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

NIMH Data Archive

Data Submission Agreement

Last updated: March 2026

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NIMH Data Archive Submission Agreement

Introduction

This Data Submission Agreement (DSA) is used to request permission to submit data to a data repository within the National Institute of Mental Health (NIMH) Data Archive (NDA) and outlines the terms and conditions associated with data submission.

By signing and submitting this NDA DSA, you and your institution are accepting terms for responsibly submitting human subjects' data. Read the entire DSA carefully before signing and submitting this agreement.

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. See https://nda.nih.gov/nda/about-us for a current list of NDA Data Repositories.

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 high quality data are made **broadly available**, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Data submitted to NDA should be 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 requests to access data in NDA require acceptance of the Data Use Terms and Conditions contained in the NIMH Data Archive Data Use Certification (DUC), which is a separate document (https://s3.amazonaws.com/nda.nih.gov/cms/prod/NDA-Data-Access-Request-DUC-FINAL.pdf).

Data Submission Terms and Conditions

I request permission to submit to NIMH Data Archive (NDA) human subjects' data that were collected as part of the "Research Project" described below. These data will be made accessible to authorized users for the purpose of scientific investigation, scholarship or teaching, or other forms of research and research development. I, and any other staff involved in the submission of data, agree to the following terms:

1. Scope of Data Submitted

Data will be submitted solely in connection with the "Research Project", specifically indicated and described in Submitter Information and Certifications form of this document. Each institution that will submit Research Project data directly to NIMH Data Archive (NDA) should submit a separate NDA DSA. 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 terms of the DSA is required. Submitter agrees to notify NDA of substantive changes to the Research Project and a change in their institutional affiliation. A change of PI also requires a new DSA.

3. De-Identification of Data

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 NDA staff or secondary data users (https://nda.nih.gov/nda/standard-operating-procedures#sop5). 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 have been submitted

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

Submitter agrees to collect the information required to generate a Global Unique Identifier (GUID) for all research participants, using software provided by NIMH Data Archive (NDA) (https://nda.nih.gov/nda/using-the-nda-guid). The GUID is a computer-generated alphanumeric code that is unique to each research participant and is securely generated using locally stored personally identifiable information, without submitting any identifiable information to NDA. The GUID allows NDA to link together all submitted information on a single participant, giving authorized researchers access to information even if the data were collected at different locations or through different studies.

Submitter may use the NDA GUID Tool to generate pseudoGUIDs if their Institutional Review Board determines that the information required to create a GUID may not be collected from research participants. Submitter agrees to submit all subject data to NDA with a GUID or pseudoGUID.

5. Appropriate Consent and Compliance with Institutional Requirements

Submitter acknowledges that data are submitted to NIMH Data Archive (NDA) in accordance with informed consent of research participants and/or with the approval of the Institutional Review Board. Submitter agrees that data and Supporting Documentation submitted to NDA may be accessed and **used broadly** by approved users for research and other activities as authorized by and consistent with law. In some cases, Submitter will demonstrate that their Institutional Review Board has approved a research protocol in which research participants may or have consented to limitations on the use of their data, as outlined in the NIH Genomic Data Sharing Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html). These Submitters agree to indicate consent- based exceptions to broad research use in section 4 of the *Submitter Information and Certifications* form below and to provide to NDA a signed Institutional Certification prior to or upon submitting this DSA (https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form#step-0). Submitter further acknowledges that the data was collected in a manner consistent with all applicable national, Tribal, and state laws and regulations as well as relevant institutional policies and that submission of the data is consistent with applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.

6. Institutional and Individual Sponsorship

Submitter expressly certifies that NIMH Data Archive (NDA) 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. See https://nda.nih.gov/nda/standard-operating-procedures#sop4a for information about NDA Data Access Request (DAR) Procedures. Submitter understands that the type of data access sponsorship may be changed by the Submitter with 30 days' advanced written notice to NDA by completing a new Data Submission Agreement (DSA).

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.

Submitter acknowledges that 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. Individual sponsorship is uncommon and not recommended.

7. Data Accuracy, Completeness, and Timeliness

Submitter certifies to the best of their knowledge and belief that the data submitted to NIMH Data Archive (NDA) are accurate and complete for the Research Project described below. Submitter agrees to perform validation and quality control activities at the outset of each submission cycle (see https://nda.nih.gov/nda/sharing-regimen for submission cycle dates) using the NDA Validation and Upload Tool (https://nda.nih.gov/nda/nda-tools#vt). Submitter agrees to correct data quality concerns identified in NDA Quality Assurance/Quality Control procedures on data submissions (https://nda.nih.gov/nda/standard-operating-procedures#sop5) and to re- submit data no later than the following submission cycle.

Submitter agrees to provide to NDA supporting information, materials, and documentation ("Supporting Documentation") to enable efficient and appropriate use of the submitted data by authorized investigators. Supporting Documentation is expected to be submitted to the Research Project's NDA Collection and shared prior to the end of the Research Project. Examples of supporting documentation include:

- Research protocol(s)
- Questionnaire(s)
- Study manuals
- Clinical Trial protocol(s)
- Manual of Procedures and Case Report Forms

Submitter certifies that they have read and agree to the Data Sharing Terms and Conditions for the NDA data repository to which they are submitting Research Project data (https://nda.nih.gov/nda/sharing-regimen). The Data Sharing Terms and Conditions outline key milestones and timelines to ensure that data are made available to qualified investigators in a timely manner.

8. Access to the NDA Collection Module and Security Best Practices

Once this DSA is fully executed and accepted by NIMH Data Archive (NDA), Submitter will be given privileged access to an NDA Collection where subject-level data, metadata, and Supporting Documentation will be submitted and managed and where the Submitter can provision role-based access to other users with NDA accounts. Submitter agrees to follow security best practices in managing user permissions for their NDA Collection, including but not limited to:

- Adhere to the principle of least privilege when assigning user permissions.
- Remove users who are no longer part of the Research Project team.
- Ensure that users accessing the NDA Collection are not sharing account information.

Submitter further agrees to utilize all NDA system resources in a manner consistent with security best practices. NDA may remove user access to the NDA Collection in the event of a policy violation or other incident.

9. Sharing Results through an NIMH Data Archive Study

Submitter agrees to create and share an NIMH Data Archive (NDA) Study (https://nda.nih.gov/nda/manuscript-preparation) for each publication (or other public disclosure) of results from the analysis of data submitted to NDA, whether reporting positive or negative results, thereby linking it to the underlying data. Submitters agree to create the NDA Study when a manuscript is submitted for review and share the Study when the publication is released.

10. Acknowledgements

Submitters agree to acknowledge the appropriate NIMH Data Archive (NDA) data repository and the relevant Digital Object Identifier(s) (DOI), which will be minted upon NDA 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.

11. System Disclaimers

Submitter acknowledges that the NIH does not and cannot warrant the performance or outputs of data validation, submission, management, or download tools made available free-of-cost to NDA Submitters. The NIH disclaims all warranties as to the performance or fitness of these tools for any particular purpose.

12. Non-Research Access to Data

Submitter acknowledges that data and Supporting Documentation submitted to NIMH Data Archive (NDA) 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. The release of un-redacted NDA data in response to a FOIA request would constitute an unreasonable invasion of personal privacy under FOIA Exemption 6, 5 U.S.C. § 552 (b)(6). Therefore, NDA would redact individual-level research data from disclosures made in response to FOIA requests and would deny requests for un-redacted datasets.

NDA holds a Certificate of Confidentiality for individual-level research data housed in all NDA data repositories. Further information about Certificates of Confidentiality is available at the following website: https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc.

13. 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).

14. Permission to Post Project Information Publicly

Submitter agrees to permit NIMH Data Archive (NDA) to publicly summarize the Submitter's Research Project and release on the public NDA website the information provided in the Submitter Information and Certifications form below.

15. 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/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 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 NIMH Data Archive (NDA).

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. Additionally, the NIH may terminate this agreement immediately 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.

NIMH Data Archive (NDA) will retain a copy of all data already submitted to NDA for which data quality activities have been completed, except in the event that research participants withdraw consent for sharing of their data through NDA 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 NDA, but it will not seek to retrieve data from authorized data Recipients.

18. Violations

Failure to adhere to any of the terms and conditions of this DSA could result in denial of access to NIMH Data Archive (NDA) system and services. Submitters agree to immediately report violations of this agreement to NDA by emailing the NDA Help Desk (NDAHelp@mail.nih.gov).

19. Accurate Representations

Submitter expressly certifies 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.

NIMH Data Archive Submitter Information and Certifications

1. Submitter Information

First Name: _____ Last Name: _____

Degree: _____ Institution: _____

City: _____ State/Province: _____ Country: _____

Phone: _____ Email address: _____

2. Data Repository

See https://nda.nih.gov/nda/about-us for a current list of NDA data repositories.

_____

3. Research Project

Research Project Title

Funding Source: _____ Grant/Contract Number: _____

If the Research Project is a Clinical Trial, provide the Clinical Trial ID below:

Clinical Trial ID (NCT#): _____

If the Research Project will utilize existing samples or data, provide the Source name(s):

Existing Samples/Data – Source(s)

If the Research Project will enroll human subjects, provide expected enrollment numbers:

Subject Enrollment – Targeted/Planned Enrollment: _____

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

Program Official: _____

Program Official Email: _____

Grant Management Officer Contact: _____

Grant Management Officer Email: _____

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

4. Participant Consent

NIMH expects that most data submitted to NIMH Data Archive (NDA) will be consented for broad research use. Research Projects submitting data to NDA that have consent-based data use limitations must provide with this DSA an Institutional Certification (https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds/completing-institutional-certification-form#step-0), signed by the Submitter and an Authorized Institutional Business Official, that describes consent-based data use limitations. Submitted data with consent-based data use limitations will be made available to authorized users in a controlled access Permission Group (https://nda.nih.gov/nda/standard-operating-procedures#sop4a).

Check here if data have consent-based limitations on research use ☐

5. Other Repository Information

Indicate below if the Research Project has and/or will submit samples and/or data to another repository and provide the repository name(s) and specimen or data identifiers (e.g., serial numbers). Pre-shared NDA data may be provided to external repositories for curation.

Tissue/Biomedical Yes ☐ No ☐ If Yes, repository name: _____
Serial Number: _____

Genomic Data Yes ☐ No ☐ If Yes, repository name: _____
Serial Number: _____

Other Data Yes ☐ No ☐ If Yes, repository name: _____
Serial Number: _____

6. Sensitive Information

Does the information to be submitted include identifiable, sensitive information?

○ Yes ○ No

***IMPORTANT**: Research in which identifiable, sensitive information is collected or used includes research that:*

- *Meets the definition of human subjects' research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46)), including exempt research in which participant information cannot be identified or their identity cannot readily be ascertained, directly or through identifiers;*
- *Is collecting or using human biospecimens that are identifiable or that have at least a very small risk of being used to deduce the identity of an individual;*
- *Involves the generation or use of individual level human genomic data from biospecimens, regardless of identifiability; or*
- *Involves any other information where there is at least a very small risk that a person could be identified.*

Is the identifiable, sensitive information to be submitted covered by a CoC?

○ Yes ○ No

***IMPORTANT**: Note that research subject to the NIH Certificates of Confidentiality Policy that involves the generation, collection, or use of identifiable, sensitive information that is funded in whole or in part by NIH is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage.*

7. Submitter Attestations

Submitter attests that:

☐ Expectations with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, as applicable, or as otherwise determined by the Submitting Institution, will be delineated at submission and that metadata and supporting information, materials, and documentation to adequately describe and facilitate interpretation will be submitted to NIH controlled-access data repositories at submission.

Submitter further attests that different offices or components of an institution with appropriate roles and expertise (such as an Institutional Review Board (IRB), Privacy Board, Human Research Protection Program (HRPP), or equivalent body) has reviewed the investigator's proposal for data submission and assures that:

☐ Submission for subsequent sharing and use of the data for research purposes is consistent with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, or as otherwise determined by the Submitting Institution.

☐ The submitted data has been de-identified to the extent required by the NIH controlled-access data repository, applicable laws, regulations, and NIH policies.

☐ Consideration has been given to risks to individual participants and their families associated with data submitted to NIH controlled-access data repositories and subsequent sharing. Consideration has been given to risks to groups or populations associated with submitting datasets to NIH controlled-access data repositories and subsequent sharing.

8. Data Access

Sponsorship

Select the type of sponsorship required for NDA users to request access to data from this Research Project. See Section 6 above for more information on data access sponsorship types.

☐ Institutional: Data access requires sponsorship by an Institution on behalf of Recipient(s)

☐

Individual: Data access allowed without the need for Institutional sponsorship

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9. 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: _____

8. Signatures

By signing and dating this DSA to submit data to the NIMH Data Archive (NDA), I and my Institutional Business Official 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 NDA. My Institutional Business Official 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:

Division of Data Science and Technology (DST), Program Director National Institute of Mental Health | National Institutes of Health
6001 Executive Boulevard, Room 8125, NSC 9640 | Bethesda, MD 20892-9640 | Email: NDAHelp@mail.nih.gov