# Data Use Certification for NIH Brain Development Cohorts

OMB No: 0925-NEW

Expiration Date: XX/XX/XXXX

Public reporting burden for this collection of information is estimated to average 60 minutes 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-NEW). Do not return the completed form to this address.

## Introduction

This Data Use Certification (DUC) Agreement outlines the terms of use for access to data from NIH Brain Development Cohorts, including the Adolescent Brain Cognitive DevelopmentSM (ABCD) Study. The ABCD Study(R) is a longitudinal study of nearly 12,000 youth beginning at ages 9-10 and continuing for 10 years into early adulthood to assess factors that influence individual brain development trajectories and functional outcomes. The ABCD Study has 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 are available to authorized users affiliated with an NIH-recognized institution with Federal Wide Assurance (see <https://ohrp.cit.nih.gov/efile/FwaStart.aspx> for more information). Authorization requires users to submit a signed DUC that includes signature by the user’s institution business official.

The NIH encourages the use of these resources to facilitate rapid scientific progress. To take full advantage of such resources and maximize their research value, it is important that data are made **broadly available**, with appropriate terms and conditions, to the largest 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 this DUC, you and your institution are accepting terms for responsibly using human subjects’ data. Read the entire DUC carefully before signing and submitting this agreement. Ensure that all listed 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.**

**Note that Recipients who intend to disseminate findings from descriptive and/or inferential analyses of AI/AN data (e.g., via presentations, pre-prints, publications, website posts, etc.) must submit a second DUC governing use of AI/AN data (AIAN Data Use Certification, or A-DUC) after receiving approval of a general DUC.**

The NIH Brain Development Cohorts Data Repository

The NIH Brain Development Cohorts data repository contains human subjects research data and metadata from multiple ontology domains, providing a rare and valuable scientific resource. As such, the data sharing platform hosting the data accommodates multiple types of data, as well as user customization, workflow development, documentation, and user training. 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 these data are expected to adhere to all terms and conditions of use outlined in this DUC.

Data Use Terms and Conditions

I request access to NIH Brain Development Cohorts shared data for the purpose of scientific investigation, scholarship or teaching, or other forms of research and research development as described in the following Data Use Certification (DUC).

**Failure to adhere to these terms and conditions will result in a report to your institution business official. It could also result in denial of access to NIH Brain Development Cohorts data and will be elevated to NIH leadership for further action.**

I, and any Other Recipients listed in this DUC, agree to the following terms:

### Non-transferability of Agreement

### This DUC is not transferable to another institution. Recipients must notify the NIH Brain Development Cohorts at adolescentbrain@mail.nih.gov if they move to a different institution, at which time they must submit a new DUC with appropriate sponsorship from the new institution to retain access. The Lead Recipient may identify another Recipient on the DUC at the original institution as a replacement.

### Data for Research Use

### These data will be used by the Recipient for investigation, scholarship or teaching, or other form of research and research development in connection with the purpose indicated and described in the Research Data Use Statement on the DUC. Data use includes accessing and interacting with the data up through and including manuscript submission, revision, and publication.

### No Distribution of Data

### Recipients agree to retain control over data and to not share, 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 any derived individual-level data.

### Collaboration with Shared Data

Recipients may share data from NIH Brain Development Cohorts with authorized researchers at the same institution who are listed on the same DUC. Sharing data with authorized researchers who are listed on a different DUC can only be done through a secure sharing mechanism supported by the NIH Brain Development Cohorts Data Sharing Platform. Recipients are responsible for ensuring that collaborators are authorized researchers. If a collaborator’s DUC has expired, or will expire within one calendar month, it must be renewed prior to sharing data. Note that an active DUC is required for as long as the data are being used from analysis through manuscript submission, revision, and publication.

Note that authorized researchers may share *aggregated, summary-level data* with researchers who are not listed on a DUC only in educational settings (e.g., data use workshops). **The collaboration must occur through a secure sharing mechanism facilitated by the NIH Brain Development Cohorts Data Sharing Platform. Collaborating on individual-level data is permitted only when all parties are authorized users.**

1. No 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. Recipients agree to not publish or disseminate any derived data that could aid in the identification of any of the study participants (or their relatives). **To that end, Recipients agree to adhere to a minimum cell threshold of 10 in public reporting of data, including scientific publications and presentations**. Please visit (insert link) for additional guidance on mitigating risk of participant identification. Any questions concerning whether derived data can aid in the identification of a research participant should be sent to [adolescentbrain@mail.nih.gov](mailto:adolescentbrain@mail.nih.gov) before the derived data are published. Consultation with Recipient’s institutional IRB may also be helpful in these cases.

Recipients agree to notify the NIH at adolescentbrain@mail.nih.gov as soon as possible if, upon use of NIH Brain Development Cohorts data, identifying information is discovered.

### No Stigmatizing Research

Research can produce significant harm, for both participants and people more generally, by promoting stigma. Stigmatizing research is any research project, question, analysis, or interpretation that has the potential to instigate or promote marginalizing, discrimination, or loss of status to a person or group of people. Recipients agree to NOT use the data for research that is discriminatory or stigmatizing of individuals, groups, families, or communities. For more information, please visit [insert link].

### Ethical Use of Data from American Indian/Alaska Native (AI/AN) Individuals

Inclusion of participants in research who self-identify as AI/AN is essential for developing solutions to health challenges facing AI/AN communities. Recipients agree to follow the code of conduct for the analysis and interpretation of AI/AN data found at [insert link] to ensure data is handled in a way that is respectful of and meaningful to AI/AN communities and is consistent with Tribal sovereignty. Please note that **Recipients who intend to disseminate findings from descriptive and/or inferential analyses of AI/AN data (e.g., via presentations, pre-prints, publications, website posts, etc.) must submit a second DUC governing use of AI/AN data (A-DUC) after receiving approval of a general DUC.**

Responsible Data Use Training

Recipients are required to complete a training module on responsible and ethical data use and achieve a pass rate of 90% in order to gain access to the data. Recipients are then granted access to the data for a period of one calendar year.

1. Security

Recipients agree to protect data from the NIH Brain Development Cohorts 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.

### Deletion of Data

Recipients are strongly encouraged to keep data stored in the data sharing platform and not download data locally, to avoid download costs and unnecessary data duplication.

Recipients agree that data that have been downloaded will be permanently deleted from all local or cloud-based machines when research is completed or this Agreement is expired, whichever comes first.

### Supporting Documentation

Data and Supporting Documentation 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 to enable efficient and responsible use of the shared data by Recipients unfamiliar with the data or the research project. Examples of supporting documentation include:

* Research protocol(s)
* Questionnaire(s)
* Data Release Notes

### Identifying Derived Data Used in Publication or Presentation

Recipients agree to identify the data that are included in a publication, computational pipeline or other public disclosure of results derived from the analysis of data accessed in the NIH Brain Development Cohorts Data Sharing Platform, thereby linking it to the underlying data. Recipients further agree to cite the appropriate Digital Object Identifier for the data release referenced in the disclosure of results. Recipients are strongly encouraged to share codes and algorithms used to compute on the data.

### Acknowledgements

Recipients agree to acknowledge the relevant Digital Object Identifier(s) (DOI) in all oral and written presentations, disclosures, and publications (including abstracts, as space allows) resulting from any and all analyses of data. The oral or written presentation, disclosure, or publication should include an acknowledgement statement, which includes a disclaimer of NIH endorsement, as appropriate. Acknowledgements specific to the data repository are maintained at \_\_\_\_\_. 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.

1. Register Pending Publications in Online Registration Platform

Recipients agree to register pending publications with an online registration platform, such as Open Science Framework (<https://help.osf.io/article/330-welcome-to-registrations>) upon submission of manuscript for publication, at the latest.

### Data Disclaimers

Recipients acknowledge that the NIH does not and cannot attest to the validity of the results that may be obtained by using any data or data analysis tools included in the data sharing platform. The NIH disclaims all warranties as to the accuracy of the data in the data sharing platform or the performance or fitness of the data or data analysis tools for any particular purpose.

### 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 on Drug Abuse. The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

### Recipient’s Compliance with Institutional Requirements

Recipients 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.

### Recipient’s Permission to Post Information Publicly

Recipient agrees to permit the data sharing platform 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.

### 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%2](https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/Privacy%20Act%20Systems%20of%20Records%20Notices%20(SORNs)%205-1-15.pdf) [0Records%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 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 NIH Brain Development Cohorts data.

1. Amendments

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

### 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 NIH Brain Development Cohorts 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. Alternatively, the NIH may, in its sole discretion, provide a Recipient with 30 days’ advanced written notice to remedy the breach before termination.

### Term, Access Period, and Renewal

Recipients are granted permission to access requested and approved data from the data sharing platform for a period of one year and this DUC will automatically terminate at that time. Data access may be renewed upon receipt of a new DUC. Renewal applications will be reviewed to ensure that all terms and conditions of the previous access period have been met.

23. Adherence to NIH Brain Development Cohorts Data Sharing Policy

Recipients agree to conduct research that follows all NIH Brain Development Cohorts data sharing policy requirements, including those not expressly mentioned in this document. Recipients should check the ABCD Study data sharing page (<https://abcdstudy.org/scientists/data-sharing/>) for up-to-date information.

24. Accurate Representations

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

## Recipient Information and Certifications

### 1. Access Request

Request Type: New \_\_\_ \_\_\_ Renewal: \_\_\_\_\_\_

### 2. Lead Recipient

First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Degree: \_\_\_\_\_\_

Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ State/Province: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Country: \_\_\_\_\_\_\_

### 3. Research Data Use Statement

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 data from NIH Brain Development Cohorts. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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### 4. Renewal Applicants Only:

*Researchers who conduct secondary analyses on shared data, are expected as part of the Terms of Use (above) to report their results (See #12 in the general DUC).*

Has a publication, computational pipeline, or other public disclosure of results from the analysis of data accessed from NIH Brain Development Cohorts resulted from a Recipient’s previous access period? Note that *publication* includes preprint services (e.g., PsyArXiv, BioRxiv). Yes: \_\_\_ No: \_\_\_

If Yes, have the derived data used in disclosure of results been identified? Yes: \_\_\_ No: \_\_\_

List the DOI(s)

List the PubMed ID(s) or citation(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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### 5. Other Recipient(s) at Lead Recipient’s Institution

### 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. Please note that you may only list individuals from the same institution as the lead recipient. Listing individuals from multiple institutions is not permitted.

First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Degree: \_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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### 6. Authorized Institution Business Official:

Requests to access data requiring an Institutional sponsorship must list an individual with a signing official role as defined in the NIH eRA Commons - [*https://commons.era.nih.gov/commons*](https://commons.era.nih.gov/commons/)

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### 7. Signatures:

By signing and dating this DUC to request access to data in the NIH Brain Development Cohorts Data Sharing Platform, I and my Institution Signing Official 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 NIH Brain Development Cohorts, and that they have read and agreed to the terms of this document. My Institutional Signing Official *(if required)* also acknowledges that they have shared this document with appropriate institutional organizations.

Lead Recipient Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Authorized Institution Business Official Signature (if required): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Inquiries and requests to access data from the NIH Brain Development Cohorts Data Sharing Platform should be sent to adolescentbrain@mail.nih.gov.