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Data Sharing FAQ

Why share data?

Barth syndrome (BTHS) is an ultra-rare disease that affects 130 individuals in the US and 300+ individuals worldwide. Given that rare disease research is replete with challenges – from limitations in eligible participants, resources, and funding – each piece of data generated through research participation is of outsized importance.

Data silos further promote redundant data, uncoordinated parallel studies and are a poor use of time and resources¹, which are two luxuries Barth syndrome research does not have. Thus, collaboration among our community of researchers, clinicians, and participants is critical in driving scientific progress and development of much-needed treatments.

How can we share data?

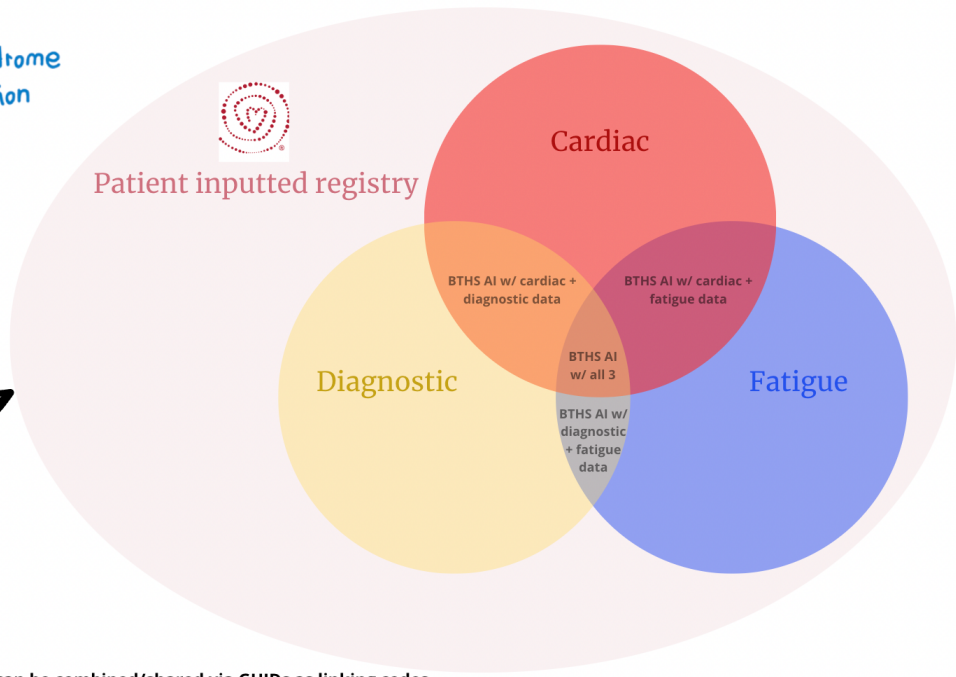
The Barth Syndrome Foundation (BSF) recognizes the need for open and responsible sharing of data in the Barth syndrome research space. To help researchers navigate data sharing, we have outlined a mechanism to create de-identified linking codes and guidelines for a data sharing plan.

De-identified Linking Codes or Global Unique Identifiers (GUIDs)

Through our [Research Global Unique Identifier \(GUID\) Program](#), researchers can generate a linking code used to share data on a study participant without revealing any personal identifiable information (PII) or protected health information (PHI). The GUID enables matching participants across time, different research sites, labs, and data repositories. Ultimately, this allows researchers to link their data to others across the Barth syndrome research field and generate richer datasets (See Figure 1).



• ~300 BTHS affected individuals (AI) worldwide
 ○ 138 registry enrollees



Datasets are de-identified and can be combined/shared via GUIDs as linking codes.
 Over time, more spheres are added as new studies recruit and the overlap across datasets grows with enrollment + GUID validation.

Figure 1: Schematic of research data available via GUIDs and its application for maximizing datasets

Data Sharing Expectations

BSF understands that policies surrounding data sharing may vary across different institutions, organizations, or companies. Rather than being prescriptive, we are asking researchers to develop and describe a data sharing plan consistent with their own internal policies and that the plan demonstrates a commitment to enable data access to other researchers. BSF’s only requirement is a mechanism for GUIDs to be shared back to BSF, with the intent to share what type of data has been collected for each GUID. Requests for actual data need to be made directly to the PI and are subject to approval by the individual governing institutions. Data contributors should be credited if combined data is utilized or reported in the literature.

Data Sharing Plan Guidelines

Consistent with the National Institutes of Health (NIH)’s guidelines² on crafting a data sharing plan, BSF recommends inclusion of the following elements:

- Data Types*
 - What types of data will be shared?
 - Are they raw or processed, and in what formats?
- Timeline for data sharing
 - When will data be made available for sharing?
 - Are there any anticipated embargo periods?
- Data access and use
 - What is the mechanism for access and using the shared data?
 - Will access be public, or are there specific access controls and levels?
- Data security and privacy*
 - What measures are taken to protect the privacy and confidentiality of study participants?
- Data standards and quality

- What steps will be taken to ensure data are reliable, valid, and interpretable?

*Sections where GUID implementation may be applicable

If you would like help on developing a data sharing plan, contact Melissa Huang (melissa.huang@barthsyndrome.org) for assistance.

Data Sharing Plan Example

Data Types

De-identified demographic, survey (self- or caregiver-reported), and baseline cardiac MRI from *Study Name* will be available for sharing. Demographic and survey data will be text/alphanumeric in nature and in .csv or .xlsx format. The Cardiac MRI is for research purpose only and not meant for medical care. These will be available in raw DICOM image format.

Global Unique Identifiers (GUIDs) will be shared back to BSF through a data use agreement between *Institution Name* and BSF.

Timeline

The research community will have access to data starting 90 days after *Study Name* has concluded.

Data Access and Use

Raw data generated from *Study Name* is not public. To request access, researchers can fill out a data request form. The application will be reviewed by the *Principal Investigator* and *Institution Name's Research Office* for final decision whether access will be granted.

Data Security and Privacy

No identifiable data will be shared. A GUID will be generated for each research participant. This enables data to be associated with a research participant without exposing or transferring the research participant's personally identifiable information (PII). It is randomly generated, alphanumeric code that is not generated directly from PII. This capability allows data about a research participant to be accumulated across projects over time, regardless of where and when that data were collected.³ Data files will be transferred through a secure system and password-protected.

Data Standards and Quality

To ensure data quality, data will be checked by research staff for any errors or duplicates.

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More examples of Data Sharing Plans can be found [here](#).

DATA ACCESS AGREEMENT

This Data Access Agreement (the “Agreement”) effective as of *REDACTED* (the “Effective Date”), by and between *REDACTED* (“Provider”), and Barth Syndrome Foundation (“Recipient”).

WHEREAS, Recipient wishes to access de-identified global unique identifier (GUID) data (the “Data”) which is owned by Provider for use in the project described in Exhibit A (the “Purpose”); and

WHEREAS, Provider is willing to grant Recipient access to the Data for the Purpose, subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions contained herein, Provider and Recipient agree as follows:

Provider shall provide the Data to Recipient and grants Recipient a royalty-free license to access and use the Data solely for the Purpose, including sharing access and use of the Data with third-parties as set forth on Exhibit A. Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.

Recipient may access and use the Data from the Effective Date through *REDACTED* (the “Term”), provided that the Term shall subsequently automatically renew each year unless a party terminates the Agreement as set forth in the next paragraph.

Provider or Recipient may terminate this Agreement for any reason upon thirty (30) days prior written notice. Upon termination Recipient will return the Data to Provider or destroy the Data at the option and in accordance with the instructions of Provider.

Recipient shall not use the Data except as authorized under this Agreement. Recipient will use the Data solely for the Purpose and will access the Data through access to Provider’s systems or as otherwise agreed to by the parties. Recipient will not download, save, or otherwise use or access the Data in any manner not permitted by this Agreement.

Recipient will use the Data in compliance with all applicable laws, rules and regulations and will not attempt to re-identify the information contained in the Data or contact the people who are the subjects of the Data. Recipient may not retransfer the Data except as permitted by the Purpose or unless authorized in writing by the Provider and then may only retransfer the Data for the Purpose under an agreement with substantially similar restrictions on use as those set forth in this Agreement. Notwithstanding the foregoing, Recipient may make the Data available to researchers.

Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient’s research using the Data, as appropriate in accordance with scholarly standards.

Provider represents that it has the legal right and authority, including applicable consent if required, to provide the Data to Recipient as anticipated hereunder. Unless due to a wrongful or negligent act of the Provider or breach of Provider of this Agreement, Recipient assumes all liability for damages which may arise from Recipient’s use, storage, disclosure, or disposal of the Data. Provider will not be liable to Recipient for any loss, claim, or demand made by Recipient, or made against Recipient by any other party, due to or arising from use of the Data by Recipient, except to the extent permitted by law when caused by the negligence or willful misconduct of Provider.

The undersigned for Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement.

PROVIDER

RECIPIENT

Date: _____

Date: _____

Exhibit A
Project Description

The GUID data shared by Provider to Recipient will be housed in the Barth Syndrome Registry and Repository (BRR). Researchers/investigators who are approved to access the BRR will be able to use GUID data to see which of the different Barth syndrome research studies have available data at various institutions (Provider being one of them). If the investigator wants study-specific data for a particular subject, they will reach out directly to the institution.

References

¹ [Data silos are undermining drug development and failing rare disease patients](#)

² [NIH Writing a Data Management & Sharing Plan](#)

³ [NIH BRICS GUID Manual](#)