

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

## Introduction

The American Indian/Alaska Native Data Use Certification (A-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 Development<sup>SM</sup> (ABCD) Study and the HEALTHy Brain and Child Development (HBCD) Study. **Recipients who intend to disseminate findings from analyses of AI/AN data separated out from other groups in presentations, pre-prints, publications, website posts, etc. must submit this A-DUC after receiving approval of a general NIH Brain Development Cohorts DUC. Note that including AI/AN data in a demographic table that describes the cohort does not require submission of A-DUC.**

The ABCD Study<sup>®</sup> 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 HBCD Study is a longitudinal study of early brain and child development that will follow participating families from pregnancy through early childhood. These 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. Authorization requires users to submit a signed DUC that includes signature by the user's institution business official, attestation of compliance status with NIH Security Best Practices for Users of Controlled-Access Data, and completion of Responsible Data and Biospecimen Use Training.

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. **Lead Investigators on group-level DUCs are responsible for ensuring that all other Recipients listed on the DUC comply with these terms and conditions. Read the entire DUC carefully before signing and submitting this agreement. You and your institution are responsible for the way that you use the data.**

The NIH Brain Development Cohorts Data Repository

The NIH Brain Development Cohorts Data Hub 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 or biospecimens and will be elevated to NIH leadership for further action.**

I 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

The A-DUC is not transferable to another institution. Recipients must notify the NIH Brain Development Cohorts Data Hub at [nbdc@mail.nih.gov](mailto:nbdc@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. Lead Investigator Recipient on a group-level DUC may identify another lead investigator 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 stigmatizing of individuals, groups, families, or communities. The A-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 in the NBDC Responsible Data and Biospecimen Use Training 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. Submit Manuscripts Analyzing AI/AN Data for Pre-Publication Review

Recipients analyzing AI/AN data must submit manuscripts for pre-publication review of ethical use of data. Please send your manuscripts to [nbdc@mail.nih.gov](mailto:nbdc@mail.nih.gov). The NBDC data access committee will respond within 14 business days.

#### 5. Term, Access Period, and Renewal

Recipients are granted permission to analyze AI/AN data from the NIH Brain Development Cohorts for a period of up to one year. This A-DUC will automatically terminate at that time, or when the general DUC expires (whichever comes first). The A-DUC may be renewed upon receipt of a new general DUC. Renewal applications will be reviewed to ensure that all terms and conditions of the previous access period have been met.

#### 6. Accurate Representations

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

OMB No: 0925-0780

Expiration Date: 10/31/2026

#### Burden Disclosure Statement

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 (0925-0780). Do not return the completed form to this address.

### Recipient Information and Certifications

#### 1. Access Request

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

## 2. Recipient or Lead Investigator

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. Include detailed information about study aims pertaining to use of data from AI/AN participants, including plans for addressing the AI/AN code of conduct (e.g., engaging AI/AN communities in design, analysis, and communication of research findings), and mitigating risk of harm to individuals and communities (See Term #3).

4. Renewal Applicants Only:

Researchers who conduct a secondary analysis on shared data, are expected as part of the Terms of Use (above) to report their results (See #13 in the general DUC).

1. 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, has the publication been reported on the NBDC Data Hub? Yes: \_\_\_ No: \_\_\_

List the DOI(s)

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

2. Progress Report. Recipients requesting a renewal of an expiring A-DUC should provide a Progress Report on research conducted with data from the NIH Brain Development Cohorts Data Hub The Progress Report should also describe any updates to the original Research Data Use Statement.

Progress Report Statement:

5. 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 Hub, I and my Institution Signing Official certify that we will abide by the Data Use Terms and Conditions defined in this DUC. My Institution Official (*if required*) also acknowledges that they have shared this document with appropriate institutional organizations.

Recipient or Lead Investigator Signature: \_\_\_\_\_

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

Authorized Institution Business Official Signature: \_\_\_\_\_

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