

# Sample LCE Grant Plan

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**Funder:** National Institutes of Health (nih.gov)

**Funding opportunity number:** Dummy Funding ID

**Grant:** <https://theglia.org/>

**Template:** NIH-GEN DMSP (Forthcoming 2023)

**Project abstract:** Leukodystrophies are inherited diseases that affect the white matter of the brain due to the loss or absence of myelin, the lipid membrane that insulates axons in the nervous systems. The leukodystrophy community is at a key turning point. Novel molecular approaches have increased diagnosis and disease recognition. At the same time key disorders now have potential treatment pathways. (1-3) There is urgent unmet need in clinical trial readiness, lest the promise in pre-clinical development be unable to be translated to well-designed clinical trials due to lack of COA, biomarkers and natural history. This gap in knowledge has galvanized clinician scientists and advocacy groups alike to establish a research-based consortium to meet the needs of stakeholders in the disease community.

**Start date:** 11-17-2022

**Last modified:** 11-18-2022

**Grant number / URL:** <https://theglia.org/>

## Data Type

**Types and amount of scientific data expected to be generated in the project: Summarize the types and estimated amount of scientific data expected to be generated in the project.**

**Describe data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)**

This project will produce tabular natural history data generated/obtained from abstraction of medical records. Data will be collected from 100 subjects with a confirmed diagnosis of Leukodystrophy. This will generate a unified dataset approximately 5 megabytes in size. The following data files will be used or produced in the course of the project: raw data file and statistical analysis files. Raw data will be transformed using the R statistical computing language and the subsequent processed dataset used for statistical analysis. To protect research participant identities, aggregated data will be made available for sharing.

**Scientific data that will be preserved and shared, and the rationale for doing so: Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.**

All data produced in the course of the project will be preserved and shared.

**Metadata, other relevant data, and associated documentation: Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.**

Study protocol, data extraction SOP, REDCap data dictionary

## Related Tools, Software and/or Code

**State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.**

Data will be made available in standard formats including csv and dicom.

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## Standards

**State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.**

Data will be stored in common and open formats, such as csv for our natural history data. Information needed to make use of this data [e.g. the meaning of variable names, codes, information about missing data, other metadata etc] will be recorded in REDCap data dictionaries that will be accessible to the research team and will subsequently be shared alongside final datasets.

## Data Preservation, Access, and Associated Timelines

**Repository where scientific data and metadata will be archived: Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see [Selecting a Data Repository](#)**

All dataset(s) that can be shared will be deposited in \_\_\_\_\_ [Add appropriate NIH-supported data repositories] OR \_\_\_\_\_ [Add appropriate subject or disease repositories]

**How scientific data will be findable and identifiable: Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.**

The \_\_\_\_\_ [Insert repository name] provides metadata, persistent identifiers (i.e., insert whether DOI, handles, other), and long-term access. This repository is supported by \_\_\_\_\_ [Insert funder/organization] and dataset(s) are available under a \_\_\_\_\_ [Insert license information] OR through a request process \_\_\_\_\_ [Insert information about request process].

**When and how long the scientific data will be made available: Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.**

Data will be made available as soon as possible or at the time of associated publication.

## Access, Distribution, or Reuse Considerations

**Factors affecting subsequent access, distribution, or reuse of scientific data : NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See [Frequently Asked Questions](#) for examples of justifiable reasons for limiting sharing of data.**

Data sharing will be limited by compliance with IRB guidance and compliance with HIPPA.

**Whether access to scientific data will be controlled: State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).**

Data will be controlled.

**Protections for privacy, rights, and confidentiality of human research participants: If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through deidentification, Certificates of Confidentiality, and other protective measures).**

In order to ensure participant consent for data sharing, IRB paperwork and informed consent documents will include language describing plans for data management and sharing data, describing the motivation for sharing, and explaining that personal identifying information will be removed. To protect participant privacy and confidentiality, shared data will be de-identified in accordance with HIPPA.

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## Oversight of Data Management and Sharing

*Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).*

The following individuals [or just the position titles if unknown] will be responsible for data collection, management, storage, retention, and dissemination of project data, including updating and revising the Data Management and Sharing Plan when necessary.

- Name, Position Title, Host Institution, ORCID, email

## Sample Language for budgeting requirements

This project includes the following costs associated with data management and sharing. For data curation and the development of related documentation, the project is requesting \$\_\_\_\_\_. These funds will allow us to prepare data for sharing including deidentification of data, the incorporation of metadata to ensure discoverability and the data transfer process to \_\_\_\_\_ repository for preservation and access. An additional cost of \$ \_\_\_\_\_ is required to cover data deposit fees for \_\_\_\_\_ repository, which will cover \_\_\_\_\_ years of hosting.

## Planned Research Outputs

### Dataset - "Natural history dataset"

De-identified subject level tabular dataset.

#### Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Natural history dataset	Dataset	Unspecified	Open	None specified	5 MB	Creative Commons Attribution 4.0 International	None specified	Yes	No

