NIMH Data Repositories

Data Submission Request

Last updated: TBD

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NIMH Data Repositories Data Submission Request

The NIMH Data Repositories are a group of Federal data repositories based on an informatics platform for human-subjects research domains related to mental health, initially established as the National Database for Autism Research to support autism-related research. As of June 2014, the system has expanded to include the following repositories:

- National Database for Autism Research (NDAR)—data submission and access
- National Database for Clinical Trials Related to Mental Illness (NDCT)—data submission and access
- Research Domain Criteria Database (RDoCdb)—data submission and access
- NIH Pediatric MRI Repository (PedsMRI)—data access only

The appropriate Data Access Committee (DAC) approves submission of data and/or images to the NIMH Data Repositories. The DAC will review the NIMH Data Repositories Data Submission Request from each Submitter submitting data and will decide whether to permit the submission based on the expectations outlined in the NDAR Policy and the NIH Guide Notice, Data Sharing Expectations for NIMH-funded Clinical Trials (NOT-MH-14-015). In the event that submissions raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAC will consult with other experts as appropriate.

Submitters may use this Data Submission Request to 1) only submit data to one of the repositories listed above; or 2) submit data to one of the repositories and for subsequent analysis with NIMH Data Repository tools by the Submitter. Both types of requests are subject to approval by the appropriate DAC. Completing this Submission Request is a necessary step to submit data to the NIMH Data Repositories. Access to other data within the NIMH Data Repositories for analysis purposes may be subject to the NIMH Data Repositories Access Request and procedures.

Steps to Request to Submit Data and/or Images to the NIMH Data Repositories

1. Participate in an introductory phone call to begin planning for data submission. The NIMH support staff will discuss with investigators a) data submission expectations; b) supporting materials submission expectations; c) data access preferences; d) technical specifications; and e) data accuracy as it relates to the NIMH Data Repositories. For federal grant recipients, this step should be completed as soon as possible after the grant is awarded, so that appropriate plans can be made prior to data collection, which allow for an easier submission process.
2. If the NIMH Data Repositories can accommodate the data, the investigator submitting the data is encouraged to read NIMH Data Repositories Data Submission Agreement (SA) and complete and sign the SA, cosigned by a business official from an NIH sponsored institution, on the Submitter Information and Certifications form.
3. Request an account at https://ndar.nih.gov/request_access.html uploading a scanned electronic version of the Submitter Information and Certifications form.
4. Data submission review: The appropriate DAC will review requests to submit data to the NIMH Data Repositories. Such reviews are generally completed within 10 business days. The DAC may allow NIMH Data Repositories staff to approve data submission requests on their behalf.
5. The DAC will notify NIMH Data Repositories staff if the submission request has been approved and access will then be provided. Once a Submitter has permissions to submit data to the NIMH Data

Repositories, he or she should follow the steps for data submission as defined at: http://ndar.nih.gov/contribute.html.

Data Submission Agreement—Terms and Conditions

I request approval to submit data and/or images to the NIMH Data Repositories for the purpose of sharing data for research purposes. I agree to the following terms:

1. Research Project. These data will be submitted solely in connection with the "Research Project", specifically indicated and described in the Submitter Information and Certifications section.

Data submitted to the NIMH Data Repositories may be made available by the NIH for either collaborative research (i.e., to accelerate research on ongoing studies) or general research purposes (i.e., meta-analyses and other secondary uses of the data).

This Submission Agreement (SA) covers only the Research Project as contemplated in the Submitter Information and Certifications section and only for submission to the NIMH Data Repository specified. Submitter will submit a completed SA (this document) for each research project for which submission is requested.

2. Non-transferability of Agreement. This SA is not transferable. Submitter agrees that substantive changes Submitter makes to the Research Project requires execution of a new SA, in which the new Research Project is designated. If the Submitter changes institutions and wishes to retain submission privileges to the NIMH Data Repositories, a new SA in which the new institution acknowledges and agrees to the provisions of the SA is necessary.

3. Use of NIH Global Unique Identifier Client. Submitter has used the software program provided free-of-charge by NIH to assign GUIDs, subject to the NDAR Global Unique Identifier (GUID) terms of use, to assign GUIDs to each participant as described in Policy for the National Database for Autism Research, which is applicable across the NIMH Data Repositories (see http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy.pdf and NOT-MH-14-015), and have re-sorted the data according to the GUID..

4. Non-Identification of Subjects. Submitter agrees the data and/or images have been 'de-identified' according to the following criterion: the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users (45 C.F.R. 46.102(f)). Submitter further agrees not to disclose the identities of research participants to the NIMH Data Repositories in the future and to verify that data and/or images lack identifiers after submission. Submitter agrees to notify NIH as soon as possible if, upon review of NIMH Data Repositories data, the Submitter discovers identifying information in that data.

5. Data Disclaimers. Submitter agrees that NIH does not and cannot warrant the results that may be obtained by using any data or data analysis tools included in the NIMH Data Repositories. NIH disclaims all warranties as to the accuracy of the data in the NIMH Data Repositories or the performance or fitness of the data or data analysis tools for any particular purpose.

6. Supporting Materials. Submitter agrees to provide the NIMH Data Repositories 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
- Description of variables measuresOther supporting documentation, as appropriate, such as the creation of an NDAR Study (see http://ndar.nih.gov/data_from_papers.html)

7. Data Accuracy. Submitter certifies to the best of his/her knowledge and belief that the data submitted to the NIMH Data Repositories are accurate. Submitter also agrees to perform the specified quality control activities within a timeframe specified by the NDAR Policy and/or NOT-MH-14-015 (see above). Submitter further agrees to notify NIH as soon as possible if, upon review of NIMH Data Repositories data, the Submitter discovers data quality concerns.

8. Notification to NIH of Publication. Prompt publication or other public disclosure of the results of the Research Project is encouraged. Submitter agrees to notify the NIH via email at NIMHDRHelp@mail.nih.gov as to when and where a publication (or other public disclosure) of a report from the Research Project will appear. Notification of such publications can occur by sending an email to NIMHDRHelp@mail.nih.gov with the title, authors, place of publication, and publication date. Notification of such publications can also occur by sending to NIH an updated biographical sketch or CV of the publishing author. The definition of an NDAR Study serves as appropriate notification of a publication.

9. Data Access for Research. Submitter agrees that data and Supporting Materials submitted to the NIMH Data Repositories may be accessed and used broadly by qualified researchers for research and other activities as authorized by and consistent with law. This access may result in duplication of research data.

10. Non-Research Access. Submitter acknowledges that data and Supporting Materials submitted to the NIMH Data Repositories become U.S. Government records that are subject to the Freedom of Information Act (FOIA). NIH is required to release Government records in response to (FOIA) requests unless they are exempt from release under one of the FOIA exemptions. Submitter further acknowledges that data and Submitting Materials may be used or released consistent with law.

11. Acknowledgments. In any and all publications based upon dataset(s) submitted to the NIMH Data Repositories, Submitter agrees to cite the NIMH Data Repositories, the relevant dataset identifier (a serial number), and the Submitters' federal research funding sources in each publication to which such datasets contribute (for abstracts, as space allows), use an NDAR Study identifier, or an NIMH Data Repositories Digital Object Identifier. The manuscript should include the following acknowledgement:

> Data used in the preparation of this article reside in the NIH-supported NIMH Data Repositories in [dataset identifier]. This manuscript reflects the views of the authors and does not reflect the opinions or views of the NIH.

Submitter agrees to acknowledge the contribution of the NIMH Data Repositories in any and all oral and written presentations, disclosures, and publications resulting from substantive analyses of data using NIMH Data Repositories tools. The manuscript should include the following acknowledgement:

Data and research tools used in the preparation of this article reside in and were analyzed using the NIH-supported NIMH Data Repositories, a collaborative informatics system created by the National Institutes of Health to provide a national resource to support and accelerate research in mental health related conditions. Dataset identifier: [dataset identifier]. This manuscript reflects the views of the authors and does not reflect the opinions or views of the NIH or of the Submitters submitting original data to the NIMH Data Repositories.

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

13. Submitter's Compliance with Institutional Requirements. Submitter acknowledges that these data were collected in manner consistent with all applicable laws and regulations, as well as institutional policies. Submitter further acknowledges 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 45 CFR Part 46, or applicable foreign law concerning the protection of human subjects, and other applicable U.S. federal and state laws, if any.

14. Submitter's Permission to Post Information Publicly. Submitter agrees to permit NIH to summarize and release for public use on the appropriate NIMH Data Repositories Web site the Supporting Materials along with the Submitter's name and organizations/institutional affiliation.

15. Privacy Act Notification. The Submitter agrees that information collected from the Submitter, as part of the SA and submission certification, 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 Submitter comes from the authorities regarding the establishment of the National Institutes of Health, 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 (http://oma.od.nih.gov/public/ms/privacy/pafiles/0200.htm) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate the submission of data from clinical, basic, and population-based research activities and to notify Submitters in the event 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 Submitter's NIH records. NIH will use the data collected for the purposes described above. In addition, the Act allows the release of some information in the Submitter's records without the 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 the NIMH Data Repositories.

16. Security. Submitter acknowledges the expectations set forth by the attached "NIMH Data Repositories Information Security Best Practices" for the use and security of data.

17. Amendments. Amendments to this SA must be made in writing and signed by authorized representatives of both parties.

18. Termination. Either party may terminate this SA, without cause, provided 30 days' written notice to the other party. The NIMH Data Repositories will retain a copy of all data already submitted to the NIMH Data Repositories for which data quality activities have been completed, except in the event that research participants withdraw consent for sharing of their data through the NIMH Data Repositories and NIH is informed by the Submitter to withdraw the data. Submitters agree to immediately report violations of NDAR Policy and/or NOT-14-015 to the appropriate NIMH Data Repositories DAC. Additionally, the NIH may terminate this agreement with 5 days written notice if the NIH determines, in its sole discretion, that the Submitter has committed a material breach of this SA. The NIH may, in its sole discretion, provide 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.

19. Term and Submission Period. Researchers are granted permission to submit data to a Collection within the NIMH Data Repositories for a period of one year after the project end date. This SA will automatically terminate at that time, as appropriate. Permission to submit data to a Collection may be renewed upon recertification of a new SA. User accounts and/or Collections that remain inactive for 12 consecutive months may be closed at the discretion of NIH.

NIMH Data Repositories Information Security Best Practices

The purpose of these Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use the NIMH Data Repositories to submit, access, and analyze data. Keeping NIMH Data Repositories information secure through these best practices is important. Subject to applicable law, Submitters agree to immediately report breaches of data confidentiality to the NIMH Data Repositories DAC.

Best Practices

We suggest that you:

- Do not attempt to override technical or management controls to access data for which you have not been expressly authorized.
- Do not use your trusted position and access rights to exploit system controls or access data for any reason other than in the performance of the proposed research.
- Ensure that anyone directed to use the system has access to, and is aware of, NIMH Data Repositories Information Security Best Practices and all existing policies and procedures relevant to the use of the NIMH Data Repositories, including but not limited to, the NDAR Policy at http://ndar.nih.gov and 45 CFR Part 46.
- Follow the NIMH Data Repositories password policy which includes:
  - Choose passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
  - Change your passwords every six months.
  - Protect your NIMH Data Repositories password from access by other individuals—for example, store it electronically in a secure location.
- Notify the NIMH Data Repositories staff at NIMHDRHelp@mail.nih.gov of security incidents, or any incidents of suspected fraud, waste or misuse of NIMH Data Repositories or when access to NIMH Data Repositories is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data by your institution.
- Neither store nor transmit links between personally identifiable information and GUIDs.
- When you download NIMH Data Repositories data, download the data to a secured computer or server with strong password protection.
- For the computers hosting NIMH Data Repositories data, ensure that they have the latest security patches and are running virus protection software.
- Make sure the data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines such as Google or MSN.
- If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing data on a laptop or other portable medium. If storing data on such a device, encrypt the data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system. (Windows = EFS or Pointsec and Mac OSX = File Vault)
- When finished using the data, destroy the data or otherwise dispose of it properly

OBM Control Number: 0925-0667
Expiration Date: 09/30/2016

Burden Disclosure Statement

Public reporting burden for this collection of information is estimated to average 95 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.

Submitter Information and Certifications

OBM Control Number: 0925-0667
Expiration Date: 09/30/2016

Submit Data to the following Repository *(check only one)*:

___ National Database for Autism Research (NDAR)
___ National Database for Clinical Trials Related to Mental Illness (NDCT)
___ Research Domain Criteria Database (RDoCdb)

1. Submitter Information:

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title): _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Country: _____ Phone: _____ FAX: _____

Institutional E-mail Address: _____

Institution's Point of Contact Name *(if different from the Submitter)*: _____

Institution's Point of Contact Phone: _____ E-mail: _____

Research Project (title and brief description): _____

_____

_____

If data are from biospecimens that have restrictions on sharing, please state those restrictions here:

_____

2. Certificate of Confidentiality *(please circle one)*: Applied Obtained Does not have

3. Attachments:
Upload electronic copies of the study protocol, questionnaires, study manuals, variables measured, and other supporting documentation, as appropriate via the appropriate NIMH Data Repositories Web site.

4. Signatures:
By signing and dating this SA as part of submitting data to the NIMH Data Repositories, my Institutional Officials and I certify that we will abide by the SA and the NIH principles, policies and procedures for the use of the NIMH Data Repositories. I further acknowledge that I have shared this document and the NIH policies and procedures with any research staff who will participate in the use of NIMH Data Repositories. My Institutional Business Official(s) also acknowledges that they have shared this document and the relevant NIH policies and procedures with appropriate institutional organizations.

Signature: _____ Date: _____

Authorized Institutional Business Official *(as registered in the NIH eRA Commons: https://commons.era.nih.gov/commons)*

Name: _____ Title: _____

FWA#: _____

Signature: _____ Date: _____