an amendment to their original application (eg adding methods which don't alter the ultimate aims of the study or requesting additional samples) should make contact with the NIB Administrator, in the first instance. If requested by the NIB, the full protocol must be updated with changes clearly highlighted and the version clearly marked. Once completed the new version of the protocol will reviewed by the NIB Scientific or Deputy Scientific Director who will

decide if the amendment is acceptable or if a new full scientific application is required.

## **5. Other Information**

### **a. Feedback Reports to the Biobank**

Researchers will be expected to give feedback to the NIB via the completion of an End of Project Report on or shortly after the project end date. Further requests for samples from the applicant (or research group) in this specific area of research pertaining to the application will not be accepted and/or approved until feedback data from previous projects has been obtained.

### **b. Applications for Quality Control & Method Development**

In addition to applications for research projects, the NIB will also accept applications for use of samples for quality control and method development work including validations for biomarkers. The application process for these types of projects will differ in several ways:

- These projects may be approved by the Scientific Director or Deputy Scientific Director, without the need for independent review.
- Results obtained from the validations must not be used for publication without making a separate independent application to the NIB, for peer review.
- Availability of samples for quality control or method development work should be checked with the NIB prior to application. Where specific tissue types are required, this should be discussed with the NIB before submission of an application as it may be possible for the biobank to obtain such samples from the BHSCCT archive.