CURE CITIZENS UNITED FOR RESEARCH IN EPILEPSY

CURE Grants Policy

Research grants awarded by Citizen's United for Research in Epilepsy ("CURE") are governed by the policy set forth herein. Terms of this policy are subject to revision or alteration at any time.

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SECTION I: MISSION AND FUNDING PRIORITIES

CURE's mission is to find a cure for epilepsy, by promoting and funding patient-focused research.

The following priority areas reflect CURE's focus on advances that have the potential to truly transform and save lives. Prevention and disease modification/elimination are critical goals and consistent with our mission.

- Transformative research to enhance our understanding of the cellular, molecular, genetic and systems-level mechanisms that lead to any of the epilepsies, facilitating the continued investigation of disease-modifying or preventative strategies
- Innovative approaches that can prevent, modify and/or arrest the development of acquired epilepsy after stroke, tumor, viral infection, etc.
- Research that will inform the development of novel therapies to prevent onset or halt the progression of the severe pediatric epilepsies
- Research focused on new, effective treatments for the >30% of the epilepsy population who are pharmacoresistant.
- Novel research that furthers our understanding of the causes and ultimate elimination of SUDEP
- Translational, clinical, and clinically-informed basic research that will facilitate elevated understanding of the cellular-, molecular-, and systems-level mechanisms that underlie the relationships between sleep and epilepsy.

SECTION II: RESEARCH PROGRAMS AND INITIATIVES

Unless otherwise specified, these policies and procedures pertain to CURE's grant awards, as well as CURE-driven initiatives. CURE funds researchers working at universities, companies and non-profit institutions.

1. Programs

1. Taking Flight Award

a. Program Overview

CURE seeks to promote the careers of young researchers to allow them to develop a research focus independent of their mentor(s). Researchers may propose basic or clinical studies, but this award mechanism is not intended to support clinical trials. Research that involves collaboration and a multidisciplinary approach is desirable. The applicant researcher will be required to discuss how this avenue of research is independent from his or her mentor's research and will lead him or her to a path of independent epilepsy research. We encourage studies that will provide new directions for epilepsy therapy, prevention and, ultimately, a cure and that will allow Grantees to collect the data necessary to support grant applications to the National Institutes of Health or similar granting agency. Information on CURE's priority areas can be found on CURE's website and in the Taking Flight Guidelines.

Requests may be made for up to $100,000 for one year.

b. Eligibility Requirements

Applicant researchers must fall into one of the following categories to be eligible for the Taking Flight Award:

- A senior postdoctoral fellow who has a minimum of 3 years postdoctoral experience
- A clinical fellow who is a Neurology Resident in his/her Neurology training and considering Epilepsy Fellowships
- Newly appointed faculty within one year of having completed postdoctoral training

International applicants are welcome. All materials must be submitted in English.

2. CURE Epilepsy Award

a. Program Overview

The CURE Epilepsy Award priority areas reflect CURE's continued focus on scientific advances that have the potential to truly transform the lives of those affected by epilepsy, with prevention and disease modification as critical goals. These areas include: transformative research to enhance our understanding of the cellular, molecular, genetic and systems-level mechanisms that lead to any of the epilepsies; innovative approaches that can prevent, modify and/or arrest the development of acquired

epilepsy; research that will inform the development of novel therapies to prevent onset or halt the progression of the severe pediatric epilepsies; research focused on new, effective treatments for the >30% of the epilepsy population who are pharmacoresistant; and research into SUDEP and sleep and epilepsy. More information on CURE's priority areas can be found on CURE's website and in the and in the CURE Epilepsy Award Guidelines.

b. Eligibility Requirements

This award is available to both established and early career researchers. Researchers who serve on CURE's Scientific Advisory Council are ineligible to apply for or sponsor a grant for the duration of their term.

Researchers from the same institution can submit letters of intent and apply for the same award. Researchers cannot receive funding on two different CURE awards at the same time. If applying for an award with a collaborator who is currently funded by CURE, they must be listed as collaborator and not Co-Principal Investigator. A co-Principal researcher can request a salary, where as a collaborator cannot.

International applicants are welcome. All materials must be submitted in English.

B. Grant Application Process, Budget and Implementation

1. Letter of Intent Phase

All applicants must submit a Letter of Intent (LOI). Updated guidelines specific to each award will be announced and can be found on CURE's website.

Applicants can submit more than one application per award mechanism and are also allowed to submit applications to more than one award mechanism (if eligible), but the goals, hypothesis and outcomes for each application must be distinctly unique.

LOIs must be submitted in proposalCENTRAL (https://proposalcentral.altum.com). LOIs sent to CURE directly will not be accepted.

2. LOI Review Process

LOIs are reviewed by CURE's Research Team and a panel of scientific peer reviewers. When assessing applications, reviewers consider:

1) quality of the science;
2) whether the work proposed can be achieved within the parameters of the award;
3) whether the proposed work meets the goals of the program;
4) whether the proposed project is aligned with CURE's mission; and
5) whether the applicant followed instructions and stayed within page limits.

Applicants are notified via proposalCENTRAL as to whether they have been invited to advance to the full proposal phase.

c. Full Proposal Phase and Review

Applicants who are invited and advance to the full proposal phase are required to submit a full proposal which will include information on project background, hypothesis, specific aims of the research, preliminary data (if available), expected outcomes and interpretations for proposed objectives.

Each grant proposal is reviewed by three external scientific reviewers who are selected because of their expertise in different sub-specialties of epilepsy research as well as a member of CURE's Lay Review Council (LRC). The LRC is made up of people with epilepsy and the loved ones of people with epilepsy who have a special interest in finding a cure. Members of the LRC contribute to CURE's grant review process by reading research proposals from a lay perspective, which helps ensure that the stakeholder point of view is critically represented during the grant review process.

Applications are discussed among the committee members and CURE Research Team and scored. It is important to keep in mind that a key factor that reviewers consider when assessing applications is feasibility. Lower scores will be given to proposals that are not realistically achievable within the allotted timeframe.

Applicants should refer to the Guidelines available on the CURE website for specific details.

Should a full proposal not be selected for funding, applicants are encouraged to re-apply starting with re-submission of a LOI.

d. Budget

Applicants agree that grant funds shall be used only for the direct support of research and only in the manner and for the purposes indicated in the grant proposal. Changes in the expenditure of budgeted funds require the approval of CURE. **CURE funds shall not be used to pay for institutional overhead or any other indirect costs**. In addition, Applicants agree that grant funds given by CURE shall not duplicate funds obtained from any other source.

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

Applicants agree that the decision to provide any grant funds to subcontractors of grantees is the sole responsibility of grantee(s), and that grantee(s) 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 the grant proposal.

i. **CURE Epilepsy Award**:
Requests may be made for up to $250,000.00 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-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.**

ii. **Taking Flight Award:**
Requests may be made for up to $100,000.00 for one year. 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-funded research. Funds are not to be used to purchase equipment. **Indirect costs are not supported.**

a. Authorized Expenses

When CURE 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 award specifically to execute the approved scope of the project unless cost-shared with another funding source. Limited equipment purchases that are required to complete goals will be considered for the CURE Epilepsy Award. Equipment purchases are not allowed for the Taking Flight Award. Unless otherwise stipulated at the time of the award equipment purchased with CURE funds will be considered property of the Principal Investigator to whom the grant was awarded. The Principal Investigator is explicitly responsible for the maintenance, control, and all associated costs of equipment in its custody and control.

b. Travel Expenses:

i. Are limited to Personnel listed on the CURE project.
ii. Must be directly related to the implementation of the research and/or expressly and solely for the purpose of reporting the results of CURE-supported research at 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 $1,000.00 USD maximum per year for US and Canadian applicants and $1500.00 USD for international applicants.
v. May include any domestic and/or international journeys.

c. Unauthorized Expenses

The following non-exclusive list of expenses are not permitted under the CURE research grants program:

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 must be reconciled within the researcher's Institution. Any non-CURE funds spent on a CURE project more than the awarded budget amount are not entitled to reimbursement from CURE.

d. Support from Other Sources

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

decide about the allocation of its research award, which may include return of funds.

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

5. Contracting

Once an applicant has been notified that they have been selected for funding, they will receive a grant Agreement for review and execution by their institution from CURE within two (2) business days. A fully executed contract is required for release of funds and initiation of work.

6. Post-Award Reporting Requirements

a. Scientific Progress Report (Interim/Final)

Interim Scientific Progress Reports must be written bi-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.

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.

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.

b. Report of Expenditures (Interim/Final)

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.

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.

c. Consent Form

A signed **Consent to Public Disclosure** form is required with all progress report submissions. By signing this form, you acknowledge that the Public Statement included in your report may be shared with donors and that it was prepared with the **understanding of non-confidentiality.** The Consent to Public Disclosure form may be found in proposalCENTRAL, or you can request a copy from CURE via Research@cureepilepsy.org.

7. Payment Procedures

The first scheduled payment will occur at the commencement of the award. All subsequent payments will be made bi-annually (every 6 months) subject to several factors:

a. Receipt of interim reports: Payments subsequent to the first payment will only be made after receipt and approval of the Interim Scientific Progress Report, Interim Report of Expenditures and signed Consent to Public Disclosure. CURE will review these reports after receipt, and if an issue becomes apparent (e.g. consent form is not signed or report does not follow the required format), the Grantee 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 Grantee from CURE.

b. Assessment of expenditures: upon receiving each Report of Expenditures, CURE 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. Additional reasons for the withholding of funds may be found in Section III.1.b.
c. Receipt of Final reports: The final payment of $5,000.00 will not be approved until receipt and approval of the Final Scientific Progress Report, Final Report of Expenditures and Final signed Consent to Public Disclosure. The final payment will also be subject to review of the amount of funds spent (see section 8 for further detail).

8. Award Close Out

a. Final Payment

CURE 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, Final Report of Expenditures and Final Consent to Public Disclosure form).

b. Unexpended Funds

In cases where final expenditures fall short of the award amount by more than $5,000.00, no final payment will be issued, and the Principal Investigator will be required to return unspent funds to CURE within sixty (60) days of the award end date. If final expenditures equal the total award amount minus $5,000.00, no final payment will be issued. In cases where final expenditures fall short of the award amount by less than $5,000.00, a final payment will be issued by CURE 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: 430 West Erie Street, Suite 210
Chicago, IL 60654

SECTION III: CURE RESEARCH POLICIES

1. Budget Policies

a. 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 plans. Any desired revisions to the original budget must be justified in writing and be submitted to and approved by CURE before any funds are spent on unapproved items.

b. Withholding of Funds

CURE 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 that the Grantee's current funds are sufficient to complete research
ii. Deliverables were not submitted; payments are made after reports are received and approved
iii. If the required financial and scientific progress reports specified in Section II.B.7 indicate that the grantee(s) are not working toward achieving the purposes for which the grants was awarded or has mismanaged funds, CURE may conduct an investigation. Grantees understand that if CURE determines, in its sole and absolute discretion that they have not met the terms and conditions of this grant, it 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 the CURE may withhold any further payments until such time as it is satisfied that all obligations under this agreement are met.

2. 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 must request such an extension in writing stating the funds remaining and a detailed justification for the extension satisfactory to CURE. 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.

3. Change in Status Policy

The continued use of grant funds following any major change in status of the Principal Investigator requires prior written authorization from CURE. 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 authorization. The Principal Investigator must contact the CURE 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 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 investigator-in-charge
v. Signature of the 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 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. The Principal Investigator must write to the CURE 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. Titles and periods of support of all CURE grants 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 requires evidence of transfer of funds. CURE 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 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

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 CURE's 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 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.

d. **Termination of Grant**

i. Any party may terminate the grant Agreement at any time for material breach by another party. Within ten (10) days of such termination, the Principal Investigator shall return any unspent and uncommitted grant funds to CURE and provide CURE with a copy of all scientific and financial reports prepared up to the date of termination.

ii. Any party may terminate the grant Agreement upon the death or permanent disability of the Principal Investigator. Within thirty (30) days of the date of Principal Investigator's death or permanent disability, the Institution shall return any unspent and uncommitted grant funds to CURE and provide CURE with a copy of all scientific and financial reports prepared up to the date of death or permanent disability.

iii. Any party may terminate the grant 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 of the date of such termination, the Principal Investigator shall return any unspent and uncommitted grant funds to CURE and provide CURE with a copy of all scientific and financial reports prepared up to the date of the termination, unless and until CURE, 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.

4. Conflict of Interest Policy

Any potential conflict of interest the Principal Investigator(s) or collaborator(s) may have relating to the project must be revealed. Such conflict would include (but may not be limited to) having a proprietary interest that may be affected by the outcome of a research project. It is expected that CURE Principal Investigators will observe the highest ethical standards in the conduct of research.

5. Presentation, Scientific Presentation, and News Release

CURE's Research Department expects timely publication of the results of all research projects it supports and requires that every such publication or presentation, whether in peer-reviewed journals, meeting abstract formats, platforms, and poster presentations or in review articles or similar publications, contain the following statement or its equivalent: "Supported by Citizen's United for Research in Epilepsy (CURE)."

Funds to support CURE's research program come primarily from donations from private citizens. It is essential to the growth and maintenance of CURE and its research program that these donors as well as individuals and families affected by the epilepsy covered under its programs are kept fully informed of research progress. For these purposes CURE 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 occasion of the publication of an article in a professional journal or a presentation at a scientific or medical meeting.

6. Public Access to Results Policy

CURE expects that 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 funding by accessing it on PubMed Central at no charge.

7. Animal and Human Subjects/Tissue Research Protocols

a. Institutional Animal Care and Use Committees and Institutional Review Boards CURE 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 the Grantee Institution's animal care and use programs, facilities, and procedures. Institutions that utilize human subjects in research as defined by the Federal government must establish an Institutional Review Board (IRB) or Ethics Committee (EC). See NIH's federal guidelines for more information.

b. CURE Requirements The Grantee 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.

All projects with human subjects and/or animal research must have up-to-date ethics approval documentation at all times. For projects involving non-exempt human research, the Grantee 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.
Where possible, CURE strongly encourages the use of a Central IRB to improve the efficiency of conducting multi-site clinical studies. The Grantee Institution must ensure that CURE 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.

In the event that the IRB/EC has determined that the study is exempt, the documentation demonstrating the exempt status must be submitted to CURE.

The Grantee Institution must notify CURE 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.

c. Foreign Institutions: Ethical approval documentation submitted in a language other than English require a cover letter signed by the Grantee Institution's department head (in English) verifying the content of the form and countersigned by the Grantee Institution's Research Office of record.

d. 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 the Institution to ensure that the 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.

8. Food and Drug Administration Policy

When experimental drugs and/or experimental medical devices are to be administered to patients, the Principal Investigator and the Institution must ensure that the Institution has the following on file and uploaded to their proposalCENTRAL file:

a. 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
b. 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.

9. Patent and Licensing Policy

Grants awarded by CURE are subject to the following Patent and Licensing Policy. By accepting a grant offered by CURE, the Principal Investigator and the Principal Investigator's Institution each agree to be bound by the terms and conditions of this Patent and Licensing Policy (as set forth below).

Copyrights

a. All works subject to a claim of copyright developed under, or in the course of work related to, any grant awarded by CURE must be promptly reported to CURE.
b. All works developed pursuant to subsection (a) above, shall be subject to the following:
    i. all such work shall be considered "work for hire" and CURE shall be deemed to be the author of such work and the owner of all copyright in and to the work;
    ii. the Principal Investigator and the Principal Investigator's Institution shall each assign all rights, title and interest in and to the work and copyright therein to CURE upon the written request of CURE; and
    iii. the Principal Investigator and the Principal Investigator's Institution shall each grant CURE with a non-exclusive, royalty-free license to reproduce and distribute the work, and to prepare, reproduce and distribute derivative works related to the work.
c. CURE will not claim copyright ownership in articles or publications describing research supported (in whole or in party) by CURE, unless the article or publication has been written at CURE's request, in which case such article of publication shall be deemed a "work for hire" and be subject to this Patent and Licensing Policy.

Patents

a. Any discovery, whether an invention, product, process, apparatus or design, conceived, originated or developed with the support of CURE funds (in whole or in part), shall be reported to CURE either prior to or within two (2) weeks following the time of initial publication or reduction to practice of the patentable product.
b. If a joint sponsor organization (e.g., a Grantee Institution or any other organization providing funds and co-sponsoring the Grantee Investigator's research with CURE) has established patent policies and procedures relating to the administering patents and inventions, then such organization's patent policies and procedures shall govern the administration of patents and inventions.
c. CURE shall have the right to determine the disposition of invention rights solely in cases where (i) CURE is the sole sponsor of research resulting in a patentable invention, product,

process, apparatus or design, (ii) CURE is the major sponsor of such research or (iii) the joint sponsor organization does not have established patent policies and procedures for administering patents and inventions. In such cases, CURE may:

i. require the inventor to transfer title of any patent to CURE for management and development in exchange for a portion of the royalties;

ii. release the invention to the inventor or his designee, subject to CURE's retention of royalty rights;

iii. submit the invention, product or materials to a qualified non-profit organization for administration and licensing;

iv. sell or license such patent to a third party for commercial development; or

v. decide that no patent applications are to be filed.

d. In cases where CURE has made a grant or award to a non-profit institution which leads to the development of a patentable product, and where the non-profit institution has a formal patent policy, CURE will defer to the patent policy of such institution, subject to the following:

i. title to any invention or patentable product or material may be permitted to reside in the investigator or any other individual with the prior written consent of CURE;

ii. no patent or patent application will be abandoned without first notifying CURE and giving CURE the opportunity to take title to the invention and to continue the patent or the patent application at its own expense;

iii. the investigator will share in royalty income according to the established policy of the institution where the work leading to the invention was done, except as otherwise provided in subparagraph (d)(iv) below; and

iv. CURE will participate in the income derived from the invention or patentable product or material to an extent to be determined within one year after reporting of an invention, product or material to CURE, by mutual agreement between the institution and CURE.

e. If any invention is made with the joint support of CURE and any agency or department of the United States Government, CURE may defer to the patent policy of that agency or department upon receipt of a written statement by the appropriate agency of government notifying CURE of its position with respect to the invention, product or material in question. Where a government contractor is permitted to retain title of his or her invention, product, or material, CURE will pursue its options mentioned in subparagraph (d) above. CURE may also receive a non-exclusive, royalty-free license to inventions, products, or materials to which the government retains title to the extent that CURE is a party to a funding agreement with the government. CURE will comply with any patent policy requirements placed upon it by the Federal government where it is itself a government contractor, and to the extent that anything in this policy is at variance with the government's requirements, CURE will defer to the government's policy.

f. If any invention, product or material is produced with the joint support of another sponsor, not an agency of the U.S. Government, the grantee (whether an institution or an individual) shall promptly notify the sponsor of CURE's support and of CURE's copyright and patent

policy. The sponsor shall, in turn, notify CURE in the event that a patentable discovery or invention occurs, and shall not prosecute a patent application or otherwise make a determination of invention rights without negotiation with CURE of a mutually satisfactory agreement regarding those rights.