Research on Animal, Human Subjects and Tissue Use in Research

CURE Epilepsy is committed to the humane, ethical, and responsible treatment of humans and animals used in research intended to understand epilepsy and develop the knowledge that may lead to cures. 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 utilize 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.

All terms related to use of animals, human subjects and tissues are described in the CURE Epilepsy Grant Agreement and acknowledged by the Institution and Principal Investigator prior to the start of the research project.

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. It is the responsibility of the Principal Investigator and Institution to ensure that Institution has the following on file and uploaded to their CURE Epilepsy 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.

c. 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.

d. 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.

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

f. 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.

g. **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.