Policy title: *Policies and Procedures for Sharing Data*
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Epilepsy Learning Healthcare System (ELHS) Policies and Procedures for Sharing Data

Overview

The Epilepsy Learning Healthcare System (ELHS) network collected data between 2019-2025 from clinical encounters with patients diagnosed with epilepsy. Data from over 43,000 individuals was aggregated into the ELHS Registry, with site-specific and network-wide quality measures calculated. The primary purpose of this data collection was for quality improvement of care to lead to better outcomes. However, these data also offer the opportunity to analyze variability in care pathways, trends in population health, and other questions via secondary analysis. The centers who contributed ELHS data permitted the de-identification in their HIPAA business associate agreements with ELHS and recognize that sharing de-identified data with appropriate partners can contribute to generalizable knowledge that benefits patients and families living with epilepsy. The purpose of this policy is to describe ELHS requirements and processes for sharing ELHS Registry data.

Who may request access to ELHS Data?

The ELHS network will consider requests from academic, non-profit investigators and internal ELHS Network researchers. An investigator is considered an internal ELHS Network researcher if he/she is affiliated with a participating ELHS center or non-profit organization.

(Requests from external researchers, for-profit and industry entities are reviewed and managed using a separate process; contact elhs@efa.org for more information).

A common procedure and protocol will be used for all data requests from investigators. This will be done using the **ELHS Standard Data Request Form.** The request form will include questions which will help assess the proposal against the below administrative criteria. These criteria must be met for the proposal to pass administrative review and be considered for scientific review by the ELHS Data Governance Committee.

1. Investigator is affiliated with an ELHS center,,an academic institution and/or non-profit organization. *(Requests from external researchers, for-profit and industry entities are reviewed and managed using a separate process; contact elhs@efa.org for more information).*
2. Investigator has documentation of human subject protection training.
3. The research question aligns with ELHS's research agenda and is not being addressed by another investigator currently. In case of overlap, the ELHS Operations Team may suggest the investigator connect with the research team already working on a similar research question.
4. The research questions proposed can be answered with the de-identified ELHS dataset. The investigator will need to list the variables needed for completion of the study.
5. The Investigator is affiliated with or has access to an IRB that will provide review, including documented exemption or "not human subject research" determinations and further, the investigator is subject to institutional policies and procedures to address protocol or other non-compliance, for example, if the requestor fails to meet the

expectations (e.g., re-identifies data). A data sharing expectations document needs to be submitted to the requestor's IRB along with the protocol and should be retained by the Investigator with the IRB's determination letter.

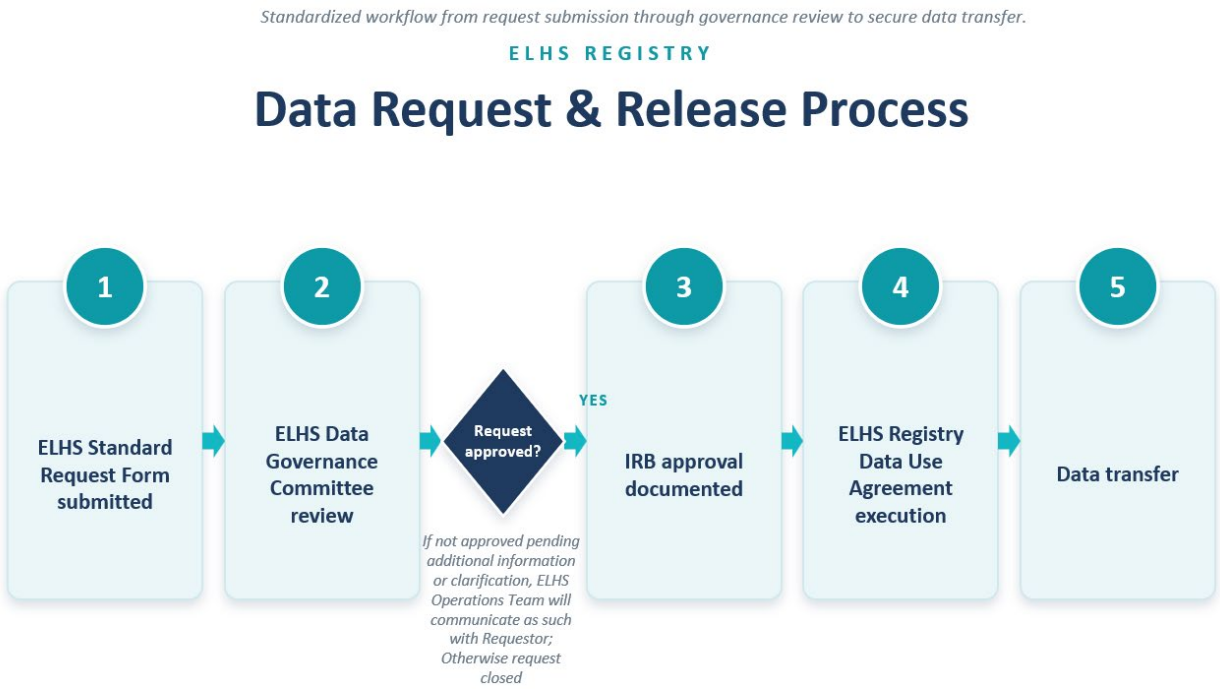
6. The investigator, if a trainee, has identified a senior mentor. The name of the mentor will be reported on the standard request form / letter of intent. If no mentor has been identified, the investigator may ask for assistance in identifying a mentor among the ELHS centers.

The ELHS Operations Team is charged with quickly supplying deidentified data sets to investigators conducting research projects that have been approved by the ELHS Data Governance Committee.

ELHS Data Governance Committee

The ELHS Data Governance Committee will provide oversight of what constitutes an approved/approvable research project and will review and approve all research projects and protocol submissions. This group will be comprised of Drs. Brandy Fureman and Kathleen Farrell (ELHS Operations Team), Jonathan Scheinman (Vice President, Data Strategy, Epilepsy Foundation), one ELHS clinical site Principal Investigator (representative rotating annually) and one ELHS Patient Family Partner (PFP; representative rotating annually).

Procedure for Sharing Data



1. When an ELHS researcher has a research idea for which the researcher wants to use the ELHS database to answer, the researcher submits the ELHS Standard Data Request

Form to the ELHS Operations Team for approval. The standard request includes an administrative section to assess compliance with the above criteria, and a scientific section that incorporates the researcher's proposed research question(s) and analytic plan. The Operations Team assesses if the request meets the above administrative criteria. Assuming it does, the Operations Team shares the request with the ELHS Data Governance Committee.

2. The ELHS Data Governance Committee reviews, provides feedback on, and either accepts or rejects the proposal. The reviewers can also suggest the researcher be paired with another researcher to serve as mentor, and/or may connect the investigator with another one working on a similar study.
3. If accepted, the ELHS researcher will then submit the protocol to their local IRB to obtain approval or a determination in accordance with federal law that the research is "exempt" or "not human subject research." If the investigator site previously relied on ELHS central IRB, local IRB can cede review to central if preferred. The investigator is responsible for obtaining a Reliance Agreement or other documentation of the transfer of oversight responsibility.
4. All IRB determination document(s) must be made available to the ELHS investigator, ELHS Operations Team and ELHS Data Governance Committee:
    - The ELHS investigator submits an IRB determination letter from the local IRB, or the ELHS IRB when applicable, to the ELHS Data Governance Committee.
    - The ELHS Data Governance Committee Lead notifies the ELHS Data Manager of the IRB determination and any other needed approvals or determinations.
5. The Investigator and the Epilepsy Foundation, on behalf of the Epilepsy Learning Healthcare System, execute the ELHS Registry Data Use Agreement.
6. A de-identified dataset is gathered and securely transmitted* digitally via time-limited access to a secure shared folder such as Sharepoint or Dropbox to the ELHS investigator, with data files as either SAS data set(s) or .csv files. *Note that .csv files are not available for researchers using Excel 2003 due to a limit of 256 columns in Excel.

Notes and Exceptions

- Internal ELHS investigators may request de-identified data only.
- Data has been de-identified as provided for by 45 C.F.R. § 164.514.
- A data dictionary will be made available to requestors to accompany this policy, so that requestors can identify which fields/elements are of interest.
- Only data sets including data elements that the researcher requested in the proposal will be provided/granted.

Data handling expectations

- De-identified data must be transmitted only through governed, enterprise-managed file-sharing platforms that are covered by a business associate agreement (BAA) between Investigator/Recipient and the platform. Examples of platforms which provide a BAA include Microsoft 365 Sharepoint and Google Workspace – it is the responsibility of the Investigator/Recipient to ensure BAA is in place. Approved platforms must encrypt data in transit and at rest, restrict access through time-limited, credentialed links or user-specific permissions, and contractually prohibit the platform provider from mining,

indexing, or otherwise using the transmitted data for any purpose, including to train or improve any artificial intelligence or machine learning model. Free or personal-tier file-sharing accounts do not meet this standard.

- Data transferred to the requestor may be used solely for the project and publication submitted and reviewed by the Data Governance Committee. New publication proposals must be submitted for review and approval by the ELHS Data Governance Committee, even when using the same dataset.
- The cleaned, final analysis dataset used for publication must be shared back to the ELHS Operations Team to allow future repeat analysis or result verification.
- Any data requests directed to requestors/publishing parties must be referred to the Epilepsy Foundation – dissemination of the data is not allowed beyond the original requestor/investigator. In resulting publications, consider including the statement "Data is available via request to the Epilepsy Foundation – please contact elhs@efa.org" or similar based on guidelines of publishing journal or other location.
- Resulting manuscripts and publications should adhere to guidance outlined in the ELHS Publications Policy, including the acknowledgement: "The author(s) acknowledge the Epilepsy Learning Healthcare System as the source of the data used in this paper. The analysis, interpretations and conclusions expressed do not necessarily reflect the views or policies of the Epilepsy Learning Healthcare System."

Notifications & Timelines

- Every attempt will be made to communicate expected timing of review +/- data release with both the requesting researcher and the Data Governance Committee.
- The Data Governance Committee reserves up to 4 weeks to review the investigator's standard request form or letter of intent and decide on next steps. Individual researchers should keep this in mind when developing their research protocols.
- If the Committee approves the data request and the requestor provides IRB approval documentation, the relevant dataset will be made available to the requestor within 30 days of the submission of the IRB documentation.
    - Requested fields which are not already available in the dataset within Epilepsy Foundation's data lake or a request for the addition of new fields, may result in extended timelines to the ones described above.
- Any publication that results from the study must be reviewed by the ELHS Data Governance Committee before being released to ensure adherence to the original request/protocol/study plan and inclusion of appropriate acknowledgement, with at least 30 days allowed for review and extendable to 60 days based on reasonable request.
- If a suspected data breach or unauthorized disclosure has occurred, the breach or unauthorized disclosure must be reported to the Epilepsy Foundation's designated representative within 72 hours of learning of the incident