

# **National Muscle Disease Bio-databank (NMDB)**

## **Access Policy for NMDB Use.**

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Access Policy	Authorised by: Professor Catriona McLean	Version 1, 19 <sup>th</sup> of September, 2022

## 1. Introduction

The National Muscle Disease Bio-databank (NMDB) was established in 2022 to facilitate research into various types of genetic muscle diseases. Through the collection of samples, clinical information and national collaboration the NMDB aims to develop future feasible and precise therapies. External researchers wishing to obtain samples and data from the NMDB are required to make an application to the Access Committee for approval.

## 2. Sample and Data External Enquiries

### 2.1 Initial Enquiry

External researchers interested in obtaining data and samples will initially e-mail the NMDB Coordinator to check availability. The NMDB Coordinator will search our database to establish the approximate number of samples, data and feasibility of providing samples which meet the researcher's requirements. The researcher will be informed and invited to apply. As stated in the 'Application Form for Samples and Data' (see appendix 1), they first must agree to this 'Access Policy for NMDB Use.'

### 2.2 Application

Once the Application Form has been submitted:

- The completed application will be reviewed by the Access Committee within one month of submission. Applicants will be informed of the outcome by e-mail.
- If approved, the Material Transfer Agreement (MTA) or Research Collaborative Agreement (RCA) will be sent to the researcher via email. This must be reviewed and approved by both parties' legal team.
- Samples will be held for the researcher for 3 months from the date of approval by the NMDB. It is the researcher's responsibility to inform the NMDB of any delays in gaining governance and ethics approval. If the application is denied, NMDB will explain what amendments are required.
- Costing details confirmed.
- Samples and data released.

### 2.3 Cost Recovery

Cost recovery will be discussed and confirmed by the Access Committee on a project-by-project basis. The NMDB Coordinator will be in contact with costing details.

## 3. Access Committee Members

Professor Catriona MCLEAN  
Professor Michelle FARRAR  
Professor Michael FAHEY  
Dr Peter HOUWELING  
Dr Damian CLARK

Dr Eppie M YIU  
Dr Megan MCGRATH  
Dr Avnika RUPARELIA  
Ms Emily GALEA

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## 4. Terms and Conditions

- 1.1** Prior to use of the data and/or samples, the researcher will have obtained approval of the project by an appropriate HREC.
- 1.2** The researcher must comply with all applicable privacy legislations in relation to the use, disclosure and storage of the data and/or samples.
- 1.3** The requested data and/or samples are consistent with the research protocol approved by the HREC.
- 1.4** The data will be stored in a secure place (e.g., password lock on electronic data), the user name and password will be secure and not shared.
- 1.5** The data and/or samples will be analysed, stored, retained and disposed of in accordance with the research protocol approved by the HREC. In addition, any other governing bodies and legislative requirements.
- 1.6** Keep the non-identifiable patient ID with the record so that the subject can be re-identified, if required for ethical reasons.
- 1.7** The data and/or samples released may only be used by researchers under the supervision of the approved Principal Investigator for the project, for the term of the project.
- 1.8** Never publish or communicate data where the sample size and data would allow unintended identification.
- 1.9** Applicants must ensure that their application to access samples and data are complete.
- 2.0** The Access Committee must approve external applications for NMDB use.
- 2.1** Any materials released to the researcher will be subject to a Materials Transfer Agreement (MTA) or Research Collaboration Agreement (RCA) between both parties. These agreements must be approved by both parties' legal team.
- 2.2** The researcher must ensure any remaining materials after completion of the project are destroyed or returned to the NMDB, as agreed and in accordance with relevant legislation/s. The integrity of the sample communicated to the NMDB as best as possible
- 2.3** All costs of retrieval, processing and transportation of materials and any other costs associated with the study will be met by the researcher unless otherwise stated.
- 2.4** As per MTA or RCA, the researcher must acknowledge the NMDB. Additionally, co-authorship on resultant publications with all NMDB Access Committee members is expected.
- 2.5** THE NMDB must be acknowledged in all oral and written presentations arising from sample and data use.
- 2.6** NMDB strive for collection and storage of high-quality samples and data. Samples provided may have no guarantee as to the accuracy or validity of any diagnosis attached to any material provided. NMDB can offer no guarantee that materials are devoid of infectious agents.
- 2.7** It is the responsibility of the researcher to ensure that all staff are appropriately informed and trained in relation to the dangers and procedures in the handling of human materials and that they are trained in, and adhere to, local conditions and Occupational Health and Safety regulations.
- 2.8** No responsibility will be taken by NMDB for an injury, damages or loss that may occur as a direct or indirect result of the use of materials provided.

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**2.9** The researcher agrees to assume all responsibility and risks for the receipt, storage, handling and use of all samples and/or data obtained from NMDB.

**3.0** The Principal Investigator agrees to submit annual reports and research progress to the NMDB Coordinator until completion of the project, as per MTA or RCA.

**3.1** Any disputes to be forwarded to the Coordinator. If unable to resolved, this will go to the Principal Investigator/s of the NMDB for resolution

**3.2** Applications must accept that resources are limited and decisions may be based on availability.

**3.3** When submitting research grants which plan to use NDMB samples and/or data, we recommend you contact the NMDB Coordinator first to estimate cost of sample procurement to be factored into the application budget.

*Please note these terms and conditions are subject to change.*

## 5. NMDB Contact

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