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**Data and Materials Access Proposal Form**

**Please read** [**DecodeME study documents**](https://www.decodeme.org.uk/documents/) **before requesting access to the study data or materials.**

**Please consult** [**DecodeME Privacy Notice**](https://www.decodeme.org.uk/privacy-notice/) **for more information on the data collected from researchers during the Data Access process.**

**Note that we provide free access to summary data statistics available via –** [**OSF | DecodeME**](https://osf.io/rgqs3/)

**Please fill out Part A and submit a copy of your request and the annexes requested in section 2.3 to** [**Project.DecodeME@ed.ac.uk**](mailto:Project.DecodeME@ed.ac.uk)**.**

**DecodeME Data Access process follows the** [**MRC UKRI guidelines for Data Sharing**](https://www.ukri.org/publications/mrc-data-sharing-policy/data-sharing-policy/)**. Please note your application will be reviewed by all Data Access Committee members, including independent and patient/public representatives.**

**Part A – Request form**

**Section 1: Applicant(s) information**

**1.1 Principal Applicant**

|  |  |
| --- | --- |
| Title |  |
| Name |  |
| ORCID ID |  |
| Job post |  |
| Organisation |  |
| Department |  |
| Email contact |  |
| Tel. contact |  |
| Address |  |

**1.2 Co-Applicant(s) (please provide information for every co-applicant, if applicable)**

|  |  |
| --- | --- |
| Title |  |
| Name |  |
| ORCID ID |  |
| Job post |  |
| Organisation |  |
| Department |  |
| Email contact |  |
| Tel. contact |  |
| Address |  |

**1.3 Data recipient(s) (please provide information for every data recipient, if applicable)**

|  |  |
| --- | --- |
| Title |  |
| Name |  |
| ORCID ID |  |
| Job post |  |
| Organisation |  |
| Department |  |
| Email contact |  |
| Tel. contact |  |
| Address |  |

**Please note that the lead applicant is responsible for meeting the conditions described in the application and data or materials transfer agreement. The data must be kept secure, only accessed by the lead applicant, co-applicant(s) and data recipient(s) listed on the application, and only used for the purpose of the study described in this application. If a PhD supervisor or line manager is listed as a co-applicant, each PhD student accessing and analysing the data should also be listed as a data recipient in the application.**

**1.4 Experience and Expertise assessment**

|  |  |
| --- | --- |
| Please describe how the lead applicant and the co-applicant (s) relevant experience and expertise is going to be applied to the proposed study. |  |
| If the applicant is a PhD supervisor/line manager, please describe how the PhD student(s) with access to the data, will have adequate supervision and training necessary to access the data and carry out the data analysis securely. |  |

**Please submit with the application the CV and a short list of most recent and relevant publications for each Lead, Co-applicant, and PhD supervisor/line manager if PhD students have applied. Please refer to section 2.3 and provide information as annex to this form.**

**Section 2: Project application**

**2.1 Project information**

|  |  |
| --- | --- |
| Title |  |
| Start and End dates |  |
| Plain, simple language summary (< 300 words)  *Please note that this summary will appear on DecodeME’s website following approval of your application* |  |
| Please provide a Research proposal (max 2 pages) and data analysis plan (max 1 page), including a justification for using DecodeME’s resources, the minimum data/sample size statistically required and how you are planning to use the data or samples requested to achieve the project objectives. | Please refer to section 2.3 and provide information as annex to this form |
| Current funding application status. Please select from the list: | Planned  Applied / Under review  Approved  Not required |
| Funding duration (if applicable)   * Start/End dates |  |
| Funders (if applicable) |  |
| Has the project been peer reviewed (including statistically)?   * If “Yes”, by whom * If “No”, please justify |  |
| Has the project been ethically reviewed and obtained a favourable opinion?   * If “Yes”, please provide the reference and the Research Ethics Committee * If “No”, please explain why the study does not require to be ethically reviewed and could be covered by existing DecodeME ethics permissions. Please refer to DecodeME Data Access policy for more information. | Please refer to section 2.3 and provide information as annex to this form |
| Please describe how the study will benefit patients, health and/or social care, including expected measurable benefits. |  |
| 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, we will ask how the research project meets the [UK Standards for Public Involvement in Research](https://sites.google.com/nihr.ac.uk/pi-standards/home), or international equivalent where appropriate, or for detail on why it is not possible for the project to do so.  For guidance on PPI in research, please consult [PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes | NIHR](https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437) and for guidance on how to adapt your project to be suitable for people with ME/CFS to participate or contribute as PPI members, please consult “[How to involve PwME in research](https://www.actionforme.org.uk/uploads/images/2023/08/Info_for_ME_researchers_FINAL.pdf#:~:text=The%20aim%20of%20this%20document%20is%20to%20present,the%20research%2F%20Patient%20and%20Public%20Involvement%20%28PPI%29%20team.)”, S.Tyson, 2023 | Please refer to section 2.3 and provide information as annex to this form |
| How have you considered Equality, Diversity, and Inclusion (EDI) in your proposal? Please provide a short overview of your considerations and how these have been implemented where possible.  For guidance, please refer to [Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project | NIHR](https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435) |  |
| Is this proposal linked to a previous access request?   * If “Yes”, please provide the proposal number, project title and the outcomes resulting from the application |  |
| Please describe how you will disseminate the study findings (please refer to DecodeME Data access policy)? |  |
| Do you have a deadline to receive the data or materials? |  |

**2.2 Resources information**

**Disclaimer:** The consent to share information with other research projects is optional in DecodeME. Please be aware that approximately 14% of DecodeME’s cohort chose not to consent to share their data with other researchers, therefore we cannot share their data or materials.

|  |  |
| --- | --- |
| Please select from the list which resources you would like to have access to: | Genotype data  Phenotype data  Demographic data  DNA samples  Saliva samples |
| Please provide further details on the type of resources and quantities required (if applicable) |  |
| Would you require for DecodeME to share information about the project with the participants? |  |
| Do you anticipate any risks to individual privacy, and if so, what steps have you made in your proposal to mitigate these? |  |

**Please note that costs to cover sample picking and transport will apply to projects that require access to DecodeME samples.**

**2.3 Additional documents**

Please include in annex the following documents:

|  |  |  |
| --- | --- | --- |
|  | **Document** | **Max length** |
|  | CV for each lead and co-applicant (refer to section 1.4) | 2 pages (each) |
|  | Short list of recent and relevant publications for each lead and co-applicant (refer to section 1.4) | 1 page (each) |
|  | Detailed Research proposal (refer to section 2.1) | 2 pages |
|  | Data analysis plan (refer to section 2.1) | 1 page |
|  | PPI project plan (refer to section 2.1) | 1 page |
|  | Ethics approval letter (refer to section 2.1) | 2 pages |

**Please fill out Part A and submit a copy of your request and the annexes requested in section 2.3 to** [**Project.DecodeME@ed.ac.uk**](mailto:Project.DecodeME@ed.ac.uk)

**The DAC (Data Access Committee) will review the proposal in their next meeting and a copy of the review report will be shared with the applicant. DAC meetings are normally scheduled once a quarter.**

**If the proposal is approved, the 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.**

**If your proposal is rejected, please refer to DecodeME Data Access policy for guidance on how to appeal.**

**Part B – Review report**

|  |  |
| --- | --- |
| **Proposal number:** |  |
|  |  |
| **Applicant assessment** |  |
| Responsible | Response/Comments |
| **Data management assessment** |  |
| Responsible | Response/Comments |
| **PPI standards assessment** |  |
| Responsible | Response/Comments |
| **Governance assessment** |  |
| Responsible | Response/Comments |
| **Materials assessment** |  |
| Responsible | Response/Comments |
| **Resource and Process assessment** |  |
| Responsible | Response/Comments |

|  |  |
| --- | --- |
| **Committee’s decision:** |  |
| Additional notes/conditions: |  |
| Date: |  |

**Document change history:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date** | **Edited by** | **Role** | **Version** | **Description** |
| 2023-07-25 | DG | PM | 1 | New document created |
| 2023-07-27 | SMK | Co-I | 1.1 | Modifications to PPI Section 2.1 and minor stylistic changes throughout |
| 2023-08-01 | SMK | Co-I | 1.2 | Modifications to PPI section 2.1 in response to MG review |
| 2023-10-18 | DG | PM | 2 | Update PPI section 2.1 with weblinks and additional information to support researchers. Project value assessment section removed. |
| 2024-04-09 | SK/DG | CoI/PM | 3 | Included additional guidelines to support applicants through the process and access the relevant project information, such as the researcher's privacy notice and the MRC UKRI guidelines.  Updated Section 1 to request more information on applicants’ professional experience and expertise.  Updated Section 2 to include lay summary, information on research benefits, annexes, data privacy risks, participants inclusion, project deadlines, dissemination of results and clarification on the ethics permission request. |