ACCESS POLICY

The Newcastle Mitochondrial Research Biobank (REC Ref: 21/NE/0204)

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1 Background

The Newcastle Mitochondrial Research Biobank (NMRB) is situated within the Wellcome Centre for Mitochondrial Research (WCMR) at Newcastle University. Its overall aim is to support, underpin and drive research to improve the lives of patients with mitochondrial disease and their families.

The collection contains samples from patients with suspected/confirmed mitochondrial disease, tissues from family members of patients with suspected/confirmed mitochondrial disease and control tissues from both adults and children known to be unaffected by mitochondrial disease. The stored samples include (but are not limited to) blood (whole, plasma, serum, DNA), urine, saliva, muscle tissue and cell lines as well as post-mortem samples.

Approval exists to prospectively collect samples for research when agreed by the NMRB Oversight Committee (MRBOC) and The Newcastle Upon Tyne Hospitals NHS Foundation Trust and Newcastle University Joint Research Office.

The Wellcome Centre for Mitochondrial Research Patient Cohort: A Natural History Study and Patient Registry (the MitoCohort, REC Ref: 13/NE/0326) is a longitudinal study and research database/registry with longitudinal clinical data collected from patients with mitochondrial disease. Where samples are requested from NMRB for patients who are also participants in the MitoCohort, approval exists to request anonymised clinical data associated with that participant from the MitoCohort database (with patient consent and MitoCohort oversight committee approval).

2 Access Policy

The general policy for access to samples/data from NMRB is as follows:

- Applications are invited from all researchers whether academic, NHS or commercial.
- The MRBOC are responsible for reviewing applications and determining whether the proposed research meets the required standard of quality and contributes to the overall aim of the NMRB.
- Samples and data will only be provided for high quality research which contributes to the overall aims of the resource
- Samples will only be released for research in disease areas other than mitochondrial disease, in exceptional circumstances and where it is the opinion of the MRBOC that there is a potential relevance or benefit to mitochondrial disease patients.
- A cost recovery process will be applied to all requests external to the WCMR
- Applications from researchers directly associated with the Biobank, its management and/or its oversight committee (MRBOC) must be submitted and will be dealt with in precisely the same way as applications from all other members of the WCMR or other external applicants. Furthermore, MRBOC members will be excluded from discussions and decision-making concerning applications in which they are named.

3 Application Procedure

3.1 Initial Enquiry

Applicants wishing to use samples from the Biobank should first make an initial enquiry to the NMRB using the NMRB Initial Enquiry (IE) Form. Following acknowledgement of receipt of the IE form, the

NMRB Administrative Team and Biobank Manager will review and process this enquiry and will respond within 3 working days. They will be able to advise on whether the types of samples required are already in the Biobank and if not how long it would take to collect these samples. Advice on whether a formal application should be made will also be given.

3.2 Formal application

To submit a formal application, the NMRB Sample Request Form must be completed and submitted. In addition:

- Applicants external to the WCMR must submit a CV
- Applicants requesting samples as part of a project with its own specific Research Ethics Committee (REC) approval must submit the original ethics application, protocol and REC approval

3.3 Application Review

The NMRB Administration Team will check all submitted applications. A unique reference number will be assigned to the application and communicated to the applicant along with a confirmation of receipt of a valid application. Only complete applications will be sent to the MRBOC for review; incomplete submissions will be returned.

The MRBOC will review the applications on an ad hoc basis as received, according to the MRBOC Guidelines, which outline the standards and criteria for assessment of applications. Factors that will be considered by the Committee include but are not limited to:

- Use of a validated methodology (if applicable)
- Justifiable sample size
- Well-defined research question
- Feasibility of study
- Reputation of applicant

Should an applicant require clinical data that are not directly linked to the requested sample, these may be requested from the MitoCohort (provided the patient is enrolled in the study). The application will need to be reviewed by the MitoCohort Oversight Committee (MDOC); this will be arranged by the NMRB Administrative Team.

3.4 Decisions on Applications

The MRBOC (and MDOC if applicable) will issue a decision via email within 5 working days of receipt of a valid application. In the case of queries or requests for additional information from the MRBOC, the clock will be stopped and re-started following receipt of a response/the requested information from the applicant.

Decisions on applications will fall into one of the following categories:

- Approved with no alterations/conditions
- Approved with conditions/minor changes required
- Approval not granted – major changes and/or resubmission required
- Approval not granted – Biobank will not consider supplying samples for this type of project

If the proposal has not been approved, clear reasons will be provided. Appeals for rejected projects will not be considered.

If an application is successful, a separate Material Transfer Agreement or similar contract may be required before any samples and data are transferred. Applicants will be advised of the requirements once an approval has been issued. Sample provision costs will also be provided at this time.

3.5 Sample issue

If a decision is favourable, samples and data will only be released once an appropriate MTA/SLA/DTA is in place and fully executed. Upon receipt of samples, the applicant must complete and return the NMRB Sample Receipt form within 5 working days.

3.6 Amendments/sample re-issue

Applicants wishing to submit an amendment to their original application (e.g. adding methods, which do not alter the ultimate aims of the study, or requesting additional samples/data) can do so using the NMRB Application Amendment Form.

Applicants from within the WCMR may request samples to be re-issued (e.g. if experiments have failed) within 4 weeks of the initial receipt of samples without the need for completion of an amended request. The NMRB Sample Re-issue form should be used. Applicants can expect a response within 3 working days. Sample re-issue requests will not be accepted from researchers external to the WCMR.

4 Standard Conditions of Access

Access to samples and data from NMRB is subject to the following standard conditions plus any other relevant contracts and agreements e.g. fully executed Material Transfer Agreement (MTA), Data Transfer Agreement (DTA) or Service Level Agreement (SLA) and additional conditions as specified by the NMRB Oversight Committee (MRBOC)

4.1 Fees

Applications for access to samples and data from researchers external to the WCMR (i.e. without a named WCMR staff member as collaborator) will be subject to a cost recovery fee for preparation and transfer of samples and data.

Applications from commercial researchers (whether in collaboration with WCMR staff or not) will be subject to an application processing fee in addition to a cost recovery fee.

Fees are non-negotiable and calculated on a per-application basis that is dependent on the complexity and scale of the request. Fees must be paid in full prior to release of samples/data. No profit will be generated from the use or storage of the samples.

4.2 Evidence of Training

Applicants are expected to have received training regarding Human Tissue Act (HTA) practices and conduct their research in accordance with any relevant regulations. NMRB reserve the right to request evidence of HTA training or any other training as applicable.

4.3 Summary of Project

Researchers agree that a lay summary of their project will be provided by NMRB to the North East-Newcastle and North Tyneside 1 REC as part of the Biobank's annual progress report.

Researchers also agree that a summary of their project may be published on the website of the WCMR or on other Biobank promotional materials provided to patients, stakeholders and the general public.

4.4 Usage Limitations

Samples and tissue supplied must only be used for the intended purpose as specified in the NMRB Sample Request Form.

Changes to the intended use, or to proposed timelines, must be agreed in advance with the MRBOC and Biobank Management team as an amendment and will require submission of a NMRB Application Amendment Form. Any amendments must be approved in writing prior to being actioned. Any changes to the research team and key collaborators as specified on the NMRB Sample Request Form should be notified to NMRB in a timely manner.

Use of samples/data outside of the approved purpose will result in revocation of MRBOC approval for the project and will be reported as applicable to The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle University and the Research Ethics Committee.

4.5 Onward transfer to collaborators

Samples supplied to the recipient may only be transferred to collaborators if any such transfers are described in the NMRB Sample Request Form or in a subsequent amended request.

4.6 Clinically significant research findings

Research findings that are suspected to have potential clinical significance for the sample donor and/or their family members must be immediately communicated to the NMRB Administrative team (within 24 hours of researcher awareness).

4.7 Confidentiality and Inadvertent Identification

Recipients of samples must agree not to link the anonymised samples and data supplied by NMRB with any other data sets.

Should recipients believe they have inadvertently identified any individual, they should not record this, nor share the identification with any other person or attempt to contact the individual. Additionally, the NMRB Administration team should be notified of the identification within 3 working days.

4.8 Tracking of Samples

Recipients of samples are expected to have robust process and procedures in place to appropriately track and store samples and data provided by NMRB. Recipients should be able to immediately provide details on the status and location of any samples provided to them by NMRB should this be requested.

4.9 Withdrawal of Consent

If consent is withdrawn for issued samples, research recipients will be informed of the relevant sample numbers, asked to destroy any unused samples immediately and certify that they have done so. Results already obtained from samples that have been used for research need not be destroyed.

4.10 Post research requirements

Following completion of the project, researchers are required to destroy any remaining samples in accordance with the Human Tissue Act 2004 (https://www.hta.gov.uk/policies/human-tissue-act-2004). Confirmation of the destruction must be provided to NMRB within 7 days of the project end.

Should any extensions to the project time line be required, applicants must submit an amendment to the MRBOC at least a month before the project end date.

A brief (lay summary) of the findings is also required. This should be provided to the NMRB Administrative team within 3 months of the end of project date.

Details of any relevant publications or presentations arising from research on samples/data from NMRB must also be provided to NMRB.

4.11 Publication Policy

Any publications or presentations using data or samples provided from the collection must acknowledge support from NMRB and should reference the NMRB Application ID for the sample/data request. The following wording is suggested: *Mitochondrial disease patient tissue [and ethical approval-delete if not applicable] was provided by the Newcastle Mitochondrial Research Biobank (REC reference 16/NE/0267- Application Ref: MRBOC ID XX), supported by the Wellcome Centre for Mitochondrial Research (203105/Z/16/Z) and UK NHS Highly Specialised Service for Rare Mitochondrial Disorders'.*

Any contribution to the design/conduct of research by Biobank members must be clearly stated in journal articles/presentations etc.

4.12 Audit and Compliance

Any research conducted on samples/data obtained from NMRB will be in compliance with and have regard for any relevant regulations and national guidance including the UK Framework for Health and Social Care Research and Human Tissue Act (2004).

NMRB, The Newcastle Upon Tyne Hospitals NHS Foundation Trust and Newcastle University (where applicable) reserve the right to audit the recipients of samples/data necessary.

Failure to comply with any of the conditions outlined above will result in:

- Approval for the project being revoked
- A request for return/destruction of the samples and data
- Any relevant Research Ethics Committees, project sponsors, funders or host institutions being notified
- Future applications to NMRB being rejected.

5 Biobank Contact Details

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