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ACCESS POLICY

USERS MUST ENSURE THEY ARE ACCESSING THE MOST RECENT APPROVED VERSION OF THIS POLICY. THE DEFINITIVE VERSIONS OF ALL NIB DOCUMENTS ARE AVAILABLE ELECTRONICALLY VIA THE NIB QMS SHAREPOINT SITE.

DOCUMENT DETAILS	**DATE**
Prepared by: Dr Claire Lewis	20/07/2021
Approved by: Professor Jacqueline James	22/07/2021

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Version History Log

This area must detail the version history for this document and include a description of the key changes to each version

Revision History		
Version No.	**Effective Date**	**Description**

1 Purpose

The purpose of this policy is to outline the eligibility criteria and application process for access to samples from the Northern Ireland Biobank (NIB).

2 Responsibility

Implementation and monitoring of this policy is the responsibility of the NIB senior management team.

3 Background

The Northern Ireland Biobank (NIB) was established in 2011 to facilitate translational biomarker research. The repository is based in Patrick G Johnston Centre for Cancer Research (PGJCCR), Queen's University Belfast (QUB) and is core funded by The Research and Development Division of the Health and Social Care Public Health Agency in Northern Ireland.

NIB support two core 'collection' strategies. The first is a prospective collection of human samples (tissues, matched bloods, and bodily fluids) which are listed in Section 4.1. Patients are asked to provide broad informed consent for the use of their samples and de-identified data to be used for research purposes. Increasingly, the prospective collections are hypothesis led to support specific study requests from researchers.

The second collection involves regulated access to surplus clinical material following diagnostic testing. This collection avails of regulated access to archived Formalin Fixed Paraffin Embedded (FFPE) samples and residual material (nucleic acids, plasma, or serum) which is left over after diagnostic testing in regional pathology laboratories.

Aside from sample collection and distribution, NIB also offer a hosting service for translational samples collected as part of clinical research studies. Services include receipt of samples, storage in secure facilities, and release of samples subject to appropriate approvals in place for their further use.

NIB provide the infrastructure to support requests for access to samples from patients with cancer, as well as other non-malignant conditions such as endocrinology and respiratory diseases.

4 Policy statements

4.1 Sample collections: Prospectively collected samples from consented donors

NIB have approvals in place to collect the following samples:

- Frozen normal
- Frozen tumour
- Fresh normal
- Fresh tumour
- FFPE fixed normal
- FFPE fixed tumour
- Blood
- Urine
- Saliva
- Fluids from body cavity (eg ascites)
- Nasal and/or throat swabs

Tissue samples and fluids from body cavity are surplus to diagnostic requirements. NIB aim to collect matched bloods from each patient; saliva and urine are collected dependent on the donor's underlying diagnosis and/or specific project request.

4.2 Sample collections: Access to material leftover from diagnostic procedures

4.2.1 Residual FFPE Tissues

NIB have regulatory approvals for the NIB tumour collection to cover the use of the archived tissues held in the cellular pathology laboratories of the NI HSC Trusts for approved research studies. The NIB has agreement from the cellular pathology laboratories and research

governance offices across the NI HSC Trusts to create a regional network of managed access to archived FFPE samples.

The NIB will coordinate the retrieval and distribution of paraffin sections. Where possible, NIB will request applicants who wish to access residual FFPE blocks from the HSC archives to involve a Consultant Pathologist for case selection and review.

4.2.2 Residual blood and nucleic acid samples

NIB can facilitate access to residual material (for example, nucleic acids, serum, or plasma) which is left over after testing in regional pathology laboratories.

4.3 Sample Services

4.3.1 Aliquots and Derivatives

Blood samples are available in 1ml whole blood, serum, buffy coat and/or plasma aliquots. NIB do not release FFPE tissue blocks to individual research projects. Fixed samples are therefore issued as paraffin sections mounted on glass slides or as scrolls.

4.3.2 DNA extractions

NIB offer a DNA extraction service using the automated Promega Maxwell Instrument. DNA extraction, purification and QC can be undertaken from sample types including fresh frozen tissue, FFPE tissue, and whole blood.

4.3.3 Whole Slide Images

NIB have the capacity to scan and store de-identified Whole Slide Images (WSI) for release to approved research studies.

4.3.4 Tissue Microarrays (TMAs)

NIB offer a TMA construction service using an automated 3D Histech TMA Grandmaster device to create bespoke TMAs. The TMA Grandmaster offers core size options of 0.6mm, 1mm, 1.5mm, and 2mm.

All TMA blocks constructed through NIB will remain 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.

4.3.5 Clinical Trial Hosting Service

A hosting service is available for translational samples collected as part of clinical research studies. Services include receipt of samples, storage in HTA compliant facilities, and release of samples subject to appropriate approvals in place for their further use. Sample hosting is subject to application and prior to transfer of samples a hosting agreement must be executed between the study sponsor and NIB. Sample hosting will incur costs which will vary depending on the number of samples requiring storage, the type of storage required, and the duration of storage.

4.4 Ethical Approval

NIB is an NHS Research Ethics Committee (REC) approved Research Tissue Bank. This allows NIB to bestow ethical approval onto studies using NIB samples so long as the research falls within the remit of the NIB's overarching ethical approval.

The ethics covers a wide variety of research areas and tests including morphological studies, tissue hybridization and molecular analysis of nucleic acids; there will be no release of tissues or bloods to groups undertaking studies of a sensitive nature such as cellular or therapeutic cloning, use of stem cells, reproductive research. Researchers wishing to undertake whole genome sequencing of samples from the NHS pathology archives, for which there is no donor consent, will be advised to seek independent ethical approval from a Health Regulatory Authority Research Ethics Committee. Studies where there is an intention to link the results to specific patient identifiers (family names etc) will not be supported.

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.

4.5 Process of Application for Samples

NIB will accept applications from researchers internal and external to QUB. Researchers can be from an academic, healthcare, or commercial background. Applications must be made in the name of the Chief Investigator.

All researchers (academic or commercial) wishing to access samples from the NIB must first register on the NIB application portal: https://www.nibiobank.qub.ac.uk/nibresearcher. Once their account has been approved, they will be invited to submit a preliminary application form to include a study abstract and details of the number and types of samples required. 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 timeframe.
- There is evidence of sufficient funding to carry out the research for which the tissue or fluid samples are requested.

If the NIB Senior Management Team are satisfied the preliminary application meets the above criteria, the NIB Administrator will invite the researcher to complete the full application form online. Completed full application forms must include comprehensive details of the study design and will be assigned a unique NIB reference number. The application process may be preceded by e-mail or discussions with the NIB Senior Management Team to ascertain the feasibility of the proposal.

4.6 Application Review and Approval

Applications for use of samples will be reviewed by two 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
- Revise and resubmit
- Is inappropriate and should not proceed

Based on the recommendations of the reviewers and any other project logistics and operational issues, the NIB Senior Team will either approve or reject the application. The applicant will receive an e-mail informing them of the decision. If the proposal has not been approved, clear reasons will be given. In the event of conflicting reviewers' recommendations, the opinion of a third referee will be sought. Where demand for material exceeds its availability, access will be assessed on the technical and scientific merit of the studies requesting material. NIB will always seek to ensure the most efficient use of samples.

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.

Once the application has been approved the applicant will receive a formal approval accompanied by an Invoicing Request Form and a Material Transfer Agreement for signature. These must be completed, and the MTA signed, before release of samples.

Researchers must also 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

4.6.1 Amendments

Researchers wishing to submit an amendment to their original application should contact 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 Senior Team who will decide if the amendment is acceptable or if a new full scientific application is required. If required, extra schedules may be added to the material transfer agreement.

4.7 Charges

NIB recover the costs associated with sample and data collection, as well as an administrative fee for project management. Commercial applications are charged at full economic costs whereas academic applications are subsidized. Costs will vary between applications depending on the types and numbers of samples required.

4.8 Withdrawal of Consent

Donors have the right to withdraw their consent from the use of their samples and data in research. If a donor requests their consent to be withdrawn, all samples and data held by NIB will be destroyed. If samples have already been released, NIB will seek to request the return of any unused samples and data.

4.9 Applications for Quality Control & Method Development

In addition to applications for research projects, the NIB will also accept applications for use of samples for non-research purposes including quality control and method development work eg. validations for biomarkers.

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.

4.10 Appeals

Appeals for rejected projects will be considered on a case-by-case basis by the NIB Steering Committee who oversee the practices of NIB.

4.11 Study Reports

Researchers are expected to submit a Study Report on, or shortly after, their study end date (this is the date their ethical approval will expire). Requests can be made to the NIB Administrator to extend the study end date if required.

4.12 Confidentiality

NIB are committed to ensuring integrity in the application review process. Reviewers must sign a confidentiality disclosure agreement before undertaking any reviews.

NIB are expected to report on an annual basis to OREC NI. This report will include the names of the Chief Investigators and abstracts of studies to which NIB have released samples and is a publicly available document. Researchers must take this into consideration when completing their abstract if it contains sensitive or confidential information pertaining to study methods.

5 References

None

6 Appendices

None

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