OMB Control Number: 0925-0667
Expiration Date: 06/30/2026

NIMH Data Archive

Data Use Certification

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NIMH Data Archive Data Use Certification

Introduction

This Data Use Certification Agreement outlines the terms and conditions for requesting access to data maintained in the National Institute of Mental Health (NIMH) Data Archive.

Researchers accessing human subjects' data and their research institution are responsible for maintaining the privacy of those subjects and the confidentiality of their data. By signing and submitting this NIMH Data Archive Data Use Certification (DUC), you and your institution are accepting the terms and conditions for responsibly using human subjects' data. Read the entire DUC carefully before signing and submitting this agreement. Ensure that all members of your research team who will have access to the data under this DUC (Recipients) have also read the DUC and have agreed to abide by the terms of the DUC. You and your institution are responsible for the way that all listed Recipients use the data. Failure to adhere to the terms and conditions of this DUC could result in denial of further access to NIMH Data Archive data and in other actions.

The NIMH Data Archive

The National Institute of Mental Health (NIMH) Data Archive (NDA) is an NIH-funded collaborative resource that contains harmonized human subjects research data and metadata from multiple research Data Repositories, providing a rare and valuable scientific resource. Access to shared record-level data in NDA is provisioned at the level of a Permission Group. NDA Permission Groups consist of one or multiple NDA Collections that contain data with the same subject data use consents and sponsorship requirements. An NDA Collection generally contains data associated with a single grant award.

See https://nda.nih.gov/nda/about-us.html and https://nda.nih.gov/user/dashboard/data_permissions.html for a current list of NDA Data Repositories and NDA Permission Groups. NDA Data Access Request Standard Operating Procedures are maintained at https://nda.nih.gov/nda/standard-operating-procedures.html#sop4a and include a description of sponsorship requirements.

Data submitted to NDA have been stripped of all individual identifiers. However, the unique and intrinsically personal nature of clinical data, genomics data, brain imaging data, and other derivative data of which are included in these repositories, combined with new analytical methodologies and decreasing computing and storage costs, has altered the framework through which "identify-ability" can be defined. To protect and assure the confidentiality and privacy of all participants, all Recipients who are granted access to these data are expected to adhere to all terms of use outlined in this DUC.

The NIH and NIMH seek to encourage the use of these resources to achieve rapid scientific progress. Moreover, NIMH has made data sharing a requirement for all clinical research it funds (see NOT-MH-23-100). 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.

To submit data to the NIMH Data Archive, the NIMH Data Archive Data Submission Agreement (DSA) must be completed, which is a separate document (https://nda.nih.gov/ndapublicweb/Documents/NDA+Submission+Request.pdf).

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. Non-transferability of Agreement

This DUC is not transferable. Recipients must notify the NIMH Data Archive of changes in institutional affiliation. Recipients who change institutional affiliation will be removed from the DUC and they must submit a new DUC from their new institution in order to retain access. If the Lead Recipient changes institutions, they may identify another Recipient on the DUC as a replacement.

2. Data for Research Use

Recipients agree to use data for scientific investigation, scholarship or teaching, or other form of research and research development. Generally, data will be used by the Recipient in connection with the purpose indicated and described in the *Research Data Use Statement* in the *Recipient Information and Certifications* below. Recipients are encouraged to explore shared, *broadly consented* 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*.

3. No Distribution of Data

Recipients agree to retain control over data and to not distribute, sell, or move data, with or without charge, in any form, to any other individual, entity, or third-party system except to authorized collaborators as specified below. This includes raw data from any individual participant and derived subject-level data if the derived data can aid in the re-identification of a research participant.

There may be some judgement concerning whether derived data can aid in the re-identification of a research participant especially for imaging data. Any questions concerning this issue should be directed to the Recipient's Institutional Review Board (IRB) or sent to the NIMH Data Archive Help Desk (ndahelp@mail.nih.gov). Before subject-level derived data are distributed outside of an NDA Study, approval should be sought from the Help Desk.

4. Collaboration with Shared Data

Recipients may distribute (share) data from the NIMH Data Archive with authorized researchers (collaborators) who are listed on a non-expired DUC for the same Permission Group and have agreed to the terms in this DUC, for the purpose of collaboration on research projects only. Recipients are responsible for ensuring that collaborators are authorized researchers. Recipients may contact the NIMH Data Archive Help Desk at ndahelp@mail.nih.gov to receive written confirmation that the DUC for collaborators is not currently expired. If the DUC has expired, or will expire within one calendar month, it must be renewed prior to sharing data.

5. No Re-identification of Subjects

Recipients agree that data will not be used to attempt 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.

Recipients agree to not publish or distribute any derived data that could aid in the re-identification of any of the study participants (or their relatives), including structural MRI images or genomic data that have been reprocessed using data

obtained from NDA. Any questions concerning this issue should be directed to the Recipient's IRB or sent to the NIMH Data Archive Help Desk (ndahelp@mail.nih.gov) at the NIMH Data Archive.

6. Compliance with Applicable Human Subjects Protection and Institutional Requirements

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 are responsible for determining whether their proposed research with data from the NIMH Data Archive necessitates consultation with their Institutional Review Board.

Recipients agree to conform to the principles for ethical conduct of biomedical and behavioral research as outlined in Section B of the Belmont Report (Respect for Persons, Beneficence, and Justice). Recipients must consider any psychological, social, economic, and other potentially harmful impacts their research results could have on individuals, communities, and society, and take steps to minimize them.

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.

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).

7. Additional Human Subjects Research Requirements

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. In this case, recipients must comply with the requirements contained in 45 C.F.R. 46, as applicable, which may require IRB approval of the *Research Data Use Statement*.

8. Security

Recipients agree to protect data from the NIMH Data Archive by implementing the controls needed to maintain the confidentiality integrity, and availability of the data. By signing this agreement, Recipients acknowledge that they have implemented a security plan to prevent data loss or breach, whether the data are stored on local machines or with a cloud service provider. Recipients agree that the data will be protected in a manner consistent with security best practices which include, but are not limited to, the following:

- Accounts and passwords are not shared.
- Data are protected from anonymous access and are never exposed to the internet.
- Data are protected using standard encryption protocols and/or strong password protection.
- Software patches are kept up to date.

9. Deletion of Data

Recipients agree that data that has been downloaded from the NIMH Data Archive will be permanently deleted from all local or cloud-based machines when research is completed or this DUC is expired, whichever comes first. Recipients are strongly encouraged to keep data stored in the NIMH Data Archive cloud environment and not download data locally, to avoid download costs and unnecessary data duplication.

10. Supporting Documentation

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 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

11. Sharing Results with an NIMH Data Archive Study

Recipients agree to create and share an NIMH Data Archive Study (https://nda.nih.gov/nda/manuscript-preparation.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 NDA Study when the publication is released. Recipients submitting renewal data access requests agree to report their results and list each related NIMH Data Archive Study in the *Progress Report* section below.

12. Acknowledgements

Recipients agree to acknowledge the appropriate NIMH Data Archive data repository and the relevant Digital Object Identifier(s) (DOI), which will be minted upon NIMH Data Archive Study creation, in any and all oral and written presentations, disclosures, and publications (including abstracts, as space allows) resulting from any and all analyses of data. Acknowledgements specific to each NDA data repository are maintained at https://nda.nih.gov/nda/manuscript-preparation.html. Oral or written presentations, disclosures, or publications should include the appropriate acknowledgement statement(s).

13. 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.

14. 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).

15. 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, as listed in this DUC.

16. 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/DMS/Pages/Privacy-Program-Laws-Policies-Memoranda.aspx) 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.

17. Amendments

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

18. Termination

Either party may terminate this DUC, without cause, provided 30 days' advanced written notice to the other party. Additionally, the NIH may terminate this agreement immediately 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.

19. 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. Data access renewal requests will be reviewed for compliance with the terms and conditions of this DUC.

20. Violations

Failure to adhere to any of the terms and conditions of this DUC could result in denial of further access to NDA data and in other actions. Recipients agree to immediately report violations of this agreement to the NIMH Data Archive by emailing the NDA Help Desk (ndahelp@mail.nih.gov).

21. Accurate Representations

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

NIMH Data Archive Recipient Information and Certifications

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.

1. Access Request

DAR ID: _____

Access to shared record-level data in NDA is provisioned at the level of a Permission Group. See https://nda.nih.gov/nda/about-us.html and https://nda.nih.gov/user/dashboard/data_permissions.html for a current list of Permission Groups and their specific data access requirements.

Request Type: New ☐ Renewal: ☐

NDA Permission Group: _____

Permission Group Description

Data Use Limitations

Requires IRB Approval: Yes ☐ No ☐

Requires Institutional Sponsorship*: Yes ☐ No ☐

**Institutional sponsorship requires the signature of an Authorized Institutional Business Official and an active Federal Wide Assurance (FWA) number in the Signatures section below.*

Requesting access to sensitive data*: Yes ☐ No ☐

** Requests for sensitive data such as geolocation data from personal tracking devices would require additional documentation confirming IRB awareness of additional security concerns. Consult NDA Help Desk if sensitivity of requested data is unclear.*

2. Progress Report (For Renewal Requests Only)

Recipients requesting a renewal of an expiring Data Use Certification should provide a Progress Report on research conducted with data from the NIMH Data Archive. The Progress Report should also describe any updates to the original Research Data Use Statement and changes to the Other Recipient list on the Data Use Certification. Recipients who conduct a secondary analysis on data shared through NIMH Data Archive are expected as part of the DUC Terms of Use to report their results using the NDA Study feature (https://nda.nih.gov/nda/manuscript-preparation.html).

Progress Report Statement

Has a publication, computational pipeline, or other public disclosure of results from the analysis of data accessed in the NIMH Data Archive resulted from a Recipient's previous access period? Yes ☐ No ☐

If Yes, list the PubMed ID(s) or citation(s)

Has an NDA Study been created? Yes ☐ No ☐

If Yes, list the NDA Study number(s): _____

3. Research Data Use Statement

Both new and renewal access requests should complete this section.

Describe the purpose of the scientific investigation, scholarship or teaching, or other form of research and research development for which you are requesting access to the NIMH Data Archive. Describe how NDA data will be accessed by all recipients on this DUC. If data will be downloaded, describe how the data will be managed throughout the course of the proposed research, including the plan for data deletion.

If you are requesting access to controlled access data, this statement must demonstrate adherence to the consent-based data use limitations described in the NDA Permissions Dashboard.

4. Lead Recipient

Lead Recipients must submit the Data Use Certification from the NIMH Data Archive Permissions Dashboard (https://nda.nih.gov/user/dashboard/data_permissions.html).

First Name: ___________________________ Last Name: ____________________________________ Degree: _____________

Institution: ____

City: ___________________________________ State/Province: ______________________________ Country: _____________

Phone: _______________________ Email Address: ____

5. Other Recipient(s)

All Other Recipients should have the same Institutional Affiliation as the Lead Recipient. Collaborators at other Institutions should submit a separate Data Use Certification.

List all individuals who will access, use, or analyze the data regardless of position title or data use role. This should include any IT staff who clean or manage the data. Use additional sheets as needed.

First Name: ___________________________ Last Name: ____________________________________ Degree: _____________

Institution: ____

City: ___________________________________ State/Province: ______________________________ Country: _____________

Phone: _______________________ Email Address: ____

First Name: ___________________________ Last Name: ____________________________________ Degree: _____________

Institution: ____

City: ___________________________________ State/Province: ______________________________ Country: _____________

Phone: _______________________ Email Address: ____

First Name: ___________________________ Last Name: ____________________________________ Degree: _____________

Institution: ____

City: ___________________________________ State/Province: ______________________________ Country: _____________

Phone: _______________________ Email Address: ____

First Name: ___________________________ Last Name: ____________________________________ Degree: _____________

Institution: ____

City: ___________________________________ State/Province: ______________________________ Country: _____________

Phone: _______________________ Email Address: ____

First Name: ___________________________ Last Name: ____________________________________ Degree: _____________

Institution: ____

City: ___________________________________ State/Province: ______________________________ Country: _____________

Phone: _______________________ Email Address: ____

Any additional Other Recipients are listed at the end of this document

6. Authorized Institutional Business Official

List an individual with a Signing Official (SO) role as defined in the NIH eRA Commons - *https://www.era.nih.gov/register-accounts/account-roles.htm*

Name: _____

Email: _____

7. Signatures

By signing and dating this DUC to request access to data in the NIMH Data Archive, I and my Institutional Business Official *(if required)* certify that we will abide by the Data Use Terms and Conditions defined in this DUC. I further acknowledge that I have shared this document with any Other Recipients who will participate in the use of data from the NIMH Data Archive. My Institutional Business Official *(if required)* also acknowledges that they have shared this document with appropriate institutional organizations.

_____	_____
Lead Recipient Signature	Date
_____	_____
Authorized Institutional Business Official Signature	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