

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>) 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>. 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/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 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.

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.