



## **UK MND COLLECTIONS – TERMS AND CONDITIONS FOR USE**

These terms and conditions cover access to the DNA and Cell Bank and also the Epidemiology Dataset. General terms and conditions form the majority of this document, with paragraphs specific to the DNA and Cell Bank and the Epidemiology Dataset in sections 10 and 11 respectively.

Requests for information on the samples and data available should be made to Sarah Thompson, Research Co-ordinator at the MND Association ([mndcollections@mndassociation.org](mailto:mndcollections@mndassociation.org)).

The MND Association acts as custodian of the samples and data. The principles of the custodianship are:

- Protect participants, honour commitments made to them and act within the scope of their consents
- Ensure compliance with legal and regulatory requirements
- Ensure that the resource adheres to highest research standards and is used to further understanding of motor neurone disease
- Prioritise access to those parts of the UK MND Collections that are limited in availability
- Clarify intellectual property rights and the results that flow from the UK MND Collections.

Subject to these constraints, the MND Association will encourage and provide access to the UK MND Collections and the results that flow from it as widely and openly as possible in order to maximise its use and value for research. This will include access from the academic, commercial and public sectors in the UK and elsewhere.

### **1. General considerations**

- 1.1. In order to receive material and clinical information from the UK MND Collections, all applicants must agree to abide by the Terms and Conditions listed in this document.
- 1.2. The MND Association and its partners will only authorise the release of samples and data to researchers where a compelling case can be made to justify their use.

Specifically, access to all aspects of the UK MND Collections are restricted to studies investigating the aetiopathogenesis of, and the development of effective treatments for, motor neurone disease and related neurodegenerative disorders, including frontotemporal dementia

- 1.3. Access to cell lines is limited to researchers based within the UK. However, access may be granted if the application/project is sponsored by a PI of the Collections. DNA samples and data are available to international researchers.

## **2. Applications**

- 2.1. **All enquiries and requests must be made via the MND Association.**
- 2.2. Requests will be considered for access to the DNA and Cell Bank and the Epidemiology Dataset.
- 2.3. Application for access to material from the UK MND Collections will be treated as confidential and will be considered by:
  - the MND Association's Biomedical Research Advisory Panel (BRAP), where the Principal Investigators (PIs) of the UK MND Collections (Professors Ammar Al-Chalabi, Karen Morrison and Pamela Shaw) are co-opted onto the Panel for these discussions.
  - Co-option of scientists with specific expertise may be required from time to time. All co-optees will be bound to treat the applications confidentially.
  - The CIGMR Biobank Technical Access Committee (TAC). The TAC will only be consulted for requests for DNA stored at CIGMR Biobank (see DNA and Cell Bank section 10)

### BRAP

- 2.4. The BRAP is appointed by the MND Association's Board of Trustees. The panel's overall function is to oversee the MND Association's biomedical research activities and provide strategic guidance, ensuring good governance.
- 2.5. With regard to the UK MND Collections, the BRAP's function is to oversee the governance and the strategic development of the UK MND Collections, ensuring that the resources are utilised in an appropriate fashion.

### TAC

- 2.6. The TAC will verify that the type and quantity of DNA required is reasonable, feasible and appropriate for the type of study and the technology platform to be used. It will also seek to ensure that any leftover samples are returned or destroyed.

#### Access process

- 2.7. The BRAP will consider requests for access to i) samples within the DNA and Cell Bank (a standard, minimum dataset of phenotype will be provided with all samples with extended phenotypic data on request); ii) data within the Epidemiology Dataset and iii) data arising from primary analyses of the collections in i) and ii).
- 2.8. All initial approaches for access to the Collections will be considered by the BRAP. They will judge the scientific merit of the proposed work and its relevance to MND, novelty/innovation and track record of the applicants.
- 2.9. The BRAP will review requests for access at least every three months.
- 2.10. Generally, the MND Association will permit the user up to a specified, time limited period, for use of samples / data in approved studies, from the date of release of samples/data.
- 2.11. An extension of use may be permitted, upon request, where circumstances merit it. Such a request must be made to the MND Association either at the point of application or within two calendar months before or after the original expiry date.

#### Prioritisation of requests

- 2.12. The UK MND Collections will be managed in order to optimise their use and value for research.
- 2.13. The MND Association will not offer access to any particular part of the UK MND Collections to any single user or group of users on an exclusive basis, though access to the depletable aspects of the Collections may necessarily be limited. All applications for access will be judged on merit.
- 2.14. Prioritisation and approval of requests for access to the Collections will be determined according to criteria to be set by the MND Association on advice from the BRAP.

### **3. Conditions of access**

#### Funding

- 3.1. Applicants must have the necessary funding for the research they are intending to undertake.
- 3.2. Provisional access may be obtained prior to securing funding. However samples will not be released prior to obtaining funding.

- 3.3. If funding is obtained on the basis of claiming access to the Collections, before provisional access has been granted, applications for access may be rejected.
- 3.4. Evidence of funding, for example a grant offer letter, should be provided before the release of samples or data.
- 3.5. The applicant must inform the MND Association as soon as possible of any significant changes to the logistics of the study (such as change of key personnel or location of research).
- 3.6. Where an application for **funding** to use the UK MND Collections is submitted to the MND Association, the normal process for funding applications will be followed (see our Research Governance Overview document on our website for further information). A request for access to UK MND Collections must be submitted separately in these cases.

#### Peer review

- 3.7. All scientific proposals in which samples or data from the UK MND Collections will be used should be peer reviewed. Evidence of peer review will usually be in the form of receipt of independent funding for the proposal.
- 3.8. In the absence of this evidence the MND Association may seek further information from the applicant or subject the proposal to our own peer review. The confidentiality of the proposal will be respected at all times.

#### Fees

- 3.9. Applicants must meet all costs connected with supplying (and destroying) samples and data from the UK MND Collections.
- 3.10. Researchers accessing samples from the DNA and cell line bank will pay the standard costs for preparation and shipping of samples.
- 3.11. Costs for access to academic and public researchers will be kept at a minimum, to encourage use.
- 3.12. The MND Association may charge an administration fee and a surcharge to commercial users. However, consideration will be given to the impact of charges on the full range of potential users and uses including, for example, collaboration between academia and industry, smaller companies or innovative use in larger companies.

#### Compliance with regulations

- 3.13. Applicants must provide documentary evidence that their proposal has the approval of and complies with the relevant ethical or regulatory bodies (non-UK institutions must refer to their national regulations, as required).

Specifically:

- 3.14. All applicants must have ethical approval for the research they are planning to perform.
- 3.15. All applicants must ensure that human tissue licences are in place when using 'relevant material'<sup>1</sup> as defined by the Human Tissue Authority.

Access to data accompanying samples

- 3.16. Under no circumstances should the applicant, or anyone acting on their behalf, attempt to identify or contact any of the participants.

**4. General Conditions**

- 4.1. Applicants must not perform any research on data or material from the UK MND Collections that was not agreed as part of their initial application, without permission, in writing, from the MND Association.
- 4.2. Any changes to the original approval must be approved and documented by an appropriate amendment form.
- 4.3. Applicants must not release any material from the UK MND Collections to third parties without the explicit written consent of the MND Association.
- 4.4. Applicants must return or destroy any material not used in their research after the designated period, unless specific consent for retention has been obtained, in writing from the MND Association.
- 4.5. Applicants must accept full responsibility for all aspects of safety and confidentiality concerning the storage and use of material they receive. The MND Association and their respective agents do not accept any responsibility for loss or injury, legal recourse caused by use of any material supplied.
- 4.6. Failure to comply with the Terms and Conditions may result in the application of sanctions to the applicant, not limited to but including: restrictions on future access and notification to pertinent funding bodies, the researcher's Institution and journal editors.

**5. Dissemination**

Details of access approved

- 5.1. Details of approvals for access will be treated in the utmost confidence until publication of results by successful applicants. However, the

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<sup>1</sup> A list of relevant material according to the Human Tissue Authority is given on their website: <https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004>

MND Association reserves the right to publish the title of the project for which access to the resource has been granted.

- 5.2. The timing of this publication will be after samples have been released and prior to the identification and/or publication of any results. Users will be consulted in advance and may suggest modification of titles to preserve future confidentiality, intellectual property (IP) rights or protect commercially sensitive information.

#### Progress reports

- 5.3. **Users are required to provide the MND Association with at least annual updates on the uses of samples or data from the UK MND Collections.** These updates are checked and signed off by the Programmes and Partnerships Manager at the Association (if funding to conduct the research has been sourced externally) or as part of their annual funding progress reports by two members of the BRAP (if funding is provided by the Association).
- 5.4. Annual updates on the use of the samples are provided to the BRAP and to the Association's Board of Trustees.
- 5.5. **Users will notify the MND Association of their progress within six months of expiry date of sample or data usage, by completion of a proforma report form.** It is recognised that a delay prior to dissemination is often necessary in order to enable a larger project to be completed, a patent to be filed or other competitive advantage to be pursued.
- 5.6. The MND Association must be informed as to the reason why full details cannot be communicated in the report form and users will agree to notify the MND Association of their results by completion of a further report form at the earliest opportunity.

#### Dissemination of results

- 5.7. Users will disseminate the results of their research as rapidly and widely as possible. They will be encouraged to discuss their research with other scientists and the public and to share relevant data and materials as openly as possible.
- 5.8. Authors of peer reviewed papers, directly reporting the results from the use of the UK MND Collections, are eligible to apply for the payment of open access fees by the MND Association. Such research papers should be available within the Europe PubMed Central (Europe PMC) repository as soon as possible, but definitely within six months of publication of the paper (for more information see [www.mndassociation.org/openaccess](http://www.mndassociation.org/openaccess)).
- 5.9. The MND Association should be notified of any dissemination of data or results resulting from the supply of samples or data (see also Section 7 Data Sharing).

- 5.10. In order to assess the utility and impact of the UK MND Collections and facilitate further research, the MND Association will hold details of all published findings and published patent applications.
- 5.11. Reprints of publications arising from use of the resource must be sent to the MND Association when available. If necessary, users should also provide additional details of their techniques so that other researchers will be able to comprehend the results.

## 6. Acknowledgements

- 6.1. Applicants must acknowledge supply of samples or data from the UK MND Collections in all methods of dissemination of the research arising from use of material.
- 6.2. The acknowledgement should include the participants who donated samples and / or completed epidemiological surveys, clinicians of the participating collection centres and the funders for the collection as outlined below.
- 6.3. Authorship on papers is only appropriate where contributors fulfil at least three criteria set out by the International Committee of Medical Journal Editors: (i) substantial contributions to conception/design; (ii) acquisition of data; (iii) analysis/interpretation of data; (iv) drafting or critical revision of the article; (v) final approval of the version to be published. Minimum standards for three criteria must be fulfilled.
- 6.4. The MND Association will provide additional guidance if required.
- 6.5. All publications should include the following wording in the Acknowledgements Section (deleting samples or data as appropriate): **'Samples / data used in this research were entirely/in part obtained from the UK MND Collections for MND Research, funded by the MND Association and the Wellcome Trust. We would like to thank people with MND and their families for their participation in this project'**.
- 6.6. If appropriate the source of the samples should be acknowledged 'Samples were provided by CIGMR / ECACC on approval by the MND Association.'

## 7. Data Sharing

- 7.1. Data should be deposited in a publically accessible database on first publication or release of the data, whichever is the soonest (see sections 10 and 11 for data sharing for the DNA and Cell Bank and the Epidemiology Dataset respectively).

- 7.2. The MND Collection Data Access Committee should be named as the Data Access Committee for any MND Collection-derived datasets deposited within a publically accessible database. The contact details for the UK MND Collections data access committee is via [mndcollections@mndassociation.org](mailto:mndcollections@mndassociation.org) .
- 7.3. The MND Collections Data Access Committee consists of the BRAP of the MND Association, the PIs of the DNA Bank and one representative of the generators of each dataset deposited.
- 7.4. On deposition of data, researchers should nominate one representative for membership of the Data Access Committee to the MND Association.
- 7.5. Data generator representatives of the Data Access Committee will **only** be consulted when applications to use data generated from their research are considered.
- 7.6. The need for data generators to be appropriately credited for their scientific contribution and investment in data generation will be recognised. It is therefore expected that all data users both honour agreements in line with the Fort Lauderdale Principles on data sharing<sup>2</sup> and appropriately acknowledge the contributions and intellectual property (IP) of others.

## **8. Intellectual Property relating to research using the resource**

- 8.1. Intellectual Property (IP) arising out of research using the resource will vest in the investigator creating it, their Institution, or in appropriate cases, their assignees.
- 8.2. The MND Association will require users to have in place suitable arrangements to ensure that IP arising from their use of the resource vests in them, their employing institution, or their assignees, and is properly identified, managed and exploited.
- 8.3. Where the research involves a number of users and/or Institutions, suitable arrangements to manage any IP arising from the collaboration should be established in advance. This may not necessarily involve negotiating detailed agreements, but there should, as a minimum, be agreement on key terms where possible. Generally, the detailed arrangements will involve the identification of a lead institution for IP management purposes or, if appropriate, the transfer of the management or control of the IP to a third party. Before this is effected, the third party will agree to be bound by the same requirements.

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<sup>2</sup>Sharing Data from Large-Scale Biological Research Projects: A System of Tripartite Responsibility, Report of a meeting organised by the Wellcome Trust and held on 14-15 January 2003 at Fort Lauderdale, USA (aka Fort Lauderdale Principles): <https://www.genome.gov/Pages/Research/WellcomeReport0303.pdf>



8.4. The IP holder is expected to vigorously pursue the development and exploitation of IP that flows directly or indirectly from the research. The MND Association reserves the right, but not the duty, to step in to exploit IP in suitable cases if, after a period of time, the lead institution chooses not to do so. Six months notice of the intention to 'step in' will be given before proceeding.

## **9. Notification of patent applications**

9.1. We require users to provide the MND Association with details at the point of filing, publication and granting of patent applications that are based on the results of any research carried out using samples or data from the DNA Bank. Information regarding filing of patents will be kept confidential. This includes arrangements for IP in studies that involve the use of additional information, biological samples, data or otherwise go beyond the scope of the UK MND Collections.

## **10. Additional conditions for DNA and Cell Bank Access**

- 10.1. If DNA from CIGMR Biobank has been requested, on the BRAP's favourable opinion, the application will be forwarded to their Technical Access Committee (TAC). On their favourable assessment the release of the samples from CIGMR Biobank will be authorised.
- 10.2. The TAC will verify that the type and quantity of DNA required is reasonable, feasible and appropriate for the type of study and the technology platform to be used. It will also seek to ensure that any leftover samples are returned or destroyed.

### *Fees*

10.3. Please contact the MND Association in the first instance, via: [mndcollections@mndassociation.org](mailto:mndcollections@mndassociation.org). Further details may then be provided by Debbie Payne at CIGMR Biobank, and Debbie Blick at ECACC respectively.

Their contact details are:

Debbie Payne, CIGMR Biobank, University of Manchester;  
Debbie.Payne@manchester.ac.uk; 0161 275 1625

Debbie Blick, Blood Processing and Transformations Supervisor,  
Human Genetic Services, Culture Collections, Public Health England  
Porton Down; Debbie.Blick@phe.gov.uk; 01980 612611

### Access to data accompanying samples

- 10.4. The process for requesting data from the extended dataset of phenotypic information) or genetic classification data is given below. A summary of data fields collected is given in Appendix 2. Collection of these data were done on a pragmatic 'where possible' basis. Please contact the MND Association for information on which data are available for which samples.

### Access to data within the extended dataset

- 10.5. Researchers wishing to access the additional phenotypic data must first liaise with principal investigators to explore collaborative opportunities. However, formal collaboration may not be required for access to the extended dataset.
- 10.6. Access to the extended dataset will only be permitted for research that meets the Terms and Conditions for access laid out in this document.
- 10.7. These data were acquired from participants where possible, it is not a complete dataset for all participants. Thus requesting data from the extended dataset may restrict the number of samples available.
- 10.8. Family pedigree data linking family member samples to the index sample of a participant with MND form part of the extended dataset.

### *General conditions*

- 10.9. Applicants receiving samples from CIGMR Biobank must adhere to their Terms and Conditions<sup>3</sup>.

### Cell Lines

- 10.10. Applicants receiving samples from ECACC must adhere to their Terms and Conditions<sup>4</sup>.
- 10.11. Applicants are strongly advised to confirm the authenticity of cell lines at the start and end of the project prior to publication, to ensure that no mix up or contamination of cell lines has occurred throughout the project lifetime. This is in accordance to guidelines set out by the International Cell Line Authentication Committee (ICLAC)<sup>5</sup>.

### *Data sharing*

- 10.12. All data generated as a result of access to samples within the MND Collections should be made available to the wider research community by depositing the data within publically accessible database (eg the European Genome-Phenome Archive (EGA) [www.ebi.ac.uk/ega](http://www.ebi.ac.uk/ega) ).

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<sup>3</sup> Included within the CIGMR Biobank application form.

<sup>4</sup> <http://www.phe-culturecollections.org.uk/orderinginfo/terms.jsp>

<sup>5</sup> <http://iclac.org/resources/advice-scientists/>

## 11. Epidemiology Dataset

### *Use of data*

- 11.1. Data shall be adequate, relevant and not excessive in relation to the purpose for which they are processed.
- 11.2. Data processed for any purpose(s) shall not be kept for longer than necessary for that purpose or purposes.
- 11.3. The data applicant ensures that the data are stored in a secure manner and (s)he abides by the requirements to ensure confidentiality of the data. Data must be kept secure from any potential abuse.
- 11.4. Appropriate technical and organisational measures must be taken against unauthorised or unlawful data processing and against accidental data loss, destruction, or damage.
- 11.5. Data transfer onto a portable device such as a laptop, USB stick, CD or disk must ensure that the data is encrypted, so that data remain safe, even if the portable device is lost or stolen.
- 11.6. The data applicant ensures that data shall not be transmitted to another party or legal or natural person without the MND Association's permission.
- 11.7. The data applicant is liable for any damage-causing events (eg loss of data), transfer to other persons/parties/ companies etc The MND Association reserves the right – without prior notification – to retract its permission for data use. Additionally, the MND Association reserves the right to take legal action against the data applicant for compensation in case of inappropriate use of data or in case of a data procession in any manner incompatible with the purpose(s), including their right to penal actions.

## Appendix 1: Minimum Dataset



### Minimum dataset of the UK MND Collections

All approved users of the samples from the MND Collections will receive a minimum dataset of anonymised information on participants.

The minimum dataset includes the following information, as finalised and agreed by the MND Collections (DNA Bank) Management Committee at their meeting in September 2006.

- age
- gender
- affectation status (control, familial ALS, sporadic ALS etc)
- diagnostic certainty (El Escorial status)
- age of onset

## **Appendix 2: Extended dataset for the DNA Bank and Cell lines of the UK MND Collections**

An extended dataset has been collected from as many participants as possible, but is not a complete dataset.

Researchers wishing to access the additional phenotypic data must first liaise with principal investigators to explore collaborative opportunities. However, formal collaboration may not be required for access to the extended dataset.

When requesting fields from the extended dataset, please consider the most important information you require, the priorities of the information will affect the samples available to you (due to the incomplete data set mentioned above).

### **Clinical history**

- Site of presentation
- Family history of: MND, Parkinson's Disease, Alzheimers Disease, Frontotemporal dementia, other neurological condition
- Inconsistent features: sensory, autonomic, sphincter, Parkinsonian, cognitive change

### **Family tree pedigree**

- parents, grandparents, siblings, children and 'other'
- Affected/unaffected, age now, sex, alive (y/n), age at death, year of death, cause of death

### **Investigations and results**

- Nerve conduction studies: central motor, motor, Sensory conduction respectively and conduction block
- EMG: right and left upper limbs, right and left lower limbs and tongue respectively
- Blood: CK, antiganglioside Abs, Kennedy's mutation, SOD1 mutation\*
- MRI of brain, cervical, thoracic, lumbosacral spinal cord respectively

All individual investigations above are recorded according to one of the following categories: Unknown, normal, abnormal, abnormal relevant, abnormal irrelevant, not taken

### **Current medications**

- Current medications – drug and notes
- Disease modifying medications- drug, date started and notes

## **ALSFRS**

Divided into each of the 12 categories (including the with and without gastrostomy sub-categories) and a total score

### **Physical examination history**

- Upper motor neurone signs in bulbar, lower limb and upper limb
- Lower motor neurone signs in bulbar, lower limb and upper limb
- Weight in kilos (at time of giving sample)
- %FVC
- %VC

### **MRC scores:**

- Neck flexion and extension respectively
- Upper limb: shoulder abduction, elbow flexion, wrist flexion, wrist extension, thumb abduction, each for right and left side respectively
- Lower limb: hip flexion, knee flexion, knee extension, ankle dorsiflexion each for right and left side respectively

### **Notes fields:**

- Significant past medical history
- Family history
- Nerve conduction notes
- EMG studies
- Blood results
- MRI examinations]
- Other significant abnormal investigations
- Physical examination history



## **Appendix 3: Epidemiology Dataset**

### **Personal details**

- Gender
- Age
- Marital status
- Ethnicity
- Country of birth
- Parental birthplace

### **MND History**

- Year of symptom onset
- Year diagnosed
- Familial/sporadic

### **Health/Hospital Admissions**

- Head injuries
- Skeletal fractures
- Neurological illnesses – loss/change of taste/smell
- Serious illnesses
- Surgical procedures – general anaesthetic required
- Medications
- Vaccinations
- Allergies
- Body build (weight/height)
- Reproductive history – no. of children
- Dominant hand
- Female only – menstrual cycle

### **Family history**

- Medical conditions
- Siblings/parents/children - Current age or age at death

### **Socio-Economic Background**

- Education
- Employment
- Parental Occupation
- Income

**Lifestyle**

- Alcohol consumption e.g. age started, frequency of drinking
- Smoking – Cigars, cigarettes and pipe
- Air travel
- Physical Activity – team sports, frequency, age

**Electrical/Radiowave Exposure**

- Electric shocks/burns
- Work with radiowaves
- Lived near pylons
- mobile/cordless phone usage

**Exposure (from employment and hobbies)**

- Chemical
- Pesticide
- Metal
- Solvent

**Employment History**

- Type, duration, hours per year, physical activity, exposure to (see above)

**Hobbies**

- Age started/finished, how many hours, exposure to (see above)

**Residence History**

- Area type, near agriculture, water from well

**Discrepancies/notes table for surveys**