

EXHIBIT B: STANDARD TERMS FOR CURE EPILEPSY GRANT AGREEMENT

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Exhibit B

Standard Terms for CURE Epilepsy Grant Agreement

1. **Grant Agreement.** These Standard Terms are an integral part of the CURE Epilepsy Grant Agreement (the “Agreement”); and these Standard Terms are incorporated into the Agreement, as binding terms on Investigator and Institution (as those terms are defined in the Agreement). Other terms that are defined in the Agreement shall have the same defined meaning in these Standard Terms.
2. **Performance of Project.** Investigator and Institution agree to perform the Project in accordance with the Scientific Plan and Budget attached to the Agreement, and to use the funding advanced by CURE Epilepsy in accordance with the Agreement and particularly Exhibit C to the Agreement. Institution will monitor and oversee the work of Investigator to ensure compliance with the terms of the Agreement, all in accordance with customary good academic practices used for USA government research grants (e.g., NIH grants). Institution will provide for use by Investigator all appropriate facilities, systems, equipment, supplies, services, personnel, and other support that are customary to enable and assist Investigator to conduct the Project as described in the Agreement and the Project Plan.
3. **Modifications to Project.** If circumstances arise that cause Investigator and Institution to conclude that some material modification is needed for the Project’s Scientific Plan and Budget, before making any such modification, Institution and Investigator will give detailed notice to CURE Epilepsy of the desired modification; and the modification will not be made without the written approval of CURE Epilepsy, which approval will not be unreasonably withheld.

4. **Use of Funds**

- 4.1 **Budget.** Grant funds shall be used only for the direct support of research and only in the manner and for the purposes indicated in the attached Project Scientific Plan and Budget. Changes in the expenditure of budgeted funds require the approval of CURE Epilepsy. **CURE Epilepsy funds shall not be used to pay for institutional overhead or any other indirect costs.** In addition, grant funds given by CURE Epilepsy shall not duplicate funds obtained from any other source.

Funding can be divided between multiple institutions. However, CURE Epilepsy will only contract with the primary Institution, which will be responsible for negotiating subcontracts with any other institutions of any collaborators/co-Principal Investigators involved with the Project. CURE Epilepsy requires detailed budgets outlining the allocation of funds to each subcontract institution.

Any decision by the Grantee to provide any of the grant funds to subcontractors of Grantee is the sole responsibility of the Grantee, and that Grantee must assure that such funds are used only for the direct support of research and only in the manner and for the purposes indicated in this Agreement.

- a. **CURE Epilepsy Award:** Requests may be made for up to \$250,000 grant funds over two years. Funding requests may include salary support for the Principal Investigator and technical staff, supplies necessary to perform the work, animal costs, publication fees and travel to an epilepsy-related conference if the Principal Investigator is presenting CURE Epilepsy-funded research.

Computer hardware (i.e., PC's, printers, monitors, etc.) is limited to a maximum of \$5,000.00 per grant. Support for computer equipment will be limited to one (1) laptop per grant. Any request for laptops must be fully justified on the Budget Justification page of the application. Laptops for personal use will not be supported by the research award. **Indirect costs are not supported.**

- b. **Taking Flight Award:** Requests may be made for up to \$125,000 grant funds for 18 months. Funding requests may include salary support for the Principal Investigator and technical staff, supplies necessary to perform the work, animal costs, publication fees and travel to an epilepsy-related conference if the Principal Investigator is presenting CURE Epilepsy-funded research. Funds are not to be used to purchase equipment. **Indirect costs are not supported.**

- c. **CURE Epilepsy Catalyst Award:** Requests may be made for up to a maximum of \$250,000 paid over 2 years. Awards of lesser amounts and shorter duration that will accomplish key milestones needed for clinical advancement are strongly encouraged. CURE Epilepsy reserves the right to fund only select specific aims or stage funding of proposals based on achievement of milestones. Budgets may include salary support for the Principal Investigator (PI), technical staff and/or co-PIs, supplies, animal costs, vendor costs, limited equipment cost, and travel to an epilepsy-related conference only if the PI is presenting his/her CURE Epilepsy-funded research. **Indirect costs are not supported.**

This award is milestone based, and payments will be contingent upon achieving the milestones outlined in the project.

- d. **Rare Epilepsy Partnership Award:** Funding requests must be itemized and based on specific, milestone-defined scientific aims. Requests may be made for up to a maximum of \$100,000 paid over one year. CURE Epilepsy reserves the right to fund only select specific aims or stage funding of proposals based on the achievement of milestones. Budgets may include salary support for Principal Investigator (PI), technical staff and/or co-PIs, supplies, animal costs, vendor costs, limited equipment costs, and travel to an epilepsy-related conference only if the PI is presenting his/her CURE Epilepsy-funded research. **Indirect costs are not supported.**

4.2 Authorized Expenses. When CURE Epilepsy deems them justified by the research, the expenses identified below are permitted:

- (i) **Principal Investigator's salary:** An appropriate percentage of the Principal Investigator's salary plus a proportionate ratio of fringe benefits per year. Requested salaries are not to be used to replace salaries or partial salaries that are already assured by Institutional or other funds.
- (ii) **Other salaries and fringe benefits:** Co-Principal Investigators, technicians, research assistants, post-doctoral fellows, graduate and undergraduate student salaries and fringe benefits at levels appropriate to the Institution and that are reflective of the percentage of time spent working on the project. While stipend support can be provided for students, tuition is not an allowable expense.
- (iii) **Supplies:** *Supplies* are general purpose-consumable items that are used on a regular basis and have a shorter life span in use than equipment and machines.
- (iv) **Equipment:** *Equipment* is intended for the sole use of the Principal Investigator, Co-Principal Investigator, staff, and any collaborators listed as personnel on the Project Scientific Plan and Budget that are needed to execute the approved scope of the Project, unless cost-shared with another funding source. Limited equipment purchases that are required to complete goals of the Project will be considered for the CURE Epilepsy and Catalyst Awards. Equipment purchases are not allowed for the Taking Flight Award. Unless otherwise stipulated at the time of the award, equipment purchased with CURE Epilepsy funds will be considered property of the Institution to whom the grant was awarded. The Institution and Investigator are explicitly responsible for the maintenance, control, and all associated costs of equipment in their custody and control. In the event the Principal Investigator relocates to a new institution and has a need to continue to use the equipment that was purchased with CURE Epilepsy funds for the Project or a similar or complimentary project, and if CURE Epilepsy makes a written request for Institution to transfer ownership and possession of that equipment to the new institution, then Institution will do so promptly.

4.3 Travel Expenses

- (i) Are limited to Personnel listed on the Project Scientific Plan and Budget.
- (ii) Must be directly related to the implementation of the research project and/or expressly and solely for the purpose of reporting the results of the Project suitable scientific or medical meetings.
- (iii) Can be budgeted for up to two investigators (Principal Investigator and Co-Principal Investigator, if applicable) per year.

- (iv) Are limited to \$1,000 USD maximum per year for US and Canadian Investigators, and \$1500.00 USD for international Investigators.
- (v) May include domestic and/or international journeys.

4.4 Unauthorized Expenses. The following non-exclusive list of expenses are not permitted for payment from the CURE Epilepsy Grant:

- (i) Salaries, travel, and/or housing related to sabbatical leaves.
- (ii) Salaries for administrative, secretarial, and/or clerical staff.
- (iii) Life and disability insurance fees.
- (iv) Purchase or rental of office equipment; (i.e., furniture, filing cabinets, and copy machines).
- (v) Expenses normally covered by the indirect cost of the Principal Investigator's Institution.
- (vi) Fees for tuition, registration or other fees relating to academic studies.
- (vii) Membership dues, subscriptions, books, or journals – including online subscriptions/access.
- (viii) Expenses for or related to moving from one institution to another.

Note: Expenditures more than the approved Budget are not allowed. All funds exceeding the amount awarded by CURE Epilepsy must be reconciled within the Investigator's Institution. Any non-CURE Epilepsy funds spent on a CURE Epilepsy Project more than the awarded budget amount are not entitled to reimbursement from CURE Epilepsy.

4.5 Support from Other Sources

- a. **Alternate funding:** Investigator may not apply for, use or accept CURE Epilepsy funds for a research project or part of a project already supported for the SAME PURPOSE either by CURE Epilepsy or by funds from another public or private source. Accordingly, full disclosure of all funds for research support available to the Investigator from private, governmental, and institutional sources, including CURE Epilepsy, is required. Such disclosure must be made in the research grant Application. If funds from other sources become available to the Investigator during the review or tenure of a CURE Epilepsy grant, then the Investigator must so inform CURE Epilepsy in writing. CURE Epilepsy will then decide about the allocation of its research grant, which may include return of funds.

- b. **Supplemental funding:** Financial support for clearly different aspects of one project or parts of a project from separate funding sources is permitted under CURE Epilepsy grants. Such supplementary funding must be disclosed, fully, to CURE Epilepsy as part of the research grant application or at the time such funding is received.

5. **Reports**

5.1 **Scientific Progress Report (Interim/Final)**

- a. **Interim Scientific Progress Reports** must be written semi-annually (every 6 months), beginning with the effective date of the grant as Day 1. Reports should carefully detail any advances, new data and/or changes in scope that have taken place within the immediately preceding 6-month reporting period. Reports must adhere to the Scientific Progress Report guidelines and form, which can be found in the deliverables section at the bottom of the page under “deliverable templates” on ProposalCentral.

Deadlines: Interim Scientific Progress reports are due within thirty (30) days of the completion of each 6-month reporting period. For example, if an award begins January 1, reports are due within thirty (30) days of June 30 (deadline: July 30) and subsequently within thirty (30) days of January 1 of the following year.

- b. **The Final Scientific Progress Report** must reflect the cumulative results of the research conducted and should reflect overall achievements for each specific aim for the entire award duration. This report **must** adhere to the Scientific Progress Report guidelines and form, which can be found in the deliverables section at the bottom of the page under “deliverable templates” on ProposalCentral.
- c. Each of the above referenced interim scientific progress reports and the final scientific progress report must contain a “**Public Statement**” that contains only non-confidential/non-proprietary information that describes in general the nature and progress of the research for the Project; and Grantee hereby consents to CURE Epilepsy making public disclosure of the contents of the Public Statement to CURE Epilepsy donors, consultants, and constituents, as CURE Epilepsy deems appropriate.

Deadline: The Final Scientific Progress Report is due within thirty (30) days of the completion of the award. For example, for an award that closes on December 1, the Final Scientific Progress Report is due by January 1.

5.2 **Report of Expenditures (Interim/Final)**

- a. **Interim reports of expenditures** must be written bi-annually (every 6 months), beginning with the effective date of the grant as Day 1. Reports must detail all expenditures made using grant funds during the current reporting period as well as cumulative expenses since the start of the grant

(including travel, salary, and supplies). See this grant policy for a non-inclusive list of authorized and unauthorized expenses. Reports **must** adhere to the Report of Expenditures form, which can be found in the deliverables section at the bottom of the page under “deliverable templates” on ProposalCentral.

Deadlines: Interim Reports of Expenditures are due within thirty (30) days of the completion of each 6-month reporting period. For example, if an award begins January 1, reports are due within thirty (30) days of June 30 (deadline: July 30) and subsequently within thirty (30) days of January 1 of the following year.

- b. **The Final Report of Expenditures** must detail all expenditures made using grant funds during the current reporting period as well as cumulative expenses since the start of the grant. This report must adhere to the Report of Expenditures form, which can be found in the deliverables section at the bottom of the page under “deliverable templates” on ProposalCentral.

Deadline: The Final Report of Expenditures is due within thirty (30) days of the completion of the award. For example, for an award that closes on December 1, the Final Report of Expenditures is due by January 1 of the following year.

- 6. **Payment Procedures.** Payment of the Grant funds will occur as specified in Exhibit C to the Grant Agreement, subject to the terms and conditions set forth in Exhibit C and to the following conditions and provisions:

- 6.1 **Receipt of Interim Reports:** Payments subsequent to the first payment will only be made after receipt and approval of the Interim Scientific Progress Report and Interim Report of Expenditures. CURE Epilepsy will review these reports after receipt, and if an issue becomes apparent (e.g., report does not follow the required format), the Grantee Institution and Investigator will be contacted to resolve this issue. Payments will not be made until all issues are resolved. Once reports have been approved, a check will be issued to the Institution from CURE Epilepsy.
- 6.2 **Assessment of Expenditures:** Upon receiving each Report of Expenditures, CURE Epilepsy will assess the ways in which funds have been spent. Payments may be delayed or withheld depending upon the outcome of this assessment. For example, funding may be withheld should spending be slower than expected, or funds are used in an unauthorized manner.
- 6.3 **Receipt of Final Reports:** The final payment of \$5,000 will not be approved until receipt and approval of the Final Scientific Progress Report and Final Report of Expenditures. The final payment will also be subject to review of the amount of funds spent (see section [7] for further detail).

7. **Award Close Out**

7.1 Final Payment. CURE Epilepsy withholds \$5,000 of the grant for the final payment, which is paid upon timely receipt and approval of the required final reports (Final Scientific Progress Report and Final Report of Expenditures).

7.2 Unexpended Funds. In cases where final expenditures fall short of the Grant amount by more than \$5,000, no final payment will be issued, and the Grantee will be required to return unspent funds to CURE Epilepsy within sixty (60) days of the award end date. If final expenditures equal the total award amount minus \$5,000, no final payment will be issued. In cases where final expenditures fall short of the award amount by less than \$5,000, a final payment will be issued by CURE Epilepsy to Institution up to the value of final expenditures. No requests to spend additional funds may be made after receipt of the Final Report of Expenditures.

Payment instructions for unspent funds are below:

Check payable to: Citizens United for Research in Epilepsy

Mail to: 420 North Wabash Avenue, Suite 650, Chicago, IL 60611

8. Change in Scientific Scope. The Principal Investigator must inform CURE Epilepsy of any significant changes in scope to the approved project. This includes any new directions or future objectives which were not included in the approved proposal. A change in scope must be approved by CURE Epilepsy prior to any work being performed on them using CURE Epilepsy funds.

9. **Budget Policies**

9.1 Budget Revisions. Revisions to the originally approved Budget are allowed under certain circumstances, including changes in scope of the Project or scientific discoveries that warrant a change in the Scientific Plan, in each case subject to the prior written approval by CURE Epilepsy. Any desired revisions to the original Budget must be justified in writing and be submitted to and approved by CURE Epilepsy before any funds are spent on unapproved items.

9.2 Withholding of Funds. CURE Epilepsy may decide at any time to withhold additional payments. Reasons for the withholding of funds may include, but are not limited to:

- i. Assessment by CURE Epilepsy that the Grantee's current funds are sufficient to complete research for the Project.
- ii. Deliverables were not submitted as required for payments that are to be made after reports are received and approved.
- iii. If the required financial and scientific progress reports indicate that the Investigator and Institution are not working toward achieving the purposes for which the Grant was awarded or has mismanaged funds, CURE Epilepsy may conduct an investigation. Grantees understand

that if CURE Epilepsy determines, in its sole and absolute discretion, that they have not met the terms and conditions of this Agreement and the Grant, CURE Epilepsy may halt the disbursement of further funds and take all responsible and appropriate steps to recover the Grant funds or to ensure the restoration of diverted funds. Grantees further understand and agree that CURE Epilepsy may withhold any further payments until such time as CURE Epilepsy is satisfied that all obligations under this Agreement are met.

- 9.3 No-Cost Extensions.** Under exceptional circumstances, a Project may be extended for a period of either six (6) or twelve (12) months (half of the length of the original grant) beyond the Grant's original expiration date. The Principal Investigator and the Institution must request such an extension in writing stating the funds remaining and a detailed justification for the extension satisfactory to CURE Epilepsy. The request must be made no later than thirty (30) days BEFORE the termination date of the award. The originally approved Budget remains in effect throughout the extension period, inclusive of all category maximums. A no-cost extension request form can be found on ProposalCentral or requested from research@CUREepilepsy.org.

The following conditions must be met:

- a. There will be no change in the Project's originally approved scope.
- b. Additional time beyond the established expiration date is required to ensure adequate completion of the originally approved Project.

NOTE: The fact that funds remain at the expiration of the Grant is not, in itself, sufficient justification for an extension without additional funds. Submission of a no cost extension request does not denote that the request will be automatically granted.

10. Change in Status Policy

- 10.1 Status of Principal Investigator.** The continued use of Grant funds following any major change in status of the Principal Investigator requires prior written authorization from CURE Epilepsy. As described below, such changes include but are not limited to prolonged absence, change in Institution, or withdrawal from the Project.

- a. **Prolonged Absence.** Continued use of funds by or reassignment of a Project to another qualified investigator during a prolonged absence of the Principal Investigator (excluding Institutionally authorized vacation) requires prior written CURE Epilepsy authorization. The Principal Investigator must contact the CURE Epilepsy Research Team requesting such authorization at least six (6) weeks before the starting date of the period of absence. The request must contain an explanation of the reasons for the

absence and details about the arrangements made for conducting the research Project during the absence. The letter must include the following:

- i. Inclusive dates of absence.
- ii. Reason(s) for absence.
- iii. Name, address, telephone number, and curriculum vitae of the new investigator who has agreed to be responsible for the scientific conduct of the research Project.
- iv. Proposed method and frequency of communication between the Principal Investigator and the new investigator-in-charge.
- v. Signature of the new investigator referred to in item (iii) above confirming that they are familiar with all aspects of the project and accepts full responsibility for the conduct of the research during the absence of the Principal Investigator.

When a request for continued use of Grant funds during a prolonged absence of the Principal Investigator is not authorized, the Grant is terminated and all unexpended funds plus unexpended accrued interest, if any, must be returned to CURE Epilepsy accompanied by a Report of Expenditures within thirty (30) days of the date of termination.

- b. **Move to a New Institution.** Continued use of funds by a Principal Investigator who changes institutions requires prior written authorization from CURE Epilepsy. The Principal Investigator must write to the CURE Epilepsy Research Department requesting such authorization at least sixty (60) days before the effective date of change in institution. The letter must include:
 - i. Effective date - month/day/year - of change in institution.
 - ii. Title and period of support of the CURE Epilepsy Grant affected by the change in institution.
 - iii. Complete address of the new institution. The new mailing address of the Principal Investigator should also be included if it differs from that of the new institution.
 - iv. Statement of the adequacy of the new institution's facilities for conducting the research projects identified in item "ii" above.

An Agreement with the new Institution or an amendment to the original Agreement will be required. Generally, transfer of funds directly between institutions is preferred. CURE Epilepsy requires evidence of transfer of funds. CURE Epilepsy can also assist with transfer of funds between

institutions following termination of the original Agreement and re-contracting with the new institution.

Upon a transfer of a Grant, a final Report of Expenditures from the original Institution must be submitted within thirty (30) days of the transfer date.

When a transfer is not authorized, the Grant is terminated and all unexpended funds plus unexpended accrued interest, if any, must be returned to CURE Epilepsy, accompanied by a Report of Expenditures within sixty (60) days of the termination of that award.

- c. **Withdrawal from Project.** When a Principal Investigator withdraws from a Project, the Grant terminates and all unexpended funds plus unexpended accrued interest, if any, must be returned to CURE Epilepsy accompanied by a Report of Expenditures within sixty (60) days of the withdrawal from the Project.

Under exceptional circumstances, a Grant may be continued under a new Principal Investigator at the same Institution. In such cases, the Principal Investigator must write to CURE Epilepsy Research Department requesting authorization for such a continuation at least sixty (60) days before the effective date of withdrawal from the Project. The following documentation must be provided:

- i. Effective date - month/day/year - of the change in Principal Investigator.
- ii. Updated progress report on the project.
- iii. Name, address and curriculum vitae of the proposed new Principal Investigator.

The proposed new Principal Investigator must, in a separate letter, indicate to CURE Epilepsy their familiarity with the specific aims of the Project and agree to accept responsibility for all scientific and administrative aspects of the research Grant, and also provide a statement about the availability of equipment, personnel, etc., necessary to conduct the research Project.

10.2 Termination of Grant

- a. Any Party may terminate this Agreement at any time for material breach by another Party if such breach is not cured within thirty (30) days after receipt of a written notice specifying the breach. Within ten (10) days after such termination, Institution and the Principal Investigator shall return any unspent and uncommitted grant funds to CURE Epilepsy and provide CURE Epilepsy with a copy of all scientific and financial reports covering activities up to the date of termination.

- b. Any Party may terminate this Agreement upon the death or permanent disability of the Principal Investigator. Within thirty (30) days after the date of Principal Investigator's death or permanent disability, the Institution shall return any unspent and uncommitted Grant funds to CURE Epilepsy and provide CURE Epilepsy with a copy of all scientific and financial reports covering activities up to the date of death or permanent disability.
- c. Any Party may terminate this Agreement in the event Principal Investigator leaves the full-time employment of the Institution, for any reason other than death or permanent disability, prior to completion of the Project. Within sixty (60) days after the date of such termination, Institution and the Principal Investigator shall return any unspent and uncommitted Grant funds to CURE Epilepsy and provide CURE Epilepsy with a copy of all scientific and financial reports prepared up to the date of the termination, unless and until CURE Epilepsy, the Principal Investigator, and Principal Investigator's new place of employment enter into a written agreement providing for the continuation of the Project under the same conditions applicable herein or other conditions agreed to by such parties.
- d. In the event that some situation occurs that causes CURE Epilepsy to conclude, in its reasonable discretion, that it is problematic for CURE Epilepsy to fund or continue to fund a Grant (a "Problematic Event"), then CURE Epilepsy will confer with Institution and Investigator to discuss and evaluate the situation and problem and try to eliminate or mitigate the problem. Some examples of a potential Problematic Event include, without limitation, (i) funds become available to Institution or Investigator to support the same or similar focus or scope of the research that is to be funded by the Grant from CURE Epilepsy, such that there would be a "double-funding" situation, (ii) events occur that cast a material adverse view on the reputation, ethics, integrity, or character of Institution or Investigator, (iii) there are repeated problems, issues, breaches, or delays with Institution or Investigator properly performing their duties as expected by the Agreement and its Scientific Plan and Budget, (iv) Institution is having significant problems for providing the facilities, equipment, personnel, funding or oversight management support that are expected for the Grant funded research Project to be completed in a proper and timely manner, (v) Investigator is not properly and timely performing the research tasks as specified by the Scientific Plan and Budget for the Project being funded by the Grant, or (vi) Institution or Investigator make or have made any material misrepresentation related to the application for or performance of the Grant. After CURE Epilepsy confers with Institution and Investigator concerning the potential Problematic Event, if CURE Epilepsy still believes there is a Problematic Event, then CURE Epilepsy may elect to terminate the Grant and the Agreement by giving written notice to Institution.
- e. Upon any termination of this Agreement: (i) CURE Epilepsy shall cease to have any further obligation to furnish any more monies for the Grant, and

(ii) Institution and Investigator shall cease to have any further obligations to perform the Project, and (iii) any applicable provisions that are reasonably appropriate to survive the termination and remain in effect shall so survive and remain in effect, including without limitation the applicable provision of Sections 5, 7.2, 9.2, 11, 14, and 15 of these Standard Terms.

11. **Conflict of Interest Policy.** Any potential conflict of interest the Principal Investigator(s) or collaborator(s) may have relating to the Project must be fully disclosed in writing to CURE Epilepsy; which disclosure shall be made prior to signing this Agreement, or if the conflict arises after the signing, then within ten (10) days after the conflicts arises. Such conflict would include (but is not limited to) having a proprietary interest that may be affected by the outcome of the research Project. It is expected that Principal Investigator will observe the highest ethical standards in the conduct of research.

12. **Publication of Results**

12.1 Publication. It is the intention of the Parties that any meaningful new information from the Results of the Project will be published or otherwise made available for use by the scientific, medical, and healthcare communities, for the general benefit of humanity. Thus, Investigator will apply academically reasonable efforts to have such meaningful new information published or otherwise made available. CURE Epilepsy expects timely publication of the Results of all research Projects it supports, but subject to reasonable delays necessary to enable Institution to apply for patent or copyright protection. Each such publication or presentation, whether in peer-reviewed journals, meeting abstract formats, platforms, and poster presentations or in review articles or similar publications, shall contain the following statement or its equivalent: "Supported by Citizens United for Research in Epilepsy, doing business as CURE Epilepsy (CURE Epilepsy)." CURE Epilepsy shall have the right to distribute copies or summaries of any publication about the Results to CURE Epilepsy's donors and participants.

12.2 Press Release. Funds to support CURE Epilepsy research programs come primarily from donations from private citizens. It is essential to the growth and maintenance of CURE Epilepsy and its research programs that these donors, as well as individuals and families affected by epilepsy, are kept informed of research progress. For these purposes CURE Epilepsy often issues press releases on newsworthy research developments and produces various publications for the public that report research activities. Such a press release or report may be issued on the publication of an article in a professional journal or a presentation at a scientific or medical meeting.

12.3 Public Access to Results. CURE Epilepsy expects that all peer-reviewed articles that have been accepted for publication and have been supported in whole or in part by its grants will be made available in the PubMed Central online archive. While publishers most often deposit articles that have been peer-reviewed and accepted for publication into PubMed, authors are strongly encouraged to ensure submission of an electronic copy of their final peer-reviewed manuscripts in PubMed Central

upon acceptance for journal publication. The manuscript is to be made publicly available in PubMed Central no later than 12 months after the official date of journal publication. PubMed Central is a database of full-text biomedical journal articles available online without a fee. It is hosted by the National Library of Medicine in the National Institutes of Health. Once posted in PubMed Central, results of research become more accessible, prominent, and integrated, making it easier for scientists worldwide to pursue epilepsy research. Equally important, families, clinicians, individuals with epilepsy, educators, and students reap the benefits of information arising from CURE Epilepsy funding by accessing it on PubMed Central at no charge.

13. Animal and Human Subjects/Tissue Research Protocols

13.1 Institutional Animal Care and Use Committees and Institutional Review Boards. CURE Epilepsy follows U.S. National Institutes of Health (NIH) Guidelines for the humane care and use of animals in research and for the use of human subjects in research and requires the Grantee Institution to comply with such Guidelines. According to U.S. Federal law, institutions that use laboratory animals for research or instructional purposes must establish an Institutional Animal Care and Use Committee (IACUC) to oversee and evaluate all aspects of Institution's animal care and use programs, facilities, and procedures. Institutions that utilize human subjects in research as defined by the U.S. Government must establish an Institutional Review Board (IRB) or Ethics Committee (EC). See NIH's federal guidelines for more information.

13.2 CURE Epilepsy Requirements

- a. Institution must comply with all federal, state, and local government regulations regarding the participation of human subjects and the use of animals in research. No part of the award may be used to support any research involving human subjects or animal studies that does not have the approval of the appropriate EC or IRB.
- b. All Projects with human subjects and/or animal research must always have up-to-date ethics approval documentation. For Projects involving non-exempt human research, Institution bears ultimate responsibility for protecting human subjects under the award, including human subjects at all participating and consortium sites, and for ensuring that an Assurance approved by the Office for Human Research Protections (“OHRP”) and certification of IRB approval have been obtained before human subjects research can be conducted at each collaborating site.
- c. Where possible, CURE Epilepsy strongly encourages the use of a Central IRB to improve the efficiency of conducting multi-site clinical studies. Institution must ensure that CURE Epilepsy receives required, up-to-date documentation for all sites in accordance with the award milestone schedule and is current at the time of submission of award annual renewal materials

(see below for information on uploading documentation into ProposalCentral.

- d. If the IRB/EC has determined that the study is exempt, the documentation demonstrating the exempt status must be submitted to CURE Epilepsy.
- e. Institution must notify CURE Epilepsy if there are any regulatory issues, protocol violations or policy changes that impact the ability of the Principal Investigator to conduct the research as part of this award.
- f. **Foreign Institutions:** Ethical approval documentation submitted in a language other than English requires a cover letter signed by Institution's department head (in English) verifying the content of the form and countersigned by Institution's Research Office of record.
- g. **Uploading protocol information into ProposalCentral:** When human subjects, tissues and/or materials are to be used in a research Project, it is the responsibility of the Principal Investigator and Institution to ensure that Institution has the following on file and uploaded to their ProposalCentral file:
 - i. A complete copy of the research protocol approved by the Institution's Human Subjects Review Board and a copy of that Board's current approval notice.
 - ii. A copy of the Board's approved patient informed consent form(s) to be used. A copy of the Board's current approval notice and a copy of the Board's approved patient informed consent form must be submitted prior to the initiation of work and updated annually.

14. **Food and Drug Administration Policy.** When experimental drugs and/or experimental medical devices are to be administered to patients, the Principal Investigator and Institution must ensure that Institution has the following on file and uploaded to their ProposalCentral file:

A complete copy of the Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) application approved by the Federal Food and Drug Administration (FDA) and a copy of the FDA's approval notice; and copies of all correspondence during the application and award periods between the FDA and the Principal Investigator pertaining to the experimental drug(s) and/or device study.

15. **Intellectual Property Policy.** Grants awarded by CURE Epilepsy are subject to the following Intellectual Property Policy. By accepting a Grant offered by CURE Epilepsy, the Principal Investigator and Institution each agree to be bound by the terms and conditions of this Intellectual Property Policy.

- 15.1 Results.** As used in this Agreement, the term “Results” means all results from Principal Investigator and Institution performing the research Project, including without limitations as examples: any new discovery, invention (whether patentable or not), technology, data, know-how, methods, process, device, product, apparatus, design, material, algorithm, formulae, program software, and “work” as described in the USA copyright law and patent law.
- 15.2 Invention Disclosure.** Investigator shall make a prompt written disclosure to Institution of the Results from the Project that Investigator reasonably believes may be a patentable invention; whereupon Institution and Investigator will determine if it is worthwhile to file for patent protection. Promptly thereafter, Institution and Investigator shall give written confidential report to CURE Epilepsy of such invention disclosure and patent filing determination.
- 15.3 Public Disclosure.** Prior to any public disclosure of the Results, Investigator will first make the invention disclosure and patent filing determination as required by Section 15.2 above. Investigator and Institution shall promptly furnish to CURE Epilepsy a copy of any such publication.
- 15.4 Non-Exclusive License.** In the event that any aspect from the Results of the Project is given patent protection, then Institution and Investigator hereby grant to CURE Epilepsy a perpetual, transferable, non-exclusive, royalty-free license, with right to grant sublicenses, to practice and use the patented invention for constituent education or academic research purposes, but not for commercial purposes of making or selling products or services.
- 15.5 Shared Consideration.** In the event that Institution or Investigator is able to receive any consideration from third parties for the commercial development or use of the Results (e.g., option fees, license fees, royalties, milestone payments, etc.), then they shall share with CURE Epilepsy 10% of that consideration until such time as the cumulative aggregate of those payments to CURE Epilepsy equals three times the aggregate sums of the CURE Epilepsy Grant. Such payments shall be made to CURE Epilepsy within thirty (30) days after the consideration is received by Institution or Investigator.
- 15.6 Copyrights**
- a. Any work that is subject to a claim of copyright developed under, or in the course of activities related to this Grant awarded by CURE Epilepsy must be promptly reported to CURE Epilepsy.
 - b. With respect to such work, Principal Investigator and Institution shall be the owner, and they hereby grant CURE Epilepsy a perpetual, transferable, non-exclusive, royalty-free license to reproduce and distribute the work, and to prepare, reproduce and distributive derivative works related to the work. CURE Epilepsy agrees to delay any publication or licensing of any such

copyright work until the work is made public by Institution or Principal Investigator.

15.7 Confidential Information

- a. **Treatment of Confidential Information.** The Parties acknowledge and agree that any Party (the “Disclosing Party”) may disclose to the other Parties (the “Receiving Party”) confidential and/or proprietary information (the “Confidential Information”) of the Disclosing Party. With respect to all such Confidential Information of a Disclosing Party, the Receiving Party agrees that during the term of the Project and for a period of five (5) years after the Agreement expires or terminates, such Receiving Party shall (i) maintain in confidence such Confidential Information; (ii) not disclose such Confidential Information to any third party without prior written consent of the Disclosing Party, except for disclosures to agents who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Section 15.7 (a); and (iii) not use such Confidential Information for any purpose other than the performance of the Agreement.
- b. **Exceptions to Obligations.** The obligations of Section 15.7 (a) shall not apply to specific Confidential Information that the Receiving Party can demonstrate:
 - i. is at the time of disclosure by Disclosing Party, or thereafter becomes, generally available to the public through no fault of the Receiving Party, or any entity that obtained such information or materials from the Receiving Party;
 - ii. is already known to or possessed by the Receiving Party, as evidenced by its written records, predating receipt thereof from the Disclosing Party;
 - iii. is obtained from a third party without restriction and who had the legal right to disclose the same to the receiving Party; or
 - iv. has been independently developed by the receiving Party without the aid, application or use of any Confidential Information of the Disclosing Party, as demonstrated by competent written proof.
- c. **Authorized Disclosures.** If, based upon the advice of legal counsel skilled in the subject matter, a Receiving Party is required to disclose specific Confidential Information of the Disclosing Party to comply with an applicable law, regulation, legal process, or order of a government authority or court of competent jurisdiction, such Party may disclose such Confidential Information only to the person required to receive such disclosure; provided, however, that the Party required to disclose such Confidential Information shall (i) to the extent permitted by such law, regulation, process, order or rules, first have given prompt advance notice

to such Disclosing Party to enable it to seek any available exemptions from or limitations on such disclosure requirement and shall reasonably cooperate in such efforts by the Disclosing Party, (ii) furnish only the portion of the Confidential Information which is legally required to be disclosed; (iii) use all reasonable efforts to secure confidential protection of such Confidential Information, and (iv) continue to perform its obligations of confidentiality set out herein.

15.8 Abandon Patent. If Institution decides (i) to abandon the prosecution of any patent application, or (ii) to abandon the maintenance of any issued patent, or (iii) to not file a patent application, in all of the above cases for any patentable invention within the Results from performing the research Project, then Institution shall give written notice to CURE Epilepsy of that decision as soon as is reasonably feasible. If requested by CURE Epilepsy, Institution will assign and transfer to CURE Epilepsy all right, title, and interest for such patentable invention and any related patent application filings.

16. General Provisions

16.1 Indemnification. Parties agree to, and hereby do, indemnify and hold harmless the other Party, its directors, officers, employees, and agents from any and all demands, claims, suits, and expenses, including but not limited to reasonable attorneys' fees, subject to applicable law, which Parties may incur by reason of the other Parties' acts or omissions (including, without limitation, use of third party intellectual property rights) relating to, arising out of, or in connection with the Agreement, the Project or any grant award related to the Project.

16.2 Assignment. Neither Party may assign or transfer the Agreement or any right or obligation under the Agreement to any third party without the prior written consent of the other Party. The Agreement is binding upon and shall inure to the benefit of the Parties, their representatives, and permitted assigns.

16.3 Captions. The captions and section headings used in the Agreement and this Exhibit are for convenience only and are not intended to have, nor shall they be interpreted as having, any substantive effect whatsoever.

16.4 Entire Agreement. The Agreement (together with its Exhibits, including this Exhibit B), embodies the entire understanding relating to the subject matter of the Agreement, and there are no prior representations, warranties, or agreements, whether written or oral, between the Parties, not contained in this Agreement.

16.5 Governing Law. The Agreement shall be governed by the laws of the State of Illinois, without regard to the conflict of law principles thereof.

16.6 Notices. See Exhibit D for the contact information for each Party. Any notice or communication in connection with the Agreement shall be made in the English language and considered sufficient if in writing and personally delivered to an officer of the Party, or to the person who is the Principal Investigator, or if sent by

email and confirmed by USA mail or special courier at the address specified on Exhibit D, or such other address as the Party has given notice of in writing. The notice or communication shall be deemed to have been received: (a) when delivered, if personally delivered; or (b) on the third business day after dispatch, if sent by nationally recognized express delivery service. All notices shall be deemed effective upon actual receipt by a Party to whom notice is given.

A Party may change its address by providing written notice to the other Parties.

- 16.7 Severability.** If any provision of the Agreement is declared invalid or unenforceable by an arbitration or a court having competent jurisdiction, the Parties mutually agree that the Agreement shall endure except for the part declared invalid or unenforceable by order of the arbitrators or the court. The Parties shall consult and make their best efforts to agree upon a valid and enforceable provision that shall be a reasonable substitute for an invalid or unenforceable provision in light of the intent of the Agreement.
- 16.8 Waivers.** A waiver by either Party of any term or condition of the Agreement in any one instance shall not be deemed to continue to be a waiver of such a term or condition for any similar instance in the future or of any subsequent breach of the Agreement.
- 16.9 Independent Contractors.** The Parties are independent contractors. Nothing in the Agreement creates any relationship as partners, agents, employees, joint venturers, or consultants.
- 16.10 Compliance with Laws.** Each Party shall comply with all applicable laws regarding its performance of the Agreement (including without limitation, as examples, laws regarding protection of data, anti-corruption laws, environmental protection laws, health and safety laws, etc.).
- 16.11 Amendments.** The provisions in the Grant Agreement or these Standard Conditions or in any applicable exhibit may be amended or modified only by a written document that has been executed by CURE Epilepsy and any other Party that is adversely affected.
- 16.12 Use of Other Party's Name.** While the CURE Epilepsy Grant Agreement remains in effect: (i) Institution and Investigator are permitted to disclose to others that they have been awarded a Grant from CURE Epilepsy, and the dollar amount of the Grant, and the general nature of the funded research Project; and (ii) CURE Epilepsy is permitted to disclose to others that CURE Epilepsy has awarded a Grant to Institution and Investigator, and the dollar amount of the Grant, and the general nature of the funded research Project. Excepting only as set forth above, or as otherwise specified in these Standard Terms or the CURE Epilepsy Grant Agreement and its Exhibits, neither Party shall use the name of the other Party (or any abbreviation of the Party's name) in any publication, announcement, or other public disclosure.
- THE END