

Supporting Statement A for

Data Use Certification for the NIH Brain Development Cohorts (NBDC), (NIDA)

OMB Control Number 0925-0780; Exp 10/31/2026

This is a revision to the original submission, and all changes are highlighted in yellow.

Date: 06/26/23

Check off which applies:

- New
- ☒ Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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Attachments

Attachment 1 – General Data Use Statement and Progress Report

Attachment 2 – American Indian Alaska Native Data Use Statement and Progress Report

Attachment 3 – Privacy Act Memo - signed

A. Justification

Abstract:

This document reflects a revision to a package (0925-0780) which was originally submitted for approval in September 2023. These Data Use Certification (DUC) Agreements outline the terms of use for requesting access to data from the Adolescent Brain Cognitive DevelopmentSM (ABCD) Study and the Healthy Brain and Child Development (HBCD) Study, collectively known as the **NIH Brain Development Cohorts (NBDC)**. Data from **both studies** will be maintained at an outside entity contracted by the National Institute on Drug Abuse. This submission is seeking approval for collecting limited information from researchers who wish to access these data for further research studies. While the data are intended to be leveraged by other researchers, it is essential that the integrity of the data is maintained by requiring that researchers and their institutions sign the DUC agreements. **Since the time of the original package submission, we have simplified the process by including only the data use and progress report statements in the package for review, rather than the full data use certification forms, as the respondent burden is limited to completing the statements.**

The ABCD Study is an NIH-funded longitudinal study of nearly 12,000 youth beginning at ages 9-10 and continuing for 10 years into early adulthood to assess factors associated with individual brain development trajectories and functional outcomes. **The HBCD Study is a longitudinal study of early brain and child development that will follow participating families from pregnancy through early childhood. Both studies have** adopted an open science model, making data available to researchers around the world, including fast-track raw neuroimaging data that are released on an ongoing basis, as well as curated data released annually. The data will be available to authorized users via the contractor.

The NIH seeks to encourage the use of these resources to achieve rapid scientific progress. 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.

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 these **data use and progress report statements**, recipients and their institutions **agree to** responsibly use human subjects' data. **Please note that the signing process is integrated into an existing secure user authentication system, requiring no additional effort from recipients beyond what is already in place.**

The revision to this information collection includes the following:

- Clarification of inclusion of the Healthy Brain and Child Development Study (in addition to the ABCD Study). Note that this clarification necessitates changing the title so that it no longer references only the ABCD Study.
- Submission request of a research progress report at the time of DUC renewal

Revisions will not increase the burden estimate for any instrument. This is because completion of a research progress report will not be in addition to the data use statement. If a recipient chooses to renew their DUC after one year, they must submit a research progress report that briefly summarizes the current state of their research project, but they are not required to submit another data use statement.

A.1 Circumstances Making the Collection of Information Necessary

The potential for public benefit to be achieved through sharing research data from the NBDC Studies is significant. The extensive information collected by these studies and subsequently made available provides a rare and valuable scientific resource to the scientific community. Even though the information has been de-identified, protections are still required to minimize risk of identifiability. Authority for the collection of the information requested 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 Section 301 and 493 of the Public Health Service Act.

A.2 Purpose and Use of the Information Collection

This collaborative data management and sharing resource contains harmonized human subjects research data and metadata from the ABCD Study and the HBCD Study, providing a rare and valuable scientific resource to the scientific community. Data submitted have been stripped of all individual identifiers, but the unique and intrinsically personal nature of genomics data, brain imaging, and other derivative data that are included in this repository, have altered the framework through which risk for identifiability can be defined. To protect and assure the confidentiality and privacy of all participants, all recipients who are granted access to data from the ABCD Study or HBCD Study are expected to complete data use and progress report statements outlined in the general *Data Use Certification for NIH Brain Development Cohorts*. Due to the special nature of the data obtained from participants who identify as American Indians/Alaska Natives (AI/AN), recipients who intend to conduct analyses of AI/AN data specifically must submit an additional data use statement. The recipient's DUCs expire after 1 year and must be renewed, with an accompanying progress report statement, if continued data access is requested.

Data from the ABCD Study was previously maintained in the National Institute of Mental Health (NIMH) Data Archive at the National Institutes of Health. In November 2017, the NIMH received OMB approval of updates to the NIMH Data Repository DUC Form under OMB# 0925-0667, Exp. 1/31/2024. In October 2021, NIMH received OMB approval of non-substantive changes to the DUC form.

Although the NIMH Data Archive will continue to host other data repositories, data collected as part of the ABCD Study is being moved to a contractor and will no longer be held at the NIMH Data Archive. This is because the contractor is uniquely qualified to provide the necessary data ingestion, integrated data analytics, customized user experience, and flexibility to ensure ABCD data continuity in the future. The content of the collection instrument in the attached is similar to the content referenced in OMB #0925-0667, Exp. 1/31/2024. Data access governance will continue to be managed by NIH.

Following OMB approval in September 2023, NIDA discovered the need for updating the title to clarify inclusion of the HBCD Study and including the request for a progress report. In addition, it was found that certain information was not required, and that was removed, including the data use certification (DUC) terms and conditions.

A.3 Use of Information Technology and Burden Reduction

To gain access to data, an individual must obtain data access privileges. To obtain these privileges, an individual must complete, sign, and submit the DUCs, including the data use and progress report statements, to the contractor who will then route to NIH Staff for review. Information may be typed or hand-written into the forms and the forms can be uploaded via a web portal, emailed, or sent by US Mail or Private Courier. After the recipient signs the form, it will be routed to an Institutional Signing Official for their signature after which the request will be sent to the contractor and routed to the NIH Data Access Committee for review. Electronic review and adjudication of requests for access will also be implemented for the Data Access Committee portion of the workflow.

The data use and progress report statements request the following information:

- Description of the data requested.
- Contact information for the investigator seeking access (the Data Recipient), as well as for all personnel in the Recipient's laboratory who will also require access as part of the Research Project.
- The title and a summary/abstract of the Research Project for which repository data are sought. A single paragraph is sufficient.
- Co-signatures from the Recipient Investigator and the Investigator's Institutional Official certifying that they will abide by the DUCs and the NIH principles, policies, and procedures for the use of the data.
- The institution's Federal Wide Assurance (FWA) number.

Please note that the signing process is integrated into an existing secure user authentication system, requiring no additional effort from recipients beyond what is already in place.

Once completed, the data use and progress report statements are then sent for adjudication to the contractor who will route to the NIH Data Access Committee (DAC). The DAC members review submissions to ensure that the data being requested are available and that the agreements have been signed. The DAC is responsible for approving submission and access privileges to the contractor.

A.4 Efforts to Identify Duplication and Use of Similar Information

Data access requestors completing the data use or progress report statements have the option of either completing a fillable pdf form by typing information, by completing the form by handwriting the information, or by utilizing an online process. A digital signature is accepted for users and institutional business officials using either the fillable pdf form or the online workflow. For data access renewals, users can simply update information relevant to the new aspects of the project without updating basic information such as contact information, thereby reducing the burden on the user. Due to the sensitive nature of the data contained in the repository, and in accordance with existing NIH policies, such as genome-wide association studies (GWAS; see <http://grants.nih.gov/grants/gwas/index.htm>), data access approvals are granted for one year and may be renewed thereupon.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this project.

A.6 Consequences of Collecting the Information Less Frequently

The information requested in the data use and progress report statements does not ask investigators to generate any new information, because the type of information being requested is fundamental to conducting any research study. The data are collected as needed with the primary purpose of ensuring that the users are aware of and follow the terms and conditions related to data access. The statements are required to be completed once per year (if being renewed) per lead researcher/investigator request. Protecting the privacy of the research participants and the confidentiality of their data is critically important. Essential aspects of that protection are careful screening of who may obtain access to the data platform, and ongoing monitoring of the use of the platform.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Guidelines of 5 CFR 1304/24/20.5 are not applicable to this project.

A.8.1 Comments in Response to the Federal Register Notice

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment was published on November 12, 2024, pages 89019-89020 (89 FR 89019) in the Federal Register. There were no public comments received.

A.8.2 Efforts to Consult Outside Agency

Investigators and institutional business officials are consulted on a regular basis during the performance of other activities related to data access. While proactive conversations are not elicited, investigators and institutional business officials have provided feedback on the type of information requested on the data use and progress report statements. The statements submitted for approval incorporate the comments from such representatives in an effort to reduce burden and allow for the completion of the statements in a timelier manner.

A.9 Explanation of Any Payment of Gift to Respondents

No payment or gift will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The Federal Privacy Act ensures that no sensitive or personally identifiable information, located in federal systems of records (e.g., Recipient NIH records), is being shared, to the extent permitted by law. A system of records is any group of records under the control of a federal agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying information assigned to the individual. The NIH and any sites that are provided access to the datasets will have access to the data collected from the Recipient for the purposes described above. In addition, the Act allows the release of some information in the Recipient's records without his/her permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for obtaining access to data.

Each Data Access Request provides a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0200

(<https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0200.htm>) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD."

The information requested from the investigator seeking access to ABCD or HBCD data, as part of the DUCs, may be made public in part or in whole for tracking and reporting purposes. The DUC Forms provide a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156, September 26, 2002, 67 FR 60742-60794 (<https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0156.htm>) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD."

Although the repository data will be coded (or de-identified) and the data platform will not hold direct identifiers to individuals within the platform, the contractor and NIH recognize the personal and potentially sensitive nature of the data. Investigators and institutions seeking access to data or images from the repository are expected to meet data security measures and to submit data use and progress report statements co-signed by the investigator and the designated Institutional Official, as applicable.

A.11 Justification for Sensitive Questions

NIH does not ask any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; and therefore, a justification for this type of information is not applicable.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

Table 12-1 Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Individuals (standard DUC form)	1800	1	1	1800

Individuals (additional AI/AN DUC form when needed)	200	1	1	200
		2,000		2,000

A.12.2 Annual Cost to Respondents

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Individuals	2,000	\$54.03	\$108,060
TOTAL	2,000		\$108,060

Bureau of Labor Statistics: May 2023 National Occupational Employment and Wage Estimates <https://www.bls.gov/oes/current/oes191042.htm> - Mean hourly wage for medical scientists.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs other than the respondents' burden given in A12.

A.14 Annualized Cost to the Federal Government

The total annualized cost to the Federal Government is \$10,056.18. No additional operational expenses such as equipment, overhead, printing, or support staff will be needed.

Cost Descriptions	Grade/Step	Salary*	% Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Associate Director	GS-15, Step 3	\$174,603	6%		\$10,476.18.
Travel					\$0
TOTAL					\$10,056.18

* Salary/Wage Source: Office of Personnel Management 2025 Salary Table for the Locality Pay Area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB.pdf>

A.15 Explanation for Program Changes or Adjustments

The title of the instruments was changed to reflect inclusion of the HBCD Study. It now refers to the NIH Brain Development Cohorts, which subsumes both the ABCD Study and the HBCD Study. To improve clarity of Recipient burden, only the data use and progress report statements have been included in the package. The following changes were made:

- I. Introduction
 - a. First paragraph – Added information about Health Brain and Child Development Study

- II. Data Use Terms & Conditions - removed
- III. Recipient Information and Certifications
 - a. Modified instructions for Research Data Use Statement
 - b. Progress Report – added language for recipients to include progress report statement

A.16 Plans for Tabulation and Publication and Project Time Schedule

Information collected on the DUCs may be used for internal monitoring purposes.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

OMB number and expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Certification for Paperwork Reduction Act Submissions.