## Data Use Policy

## Purpose

The purpose of this document is to outline the data request process for the National Fragile X Foundation (NFXF) Data Repository™ for research and publication. This document clarifies a requestor's obligations and conditions for data use. It also defines the data access process and the various titles, roles, and responsibilities.

The Data Use Policy will be enforced by the NFXF and the NFXF Data Request Committee.

## Roles and Responsibilities

- **Primary Investigator (PI):** The responsible Investigator who conceptualizes the research questions and substantially contributes to the research and Data Access Application.
- **Data Request Committee:** Members of the committee will be responsible for the review and approval of submitted Data Access Applications.
- **National Fragile X Foundation (NFXF):** Will fulfill data access requests approved by the NFXF Data Request Committee.

## Data Access, Use, and Storage

The PI requesting data must have the experience necessary to develop a proposal and analyze the data provided; or they must identify a qualified co-investigator who meets the criteria. A literature review of previously published data must also be completed before submitting a Data Access Application.

If approved, each person who can access data must sign the acknowledgment statement (see page 3). The PI is responsible for ensuring that all co-investigators who have access to the data conform to the expectations outlined in this document. The PI at each participating site is responsible for ensuring that all staff at their site who have access to the data conform to the expectations outlined in this document. If approved, a raw data set and accompanying documentation will be provided securely to the PI. All data cleaning and analyses will be the responsibility of the PI.

The PI is responsible for the appropriate use and secure storage of data. Data should not be distributed, copied, or shared with any person(s) other than the PI's research team for the purpose specified in the application.

Any data that is published or disseminated to the public will be in aggregate to protect the individual identities of participants.

Future analyses must be approved by the NFXF Data Request Committee per the process outlined in this document. Processing, storage, and use of NFXF Data Repository data results must be consistent with HIPAA requirements and other federal regulations governing human subject research.

At the conclusion of the use of NFXF Data Repository data, data and any other material requested by the sponsoring site PI is to be securely destroyed.

# Regulatory Compliance

All actions and policies regarding data use requests must be consistent with federal regulations and guidelines governing research involving human subjects, including HIPAA.
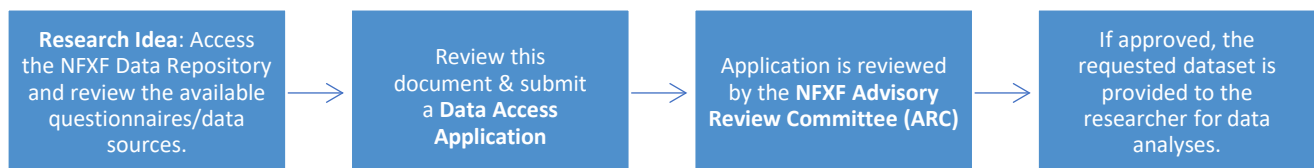
# Data Request Process

The PI proposing statistical analyses of NFXF Data Repository data must submit a Data Access Application. The following elements must be included:

1. **Project or study title**
2. **Planned research population (eligibility criteria)**
3. **Background and rationale:** *Please indicate previous findings and gaps in research knowledge that motivate your proposed use of NFXF Data Repository data. Please provide citations to prior publications.*
4. **Proposed specific aims/research objectives/research hypothesis:** *State the research questions, aims, and/or objectives of the proposed analyses using NFXF Data Repository data.*
5. **Statistical analysis:** *Describe the methods that will be used to analyze the data.*
6. **PI's biosketch, resume, or CV must be submitted**

The NFXF Data Request Committee will review the Data Access Application for its methodological soundness, anticipated contribution to the community, and lack of overlap with other completed, ongoing, or previously approved planned analyses using the same data. All requests will be reviewed within 4 weeks of submission.

**Flowchart**

| **Research Idea**: Access the NFXF Data Repository and review the available questionnaires/data sources. | → | Review this document & submit a **Data Access Application** | → | Application is reviewed by the **NFXF Advisory Review Committee (ARC)** | → | If approved, the requested dataset is provided to the researcher for data analyses. |

# Document Review

The PI must submit draft manuscripts or abstracts resulting from NFXF Data Repository to research@fragilex.org for review by the NFXF Data Request Committee. The documents must be submitted at least 4 weeks prior to the planned submission/presentation, and any concerns raised by the committee must be addressed before submission/presentation.

# Acknowledgements

Standard language acknowledging the source for the data used in the analysis should be included in manuscripts and presentations using the NFXF Data Repository. Specifically:

*This publication was supported by the NFXF Data Repository™. We are grateful to the families who contributed data for this research.*

If your application is approved, please sign below and email to research@fragilex.org.

**My signature acknowledges that I have read and understood the expectations associated with accessing NFXF Data Repository™ data.**

_____
 Name (Typed/Printed)

_____
Signature                                             Date