**mapMECFS Data Submission Agreement**

# **Overview**

The mapMECFS Data Access & Quality Committee (DAQ) approves submission of data to the data platform <https://mapmecfs.org>. The DAQ will review the mapMECFS Data Submission Request and decide whether to permit the submission based on the expectations outlined in the mapMECFS policy. If submissions raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAQ will consult with other experts as appropriate. In unusual circumstances, when people are denied approval to submit data, appeals may be sent to the National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke (NINDS) staff representative to the DAQ.

## **Steps to Request to Submit Data to mapMECFS by Data Submitters**

1. Review the capabilities of mapMECFS at <https://www.mapmecfs.org/about>

2. Contact the DAQ through mapMECFS (mapmecfs@rti.org) to set up an introductory meeting (preferably 2 months before the desired submission date) to discuss the dataset submission request and resolve technical and other issues.

The NINDS and mapMECFS staff will discuss with investigators:

1. dataset submission expectations,
2. dataset sharing expectations,
3. supporting materials submission expectations,
4. dataset access preferences,
5. technical specifications,
6. usage of common data elements and globally unique identifiers (GUIDs),
7. deidentification expectations, and
8. dataset accuracy as it relates to ME/CFS.

3. Submit a Dataset Submission Agreement (SA): Read the mapMECFS SA form (below). Submit the SA and Submitter Information and Certifications signed by all necessary parties by emailing a signed copy of this form to mapMECFS (mapmecfs@rti.org). The DAQ may determine that a submitter is exempt from an SA if the data are fully included within a peer-reviewed manuscript.

4. Dataset SA review: NINDS and mapMECFS staff will review requests to submit datasets to the mapMECFS data platform. Such reviews are generally completed within 10 business days.

5. Once a submitter has permissions to submit a dataset to mapMECFS, he or she should register for an account on mapMECFS’s registration page (<https://www.mapmecfs.org/user/register>) and follow the steps for data submission as described on the site’s About page and the instructions provided during the introductory meeting.

5a. Registrants must agree to the mapMECFS Data Use Agreement (DUA) and review the site’s privacy policy provided on the registration page.

# **Data Submission Agreement for the mapMECFS Data Platform**

Definitions

**Principal Investigator (PI)**—The individual who has full responsibility for oversight of the Research Project. The PI is responsible for assigning the submitter (if different than the PI), ensuring accuracy of the submitted agreement, and ensuring the following terms are followed.

**Submitter**—The individual responsible for data upload, who will also serve as the primary point of contact for data submission. The submitter may be supported by additional team members, who should be listed as collaborators on the submission form.

**Private Data**—Only viewable to the uploader and other users registered with the same organization as the uploader.

**Public Data**—Viewable to any approved mapMECFS user.

**Anyone filling the Project PI or Submitter roles, henceforth “PI/Submitter,” must agree to the following terms:**

1. **Data Rights**. The PI/Submitter has all necessary rights to provide the data for upload and is authorized by the affiliated institution to upload the data. The PI/Submitter requests approval to submit a dataset to the mapMECFS data platform for the purpose of enabling access to it for scientific investigation, teaching, or the planning of clinical research studies.

2. **Dataset.** Dataset(s) will be submitted solely in connection with the Research Project as defined below and described in the PI/Submitter Information and Certifications section. This SA covers only the Research Project described in the PI/Submitter Information and Certifications section. The PI/Submitter will submit a completed SA for each research project for which submission is requested.

The dataset that the PI/Submitter uploads may be shared on mapMECFS with anyone who has agreed to the terms in the mapMECFS DUA for downloading the dataset, provided that the PI/Submitter retains the ownership of the data. The PI/Submitter acknowledges that RTI International employees or contractors will be able to see and use the data for the purposes of administering the site and the data repository.

It is the PI/Submitter’s responsibility to ensure that (1) no personally identifiable information (PII) is present, (2) study participant privacy is fully protected, and (3) sharing is compliant with all other governing policies (e.g., Institutional Review Board [IRB]-approved protocols, informed consent, embargos). If data sharing regulations change or data have been shared inappropriately, it is the PI/Submitter’s responsibility to remove the data or request help from mapMECFS site administrators by emailing mapmecfs@rti.org.

3. **Nontransferability of Agreement**. This SA is not transferable. The PI/Submitter agrees that any substantive changes the PI/Submitter makes to the Research Project, or its associated datasets, requires execution of a new submission agreement. If the PI/Submitter changes institutions and wishes to retain submission privileges to mapMECFS, a new SA in which the new institution agrees to the provisions of the SA is necessary.

4. **Use of NIH Global Unique Identifier Client and Common Data Elements**. The PI/Submitter should use the software program provided free of charge by NINDS to assign GUIDs to each participant (assuming appropriate IRB and consent approval is obtained) and to re-sort the data according to the GUID. The PI/Submitter is encouraged to use the [ME/CFS Common Data Elements](https://www.commondataelements.ninds.nih.gov/Myalgic%20Encephalomyelitis/Chronic%20Fatigue%20Syndrome) as appropriate for their research.

5. **Non-Identification of Subjects**. Datasets uploaded to mapMECFS should never contain protected health information under HIPAA or PII under the Common Rule (45 CFR 46). Users should review the U.S. Department of Health and Human Services Safe Harbor Method for more information. The PI/Submitter agrees that (1) the data have been “de-identified” according to the following criterion: the identities of subjects cannot be readily ascertained or otherwise associated with the data by NIH, mapMECFS staff, or users; (2) they will not disclose the identities of research participants to NIH, mapMECFS staff, or users in the future; (3) they will verify that data lack identifiers after submission; and (4) they will notify mapMECFS staff at mapmecfs@rti.org within 5 days if they discover identifying information in that data.

6. **Data Disclaimers**. The PI/Submitter agrees that NIH and RTI International do not and cannot warrant the results that may be obtained by using any data or data analysis tools included in mapMECFS. NIH and RTI International disclaim all warranties as to the accuracy of the data in mapMECFS or the performance or fitness of the data or data analysis tools for any particular purpose.

7. **Supporting Materials.** The PI/Submitter agrees to provide mapMECFS with supporting information and documentation (“Supporting Materials”) to enable efficient use of the submitted data by investigators unfamiliar with the data. For example:

* Research protocol(s)
* Questionnaire(s)
* Study manuals
* Consent documents
* Description of variables measures
* Other supporting documentation, as appropriate
* Language to acknowledge the study that investigators who access the dataset(s) and utilize the data in publications will be required to use. This will be provided to the investigators as part of the DUA they will be required to sign.

8. **Data Accuracy.** The PI/Submitter certifies to the best of their knowledge and belief that the data submitted to mapMECFS are accurate. The PI/Submitter further agrees to notify NIH through the mapMECFS email (mapmecfs@rti.org) as soon as possible if the PI/Submitter discovers data quality concerns related to the data on mapMECFS.

9. **Notification of Publication.** For private data, prompt notification of publication or other public disclosure of the results using the uploaded dataset is required. The PI/Submitter agrees to notify NIH as to when and where a publication (or other public disclosure) of a report from the dataset will appear by sending an email to mapmecfs@rti.org with the title, authors, place of publication, and publication date. Unpublished data may be uploaded with permission and can remain private until published in a scientific journal.

10. **Data Access for Research**. The PI/Submitter agrees that data and Supporting Materials submitted to mapMECFS may be accessed and used broadly by qualified investigators for research and other activities consistent with the NIH Data Sharing Policies: <https://sharing.nih.gov/data-management-and-sharing-policy>

11. **Non-Research Access**. The PI/Submitter acknowledges that data and Supporting Materials submitted to mapMECFS become U.S. Government records that are subject to the Freedom of Information Act (FOIA), 5 U.S.C. 552. NIH is required to release Government records in response to FOIA requests unless they are exempt from release under one of the FOIA exemptions.

12. **Acknowledgments**. In all publications (for abstracts as space allows), oral and written presentations, and disclosures based on dataset(s) submitted to mapMECFS, the PI/Submitter site user agrees to cite mapMECFS, the relevant mapMECFS dataset identifier (unique dataset URL or resource ID), and the PI/Submitter’s federal research funding sources, if appropriate. The citation should include the following acknowledgement:

*Data used in the preparation of this article reside in the MECFS Network data platform* [*https://mapMECFS.org*](https://mapMECFS.org) *in [dataset identifier], supported by National Institutes of Health (NIH) and developed by RTI International. This manuscript reflects the views of the authors and does not necessarily reflect the opinions or views of the NIH, MECFS Network, or RTI International.*

The PI/Submitter may include additional required citation(s) and source of funding statement which will appear alongside the submitted data.

13. **Non-Endorsement; Liability**. The PI/Submitter agrees not to claim, infer, or imply endorsement by the U.S. Government, the Department of Health & Human Services, or the NIH of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). The U.S. Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

14. **PI/Submitter's Compliance with Institutional Requirements.** The PI/Submitter represents that these data were collected in a manner consistent with all applicable laws and regulations and institutional policies. The PI/Submitter further represents that the data were collected pursuant to an informed consent that is not inconsistent with the data submission and that the data submitted were collected in accordance with NIH regulations, or applicable foreign law concerning the protection of human subjects, and other applicable U.S. federal and state laws, if any.

15. **Permission to Post Summary Information**. The PI/Submitter agrees to permit NIH, RTI International, and the mapMECFS team to post the PI/Submitter’s name, email address, and organizations/institutional affiliation on the mapMECFS site. Uploaded dataset names and accompanying metadata will be released for public use after the PI/Submitter has requested to share the data publicly.

16. **Privacy Act Notification**. The PI/Submitter agrees that information collected from the PI/Submitter, as part of the SA, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the PI/Submitter comes from the authorities regarding the establishment of NIH, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0200 covering “Clinical, Basic and Population-based Research Studies of the NIH, HHS/NIH/OD.” The primary uses of this information are to document, track, monitor and evaluate the submission of data from clinical, basic, and population-based research activities and to notify PI/Submitters if a potential error in the dataset is identified or in the event of updates or other changes to the database.

The Federal Privacy Act protects the confidentiality of the PI/Submitter’s NIH records. NIH will use the data collected for the purposes described above. In addition, this Act allows the release of some information in the PI/Submitter’s records without the PI/Submitter’s permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for submitting data to mapMECFS.

17. **Security.** The PI/Submitter acknowledges the expectations set forth by the mapMECFS Information Security Best Practices, which is available on the [mapMECFS login page](https://www.mapmecfs.org/user/login), for the use and security of data.

18. **Amendments.** Amendments to this SA must be made in writing and signed by authorized representatives of both parties. An amendment to this SA is required to submit dataset(s) from a new Research Project.

19. **Termination.** Either party may terminate this SA without cause by providing 30 days’ written notice to the other party. mapMECFS will retain a copy of all data already submitted to mapMECFS for which data quality activities have been completed, except if research participants withdraw consent for data sharing and NIH is informed by the PI/Submitter to withdraw the data. The PI/Submitter agrees to immediately report violations of mapMECFS policy (Appendix II) to the ME/CFS DAQ. Additionally, NIH may terminate this agreement with 5 days’ written notice if the agencies determine, in their sole discretion, that the PI/Submitter has committed a material breach of this SA. The agencies may, in their sole discretion, provide the PI/Submitter with 30 days’ notice to remedy a breach before termination. Closed accounts may be reactivated upon submission of an updated Submission Request and SA.

20. **One-Year Term and Access Period.** This SA must be renewed once a year. The DAQ will request confirmation from the PI/Submitter that the Research Project and data submission is ongoing and confirm that there have been no changes to the original SA.

## **Submitter Information and Certifications**

**Principal Investigator Information**

|  |  |  |  |
| --- | --- | --- | --- |
| First Name: |  | Affiliation |  |
| Last Name |  | Telephone Number |  |
| Degree: |  | Fax Number |  |
| Email: |  |

**Submitter Information**

|  |  |  |  |
| --- | --- | --- | --- |
| First Name: |  | Affiliation |  |
| Last Name |  | Telephone Number |  |
| Degree: |  | Fax Number |  |
| Email: |  |

**Institution Information**

|  |  |
| --- | --- |
| Institution Name: |  |
| Street Address |  |
| City, State/Province |  |
| Zip/Postal Code |  |
| Country |  |

**Team**

|  |
| --- |
| Collaborators (Individuals who will be uploading dataset with the primary Submitter) |
|  | Name: |  |
|  | Email: |  |
|  | Name: |  |
|  | Email: |  |
|  | Name: |  |
|  | Email: |  |
|  | Name: |  |
|  | Email: |  |

**Research Overview**

|  |  |
| --- | --- |
| Research Project Grant # (if applicable) |  |
| Funding Agency |  |
| Research Project (title and brief description) |  |

**Certificate of Confidentiality:**

 Applied Obtained Does not have

Attachments:

Upload electronic copies of the study protocol, questionnaires, study manuals, variables measured, and other supporting documentation, as appropriate via the mapMECFS Website.

**Signatures:**

By signing and dating this SA as part of submitting a Dataset to mapMECFS, I certify that I will abide by the SA and the NIH principles, policies, and procedures for the use of the mapMECFS platform. I further acknowledge that I have shared this document and the mapMECFS policies and procedures, as outlined on the site, and NIH Data Management and Sharing Policy with any research staff who will participate in the use of mapMECFS.

|  |  |
| --- | --- |
| Date |  |
| Principal Investigator’s Signature |  |
|  | Signature |

|  |  |  |  |
| --- | --- | --- | --- |
| IRB Approval # |  | Expiration Date |  |

|  |  |
| --- | --- |
| Date |  |
| Signing Official Name |  |
| Signing Official Title: |  |
| Institutional Signature |  |
|  | Signature of Authorized Institutional Business Official |

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