

Policy title: *ELHS Registry Data Use Agreement*

Approval status: Reviewed by Holland & Knight; Final

Version date: 08/24/2026

Epilepsy Learning Healthcare System (ELHS) Registry Data Use Agreement

This data use agreement (the “Agreement”) is between the Epilepsy Foundation on behalf of the Epilepsy Learning Healthcare System (collectively, EF/ELHS) and

_____(“RECIPIENT”). The parties may be referred to individually as “Party” and collectively as the “Parties”.

WHEREAS, EF/ELHS maintains certain information that RECIPIENT wishes to use for research or public health;

WHEREAS, RECIPIENT previously requested that EF/ELHS consider transferring certain data to RECIPIENT;

NOW, THEREFORE, the Parties, in consideration of the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. EF/ELHS shall provide RECIPIENT with de-identified data (as provided for by 45 C.F.R. § 164.514) limited to an IRB-approved research Project (collectively “Data”) or a Project determined by an IRB to either be exempt or not Human Subject Research under federal law in accordance with the terms and conditions of this Agreement.
2. The Data shall remain the sole and exclusive property of the Epilepsy Foundation.
3. RECIPIENT is authorized to use the Data or any part of it, as limited to the Project, as described in the ELHS Standard Data Request Form.
4. RECIPIENT agrees as follows:
 - a. Not to use or disclose the Data or any information contained therein other than as permitted by this Agreement or as permitted or required by applicable international, federal, state and local laws, rules and regulations, including the privacy rules implementing portions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA);
 - b. Not to use or disclose the Data except as permitted by the RECIPIENT’s IRB. RECIPIENT will allow access to only the minimum number of individuals necessary to achieve the purpose for the Project and as provided for the IRB-approved protocol;
 - c. Not to distribute or release the Data outside RECIPIENT except to agents or contractors involved in Project;
 - d. RECIPIENT will ensure that any agents or contractors to whom it discloses the information will agree to and abide by the same restrictions as and conditions provided in this Agreement;

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- e. To ensure that no one will be allowed to take or send the Data to any other location, unless written permission is first obtained from EF/ELHS;
 - f. To use appropriate technical, administrative, and physical safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement or applicable law;
 - g. To report to EF/ELHS within three (3) days and make notifications required by RECIPIENT'S institutional policy and applicable law, any use or disclosure of the Data or any part of it not provided for by this Agreement of which RECIPIENT becomes aware; and
 - h. Acknowledge EF/ELHS as the source of the Data in any publication arising from RECIPIENT's use of the Data, using the following statement: "Research reported in this [work, publication, article, report, presentation, etc.] was developed from data shared by EF/ELHS.
 - i. To provide a lay summary of findings and analysis (example to be provided) to the ELHS Operations Team within 1 month of publication.
5. RECIPIENT will not use or attempt to use the Data, alone or in combination with other information, to identify the individuals or contact the individuals or families from whom the Data was derived. In the event the RECIPIENT discovers or is able to deduce the identity of a specific participant, RECIPIENT agrees not to reveal the participant's identifying information or any associated information in the Data to non-authorized persons nor attempt to contact these individuals.
6. THE DATA IS TRANSFERRED TO RECIPIENT "AS IS." EF/ELHS MAKES NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, AS TO THE DATA TRANSFERRED TO RECIPIENT AND EF/ELHS SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT CONSEQUENTIAL, SPECIAL OR OTHER DAMAGES SUFFERED OR CAUSED BY RECIPIENT FROM ITS USE OR MISUSE OF THE DATA.
7. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise in RECIPIENT's use, storage or disposal of the Data. EF/ELHS is not liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT or made against the RECIPIENT by any other party due to or arising from the use, storage or disposal of the Data by the RECIPIENT.
8. EF/ELHS may terminate this Agreement upon reasonable written notice to RECIPIENT. Upon termination for any reason, RECIPIENT shall immediately cease use of the Data, and destroy the Data, and any copies thereof, with written certification to EF/ELHS of such destruction.
9. This Agreement shall be construed according to the laws of the state of Maryland, without regard to conflict of law provisions, and shall be deemed to have been executed in the state of Maryland.

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10. The Terms and Conditions of this Agreement are for the sole benefit of EF/ELHS and RECIPIENT and do not create any third-party beneficiary rights.

IN WITNESS WHEREOF, the undersigned hereto have caused this Agreement to be executed by their respective authorized signatories.

Requestor signatory:

Signed:

Name:

Title:

Date:

EF/ELHS signatory:

Signed:

Name:

Title:

Date: