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NIMH Data Archive

Data Submission Agreement

Last updated: August 2019

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Introduction

The National Institute of Mental Health (NIMH) Data Archive (NDA) is an NIH-funded collaborative resource that contains human subjects research data from multiple research data repositories.

The NIMH Data Archive Data Submission Agreement (DSA) is used to request permission to submit data to a data repository within the NIMH Data Archive. When completing the *Data Submitter Information and Certifications* form in this document, a data access sponsorship type must be selected to specify whether data access requestors must be sponsored by an institution (Institutional sponsorship) or self-sponsored (Individual sponsorship).

- Institutional sponsorship requires a Recipient to be affiliated with an NIH recognized institution (foreign or domestic), based upon registration in the NIH's eRA Commons system, with an active Federal Wide Assurance (FWA) issued by the Department of Health and Human Services, Office for Human Research Protections (OHRP). The signature of an Authorized Institutional Business Official is also required.
- Individual sponsorship may be requested by a Recipient without the need for sponsorship by or affiliation with an NIH recognized institution and, therefore, the signature of an Authorized Institutional Business Official or an active institutional FWA is not required.

All requests require acceptance of the Data Use Terms and Conditions contained in the NIMH Data Archive Data Use Certification (DUC), which is a separate document, regardless of the type of data access sponsorship requested.

Data Submission Terms and Conditions

I request permission to submit data to the NIMH Data Archive for the purpose of scientific investigation, scholarship or teaching, or other forms of research and research development as described in the following NIMH Data Archive Data Submission Agreement (DSA). I, and any other staff involved in the submission of data, agree to the following terms:

1. Research Project

Data will be submitted solely in connection with the "Research Project", specifically indicated and described in *Submitter Information and Certifications* form of this document. Submitter will complete and submit a separate DSA for each research project for which submission is requested.

2. Non-transferability of Agreement

This DSA is not transferable. Submitter agrees that substantive changes made to the Research Project will require the execution of a new DSA, in which the new Research Project is designated. If the Submitter changes institutions, a new DSA in which the new institution acknowledges and agrees to the provisions of the DSA is required.

3. Non-Identification of Subjects

Submitter agrees that all submitted data have been 'de-identified' so that the identities of subjects cannot be readily ascertained or otherwise associated with the data by the NIMH Data Archive staff or secondary data users (45 C.F.R. 46.102(f)). Submitter also agrees to verify that submitted data lack

identifying information after submission. Submitter further agrees to not disclose the identities of research participants to the NIMH Data Archive staff in the future and to notify the NIH as soon as possible after submission if the Submitter discovers identifying information in the data that are submitted.

4. Use of the NIH Global Unique Identifier (GUID)

The Global Unique Identifier (GUID) is a computer-generated alphanumeric code that is unique to each research participant. The GUID allows the NIMH Data Archive to link together all submitted information on a single participant, giving researchers access to information even if the data were collected at different locations or through different studies. Submitter agrees to use the software program, provided free-of-charge by the NIH, to assign Global Unique Identifiers (GUID), or to generate random identifiers if the information needed to create a GUID is not available. Submitter further agrees to submit all subject data to the NIMH Data Archive with a GUID.

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 Archive. The NIH disclaims all warranties as to the accuracy of the data in NIMH Data Archive or the performance or fitness of the data or data analysis tools for any particular purpose.

6. Data Accuracy

Submitter certifies to the best of his/her knowledge and belief that the data submitted to the NIMH Data Archive are complete and accurate. Submitter also agrees to perform quality control activities within four months from the end of the submission cycle (see <https://nda.nih.gov/contribute/sharing-regimen.html> for submission cycle dates). Additionally, the Submitter certifies that no personally identifiable information (PII) is present in the submission (<https://nda.nih.gov/about/standard-operating-procedures.html#sop5>). Submitter further agrees to notify the NIH as soon as possible if the Submitter discovers quality concerns or PII in the data that are submitted. Additionally, the Submitter agrees to correct data quality concerns, whether identified by the Submitter or by the NIMH Data Archive staff and re-submit data as soon as possible.

7. Data Access for Research

Submitter agrees that data and Supporting Documentation submitted to the NIMH Data Archive may be accessed and **used broadly** by approved users for research and other activities as authorized by and consistent with law.

8. Supporting Documentation

Submitter agrees to provide the NIMH Data Archive with supporting information, materials, and documentation ("Supporting Documentation") to enable efficient use of the submitted data by investigators unfamiliar with the data or the research project. Supporting documentation is expected to be submitted to the Research Project's NIMH Data Archive Collection and shared prior to the end of the project. Examples of supporting documentation include:

- Research protocol(s)
- Questionnaire(s)
- Study manuals

9. Sharing of a NIMH Data Archive Study/Acknowledgements

Submitters agree to create and share an NIMH Data Archive Study (<https://nda.nih.gov/contribute/manuscript-preparation.html>) for each publication (or other public disclosure) of results from the analysis of data submitted to the NIMH Data Archive, whether reporting positive or negative results, thereby linking it to the underlying data. Submitters agree to create the NIMH Data Archive Study when a manuscript is submitted for review and share the Study when the publication is released. Submitters agree to acknowledge the appropriate NIMH Data Archive Data Repository and the relevant Digital Object Identifier(s) (DOI), which will be created by NIMH Data Archive staff, in any and all oral and written presentations, disclosures, and publications (including abstracts, as space allows) resulting from any and all analyses of data. The oral or written presentation, disclosure, or publication should include an acknowledgement or other similar language, which includes a disclaimer of NIH endorsement, as appropriate. Acknowledgements specific to each NDA data repository are maintained at <https://nda.nih.gov/contribute/manuscript-preparation.html>.

If the Research Project involves collaboration with Submitters or NIH staff (as indicated in the DUC), then Recipient will acknowledge Submitters or NIH staff as co-authors, if appropriate, on any presentation, disclosure, or publication.

10. Non-Research Access

Submitter acknowledges that data and Supporting Documentation submitted to the NIMH Data Archive become U.S. Government records that are subject to the Freedom of Information Act (FOIA). The NIH is required to release U.S. Government records in response to FOIA requests unless they are exempt from release under one of the FOIA exemptions.

11. Non-Governmental Endorsement; Liability

Submitter agrees not to claim, infer, or imply endorsement of the "Research Project" indicated and described in *Submitter Information and Certifications*, the entity, or personnel conducting the research project or any resulting commercial product(s) by the United States Government, the Department of Health & Human Services, the National Institutes of Health, or the National Institute of Mental Health. The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

12. 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.

13. Submitter's Permission to Post Information Publicly

Submitter agrees to permit the NIMH Data Archive to publicly summarize the Submitter's research project and release supporting documentation along with the Submitter's name and organizational/institutional affiliation.

14. Privacy Act Notification

Submitter agrees that information collected by the NIH from the Submitter, as part of the DSA, 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 Sections 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

([https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/Privacy%20Act%20Systems%20of%20Records%20Notices%20\(SORNs\)%205-1-15.pdf](https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/Privacy%20Act%20Systems%20of%20Records%20Notices%20(SORNs)%205-1-15.pdf)) 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, 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 some 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 DSA is voluntary, but necessary for submitting data to the NIMH Data Archive.

15. Security

Submitters acknowledge that users submitting data will utilize the NIMH Data Archive in a manner consistent with security best practices. Such practices include, but are not limited to, the following:

- Accounts and passwords will not be shared.
- Data are protected from anonymous access. Any data transferred or stored outside of the NIMH Data Archive will be protected using standard encryption protocols and/or strong password protection.

16. Amendments

Amendments to this DSA must be made in writing and signed by authorized representatives of all parties.

17. Termination

Either party may terminate this DSA, without cause, provided 30 days' advanced written notice to the other party. The NIMH Data Archive will retain a copy of all data already submitted to the NIMH Data Archive 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 Archive and the NIH is informed by the Submitter to withdraw the data. In this case, the NIH will, consistent with law, remove data from further distribution through the NIMH Data Archive, 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 Archive Data Access Committee. Additionally, the NIH may terminate this agreement with 5 days' advanced written notice if the NIH determines, in its sole discretion, that the Submitter has committed a material breach of this DSA. The NIH may, in its sole discretion, provide Submitter with 30 days' advanced written notice to remedy a breach before termination.

18. Accurate Representations

Submitter expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

19. Institutional and Individual Data Access Sponsorship

Submitter expressly certifies that the NIMH Data Archive has permission to provide access to data submitted as part of this Data Submission Agreement according to the type of data access sponsorship selected by the Submitter on the *Submitter Information and Certifications* form contained herein. Submitter acknowledges that selecting Institutional sponsorship for access to data submitted as part of this Research Project will require Recipients to be affiliated with an NIH recognized institution (foreign or domestic), based upon registration in the NIH's eRA Commons system, with an active Federal Wide Assurance (FWA) issued by the Department of Health and Human Services, Office for Human Research Protections (OHRP), as certified through the signature of an Authorized Institutional Business Official while selecting Individual sponsorship will allow a Recipient to request access to data without the need for sponsorship by or affiliation with an NIH recognized institution and, therefore, will not require the signature of an Authorized Institutional Business Official or an active FWA. Submitter understands that the type of data access sponsorship may be changed by the Submitter with 30 days' advanced written notice to the NIMH Data Archive by completing a new Data Submission Agreement.

Burden Disclosure Statement

Public reporting burden for this collection of information is estimated to take up to 90 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 (0925-0667). Do not return the completed form to this address.

NIMH Data Archive Submitter Information and Certifications
Submitter Information:

First Name: _____ Last Name: _____
Degree: _____ Institution: _____
City: _____ State/Province: _____ Country: _____
Phone: _____ E-mail Address: _____

1. Data Repository: See <https://nda.nih.gov/about/about-us.html> for a current list of NDA data repositories.

2. Research Project: Items marked with an asterisk (*) are required for non-NIH funded projects only.

Research Project Title: _____
Funding Source: _____ Grant/Contract Number: _____

Clinical Trials Only - Clinical Trial ID: _____

Data Source: Existing Samples/Data - Source(s): _____
 Subject Enrollment - Targeted/Planned Enrollment: _____

*Funding Amount: _____ *Project Dates: From _____ To _____

*Program Official: _____ *Program Official Email: _____

*Grant Management (GM) Contact: _____ *GM Email: _____

*Project Description (*Use additional sheets as needed.*): _____

3. Check here if data will be made available through controlled access

Controlled access dataset submissions must be accompanied by an Institutional Certification, signed by the Submitter and an Authorized Institutional Business Official, that describes consent-based data use limitations.

4. Has and/or will this project submit the following to another repository?

Tissue/Biomedical No Yes If Yes, provide repository name: _____
 Genomic Data No Yes If Yes, provide repository name: _____
 Other Data No Yes If Yes, provide repository name: _____

5. Data Access Sponsorship: Select the type of sponsorship required for user access to data from this research project. (See the Introduction section on page 1 for more information on sponsorship types.)

- Institutional - Data access requires sponsorship by an Institution on behalf of Recipient(s).
 Individual - Individual data access allowed without the need for Institutional sponsorship.

6. Authorized Institutional Business Official: List an individual with an "SO" role as defined in the NIH eRA Commons - <https://commons.era.nih.gov/commons/>

Name: _____ Email: _____

7. Signatures: By signing and dating this DSA to submit data to the NIMH Data Archive, I and my Institutional Officials certify that we will abide by the Data Submission Terms and Conditions defined in this DSA. I further acknowledge that I have shared this document with any other staff and collaborating investigators who will use the NIMH Data Archive. My Institutional Business Official (*if required*) also acknowledges that they have shared this document with appropriate institutional organizations.

 Submitter Signature

 Date

 Authorized Institutional Business Official Signature (*if required*)

 Date

Inquiries and requests to submit data to the NIMH Data Archive 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 8125, MSC 9640 | Bethesda, MD 20892-9640
 Telephone: 301-443-3265 | Email: NDAHelp@mail.nih.gov