

Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD) Data Use Agreement

REVISION May 8, 2024

This Data Use Agreement (DUA) is a formal, signed agreement between CIFASD and an investigator who is not part of CIFASD so that the external investigator may use, and properly protect and manage, CIFASD de-identified data to further the goals of research into the causes and treatment of fetal alcohol spectrum disorders. This signed DUA must be submitted with an accompanying approved Data Access Request.

Definitions

- **Approved Users** are individuals listed on a Data Access Request (DAR), and subsequently approved as part of IRB and other reviews, to be permitted access to CIFASD Research Data as part of the terms and conditions of a DAR.
- **Authorized Representative** is the individual who is authorized to act for the Qualified Investigator on behalf of his/her Institution. This official submits the Data Access Request (DAR) and assumes the obligations imposed by the requirements and conditions of the Data Use Agreement (DUA).
- **Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD)** is a collaborative of research and core projects funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA).
- **CIFASD Steering Committee** is a subset of CIFASD consortium members: Consortium Director, the Scientific Director of CIFASD, representatives from NIAAA, and current principal investigators of NIAAA-funded CIFASD projects.
- **CIFASD Research Data** are de-identified research data collected by one or more of the NIAAA-funded CIFASD research projects and held in the CIFASD Central Repository. CIFASD Research Data typically include protected health information and are therefore governed by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. As CIFASD Research Data are collected from children and pregnant women, protected classes of individuals, additional safeguards to their use apply.
- **CIFASD Non-Clinical Data** (e.g., from the study of model organisms), are not protected health information and are a subset of CIFASD Research Data.
- **The Data Access Committee (DAC)** is a subset of CIFASD consortium members, appointed by the CIFASD Steering Committee, tasked with reviewing Data Access Requests. For each data access request submitted to CIFASD, the DAC will ensure that the CIFASD Principal Investigator for the CIFASD Research Data being requested is a standing or ad hoc member of the DAC for that review.
- **Data Access Requests (DAR)** are requests from a Qualified Investigator to access and utilize de-identified CIFASD Research Data for research not affiliated with CIFASD.
- **Qualified Investigators** are those investigators who are not part of CIFASD, are in good standing at a research university or institute - or whom can otherwise petition the DAC to be considered Qualified Investigators, and can demonstrate their ability to protect CIFASD Research Data as per the above federal guidelines (applicable to all NIH NIAAA-funded projects) and their own state guidelines, as appropriate. Qualified Investigators lead DARs and take full responsibility for those requests. Qualified Investigators who are awarded DARs take full responsibility for carrying out research with CIFASD Research Data, for the protection of the human subjects data involved, and for appropriate management of any data they receive, including use of those data by any other individual that is given access CIFASD Research Data as part of their successful DAR, whether intentional or not.

CIFASD Goals

The theme of the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD) is a cross-cultural assessment of fetal alcohol spectrum disorders (FASD). The CIFASD will coordinate basic, behavioral and clinical investigators in multidisciplinary research projects to better inform approaches aimed at developing effective intervention and treatment for FASD. Input and contributions will come from basic researchers, behavioral scientists, and clinical investigators who are enthusiastic about utilizing novel and cutting edge techniques, not simply to replicate previous or ongoing work, but to move the field forward rigorously. Successful Data Access Requests (DAR) for CIFASD Research Data will contribute to this CIFASD mission.

Data Use Agreement

Qualified Investigators agree here to pursue the CIFASD Goals described above and to adhere to the CIFASD Data Sharing Policy, found at: <http://cifasd.org/datasharing/DataUseAgreement.pdf>.

Terms of Access

1. Research Use

The Qualified Investigator agrees that, if access is approved, the following personnel shall become Approved Users of the requested de-identified dataset(s):

- the Qualified Investigator, who will take on the role of Principal Investigator named in the Data Access Request (DAR) submitted to the CIFASD DAC;
- those named in the Collaborators section of the DAR; and
- any trainee or employee working on the proposed research project under the direct supervision of these individuals.

Research access to the requested de-identified dataset(s) is granted for a period of one (1) year as a default, with the ability to request additional years in the DAR, renewed on February 15. Access to the data set beyond the end of this period can be obtained through the one-year report.

Research use will occur solely in connection with the research project described in the DAR, which includes a description of the research objectives and design. Any modification of the project will require submission of an amendment to this application (e.g., the addition of new aims related to the approved project, adding or deleting collaborators from the same institution). The Applicant will be required to demonstrate institutional approval for the modified project. New uses of these data outside those described in the DAR will require submission of a new DAR.

2. Institutional and Approved User Responsibilities

The Qualified Investigator agrees, through the submission of the Data Access Request (DAR), that all Approved Users named in the DAR have reviewed and understand the principles for responsible research use and data handling of the de-identified datasets as detailed in this Data Use Agreement. The Qualified Investigators and Approved Users further acknowledge that they are each responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and regulations and any relevant institutional policies. Through submission of the DAR, the Qualified Investigator also agrees to submit data use reports to the CIFASD Data Access Committee (DAC) describing the research use of the Approved Users in either the form of an annual request for renewal of access to the de-identified dataset(s) (section 10, below) or as a final report (section 11, below).

Some CIFASD datasets contain information that could potentially be linked to the research participants (e.g., genetic data). Access to any CIFASD dataset requires prior review of the project by the Applicant's Institutional Review Board (IRB), with either a written determination that the research is not considered human subjects research or approval for human subjects research. The Authorized Representative, by approving and submitting the attached DAR, provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed. The Authorized Representative also assures through the approval of the DAR that other organizations within the institution with relevant authorities (e.g., the Office of Human Subjects Research, the Office of Information Technology, the Office of Technology Transfer, etc.) have reviewed the relevant sections of this Data Use Certification and the associated procedures and are in agreement with the principles defined.

Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of these de-identified datasets.

3. Public Posting of Approved Users' Research Use Statement

The Qualified Investigator agrees that, if the DAR is approved, information about all Approved Users and the approved research use will be posted on the CIFASD website as well as on public, US government websites that describe approved research projects. The information may include the names and institutions of the Approved User(s), project name, and Goals/Aims as described in the DAR. In addition, citations resulting from the use of CIFASD datasets may be posted on the CIFASD and relevant National Institute of Alcohol Abuse and Alcoholism (NIAAA) websites.

4. Non-Identification

Approved Users agree not to use the requested de-identified datasets, either alone or in concert with any other information, to identify or contact individual participants from whom phenotype data (including facial images) and DNA samples were collected.

5. Non-Transferability

The Qualified Investigator and Approved Users agree to retain control over the data and further agree not to distribute data obtained through this Data Access Request (DAR) to any entity or individual not covered in the submitted DAR.

If Approved Users are provided access to CIFASD de-identified datasets for inter-institutional collaborative research described in the Goals/Aims and Analysis Plan sections of the DAR, and all members of the collaboration are also Approved Users through their home institution(s), data obtained through this DAR may be securely transmitted within the collaborative group. All data security practices and other terms of use defined in this agreement and the dbGaP Security Best Practices for the raw data will be followed for the derived data, including any transmission of the data.

The Qualified Investigator and Approved Users acknowledge responsibility for ensuring the review and agreement to the terms within this Data Use Agreement and the appropriate research use of CIFASD Research Data by research staff associated with any approved project, subject to applicable laws and regulations. CIFASD de-identified datasets obtained through this DAR, in whole or in part, may not be sold to any individual at any point in time for any purpose.

Approved Users agree that if they change institutions during the access period, they will submit a new DAR and Data Use Agreement in which the new institution agrees to the conditions stipulated in this Data Use Agreement before data access or use resumes. Any versions of data stored at the prior institution for the approved use will be destroyed and the destruction documented through a Final Report as described below. However, if advance written notice and approval by the CIFASD Data Access Committee is obtained to transfer responsibility for the approved research project to another Approved User within the original institution, the data may not need to be destroyed.

6. Data Security and Data Release Reporting

CIFASD has adopted the data security and data release reporting procedures developed by the National Institutes of Health (NIH) for dbGaP and in accordance with HIPAA and HITECH legislation. The Qualified Investigator and Approved Users acknowledge that they have reviewed and agree to handle the requested de-identified dataset(s) according to the current dbGaP Security Best Practices, including its detailed description of requirements for security and encryption. These include, but are not limited to:

- all Approved Users have completed all required computer security training required by their institution, for example, the <http://irtsectraining.nih.gov/>, or the equivalent;
- the data will always be physically secured (for example, through camera surveillance, locks on doors/computers, security guard);
- servers must not be accessible directly from the internet (for example, they must be behind a firewall or not connected to a larger network), and unnecessary services should be disabled;
- use of portable media, e.g., on a CD, flash drive or laptop, is discouraged, but if necessary then they should be encrypted consistent with applicable laws;
- use of up-to-date anti-virus/anti-spyware software;
- security auditing/intrusion detection software, detection and regular scans of potential data intrusions;

- use of strong password policies for file access; and
- all copies of the dataset should be destroyed, as permitted by law, whenever any of the following occurs:
 - the Data Use Agreement (DUA) expires and renewal is not sought;
 - access renewal is not granted;
 - the CIFASD Consortium, the NIAAA or the NIH revokes access or requests destruction of the dataset; or
 - the continued use of the data would no longer be consistent with the Data Use Agreement.

In addition, Approved Users agree to keep the data secure and confidential at all times and to adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to CIFASD de-identified datasets. This agreement includes the maintenance of appropriate controls over any copies or derivatives of the data obtained through its DAR.

Approved Users agree to notify the CIFASD Data Access Committee and the NIAAA of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include the known information regarding the incident and a general description of the activities or process in place to fully define and remediate the situation.

Within 3 business days of the CIFASD Data Access Committee notification the Qualified Investigator, through the Authorized Representative, agrees to submit to the CIFASD Data Access Committee and NIAAA a more detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.

All notifications and written reports of data release incidents should be sent to:

The CIFASD Data Access Committee <https://cifasd.org/contact/> (

The NIAAA, the NIH, or another entity designated by the NIH may, as permitted by law, also investigate any data security incident. Approved Users and their associates agree to support such investigations and provide information, within the limits of applicable local, state and federal laws and regulations. In addition, Approved Users agree to work with the NIAAA and the NIH to assure that plans and procedures developed to address identified problems are mutually acceptable consistent with applicable law.

7. Intellectual Property (IP)

The CIFASD Consortium follows the intellectual property (IP) principles developed by the NIH. By requesting access to CIFASD de-identified dataset(s), the Qualified Investigator and Approved Users acknowledge that anyone authorized for research access through the attached Data Access Request follow the intellectual property principles summarized below:

Achieving maximum public benefit is the ultimate goal of data distribution through the CIFASD data repository. Following the NIH principles, the CIFASD Consortium considers these de-identified data as pre-competitive, and urges Approved Users to avoid making IP claims derived directly from the CIFASD dataset(s). However, the CIFASD Consortium also recognizes the importance of the subsequent development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public.

It is expected that the de-identified data provided through an approved DAR, and conclusions derived therefrom, will remain freely available, without requirement for licensing. The NIH encourages broad use of genomic datasets coupled with a responsible approach to management of intellectual property derived from downstream discoveries in a manner consistent with the [NIH's Best Practices for the Licensing of Genomic Inventions](#) and the [NIH Research Tools Policy](#).

8. Research Dissemination and Acknowledgement of CIFASD Datasets

It is the intent of the CIFASD Consortium and NIAAA to promote the dissemination of research findings from CIFASD de-identified dataset(s) as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Approved Users are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings, etc.

Images of individuals derived from 3D facial photography (e.g., 3D or 2.5D mesh images) are comparable to a full facial photograph and are therefore considered an individual identifier under the HIPAA rules (45 CFR 164.514). Therefore, only XYZ coordinates from these images are provided. Derived images from any individual included in a de-identified dataset obtained from CIFASD must not be used in publications or presentations. The publication of composite (e.g., averaged) facial images is permitted.

Publications and presentations describing the results of research conducted using CIFASD de-identified datasets must acknowledge the CIFASD Consortium and include the following DOI (<https://doi.org/10.5967/ntw9-h991>). They should also acknowledge any relevant CIFASD consortium publications describing the creation of the dataset, which will be posted on the CIFASD website (www.cifasd.org). Public acknowledgements should also credit the NIAAA as the source of CIFASD funding. Specifically, the following text must be included in the Acknowledgements:

Data used in the preparation of this article were obtained from CIFASD consortium (<https://cifasd.org/data-sharing/>; <https://doi.org/10.5967/ntw9-h991>), supported by the National Institute of Alcohol Abuse and Alcoholism (NIAAA). This manuscript reflects the views of the authors and may not reflect the opinions or views of NIAAA or CIFASD consortium investigators.

The DOI includes the following information to describe the CIFASD consortium:

This is a multisite study supported by the National Institute of Alcohol Abuse and Alcoholism under award numbers: U24AA014811, U24AA014815, U01AA014835, U01AA025103, U01AA014809, U01AA014834, U01AA02165, U01AA021104, UH2AA029050, UH2AA029056, UH2AA029062, U01AA026101, U01AA026102, UH2AA026106. CIFASD investigators designed and implemented the study and/or provided data but did not necessarily participate in the analysis or writing of this report. A list of CIFASD investigators can be found at <https://cifasd.org/research-projects/phase2/>, <https://cifasd.org/research-projects/phase3/>, and <https://cifasd.org/research-projects/phase4/>.

projects/phase4/. For up-to-date information on the study, visit <https://cifasd.org>.

In addition, we request that Approved Users respect CIFASD participants and all persons affected by the use of alcohol during pregnancy by using appropriate language when describing study participants.

9. Departures from the Previously Approved Research Plan

To assure that CIFASD and NIH policies and procedures for human subjects data use are adhered to, any departure from the project described in the original DAR must be reported to the CIFASD DAC prior to implementation. Such reports must demonstrate that appropriate institutional approvals for the revisions have been obtained by the Approved Users, and that the project's aims remain consistent with any data use limitations for the approved de-identified datasets. This includes changes in the project's Collaborators.

10. Renewal of Dataset Access

Approval of access to CIFASD de-identified datasets will be renewed on February 15, if requested. Principal Investigators will be emailed a link to complete a 1-year summary on January 15, which must be completed by February 15. The Approved User can request continued access to CIFASD de-identified datasets through this summary. The renewal application will describe how these data have been used during the previous year, any results that have been generated as a result of access to the data including patents and publications, and any proposed departures from the originally proposed research plan.

Renewal requests should also provide evidence of review of the renewal request by the IRB at the Approved User's institution.

This information will be used by the CIFASD DAC and NIAAA staff for program evaluation activities, and may be considered by the NIAAA as part of the NIH effort to provide ongoing oversight and management of all NIH data sharing activities.

11. Final Reporting at Termination of Dataset Access

Qualified Investigators not seeking renewal agree to complete the 1-year summary by February 15, and chose the option to close the study. This summary will provide information regarding potentially significant findings and publications or presentations that resulted from the use of the requested de-identified dataset(s), any violations of the terms of access described within this Data Use Agreement and the implemented remediation, and information on any downstream intellectual property generated as a result of the data. This Final summary should either confirm that the Approved Users' copies of the CIFASD de-identified dataset(s) have been destroyed in accordance with this document or explain why the conditions for retention of the dataset(s) described in Section 12 (below) pertain. If the conditions for retention described in Section 12 do pertain, the Final summary should address when the dataset(s) will be destroyed and arrangements for secure storage of the dataset(s) during the interim period.

This information will be used by the CIFASD Data Access Committee and NIAAA staff for program evaluation activities, and may be considered by the NIAAA as part of the NIH effort to provide ongoing oversight and management of all NIH data sharing activities.

12. Final Disposition of Dataset(s)

At the end of the approved access period, all Approved Users agree to destroy all copies of the requested dataset(s), except as required by publication practices or law to retain them. Should an Approved User require access beyond the approved access period, they must specify an amended data management plan in the final report (years to be retained and why, and when plan to destroy with final notification to CIFASD/NIAAA when destroyed). The CIFASD DAC will inform the Approved Users' IRB and Authorized Representative of the expiration/termination of the Approved Users' access to the CIFASD de-identified dataset(s) and of the need to destroy all copies of the dataset(s) provided to the previously Approved Users.

Copies of CIFASD dataset(s) may not need to be destroyed if, with advance notice and approval by the CIFASD Data Access Committee, the project has been transferred to another Approved User at the same institution. In this case, documentation must be provided that other Approved Users are using the de-identified dataset(s) under an active CIFASD DAC approved research project.

13. Non-Endorsement, Indemnification

The Qualified Investigator and Approved Users acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of CIFASD data. The CIFASD Consortium, the NIAAA, the NIH, the CIFASD Data Access Committee, and Contributing Investigators do not and cannot warrant the results that may be obtained by using any data included therein. The NIAAA, the NIH, the CIFASD Data Access Committee, and all contributors to these datasets disclaim all warranties as to performance or fitness of the data for any particular purpose.

No indemnification for any loss, claim, damage or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NIH, as an agency of the United States, may be liable only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

14. Termination and Violations

The Qualified Investigator and Approved Users acknowledge that the CIFASD Consortium, the NIH or the NIAAA may terminate this agreement and immediately revoke access to all CIFASD datasets at any time if the Qualified Investigator is found to be no longer in agreement with the policies, principles and procedures of the CIFASD Consortium, the NIAAA, and the NIH.

By submission of the attached Data Access Request, the Qualified Investigator through the Authorized Representative attests to the Approved Users' qualifications for access to and use of CIFASD de-identified dataset(s) and certifies their agreement to the CIFASD and NIH principles, policies, and procedures for the use of the requested de-identified datasets as articulated in this document, including the potential termination of access should a violation of any of these agreement terms be identified.

The Qualified Investigator further acknowledges that they have shared this document and the CIFASD data sharing policies and procedures for access and use of CIFASD de-identified datasets with all Approved Users, appropriate research staff, and all other Collaborators identified in the DAR, and that all Approved Users also agree to comply with all requirements of this document.

Authorized Representatives acknowledge that they have considered the relevant CIFASD policies and procedures, that they have shared this document and the relevant policies and procedures with appropriate institutional organizations, and have assured compliance with local institutional policies related to technology transfer, information technology, privacy, and human subjects research.

Information Technology (IT) Director (signature not required):

Printed Name _____

Position at Institution _____

Email _____

Qualified Investigator:

Printed Name _____

Position at Institution _____

Signature _____

Date _____

Email _____

Authorized Representative:

Printed Name _____

Position at Institution _____

Signature _____

Date _____

Email _____