 ***This document is intended as a resource and guide, and should be adjusted as needed for the user’s purposes.***

**CURE Epilepsy [Insert Initiative]**

**Database Data Use and Sharing Policy***CURE Epilepsy’s [Insert Initiative] Database: Collaborating for a CURE*

1. **Purpose of Data Use and Sharing Policy**

The following Data Use and Sharing Policy will serve as a guide and an agreement for access to any materials contained within the CURE Epilepsy [Insert Initiative] Database (hosted within the ([Insert Lab and Database]). This agreement will apply to any actions related to or products resulting from access to materials and knowledge gained from the CURE Epilepsy [Insert Initiative] Database.

1. **Term of Policy**

Terms set forth in this Data Use and Sharing Policy will remain in effect at least until [Insert Date], or for as long as the CURE Epilepsy [Insert Initiative] Database is in existence, should the CURE Epilepsy [Insert Initiative] Database exist past [Insert Date].

**III. Governance**

The CURE Epilepsy [Insert Initiative] Database will receive oversight from CURE Epilepsy, the CURE Epilepsy [Insert Initiative] Database Steering Committee and [Insert Lab]. In addition, each team will designate a representative with the right to grant access to individual team members for their respective team “site” within the database.

**IV. Access**

Access to the CURE Epilepsy [Insert Initiative] Database must be requested by filling out a New Collaborator Account Request and IDA user registration, information which can be obtained by contacting *Research@CureEpilepsy.org*. Applications for access will be reviewed by CURE Epilepsy, the CURE Epilepsy [Insert Initiative] Database Steering Committee and any other designated representatives from [Insert Initiative] teams. These representatives will be given “Manager” access to their respective team database sites (see section V Below for access levels).

Information contained within this database is intended for CURE Epilepsy [Insert Initiative] members, collaborators, and other identified individuals. A CURE Epilepsy [Insert Initiative] Database Administrator, the CURE Epilepsy [Insert Initiative] Steering Committee or team representative(s) may reject a request for access or for a username and password, or may block or terminate your access to the CURE Epilepsy [Insert Initiative] Database at any time, for reasons including: 1) lack of signed CURE Epilepsy Confidentiality and Non-Disclosure Agreement, 2) lack of signed Publication Policy, 3) lack of signed Data Use and Sharing Policy, and/or 4) confirmed breach of trust/confidentiality such as sharing data in prohibited manner.

Applicants can expect review of Database applications to take less than 14 days. Applicants will be notified by email of their application status. Any questions may be addressed to *Research@CureEpilepsy.org*.

**V. Database Privileges**

Datasets will be contained within the CURE Epilepsy [Insert Initiative] ‘project’ in the CURE Epilepsy [Insert Initiative] Database, while data standardization tools (case report forms) will be contained within [Insert Lab’s program]. The CURE Epilepsy [Insert Initiative] Database and [Insert Lab’s program] portal has multiple levels of authorization for datasets/case report forms. Users may have multiple access levels across different sites. The various levels of privileges are described below:

* Guest: A user with Guest permissions at a site can download and search data.
* Member: A user with Member permissions at a site has all the permissions of a Guest and can also archive data at that site.
* Leader: A user with Leader privileges at a site has all the permissions of a Member and can also edit/delete metadata.
* Manager: A user with Manager permissions at a site has all the permissions of a Leader and can also manage users at that site.

**VI. Ownership and Permissions**

The individual researchers who upload and/or contribute material will retain ownership of their respective data. Copying and distributing materials found in the CURE Epilepsy [Insert Initiative] Database or CURE Epilepsy [Insert Lab’s program] portal without authorization from both CURE Epilepsy and from team representatives is strictly prohibited.

To request permission, please fill out the application form, which can be requested by emailing *Research@CureEpilepsy.org*. You will use your username and password solely to obtain access to the CURE Epilepsy [Insert Initiative] Database. You will not share your username and password with any other person, even another researcher in your research group or institution. (Additional researchers in your group or institution may apply for separate usernames and passwords.) You will use the images and data solely to conduct the research identified in this application, and/or solely to teach or for other educational purposes. You will not publish any image or data from the CURE Epilepsy [Insert Initiative] Database that you do not own, without the prior consent from CURE Epilepsy and the [Insert Initiative] team representative of the team site wherein the requested data is found. For permission to publish an image or data, please contact the CURE Epilepsy [Insert Initiative] Database Administrator at *Research@CureEpilepsy.org* who will disseminate the request to the appropriate party.

You will not upload or contribute any content that you do not own or have the legal right to upload and contribute to the CURE Epilepsy [Insert Initiative] Database. You are solely responsible for defending any allegation regarding content that you upload or contribute, including but not limited to copyright or patent infringement allegations by Illinois law. Additional information regarding assignment of rights, including patents and inventions, can be found in the CURE Epilepsy [Insert Initiative] Subaward Agreement.

**VII. Human Subject Data**

Solely de-identified data should be deposited into the CURE Epilepsy [Insert Initiative] Database. Users will be responsible for verifying with their own institutional IRB that their study either is “exempt”, if it is no more than minimal risk, or that they have received formal IRB approval to deposit data into the database.

**VIII. Security Measures**

Disclosing or distributing information obtained from the CURE Epilepsy [Insert Initiative] Database or CURE Epilepsy [Insert Lab’s program] portal without permission from the Manager of the Database from which the information is obtained is strictly prohibited. Furthermore, if disclosure/distribution permission has been obtained from the Site Manager, it is the responsibility of the disclosing party to ensure that any individual with whom information is disclosed/distributed is in compliance with this Data Use and Sharing Policy through written acknowledgement.

Individuals who utilize the CURE Epilepsy [Insert Initiative] Database should ensure that information downloaded is downloaded on a secure server.

**IX. Liability**

CURE Epilepsy is not responsible for the correctness or usability of the images and data, or for the functionality of the database. The CURE Epilepsy [Insert Initiative] Database and access to the CURE Epilepsy [Insert Initiative] Database are provided 'AS IS,' without any representation or warranty from CURE Epilepsy. The CURE Epilepsy [Insert Initiative] Database Administrators (CURE Epilepsy Staff) do not warrant or represent the accuracy of the images or data or functionality of the CURE Epilepsy [Insert Initiative] Database, and hereby waive all representations and warranties, express or implied, including but not limited to any warranty of noninfringement, merchantability, or fitness for a particular purpose. You are solely responsible for any harm or damages that arise from or are related to your use or misuse of the CURE Epilepsy [Insert Initiative] Database. The CURE Epilepsy [Insert Initiative] Database Administrators are not liable (whether in an action for negligence, other tort, breach of contract or any other legal theory), for any loss, damage, expense, loss of profits, loss of revenue, loss of reputation, or loss or inaccuracy of data, or any indirect, incidental, punitive, special or consequential damages, even if a CURE Epilepsy [Insert Initiative] Database Administrator is advised of the possibility of such damages, in connection with: (A) your reliance on or use or inability to use the CURE Epilepsy [Insert Initiative] Database or any images or data or other aspects of this website; or (B) any failure of performance, error, omission, interruption, defect, delay in operation or transmission, computer virus or line or system failure, the CURE Epilepsy [Insert Initiative] Database or any images or data or other aspects of this website.

Data analysis for this project is expected to take years as methods for analysis of these datasets evolve. Therefore, data should be downloaded with the understanding that any processed data might be preliminary and that results may change as new methods of analysis are implemented. Individuals utilizing the Database should familiarize themselves with the analysis methods and be aware of limitations of these data prior to using them for scientific purposes.

**X. Publication Policy**

All work utilizing original data from CURE Epilepsy’s [Insert Initiative] Database is subject to the terms and conditions contained within the CURE Epilepsy [Insert Initiative] Grant Publication Policy as well as the terms and conditions contained herein.

If datasets contained within a particular site in the CURE Epilepsy [Insert Initiative] Database are utilized in a publication, the publication should cite the list of individuals associated with that dataset. This information can be requested from the site manager. Publications should also contain the following acknowledgement:

[Insert Acknowledgement]

The following disclaimers should be used, as applicable:

[Insert Disclaimers]

Additionally:

• Full citation of all published manuscripts will be provided to CURE Epilepsy upon acceptance

of manuscripts.

• A copy of the manuscript will be provided to CURE Epilepsy upon publication of the manuscript.

Because “preliminary data” will be posted on the database, any data downloaded from the CURE Epilepsy [Insert Initiative] Database for the purposes of analysis and future publication in the form of abstracts and/or publications should note the version of the data downloaded. Individuals utilizing the CURE Epilepsy [Insert Initiative] Database are responsible for determining if updated data has been provided prior to submission of any material for publication.

 **XI. Resolution of Disputes**

All disputes regarding the CURE Epilepsy [Insert Initiative] Database including usage and publication, or other public releases of data generated by the CURE Epilepsy [Insert Initiative] will be mediated by CURE Epilepsy and the CURE Epilepsy [Insert Initiative] Database Steering Committee. If necessary, CURE Epilepsy will be the final arbiter of any authorship disputes. All CURE Epilepsy [Insert Initiative] members utilizing the CURE Epilepsy [Insert Initiative] Database will sign the CURE Epilepsy [Insert Initiative] Database Data Use and Sharing Policy to agree to this process.

**XII. Data Request Application**

Applicants will complete a web-based [Insert Lab] application form and a Data Use and Sharing Policy. When the application is received and approved by CURE Epilepsy and the CURE Epilepsy [Insert Initiative] Database Steering Committee, the applicant will be given permission to access the data within CURE Epilepsy’s [Insert Initiative] Database. Access level will be determined by CURE Epilepsy, the CURE Epilepsy [Insert Initiative] Database Steering Committee and any site-specific [Insert Initiative] team representatives.

Applicants will be required to provide the following information:

• Name

• Address and Contact information

• Academic Affiliation (if any) or Institution/Company Name

• Certification to each point of the Data Use and Sharing Policy

The information transmitted in the application form will be retained for administrative purposes. The CURE Epilepsy Administrator will use reasonable efforts to maintain the confidentiality of the information submitted in the application form but is not responsible for any disclosure or misuse of such information.

Every effort has been taken to de-identify the data sets contained in the CURE Epilepsy [Insert Initiative] Database. By applying for a username and password to access the database, you agree to report to the CURE Epilepsy [Insert Initiative] Database Administrators any potential discovery of Personal Health Information (PHI) or other information which identifies a human being. If you do discover any PHI or other information which identifies a human being, you also will not further use or disclose the PHI. (For a complete PHI listing and privacy rule explanation, please refer to the U.S. Department of Health and Human Services website: http://privacyruleandresearch.nih.gov/pr\_02.asp). If you discover another aspect of the CURE Epilepsy [Insert Initiative] Database or its images or data that you believe violates a law or standard of conduct in your country, please contact the CURE Epilepsy [Insert Initiative] Database Administrators via email (*Research@CureEpilepsy.org*).

The CURE Epilepsy [Insert Initiative] Database Administrators may amend or change these terms and conditions at any time, and you agree to abide by the amended or changed terms when they are posted. CURE Epilepsy [Insert Initiative] Database Administrators will post the amended or changed terms on the CURE Epilepsy [Insert Initiative] Database web site. By using the CURE Epilepsy [Insert Initiative] Database after an amendment or change is posted, you will be deemed to have agreed to the amended or changed terms and conditions. If you do not agree to the amendment or change, do not access, or use the CURE Epilepsy [Insert Initiative] Database. Each provision of these terms and conditions is severable. If, for any reason, any provision of these terms and conditions shall be held invalid or unenforceable in whole or in part in any jurisdiction, such provision shall, as to such jurisdiction, be ineffective to the extent of such invalidity or un-enforceability, without in any manner affecting the validity or enforceability thereof in any other jurisdiction or the remaining provisions hereof in any jurisdiction. These terms and conditions are the final and entire agreement between a user and his/her employer or research organization, and the CURE Epilepsy [Insert Initiative] Database Administrators, and supersede all prior understandings, communications, or agreements on the subject matter in these terms and conditions. These terms and conditions, and your access to and use of the CURE Epilepsy[Insert Initiative] Database, shall be governed by Illinois law, without regard to its conflicts of law principles, except where prohibited by law.



**CURE Epilepsy [Insert Initiative] Database Application Form**

Please provide the following information:

• Name

• Address and Contact information

• Academic Affiliation (if any) or Institution/Company Name

• Proposed analyses with a named lead investigator on each analysis

• Certification to each point of the Data Use and Sharing Policy

Applicants will receive annual requests to update the application information. These requests

will also solicit responses to the following queries about manuscripts:

• Title of each manuscript in development

• Lead (or senior) author of each manuscript in development and contact information for that author

• Status of each manuscript in development (In development, In submission, In press/published)

• Citation of each published manuscript

• Upload a file of each published manuscript

I request access to the data stored in the CURE Epilepsy [Insert Initiative] Database for the purpose of scientific investigation, teaching or the planning of clinical research studies and agree to the following terms.

1. I agree to adhere to all policies as written in the CURE Epilepsy [Insert Initiative] Database Data Use and Sharing Policy.
2. I will receive access to de-identified data and will not attempt to establish the identity of or attempt to contact any of the CURE Epilepsy [Insert Initiative] subjects.
3. I will not attempt to make direct contact with CURE Epilepsy [Insert Initiative] PIs or staff at sites concerning the specific results of individual subjects.
4. I will not further disclose these data beyond the uses outlined in this policy and my data use application and understand that redistribution of data in any manner is prohibited.
5. I will require anyone on my team who utilizes these data, or anyone with whom I share these data to comply with this data use and sharing policy.
6. I will accurately provide the requested information for persons who will use these data.
7. I will respond promptly and accurately to annual requests to update this information.
8. I will comply with any rules and regulations imposed by my institution and its institutional review board in requesting these data.
9. If I publish abstracts using data from CURE Epilepsy [Insert Initiative], I agree to the following: I will cite CURE Epilepsy [Insert Initiative] as the source of data and the CURE Epilepsy [Insert Initiative] funding sources in the abstract as space allows, as per the CURE Epilepsy [Insert Initiative] Database Data Use and Sharing Policy.
10. I will report any use or disclosure of the data not provided for by this policy of which I become aware within 15 days of becoming aware of such use or disclosure to *Research@CureEpilepsy.org*.

I understand that failure to abide by these guidelines will result in termination of my privileges to access CURE Epilepsy [Insert Initiative] Database data.

**Signature of Requestor:**

By\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_