OMB Control Number: 0925-0667
Expiration Date: 11/30/2020

NIMH Data Archive

Data Submission Agreement

Last updated: December 14, 2017

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NIMH Data Archive Data Submission Agreement

Introduction

The National Institute of Mental Health (NIMH) Data Archive (NDA) is a collaborative resource that contains human subjects research data.

The NIMH Data Archive Data Submission Agreement (DSA) is used to request permission to submit data to 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 (by May 15 for the January 15 submission cycle/by November 15 for the July 15 submission cycle). Additionally, the Submitter certifies that no personally identifiable information (PII) is present in the submission. 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 an NIMH Data Archive Study/Acknowledgements

Submitters agree to create and share an NIMH Data Archive Study (http://ndar.nih.gov/access_ndar_study.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 NIMH Data Archive 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 the following acknowledgement or other similar language, which includes a disclaimer of NIH endorsement, as appropriate:

NDAR Acknowledgement

Data and/or research tools used in the preparation of this manuscript were obtained from the NIH-supported National Database for Autism Research (NDAR). NDAR is a collaborative informatics system created by the National Institutes of Health to provide a national resource to support and accelerate research in autism. Dataset identifier(s): [NIMH Data Archive Collection ID(s) or NIMH Data Archive Digital Object Identifier (DOI)]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the NIH or of the Submitters submitting original data to NDAR.

NDCT Acknowledgement

Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the NIMH-supported National Database for Clinical Trials (NDCT). NDCT is a collaborative informatics system created by the National Institute of Mental Health to provide a national resource to support and accelerate discovery related to clinical trial research in mental health. Dataset identifier(s): [NIMH Data Archive Collection ID(s) or NIMH Data Archive Digital Object Identifier (DOI)].

RDoCdb Acknowledgement

Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the NIMH-supported Research Domain Criteria Database (RDoCdb). RDoCdb is a collaborative informatics system created by the National Institute of Mental Health to store and share data resulting from grants funded through the Research Domain Criteria (RDoC) project. Dataset identifier(s): [NIMH Data Archive Collection ID(s) or NIMH Data Archive Digital Object Identifier (DOI)].

ABCD Acknowledgement

Data used in the preparation of this article were obtained from the Adolescent Brain Cognitive Development (ABCD) Study (https://abcdstudy.org), held in the NIMH Data Archive (NDA). This is a multisite, longitudinal study designed to recruit more than 10,000 children age 9-10 and follow them over 10 years into early adulthood. The ABCD Study is supported by the National Institutes of Health and additional federal partners *under award numbers U01DA041022, U01DA041028, U01DA041048, U01DA041089, U01DA041106, U01DA041117, U01DA041120, U01DA041134, U01DA041148, U01DA041156, U01DA041174, U24DA041123, and U24DA041147*. A full list of supporters is available at https://abcdstudy.org/nih-collaborators. A listing of participating sites and a complete

listing of the study investigators can be found at https://abcdstudy.org/principal-investigators.html. ABCD consortium investigators designed and implemented the study and/or provided data but did not necessarily participate in analysis or writing of this report. This manuscript reflects the views of the authors and may not reflect the opinions or views of the NIH or ABCD consortium investigators.

(Add the following sentence for a report that uses data from a versioned release)
The ABCD data repository grows and changes over time. The ABCD data used in this report came from [NIMH Data Archive Digital Object Identifier (DOI)]. DOIs can be found at [DOI URL].

(Add the following sentence for a report that uses data from the fast track release)
The ABCD data repository grows and changes over time. The ABCD data used in this report came from the fast track data release. The raw data are available at [NIMH Data Archive Digital Object Identifier (DOI)]. Instructions on how to create a NDA study are available at https://data-archive.nimh.nih.gov/training/modules/study.html).

Osteoarthritis Initiative (OAI)
Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the Osteoarthritis Initiative (OAI). OAI is a collaborative informatics system created by the National Institute of Mental Health and the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS) to provide a worldwide resource to quicken the pace of biomarker identification, scientific investigation and OA drug development. Dataset identifier(s): [NIMH Data Archive Collection ID(s) or NIMH Data Archive Digital Object Identifier (DOI)].

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)) 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 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.

NIMH Data Archive Submitter Information and Certifications

1. Submitter Information:

First Name: _____ Last Name: _____

Degree: _____ Institution: _____

City: _____ State/Province: _____ Country: _____

Phone: _____ E-mail Address: _____

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.)*: _____

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3. 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:	_____

4. 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.

5. **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: _____

6. **Signatures:** By signing and dating this DSA to submit data to the NIMH Data Archive, I and my Institutional Officials *(if required)* 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