

Data Use Certification for Research on NIH Brain Development Cohorts Data from American Indian/Alaska Native Individuals (A-DUC)

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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 working with data from participants who identify as American Indian/Alaska Native (AI/AN) in NIH Brain Development Cohorts, including but not limited to the Adolescent Brain Cognitive DevelopmentSM (ABCD) Study. **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 this DUC after receiving approval of a general NIH Brain Development Cohorts DUC.**

The ABCD Study[®] 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.**

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 of use outlined in this DUC.

Data Use Terms and Conditions

I request approval to conduct scientific investigation, scholarship or teaching, or other forms of research and research development using data from AI/AN participants in NIH Brain Development Cohorts, and I agree to adhere to the following **additional terms and conditions regarding specific use of AI/AN data.**

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, have an approved general DUC for NIH Brain Development Cohorts data use and agree to the following additional terms for using data from AI/AN participants, specifically:

1. 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 and the previous DUC will be terminated. Alternatively, the Lead Recipient may identify another Recipient on the DUC at the original institution as a replacement.

2. 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. Recipients agree to provide detailed information about their study aims pertaining to use of data from AI/AN participants, including plans for mitigating risk of harm to individuals and communities (See Term #3 below).

3. Ethical Use of Data from American Indian/Alaska Native (AI/AN) Participants

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 NOT use the data for research that is discriminatory or stigmatizing of individuals, groups, families, or communities. This DUC will be reviewed to protect against potential harm to AI/AN individuals and 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 are handled in a way that is respectful of and meaningful to AI/AN communities and is consistent with Tribal sovereignty.

4. 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.

5. Submit Manuscripts Analyzing AI/AN Data for Pre-Publication Review

Recipients analyzing AI/AN data must submit manuscripts for pre-publication review. Please refer to this document (insert link) for instructions on submitting manuscripts for pre-publication review.

6. Term, Access Period, and Renewal

Recipients are granted permission to access requested and approved data from the NIH Brain Development Cohorts 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.

7. 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: _____

5. Other Recipient(s):

List all individuals who will access, use, or analyze the data under this DUC 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: _____

First Name: _____ Last Name: _____ Degree: _____

Phone: _____ Email Address: _____

First Name: _____ Last Name: _____ Degree: _____

Phone: _____ Email Address: _____

First Name: _____ Last Name: _____ Degree: _____

Phone: _____ Email Address: _____

First Name: _____ Last Name: _____ Degree: _____

Phone: _____ Email Address: _____

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>

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 Institution Official (*if required*) also acknowledges that they have shared this document with appropriate institutional organizations.

Lead Recipient Signature: _____ Date: _____

Authorized Institution Signing 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.