

Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD)

Data Sharing Policy

Authored by the CIFASD Data Access Committee (DAC)

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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 consortium members comprised of the CIFASD Consortium Coordinator, the Scientific Director of CIFASD, representatives from NIAAA, and current principal investigators of NIAAA-funded CIFASD projects.
- **CIFASD Research Data** are 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, that are 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 CIFASD Research Data for research not affiliated with CIFASD.
- **Qualified Investigators** are those external 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 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 whose DARs are approved 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 to CIFASD Research Data as part of their successful DAR, whether intentional or not.

Goal

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.

Policy

- In compliance with National Institutes of Health (NIH) Data Sharing Policy (NOT-OD-03-032), CIFASD is committed to making data collected by its research projects available to Qualified Investigators.
- The CIFASD policy for data sharing will be guided by federal regulations and NIH policies.
- Data access will be subject to approval by an Institutional Review Board (IRB) that is acceptable to the DAC. Some IRBs may not require approval for study of de-identified data.
- Users of CIFASD-provided datasets recognize any restrictions on data use delineated within the original informed consent agreements of contributing studies, as identified by the submitting institutions and stated on the CIFASD website.
- The DAC will review and decide whether requests for access to CIFASD Research Data are approved or not.
- De-identified data will be made available for use by external investigators.
- Data access will be granted for research only. No commercial uses of the data are allowed.

Scope of Data covered by this Policy

- Data from completed phases of CIFASD data collection and analysis, as determined by the CIFASD Steering Committee, will be made available to investigators outside CIFASD. A listing of these data sets can be found on the CIFASD website (<http://cifasd.org/data-sharing/>).
- The date of administration field for each dataset will be used to define the date ranges for particular phase.
- Selected de-identified data will be extracted by CIFASD to a separate data set that may be accessed by external researchers. External researchers must specify which data fields, subtests, and sites they are requesting. Data descriptions, dictionaries, and definitions can be found at: <http://cifasd.org/data-sharing/>.

Data Access Request Process

- Qualified Investigators will initiate the process by creating a Data Access Request (DAR), which will be submitted by their Authorized Representative. The DAR will have the following components:
 - A cover letter with contact info on the letterhead of the sponsoring institution signed by the Qualified Investigator and their institution's Authorized Representative;
 - A description of the proposed research and/or analysis, the research goals, and why CIFASD data are necessary;
 - A listing of all IRB Approved Users who will have access to the data;
 - A description of how the data will be used;
 - A description of how long the data will be used;
 - A description of how the data will be managed and protected as part of this study;

- A signed CIFASD Data Use Agreement; and
- A commitment to appropriately cite CIFASD and CIFASD projects in resulting publications.
- All requests, documentation, and reports must be submitted in the English language.
- DARs can be submitted via the online form (<http://goo.gl/forms/edJt9Ntjqu>) listed on the CIFASD website's Data Sharing page.
- The criteria for approval of a DAR will be the perceived value of the research for advancing understanding of or therapies for treating Fetal Alcohol Spectrum Disorders, the appropriateness of CIFASD data to advance that knowledge, and the Qualified Investigator's ability to manage and protect the data.
- Each DAR will be reviewed by the CIFASD DAC, with majority approval required to authorize use.
- If the DAR is not approved, the DAC will provide a written rationale for the decision.
- If the DAR is approved, the successful Authorized Representative and Qualified Investigator who submitted the successful proposal will receive a letter of acceptance from the DAR that they may then submit to their IRB.
- Once both the proposal and IRB approval are granted, the successful Qualified Investigator will receive instructions on how to retrieve the data within 2 weeks. Approvals are valid for 1 year from the date of notification. Subsequent use will require another DAR.
- The successful Qualified Investigator will be responsible for all use of the data by all Approved Users as well as deletion of CIFASD Research Data following the study period, and will be responsible for annual progress reports to CIFASD that describes the use of the data, who has used the data, research outcomes, and any publications or communications resulting from the research.

Data Retrieval

- The successful Qualified Investigator will be provided a de-identified copy of the data CIFASD has approved for their use.
- Various formats including Excel/CSV, SAS, SPSS, R, and Stata will be provided for exporting the data.
- The Informatics Core will provide investigators with extracted de-identified data sets.
- Investigators are responsible for data security, ensuring appropriate access and use, and disposition of the data once the approved access period is completed.

Reporting

The successful Qualified Investigator will cite CIFASD in any presentations, communications, or publications deriving from the use of CIFASD Research Data. They will provide annual summaries of activities listing:

- All Approved Users who have accessed CIFASD Research Data;
- Presentations or other communications that use CIFASD Research Data;
- Publications that use CIFASD Research Data; and
- Current status of CIFASD Research Data (where stored, deleted, etc.).

Following the completion of the research, the successful Qualified Investigator or Authorized Representative will document the deletion of CIFASD Research Data, will provide a summary description

of the activities to the DAR, and will provide references to presentations, communications, and publications that resulted from the use of CIFASD Research Data.

Use of CIFASD Research Data will be cited as follows:

“We acknowledge the support of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the resources of the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD), which generated and provided the data used in this study. Information on CIFASD can be found at <http://www.cifasd.org>”. As you use data from particular research projects or resources, you will be required to acknowledge those projects as well.

This document authored by Bill Barnett, Director, CIFASD Informatics Core and the CIFASD Data Access Committee. For questions about this document, please contact Dr. Barnett at barnettw@iu.edu.