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NIMH Data Archive

Data Use Certification

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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 Use Certification (DUC) is used to request access to shared research data in the NIMH Data Archive. Shared data are available with either an Institutional sponsorship or an Individual sponsorship. All data access requests require acceptance of the Data Use Terms and Conditions contained in this DUC. (See the *NIMH Data Archive Recipient Information and Certifications* form in this document for available data and associated sponsorship types.)

- Institutional sponsorship requires 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). The signature of an Authorized Institutional Business Official is also required on this DUC.
- 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.

A Data Access Committee(s) (DAC) will objectively review a data access request sponsored by an Institution. Individual sponsorships do not require DAC review. To submit data to the NIMH Data Archive, the NIMH Data Archive Data Submission Agreement (DSA) must be completed, which is a separate document.

The NIMH Data Archive (NDA)

The National Institutes of Health (NIH) and NIMH have developed a repository to store the collection of data from participants in research studies, 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), the Research Domain Criteria Database (RDoCdb), the Adolescent Brain Cognitive Development (ABCD) Study, and the Osteoarthritis Initiative (OAI), provides a rare and valuable scientific resource. The NIH and NIMH seek to encourage the use of these resources to achieve rapid scientific progress. Moreover, NIMH has made data sharing an expectation for all clinical research it funds (see NOT-MH-15-012). In order to take full advantage of such resources and maximize their research value, it is important that data are made **broadly available**, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Data collected by the Submitters have been stripped of all individual identifiers, but the unique and intrinsically personal nature of genomics data, brain imaging, and other derivative data of which are included in these repositories, combined with the recent increase in the accessibility of conducting genotype and other sequence analyses (in terms of technological capacity and cost), has altered the framework through which "identify-ability" can be defined. To protect and assure the confidentiality and privacy of all participants, the Recipient who is granted access to these data is expected to adhere to the specifications of this DUC. Failure to do so could result in denial of further access to data.

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. Raw genomics, clinical, imaging, and neurosignal recording data and results are available.

National Database for Clinical Trials Related to Mental Illness (NDCT)
The NIMH has made data sharing an expectation for all future clinical trials funded by the 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) as well as other privately funded research projects.

Research Domain Criteria Database (RDoCdb)
The Research Domain Criteria (RDoC) initiative aligns research in 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. Omics data associated with these studies are found in genomics repositories supported by the National Library of Medicine (dbGaP and SRA).

NIH Pediatric MRI Data Repository (PedsMRI)
The goal of the NIH MRI Study of Normal Brain Development and the resulting Pediatric MRI Data Repository (PedsMRI) is to generate data that can help foster a better understanding of normal brain maturation as a basis for understanding atypical brain development associated with a variety of developmental, neurological, and neuropsychiatric disorders affecting children and adults.

Adolescent Brain Cognitive Development Study (ABCD)
The ABCD Study is a long-term study of brain development and child health in the United States. Multiple NIH Institutes and Centers and additional federal partners are supporting this ambitious project. The ABCD Consortium consists of a Coordinating Center, a Data Analysis and Informatics Center, and 21 research sites across the country where investigators will perform regular, comprehensive biological and behavioral assessments on more than 10,000 children beginning at ages 9 or 10 and continuing throughout adolescence into early adulthood. A more complete description of the study is available at https://ABCDStudy.org.

Osteoarthritis Initiative (OAI)
The Osteoarthritis Initiative (OAI) is a multi-center, longitudinal, prospective observational study of knee osteoarthritis (OA). The overall aim of the OAI is to develop a public domain research resource to facilitate the scientific evaluation of biomarkers for osteoarthritis as potential surrogate endpoints for disease onset and progression. The OAI will establish and maintain a natural history database for osteoarthritis that will include clinical evaluation data, radiological (x-ray and magnetic

resonance) images, and a biospecimen repository from 4796 men and women ages 45-79 enrolled between February 2004 and May 2006. Four 3.0 Tesla MRI scanners, one at each clinical center, are dedicated to imaging the knees of OAI participants annually over four years. The seven-year project will recruit participants who have, and those who are at high risk for developing, symptomatic knee osteoarthritis. Access to biospecimens will be by application to the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS).

Data Use Terms and Conditions

I request access to shared data from 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 Use Certification (DUC). I, and any Other Recipients listed in this DUC, agree to the following terms:

1. Research Data Use Statement

Generally, these data will be used by the Recipient in connection with the purpose indicated and described in the *Research Data Use Statement* on the DUC. Recipients are encouraged to explore shared data in the NIMH Data Archive for a variety of purposes including secondary analysis, hypothesis generation, and replication regardless of whether said exploration leads to analysis in support of a question beyond the scope of the originally identified purpose described in the *Research Data Use Statement*.

2. Non-transferability of Agreement

This DUC is not transferable. If a Recipient changes institutions and wishes to retain access to the NIMH Data Archive, a new DUC is required.

3. Non-Identification of Subjects

Recipients agree that data will not be used to establish the individual identities of any of the study participants from whom data were obtained (or their relatives) and/or contact the individual study participant, except as permitted by law (e.g., in connection with a separately negotiated collaboration with the original research team or the enrollment of the consented subject in the Recipient's study). Recipients agree to notify the NIH at NDAHelp@mail.nih.gov as soon as possible if, upon use of NIMH Data Archive data, identifying information is discovered.

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. If Recipients access data on individuals for whom they, themselves, have previously submitted data to the NIMH Data Archive, Recipients may gain access to more data about an individual participant than they, themselves, collected. Consequently, these research activities may be considered "human subjects research" within the scope of 45 C.F.R. 46. Recipients must comply with the requirements contained in 45 C.F.R. 46, as applicable, which may require Institutional Review Board (IRB) approval of the Research Data Use Statement.

5. Data Disclaimers

Recipients acknowledge 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 the NIMH Data Archive or the performance or fitness of the data or data analysis tools for any particular purpose.

6. Data Access for Research

Data and Supporting Documentation in the NIMH Data Archive are eligible for access by qualified researchers, pursuant to the terms set forth in this DUC. Recipients acknowledge that other researchers have access to the data and that downloading and duplication of research is a distinct possibility, thereby decreasing subject data protections. Raw or nearly raw research data files (e.g. fastq, bam, MRI, and EEG recordings) are made available for just in time computation, regardless of where the computational resources may reside. Therefore, data copied shall not be persisted (i.e., stored) beyond the time necessary for computation and shall be expunged once computation has been completed. Recipients are encouraged to utilize the NIMH Data Archive computational capabilities described at https://data-archive.nimh.nih.gov/tools#cloud.

7. Supporting Documentation

Recipients agree to review the supporting information, materials, and documentation ("Supporting Documentation") for the data accessed in the NIMH Data Archive to enable efficient use of the submitted data by Recipients unfamiliar with the data or the research project. Examples of supporting documentation include:

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

8. Sharing of an NIMH Data Archive Study/Acknowledgements

Recipients agree to create and share an NIMH Data Archive Study (http://ndar.nih.gov/access_ndar_study.html) for each publication, computational pipeline, or other public disclosure of results from the analysis of data accessed in the NIMH Data Archive, whether reporting positive or negative results, thereby linking it to the underlying data. Recipients agree to create the NIMH Data Archive Study when a manuscript is submitted for review and share the Study when the publication is released. Recipients 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, whether or not the Recipient is collaborating with Submitter(s). The oral or written presentation, disclosure, or publication should include the following acknowledgement, 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.

Pediatric MRI Acknowledgement

Data used in the preparation of this article were obtained from the NIH Pediatric MRI Data Repository created by the NIH MRI Study of Normal Brain Development. This is a multisite,

longitudinal study of typically developing children from ages newborn through young adulthood conducted by the Brain Development Cooperative Group and supported by the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the National Institute of Mental Health, and the National Institute of Neurological Disorders and Stroke (Contract #s N01-HD02-3343, N01-MH9-0002, and N01-NS-9-2314, -2315, -2316, -2317, -2319 and -2320). A listing of the participating sites and a complete listing of the study investigators can be found at http://pediatricmri.nih.gov/nihpd/info/participating_centers.html. Dataset identifier(s): [NIMH Data Archive Collection ID(s) or NIMH Data Archive Digital Object Identifier (DOI)].

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.

9. No Distribution of Data
Recipients agree to retain control over data from the NIMH Data Archive, and further agree not to transfer or sell data, with or without charge, in any form, to any other entity or any individual or to distribute the data to anyone other than the Other Recipients listed on this DUC who also agree to the terms in this DUC. This includes any data derived from the data in the NIMH Data Archive if the associated GUID is distributed with that derived data or if the derived data can aid in the re-identification of a research participant.

10. Non-Governmental Endorsement; Liability
Recipients agree not to claim, infer, or imply endorsement of the research project described in the *Research Data Use Statement*, 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).

11. Recipient's Compliance with Institutional Requirements
Recipients with Institutional sponsorship acknowledge that access, if provided, is for research that is approved by the Institution with which they are affiliated, which must be operating under an active Federal Wide Assurance (FWA) issued by the Department of Health & Human Services, Office for Human Research Protections (OHRP). Furthermore, Recipients agree to comply with all applicable rules for the protection of human subjects, which may include Department of Health and Human Services regulations at 45 C.F.R. Part 46, and other federal and state laws for the use of this data. Recipients agree to report promptly to the NIH any unanticipated problems involving risks to subjects or others. This DUC is made in addition to, and does not supersede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

12. Recipient's Permission to Post Information Publicly
Recipient agrees to permit the NIMH Data Archive to publicly summarize the Recipient's research use of data along with the Recipient's name and organizational/institutional affiliation.

13. Privacy Act Notification
Recipients agree that information collected by the NIH from a Recipient, as part of the DUC, 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 Recipients 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 use of NIMH Data Archive datasets, as well as to notify interested Recipients of updates, corrections 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 Recipient's records without the Recipient's permission; for example, if it is requested by members of Congress or other authorized individuals. The information requested in this DUC is voluntary, but necessary for obtaining access to data in the NIMH Data Archive.

14. Security

Recipients acknowledge that the data being made available were made available for researcher use with the expectation that the data will be protected 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.
- When finished using the data, the data will be expunged, as permitted by law.

15. Annual Update/Research Use Reporting

Recipients will provide to NDAHelp@mail.nih.gov an annual summary of research accomplishments from using the NIMH Data Archive and agree to create and share an NIMH Data Archive Study for each public disclosure of results pursuant to the Sharing of an NIMH Data Archive Study/Acknowledgements term in this DUC. The NIH encourages Recipients who publish manuscripts based on a combination of data from the NIMH Data Archive data, data derived from NDA data, and data collected independent of the NIMH Data Archive to consider submitting the complete analyzed dataset to the NIMH Data Archive.

16. Amendments

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

17. Termination

Either party may terminate this DUC, without cause, provided 30 days' advanced written notice to the other party. Recipients 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 a Recipient has committed a material breach of this DUC. The NIH may, in its sole discretion, provide a Recipient with 30 days' advanced written notice to remedy a breach before termination.

18. Term and Access Period

Recipients are granted permission to access requested and approved data from the NIMH Data Archive for a period of one year and this DUC will automatically terminate at that time. Data access may be renewed upon certification of a new DUC.

19. Accurate Representations

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

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.