OMB Control Number: 0925-0667
Expiration Date: 02/28/2018

NIMH Data Repositories

Data Submission Agreement

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I. Introduction

The National Institute of Mental Health (NIMH) Data Repositories are a group of Federal data repositories based on an informatics platform for 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

This form is for purposes of requesting permission to submit data to the NIMH Data Repositories. Submitters must use this Data Submission Agreement to submit data to one of the repositories listed above. In order to access data within the NIMH Data Repositories for analysis purposes, the NIMH Data Repositories Data Use Certification, which is a separate document, must be completed.

The Data Repositories

The National Institutes of Health (NIH) and NIMH have developed a federation of data repositories to store the collection of data from participants in research studies related to mental health, regardless of the source of funding. The extensive information collected by these studies, and subsequently stored in the National Database for Autism Research (NDAR), the NIH Pediatric MRI Repository (PedsMRI), the National Database for Clinical Trials Related to Mental Illness (NDCT), and the Research Domain Criteria Database (RDoCdb) provides a rare and valuable scientific resource. The NIH and the NIMH seek to encourage the use of these resources to achieve rapid scientific progress. In order to take full advantage of such resources and maximize their research value, it is important that data be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

National Database for Autism Research (NDAR)

The National Database for Autism Research (NDAR) is an NIH-funded research data repository that aims to accelerate progress in autism spectrum disorder (ASD) research through data sharing, data harmonization, and the reporting of research results.

National Database for Clinical Trials Related to Mental Illness (NDCT)

NIMH has made data sharing an expectation for all future clinical trials funded by NIMH (see NOT-MH-14-015). Researchers are expected to submit both positive and negative data and results from NIMH-funded clinical trials to the National Database for Clinical Trials Related to Mental Illness (NDCT). NDCT will provide a system to support the submission, sharing and access of relevant data at all levels of biological and behavioral organization and for all data types. At present, data submitted to NDCT will be the result of grants funded through a series of NIMH funding opportunity announcements (FOAs).

Research Domain Criteria Database (RDoCdb)

The Research Domain Criteria (RDoC) initiative aligns research in genetics, neuroscience, and behavioral science to develop a precision-medicine approach for classifying mental illnesses. In contrast to current symptom-based diagnostic systems for mental illnesses, precision medicine integrates many levels of information for each patient to define a precise diagnosis. Data submitted to the RDoC Database (RDoCdb) will include the results of grants funded through a series of NIMH FOAs in support of the RDoC project, as well as relevant data submitted by other interested investigators, regardless of funding source. More information on the RDoC project and related FOAs can be found at http://www.nimh.nih.gov/research-priorities/rdoc/index.shtml.

II. Definitions

For purposes of this agreement, "data" refers to the information which have been collected and recorded from participants in any study, regardless of the source of funding. For human subjects, data include all research and clinical assessments and information obtained via interviews, direct observations, laboratory tasks and procedures, records reviews, genetic and genomic data, neuroimaging data, psychophysiological assessments, data from physical examinations, etc. The following are not included as data: laboratory notebooks, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

A "Submitter" is defined as a researcher with a past or current/active grant, contract, or consulting agreement with the NIH, one of its contractors, or any other funding source, who has submitted data to the NIMH Data Repositories, according to the policies laid out in the NIMH Data Repositories Submission Agreement.

For the purposes of this agreement, the "Point of Contact" refers to an individual working on behalf of the Submitter to complete and submit this SA and who can be contacted in the event that certain questions arise in connection with this SA.

III. Instructions

1. The Submitter should review appropriate tutorials and/or contact the NIMH Data Repositories (NIMHDR) support staff to plan for data submission.
2. The Submitter must read the NIMH Data Repositories Data Submission Agreement (SA) and complete and sign Section VII, Submitter Information and Certifications. The SA must be cosigned by a business official with signature authority as defined in the eRA Commons system from the institution with which they are affiliated.
3. Request an account at https://ndar.nih.gov/request_access.html uploading a scanned electronic version of the SA.
4. The appropriate Data Access Committee (DAC) will review the SA from each Submitter and will decide whether to permit the submission based on the expectations outlined in the SA. 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. 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 staff will provide Submitter permission. Once a Submitter has permission to submit data to the NIMH Data Repositories, he or she should follow the steps for data submission at: http://ndar.nih.gov/contribute.html.

IV. Terms and Conditions

I request approval to submit data to the NIMH Data Repositories to share 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 Section VII. Submitter Information and Certifications.

This SA covers only the Research Project as contemplated in Section VII. Submitter Information and Certifications and only for submission to the NIMH Data Repository specified. Submitter will submit a completed SA 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, the Submitter must submit a new SA in which the new institution acknowledges and agrees to the provisions of the SA.

3. Use of the NIH Global Unique Identifier Client. Submitter agrees to use the software program provided free-of-charge by the NIH to assign Global Unique Identifier (GUID) or to generate random identifiers that are not associated with a research subject as described in the 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)

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 the NIH as soon as possible after submission if the Submitter discovers identifying information in the data that are submitted.

5. Data Disclaimers. Submitter acknowledges that the 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. The 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. While supporting documentation is expected prior to the end of the project, these documents need not be submitted at the same time as the Data Submission Agreement. Examples of supporting materials include:

- Research protocol(s)
- Questionnaire(s)
- Study manuals
- Description of variables/measures.
- Other supporting documentation, as appropriate, such as the creation of an NIMH Data Repositories 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 four months after data submission. Submitter further agrees to notify the NIH as soon as possible after submission if the Submitter discovers quality concerns in the data that are submitted.

8. Notification to the NIH of Publication. Submitter agrees to promptly notify the NIH via email at NDAHelp@mail.nih.gov as to when and where a publication (or other public disclosure) from the Research Project will appear. Submitter also agrees to create an NIMH Data Repositories Study (http://ndar.nih.gov/access_ndar_study.html) to further define the publication (or other disclosure) and link it to the underlying data. The sharing of an NIMH Data Repositories Study prior to publication serves as appropriate notification.

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.

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). The NIH is required to release Government records in response to FOIA requests unless they are exempt from release under one of the FOIA exemptions.

11. Acknowledgments. In any and all oral and written presentations, disclosures, and publications (including abstracts, as space allows) based upon dataset(s) submitted to the NIMH Data Repositories, Submitter agrees to cite the NIMH Data Repositories and the NIMH Data Repositories Study digital object identifier (DOI). Note that this is in addition to the acknowledgement of NIH support (http://grants.nih.gov/grants/acknow.htm). Sample acknowledgement text is provided:

Data used in the preparation of this article/presentation/etc. reside in the NIH-supported NIMH Data Repositories in [NIMH Data Repositories Study DOI].

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 a 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 consistent with the data submission.

14. Submitter's Permission to Post Information Publicly. Submitter agrees to permit the 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. Submitter agrees that information collected by the NIH from the 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 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 09-25-0156 (http://oma.od.nih.gov/public/ms/privacy/pafiles/0156.htm) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/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. The NIH will use the information 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 requested by members of Congress or other authorized individuals. The information requested in the SA 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 and Security Standards" 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 the NIH is informed by the Submitter to withdraw the data. In such case, the NIH will, consistent with law, remove data from further distribution through the NIMH Data Repositories, but it will not seek to retrieve data from authorized data recipients. Submitters agree to immediately report violations of this agreement 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 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 the NIH.

V. Information Security Best Practices and Security Standards

The purpose of these Security Best Practices and Security Standards, 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.

Security 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.
- Do not allow others to use your account. Each user must obtain and use their own account.
- Ensure that anyone directed to use the system has access to, and is aware of, NIMH Data Repositories Information Security Best Practices and Security Standards as well as 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 NDAHelp@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, with strong password protection, and encrypted storage.
- 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 protected from anonymous access from users both inside and outside of the organization.
- 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.
- When finished using the data, destroy the data or otherwise dispose of it properly.

VI. Burden Disclosure Statement

Public reporting burden for this collection of information is estimated to vary from 15 min to 1.5 hours 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 (0925-0667). Do not return the completed form to this address.

VII. Submitter Information and Certifications

1. Submitter Information:

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

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: _____

Point of Contact (POC) Name *(if different from the Submitter):* _____

POC Phone: _____ POC E-mail Address: _____

Research Project (title, brief description, grant number and funding source):

_____

_____

_____

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

_____

_____

2. 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 for the use of the NIMH Data Repositories. I further acknowledge that I have shared this document 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 with appropriate institutional organizations.

Submitter Signature: _____ Date: _____

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

Name: _____ Title: _____

FWA#: _____

Signature: _____ Date: _____

E-mail is the preferred method of submission. Paper submissions should be sent to:
Office of Technology Development and Coordination (OTDC), Program Director
National Institute of Mental Health, National Institutes of Health
6001 Executive Boulevard, Room 7202, MSC 9645
Rockville, MD 20892-9649 (if overnight delivery): Bethesda, Maryland 20852
Telephone: 301-443-3265 Email: NDAHelp@mail.nih.gov

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