DecodeME Data Access Policy

A. Applicant eligibility criteria

The DecodeME Data access committee (DAC) will assess the eligibility of the applicant before assessing the eligibility of the project proposal. If the applicant is considered ineligible, then the proposal will not be assessed and the request for data or materials access will be declined.

The requester must be employed by a reputable and bona fide academic or commercial scientific institution whose legal department is capable of signing a contract with the University of Edinburgh.

It is essential for the applicant institution to sign a legal Data and Material Transfer Agreement (DMTA) before data and/or materials are transferred. The applicant should supply and use an organisational email address at their employment institution.

To ensure the effective implementation of the research proposal, it is essential for both the lead applicant and co-applicants to possess demonstrable experience and expertise directly relevant to the research objectives. Roles and responsibilities must be clearly outlined, with particular attention given to any necessary training, especially when PhD students as co-applicants are responsible for data access and analysis.

B. Project eligibility criteria

Assessment of data management in access proposals to DecodeME follows the MRC data sharing policy (https://www.ukri.org/publications/mrc-data-sharing-policy/data-sharing-policy/) and includes the following points:

1. Data management requirements

The data analysis plan in the access proposal must demonstrate a responsible use of the data received. As stipulated in the DMTA this plan must be in place before any approved project is implemented, and the data shared must be for exclusive use in the project linked to the request.

The requester must comply with the best practices of data security and integrity during the data transfer and storage of data. The requester agrees to delete the data before the end of the project. Details must be provided to justify an extension if required.

The requester must demonstrate that the data analysis does not pose a risk to participants' individual privacy or that adequate measures have been taken to mitigate any potential risks.

The requester must demonstrate that any third parties used are clearly described and justified, and are also experienced entities capable of the allocated responsibilities. If DecodeME data is required to be shared with any third parties, requesters must provide detailed information on how data security and integrity is upheld during data sharing in their data analysis plan. NDAs (or other appropriate contracts as stipulated by DecodeME) should be in place with third parties.

2. PPI standards assessment

As a project co-produced equally by researchers, patients, and carers, DecodeME strongly believes that Patient and Public Involvement (PPI) is essential to maximise the value of any

access granted to the data and/or materials. Therefore, applicants will be asked how their research project meets the UK Standards for Public Involvement in Research, or international equivalent where appropriate, or for detail on why it is not possible for the project to do so.

Requesters must demonstrate they understand the value of PPI in research.

Requesters' PPI plans must be aligned with their project's goals and should be designed to meet the specific needs and stages of their research, considering different populations' experiences, reasons for involvement and ethical considerations, when required.

3. Governance assessment

The requester must confirm they have sufficient funding to conduct the proposed research.

The requester must agree to make their own scientific findings and summary data open access, to at least the same standard as DecodeME.

The research project must be ethically approved:

- If the project requires participants to be re-contacted, to provide new data or samples, researchers are required to obtain a separate Research Ethics Committee (REC) (or equivalent) approval before data access can be granted. Please refer to Section 8 for more information.
- If the project does not require further data or samples to be collected from participants, the Data Access Committee (DAC) must investigate, based on the details provided by the requester, whether the data access request can be covered by DecodeME's existing REC favourable opinion. Please refer to Section 8 for more information.

The requester must demonstrate the value of their research study to patients and the public, outlining measurable outcomes that contribute to advancements in the relevant field of health or social care.

The requester must demonstrate they have considered the Equality, Diversity, and Inclusion (EDI) principles during the study's design phase, ensuring that the research reflects the diversity of the population affected by the condition(s). Any limitations in implementing these principles must be clearly justified.

The outcomes proposed in the research proposal must hold significance for the target population under study.

4. Material request assessment

Sample material access requests will be reviewed based on the sample stocks remaining, the scientific value of the sample use (given that it is a depletable resource), and the volume/quantity required to conduct the research analysis. **Preference will be given to projects that aim to analyse the entire consented cohort, rather than a subset only.** The assessment will also consider if the research plan is rational, feasible and demonstrates added scientific value to the research field. DecodeME may ask for evidence of appropriate quality standards in the laboratory where samples are to be analysed.

5. Resource and Process assessment

Costs for shipment of samples, temporary storage requirements, sample handling work, and additional data transfer or processing costs will all be covered by the requester. Costs will be determined on a case-by-case basis, depending on the project requirements. VAT will be applied to external requests. The lab/transport company will directly bill the recipient.

Risk of donor fatigue must remain low for the DecodeME cohort. For projects that request participants to be re-contacted, the number and timing of invites will be assessed on a case-by-case basis and ME/CFS research projects will be prioritised over other projects.

6. Collaboration policy

DecodeME pledges to facilitate projects that accelerate high quality ME/CFS research. For the avoidance of doubt, there is no obligation for DecodeME researchers to be named as collaborators (including in scientific publications) in projects using DecodeME data or samples.

DecodeME requires that due acknowledgement is given in grant applications or manuscripts to the use of its samples and/or data (please refer to Section 7).

Any unused samples should be offered to DecodeME by the end of the project period or destroyed by agreement.

At the end of the project period, DecodeME data should be deleted. Confirmation that data was deleted and/or materials were destroyed must be received by the termination date stated in the DMTA. If an extension is required, requesters must justify the extension and the DMTA termination date must be extended.

Decisions taken by DecodeME on Data/Sample access are final.

7. Publications policy

This policy is intended to inform acknowledgements, and authorship considerations, for any scientific outputs arising from research using the DecodeME resource.

This policy applies both to "internal" publications, initiated by members of the DecodeME team, and "external" publications, initiated by external researchers which rely upon access to DecodeME individual-level data or materials. Internal publications may include original research papers based on the resource (methods, participants, data, etc). External publication is most likely to be either (a) original papers by researchers who have applied to use the resource; and (b) papers reporting research to which DecodeME has contributed data to a consortium.

The Recipient PI must acknowledge the DecodeME resource and its funding reference:

> "*DecodeME is funded by the National Institute for Health and Care Research (NIHR) and Medical Research Council (MRC), grant number MC_PC_20005. The study was also supported by the Medical Research Council University Unit award to the MRC Human Genetics Unit, University of Edinburgh, grant numbers MC_UU_00007/10 and MC_UU_00007/15*".

In many manuscripts it will be appropriate to include a statement about the Research Ethics Committee opinion and Ref Number, e.g. "*The DecodeME study was reviewed and given a favourable opinion by the North West – Liverpool Central Research Ethics Committee (21/NW/0169*)".

It may be appropriate to include as co-authors any members of DecodeME who have played a key scientific role in the generation of the data and materials used in the research. However, there is no obligation for DecodeME researchers to be named as collaborators in publications unless they have contributed sufficiently to the research project.

The corresponding author of a publication is requested to let DecodeME (Project.DecodeME@ed.ac.uk) know when their paper is pre-printed (deposit on a preprint server is encouraged) and/or accepted for peer-reviewed publication. They are also asked to contact DecodeME if they know there is going to be a press release about the publication. The publicity can then be amplified, and the participants given timely information about findings made using their data or samples.

All manuscripts resulting from access to data or materials must be reviewed by the DecodeME team (Project.DecodeME@ed.ac.uk) in advance of publication. This review is to check whether there is appropriate acknowledgement of the resource and that the DecodeME funding award reference number is included.

8. DecodeME Design and Ethics permissions

DecodeME's second objective is to build a research cohort of participants clinically diagnosed with ME/CFS and who meet the widely used Canadian Consensus or IOM/NAM criteria.

DecodeME ethics application allows for participants' questionnaires and DNA data and samples to become available to bona fide researchers whose studies were approved by the Data Access Committee (DAC) in order to accelerate research.

Participants were provided with a consent form where they were asked whether they agreed for their de-identified data to be shared with other researchers in future studies approved by DecodeME, as well as whether they wished to be contacted for future opportunities to participate in other studies approved by DecodeME that require new data and/or samples. Both consent points were optional for participants. Of all participants, 86% consented to the sharing of their data with other researchers, and 95% consented to being contacted regarding other studies.

Researchers can access the data and samples by submitting a proposal that will be reviewed by the Data Access Committee (DAC), based on several criteria, including but not limited to governance and patient and public involvement.

Researchers can also submit research proposals to recontact participants in the cohort. This cohort can be re-contactable in order to facilitate and make cost-effective many future epidemiological and biomolecular studies, including those seeking to stratify the cohort phenotypically and/or genotypically. DecodeME won't share participants personal identifiable information with other researchers but can support by contacting participants who consented to be contacted about other studies, about the opportunity to sign up for the new study.

- For these types of projects, researchers must require a separate Research Ethics Committee (REC) (or equivalent) approval before the DAC's approval is granted.
- A copy of the invitation email and reminders approved by the project's Ethics Committee, must be shared with DecodeME. Sufficient time should be allocated to allow DecodeME to update its own ethics application before the project starts.

9. Decision and appeal processes

Requesters must complete Part A of the Data and Materials Access Proposal Form and submit it to Project.DecodeME@ed.ac.uk, together with the annexes requested in section 2.3 of the form. The submission will be acknowledged by a member of the DecodeME team, who will provide a unique request number (REQ00X) and initiate the internal assessment process. The DecodeME team may enter in contact with the requester, to request further information that complements the proposal. All information will be shared with the Data Access Committee before the next meeting takes place and a decision is made.

The Data Access Committee (DAC) is formed by DecodeME representatives, including researchers and patient and public representatives, and an independent representative. DAC meetings normally take place quarterly. Once a decision has been reached, requesters will be informed of the result and receive a copy of the report (Part B, Data and Materials Access Proposal Form).

If the proposal is approved, the DecodeME team will initiate the legal process to transfer data between the University of Edinburgh and the Lead applicant institution. Legal representatives of both parties are required to sign a DMTA (Data / Material Transfer Agreement) before the transfer of data or materials process can be initiated. Further information on the data transfer method overall timeline will be provided at this stage.

If the proposal is not approved, requesters have the opportunity resubmit their proposal one more time, after making the necessary amendments, based on the report received.

To appeal the decision, requesters are required to submit a written document, outlining the reasons for the appeal, their concerns or disputes regarding the data access process and providing any supporting evidence required. This document should be submitted to Project.DecodeME@ed.ac.uk.

The Data Access Committee (DAC) will conduct a thorough examination of the appeal and relevant documentation before the next planned meeting, where a decision will be reached. The decision will be made based on the evidence provided and the principles and guidelines outlined in this document (Data Access Policy) and the MRC/UKRI Data Access Policy.

10. How to make a complaint

To raise a formal complaint about the study, please email the University of Edinburgh's Research Governance team at researchgovernance@ed.ac.uk.

We aim to meet the highest standards when collecting and handling personal identifiable data. If you'd like to complain about the handling of data in DecodeME, you can contact the University of Edinburgh Data Protection Officer via email at dpo@ed.ac.uk.

Document change history:

Date	Edited by	Role	Version	Description
2023-08-10	DG	PM	1	New document created
2023-10-09	DG	PM	2	Material request assessment updated to include assessment of the project value if there is a request for depletable resources. Data management assessment updated to clarify that requester must demonstrate due diligence when selecting third parties that use the project's data. Governance assessment section updated to make it optional for researchers to accept having an overview of their project in DecodeME website.
2023-04-09	SK/DG	CoI/PM	3	Updated Section A to provide further information on applicants' eligibility criteria. Updated Sections B 1-3 and 5 to provide information on the MRC UKRI Data sharing guidelines and expand on data management, PPI, project governance and resources assessment expectations and information. Added new Sections B 8-10.