

## 1. KEY DEFINITIONS

1. **CURE Epilepsy Conflict of Interest Committee** is made up of the Chief Financial Officer and the Chief Science Officer. The Research Operations Assistant is responsible for administering the overall policy for CURE Epilepsy
2. **Disclosure** refers to the Investigator's disclosure of Significant Financial Interests to CURE Epilepsy.
3. **Financial Conflict of Interest** (FCOI) will be deemed to exist when CURE Epilepsy's Conflict of Interest Committee reasonably determines that a Significant Financial Interest disclosed by an Investigator could directly and significantly affect the design, conduct or reporting of the Investigator's research.
4. **Foreign component** refers to the performance of any significant scientific element or segment of a research project outside of the U.S., either by the recipient or by a researcher employed by a foreign entity, whether or not grant funds are expended.
5. **Foreign entity** refers to an organization located in a country other than the U.S. and its territories that is subject to the laws of that country, regardless of the citizenship of an Investigator at such organization.
6. **Investigator** refers to the Principal Investigator (PI) or Project Director (PD) and any other person regardless of title or position who is responsible for the design, conduct or reporting of research and any others deemed appropriate by CURE Epilepsy's Conflict of Interest Committee. Collaborative and visiting researchers and subrecipient Investigators who are receiving federal funding awarded through CURE Epilepsy will also be deemed Investigators and be required to comply with this CURE Epilepsy Investigator Conflict of Interest Policy.
11. **Manage** means taking action to address, reduce or eliminate a Financial Conflict of Interest so CURE Epilepsy can ensure, to the extent possible, that those responsible for the design, conduct and reporting of research will be free from bias.
12. **Regulation or FCOI regulation** refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (grants) and 45 CFR Part 94 (contracts). Refer to **Section 19, Additional Resources**, for links to these federal regulations.
13. **Report** refers to CURE Epilepsy's report of identified Financial Conflicts of Interest to the applicable funding agency affected by the FCOI. In the case of NIH funding, a report about the identified FCOI will be entered into the eRA Commons FCOI Module. Other funding agencies may have separate reporting requirements, and these will be met as required.
14. **Senior/key personnel** means the Principal Investigator or Project Director and any other person identified as senior/key personnel by CURE Epilepsy in the sponsored research application, progress report or any other report submitted to the funding agency.
15. **Significant Financial Interest** means a financial interest of the Investigator and the Investigator's spouse or domestic partner and dependent children, alone or in combination, that reasonably

appears to be related to the Investigator's institutional responsibilities for CURE Epilepsy. Types of financial interests include remuneration, equity interests in a publicly and non-publicly traded entity, intellectual property rights and interests, and reimbursed or sponsored travel. Refer to **Section 5, *What Should be Disclosed?*** for a more comprehensive description. Utilize **Appendix 1, Annual Disclosure Form** to report any such interests to the CURE Epilepsy Financial Conflict of Interest Committee.

16. A **subrecipient** is defined as all non-CURE Epilepsy Investigators who are receiving funding awarded to CURE Epilepsy, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees.

## **2. PURPOSE OF THE INVESTIGATOR CONFLICT OF INTEREST POLICY**

Effective interactions between research institutions, government, the private sector, and industry are essential to bring about the rapid application of scientific discoveries and to maintain the efficient translation of research findings. However, the resulting relationships may involve financial interests that give rise to a Financial Conflict of Interest (FCOI) through its potential to directly and significantly impact the design, conduct or reporting of an Investigator's research in return for a financial benefit to the Investigator or his/her immediate family.

A Financial Conflict of Interest may arise even though no improper conduct or unethical behavior has occurred. CURE Epilepsy and its Investigators are responsible for identifying and then managing these Financial Conflict of Interests to strengthen accountability and transparency, promote research objectivity, and maintain the integrity of research findings and prudent stewardship of public funds.

CURE Epilepsy's Investigator Conflict of Interest Policy was developed to comply with the specific federal requirements defined in the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) and 45 CFR Part 94 (contracts). **Section 20, *Additional Resources***, includes links to the federal regulations.

All CURE Epilepsy funded Investigators are responsible for familiarizing themselves with the aforementioned regulations so CURE Epilepsy can effectively work with them to comply with these federal disclosure requirements. In turn, all Investigators will be notified about CURE Epilepsy's conflict of interest requirements, as well as their disclosure responsibilities under this Investigator Conflict of Interest Policy.

CURE Epilepsy's Conflict of Interest Committee administers this Policy and emphasizes compliance with its requirements, including the review of Annual Disclosure Forms, the training and management of Investigators regarding Financial Conflict of Interest, and the timely identification, reporting and management of FCOIs. In those instances where a funding agency or sponsor has more stringent requirements and regulations relating to conflict of interest or conflict of commitment than those in CURE Epilepsy's Investigator Conflict of Interest Policy, the requirements and regulations of that funding agency or sponsor will take precedence.

## **3. WHO MUST COMPLY WITH THE INVESTIGATOR CONFLICT OF INTEREST POLICY?**

CURE Epilepsy implemented specific procedures for annual disclosure and review of all Significant Financial Interests so that as an institution the highest standards of integrity and objectivity can be applied to the design, conduct and reporting of research carried out for CURE Epilepsy. Accordingly, this Policy applies to all CURE Epilepsy Investigators regardless of title or position who are responsible for the design, conduct or reporting of research and includes, by way of example, all PhDs, MDs, graduate students, non-faculty staff at and above the level of research associate and any others deemed appropriate by CURE Epilepsy's Conflict of Interest Committee. Collaborative and visiting researchers and subrecipient Investigators who are receiving federally funded research through CURE Epilepsy will also be required to comply with CURE Epilepsy's Investigator Conflict of Interest Policy.

#### **4. MANDATED CONFLICT OF INTEREST TRAINING & ACKNOWLEDGEMENTS FOR ALL INVESTIGATORS**

All Investigators who are subject to the Investigator Conflict of Interest Policy are mandated to document their review and understanding of this policy prior to engaging in research for or on behalf of CURE Epilepsy, and at least every year thereafter or immediately if (1) an Investigator is new to CURE Epilepsy or if CURE Epilepsy finds that an Investigator is non-compliant with CURE Epilepsy's Investigator Conflict of Interest Policy or an applicable management plan.

Subrecipient Investigators who are subject to CURE Epilepsy's Investigator Conflict of Interest Policy and participate in federally funded research are also required to acknowledge their review and understanding of this Investigator Conflict of Interest Policy.

Lever **Appendix 1, Annual Disclosure Form** to document your review, full understanding and commitment to this policy.

CURE Epilepsy's Research Operations Coordinator will maintain documentation of these acknowledgements, and ensure all acknowledgements are updated in line with the schedule noted above. The CURE Epilepsy Conflict of Interest Committee is responsible for managing any questions and clarifying understanding of the policy for all applicable Investigators. The CURE Epilepsy Research Operations Coordinator will schedule annual training to be led by the Chief Financial & Chief Science Officers for all relevant internal/external research investigators in the month of February before submission of the required annual disclosure & acknowledgement form.

#### **5. WHAT SHOULD BE DISCLOSED?**

Each of the following Significant Financial Interests should be disclosed and described on the Annual Conflict of Interest Disclosure Form (**See Appendix 1**) to the extent they reasonably appear to be related to the Investigator's CURE Epilepsy research responsibilities. In the interest of full transparency, Investigators should err on the side of disclosure, and include Significant Financial Interests of the Individual, Individual's Spouse/Domestic Partner and Individual's Dependent Children.

1. Regarding any **publicly traded entity**, domestic or foreign, the value of any remuneration received from the entity in the 12 months preceding the disclosure plus the value of any equity interest held in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000.
  - Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria and paid authorship.
  - Equity interests include stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.

**Note:** Disclosure is not required for income from investment vehicles, such as mutual funds, ETFs, and retirement accounts if the Investigator does not directly control the investment decisions made in these vehicles.

2. Regarding any **non-publicly traded entity**, domestic or foreign, (a) the value of any remuneration received from the entity in the 12 months preceding the disclosure that when aggregated exceeds \$5,000, and (b) any equity interests in the entity (regardless of value) that are held by the Investigator or his/her spouse or domestic partner or dependent children.
  - Equity interests include stocks, stock options, or other ownership interests.
  - If at the time of disclosure there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity, the Investigator must fully describe the nature of the equity interest, including the number of shares owned, voting rights, etc.
3. Financial interests received in connection with **patents, copyrights, know-how or other intellectual property rights** (e.g., royalties, license fees, equity or other consideration) that when

aggregated over the prior 12 months exceeds \$5,000, including consideration received pursuant to an agreement to share royalties related to such intellectual property rights.

4. Any **advisory relationship, consulting, outside teaching, or scientific/academic appointment** including adjunct, visiting or honorary, with any domestic entity (other than CURE Epilepsy), both paid and volunteer, as well as any unpaid appointment that provides the Investigator with access to, or in-kind support for, laboratory space, research materials, supplies, equipment, staff participation or living expenses.

**Note:** Disclosure is not required for the following:

- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center or a U.S. research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).
- Income from service on advisory committees or review panels for a U.S. federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center or a U.S. research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).

5. **Any relationship with a foreign entity or government** including, but not limited to, any involvement with a government talent recruitment program or similar-type program (e.g., Thousand Talents Program), both paid and volunteer, and any position or scientific appointment stemming from a foreign government, which includes local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.

6. All **reimbursed expenses, gifts, gratuities, favors, lodging, or entertainment offers** that when aggregated over the prior 12 months exceeds \$1,000. As a reminder, Investigators may not solicit or accept reimbursed expenses, gifts, gratuities, favors, lodging, or excessive entertainment for themselves, his/her spouse or domestic partner or dependent children, alone or in combination, or for any person or organization that does business or has the potential of doing business with CURE Epilepsy. Exempt from this prohibition are non-cash gifts of nominal value involving normal and ordinary social amenities or sales promotions.

7. **Sponsored/Reimbursed Travel** that meets the following criteria:

- travel **within the United States** received from a U.S. entity that when aggregated exceeds \$5,000.

**Note:** Disclosure is not required for Sponsored/Reimbursed Travel stemming from a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

- travel **outside the United States** received from a U.S. or foreign entity\* regardless of dollar amount.

\*Foreign entities include, but are not limited to, those stemming from a foreign company or government, including local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.

**Information needed for the disclosure of Sponsored/Reimbursed Travel:**

- Identity of the sponsor/organizer.
- Month and year of the travel.
- Financial value by range of the travel.

- Value of any associated honorarium.
- Purpose of the travel.
- Destination of the travel.
- Time duration of the travel.

## **6. WHO MUST SUBMIT AN ANNUAL DISCLOSURE FORM?**

At time of appointment/employment, all Investigators, including by way of example PhDs, MDs, graduate students, non-faculty scientific staff at and above the level of research associate and any others deemed appropriate, are required to provide an initial Annual Disclosure Form that describe all Significant Financial Interests related to their CURE Epilepsy research responsibilities and then submit a new Annual Disclosure Form each subsequent year thereafter (**see Appendix 1**). Refer to **Section 7, *Updating the Annual Disclosure Form*** for additional information. Submitted Annual Disclosure Forms are retained in the Research Shared drive. Collaborative and visiting researchers and subrecipient Investigators who are subject to CURE Epilepsy's Investigator Conflict of Interest Policy and participating in federally funded research are also required to submit an Annual Disclosure Form.

## **7. UPDATING THE ANNUAL DISCLOSURE FORM**

All applicable Investigators are required to simultaneously submit a current, accurate Annual Disclosure Form (**see Appendix 1**) that identify and describe both existing and new Significant Financial Interests related to their CURE Epilepsy research responsibilities into the Financial Conflict of Interest Committee yearly by March 1st. Updated disclosures should also include any FCOIs identified on a project that was transferred from another institution.

Investigators are required to promptly disclose Significant Financial Interests to accurately reflect their external activities as follows:

1. Disclose Significant Financial Interests no later than the time of application for federally-funded research.
2. Within 30 days of acquiring and/or discovering a new Significant Financial Interest, including through purchase, marriage, or inheritance.
3. Within 30 days of a material change to a previously disclosed Significant Financial Interest.
4. At least annually in accordance with the March 1st deadline, during the period of an award.

## **8. ANNUAL DISCLOSURE FORM REVIEWED BY THE CONFLICT OF INTEREST COMMITTEE**

CURE Epilepsy's Conflict of Interest Committee will review the Annual Disclosure Form and any new or modified Significant Financial Interests disclosed throughout the year, and as such, may request further information or clarification from the Investigator. CURE Epilepsy's Conflict of Interest Committee will review each of the Investigator's disclosures and determine whether a Significant Financial Interest is related to funded research.

If there are Significant Financial Interests related to the Investigator's funded research, these relationships must be examined and dealt with according to CURE Epilepsy and funding agency policies on conflict of interest. A personal financial interest with an entity would be reasonably considered related to an Investigator's research in circumstances such as the following:

1. Entity sponsors research at CURE Epilepsy in which the Investigator is directly involved.
2. Entity has financial interests that could reasonably be considered to have a potential influence on the

design, conduct or reporting of the Investigator's research.

3. Entity has a reasonable possibility of being financially affected by Investigator's research.
4. Entity makes monetary or in-kind gifts or loans to CURE Epilepsy that benefit the Investigator's research including a gift or loan of equipment.
5. Entity makes a product that is under study in research in which the Investigator is involved.
6. Entity licenses intellectual property from CURE Epilepsy in which the Investigator has a financial interest.
7. The entity has a Material Transfer Agreement to provide materials used in the Investigator's research or for materials provided by the Investigator to the entity.

CURE Epilepsy's Conflict of Interest Committee reviews all Significant Financial Interests and to identify and address any issues.

A FCOI will be deemed to exist when CURE Epilepsy, acting through its Conflict of Interest Committee and following the procedures described in this Investigator Conflict of Interest Policy, reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the Investigator's research. CURE Epilepsy's Conflict of Interest Committee reviews and analyzes the specific circumstances of a Significant Financial Interest by considering such factors as the nature of the Investigator's relationship to an outside entity, the dollar value of that relationship, and the overlap between that relationship and the Investigator's research. CURE Epilepsy's Conflict of Interest Committee may, if warranted, involve the Investigator in determining whether a Significant Financial Interest is related to the research in question.

## **9. MANAGING A FINANCIAL CONFLICT OF INTEREST**

If a Significant Financial Interest is identified as a FCOI, CURE Epilepsy's Conflict of Interest Committee will take action to manage the FCOI by robustly reducing or eliminating the conflict by designing a management plan or mechanism appropriate for the specific situation. During the design process, CURE Epilepsy's Conflict of Interest Committee may query the Chief Executive Officer, Research Committee, Scientific Advisor Committee or any other Committees or individuals as necessary to solicit additional information and alternate ideas. After the management plan is approved by CURE Epilepsy's Conflict of Interest Committee, they will forward a detailed letter to the Investigator describing the management plan and its implementation.

This written plan will require that the Investigator take certain steps according to guidelines approved by CURE Epilepsy's Conflict of Interest Committee. Conditions or restrictions that might be imposed to manage a FCOI include the following:

- Disclosure of the FCOI to lab personnel and collaborators.
- Disclosure of the FCOI in publications, journals, and posters, etc.
  
- Disclosure of the FCOI to audiences at conferences and seminars.
- Monitoring of research, proposals, and data by independent peer reviewers.
- Modification of the research plan.
- Removal of an affected Investigator from participation in all or the portion of the research funded by the entity affected by a Significant Financial Interest.
- Divestiture of a Significant Financial Interest by the affected Investigator.
- Limiting the dollar value of fees received and/or stock ownership.
- Severance of the relationship creating the conflict.

The Investigator will be asked to review and sign the letter to acknowledge agreement with the

management plan, or the Investigator may, at this point, appeal the findings of CURE Epilepsy's Conflict of Interest Committee to CURE Epilepsy's Chief Executive Officer. CURE Epilepsy's Chief Executive Officer has the final review and authority regarding the management of all FCOIs.

## **10. REPORTING A FINANCIAL CONFLICT OF INTEREST TO THE FUNDING AGENCY**

CURE Epilepsy will promptly notify the appropriate funding agency about any corrective action taken or to be taken in a situation of noncompliance.

1. With regard to a **new NIH - sponsored research award**, CURE Epilepsy will report the identified FCOI to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. CURE Epilepsy will submit the FCOI report before dispensing or spending any funds. If the FCOI is eliminated prior to dispensing or spending any funds, then no FCOI report is required. In addition, CURE Epilepsy is required to submit a FCOI report for FCOIs identified for subrecipient Investigators, if applicable. Refer to **Section 18, Subrecipient Conflict of Interest Compliance**, for more information regarding subrecipients.
2. With regard to an **ongoing NIH - sponsored research award**, CURE Epilepsy will report to the NIH through the eRA Commons FCOI Module information about the identified FCOI within 60 days of the FCOI's identification. For any Significant Financial Interest that is identified as a FCOI subsequent to CURE Epilepsy's initial FCOI report during an ongoing NIH funded research project, CURE Epilepsy shall within 60 days, review the Significant Financial Interest disclosure, determine whether it is related to the research, and, if so, implement on at least an interim basis, a management plan that shall specify the actions that have been and will be, taken to manage the FCOI.
3. Annual FCOI follow-up reports will be provided to the NIH for any FCOI previously reported by CURE Epilepsy. The annual FCOI report will specify whether the FCOI is still being managed, describe any changes to the management plan or explain why the FCOI no longer exists. CURE Epilepsy will provide annual FCOI reports for the duration of the project period, including extensions with or without funds, as prompted by the ERA Commons generated email that requests that the follow-up report be submitted.
4. CURE Epilepsy will meet the reporting requirements pertaining to FCOIs for other federally funded agencies, including, DOD, DOE, NSF and USDA as instructed by the particular agency.

## **11. WHAT INFORMATION IS SUBMITTED TO THE NIH ABOUT A FINANCIAL CONFLICT OF INTEREST?**

Information submitted to the NIH about an identified FCOI includes the following:

- Project number/contract number.
- Name of the Principal Investigator or Project Director, or the contact PI/PD if a multiple PI/PD model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has the FCOI.
- Statement about how the FCOI was managed.
- The nature of the FCOI (e.g., equity interest, consulting fees, intellectual property rights and interests, travel reimbursement, and honoraria).
- The value of the financial interest; \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000; or a statement that a value cannot be readily

determined through reference to public prices or reasonable measures of fair market value.

- A description about how the FCOI relates to the research and the basis for CSHL's
- determination that a Significant Financial Interest conflicts with such research.

A description of the key elements of CURE Epilepsy's management plan must also be submitted to the NIH including the following information:

- Role and principal duties of the conflicted Investigator in the research project.
- Conditions of the management plan.
- How the management plan is designed to safeguard objectivity in the research project.
- Confirmation of the Investigator's agreement to the management plan.
- How the management plan will be monitored to facilitate Investigator compliance.
- Other information as needed.

Other funding agencies outside the NIH may require that different information to be submitted, and CURE Epilepsy will meet their requirements as instructed.

## **12. PUBLIC ACCESSIBILITY TO CURE EPILEPSY'S INVESTIGATOR FINANCIAL CONFLICT OF INTEREST POLICY AND IDENTIFIED FINANCIAL CONFLICTS OF INTEREST**

CURE Epilepsy's Investigator Conflict of Interest Policy is publicly accessible on its website in the "For Researchers" section.

CURE Epilepsy maintains public accessibility to Significant Financial Interests of senior/key personnel that were identified as FCOIs and reported to the NIH. As such, CURE Epilepsy responds to all written requests for information within five business days and then releases the following information about such Significant Financial Interest.

- The name of the Investigator.
- The title and role of the Investigator with respect to the research project.
- Name of the entity with which the Significant Financial Interest is held.
- The nature of the Significant Financial Interest.
- Approximate value of the Significant Financial Interest as determined by dollar range \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

## **13. CONTINUED MONITORING OF A FINANCIAL CONFLICT OF INTEREST AND CURE EPILEPSY COMPLIANCE**

CURE Epilepsy continually monitors the FCOI and Investigator compliance with the FCOI management plan throughout the year and until the completion of the research project. As necessary, CURE Epilepsy's Conflict of Interest Committee may require and develop a project specific monitoring process, which may include appointing a CURE Epilepsy designated official to assist with monitoring the FCOI Investigator compliance.

## **14. WHAT HAPPENS AFTER FCOI IS REPORTED TO THE NIH?**

The NIH evaluates the FCOI information received through the eRA Commons FCOI Module to determine if CURE Epilepsy's actions are sufficient to manage the identified FCOI. The NIH may request and review additional information before implementing, if needed, further corrective actions to ensure research objectivity. If the NIH decides that the particular FCOI will bias the objectivity of the funded research to such an extent that further corrective action is needed or that CURE Epilepsy has not managed the FCOI in accordance with the regulation, it may impose special award conditions, suspend funding or enforce other actions until the matter is sufficiently resolved.

Other funding agencies outside the NIH may have a different process, and CURE Epilepsy will meet their requirements as instructed.

## **15. NON-COMPLIANCE AND ENFORCEMENT**

CURE Epilepsy will establish adequate enforcement mechanisms, provide for employee sanctions and take other administrative action, where appropriate, in the event an Investigator is non-compliant with the Investigator Conflict of Interest Policy or management plan. Violations of this Policy may be grounds for progressive disciplinary action including:

1. Placing a hold on the processing of new sponsored research applications from a non-compliant Investigator.
2. Withholding disbursement or distribution of project-specific funding to the Investigator's laboratory.
3. Termination of employment.

An Investigator is non-compliant and in violation of the Policy if an Investigator fails to:

1. Submit an Annual Disclosure Form or provide an update to the Annual Disclosure Form by the deadlines established for such submissions by CURE Epilepsy's Conflict of Interest Committee.
2. Provide CURE Epilepsy's Conflict of Interest Committee with written acknowledgement of a management plan.
3. Provide CURE Epilepsy's Conflict of Interest Committee with requested documentation regarding compliance with a management plan.

If an Investigator fails to comply with CURE Epilepsy's Investigator Conflict of Interest Policy or management plan, within 120 days CURE Epilepsy will:

1. Complete a retrospective review of the key elements (see below) of the Investigator's activities and the NIH funded research project to determine any bias in the design, conduct, or reporting of research.
2. Document the retrospective review.
3. Document CURE Epilepsy's determination as to whether any NIH funded research, or portion thereof, conducted during the period of the Investigator's non-compliance with the Investigator Conflict of Interest Policy or management plan, was biased in the design, conduct, or reporting of such research.

If bias is found, CURE Epilepsy will submit a mitigation report with the key elements (see below) addressing the impact of the bias on the research project, including the extent of the harm done, and any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable and the actions CURE Epilepsy has taken, or will take, to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, CURE Epilepsy may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date the FCOI is identified and the completion of CSHL's retrospective review. Thereafter, CSHL will submit FCOI reports as prescribed by the regulation.

Furthermore, if the NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by CURE Epilepsy, CURE Epilepsy shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

The following key elements apply to both the retrospective review and mitigation report:

- Project number.
- Project title.
- The PI or contact PI/PD if a multiple PI model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has a FCOI.
- Reason(s) for the retrospective review.
- Detailed methodology used for the retrospective review including the methodology of the process, composition of the review panel, documents reviewed etc.
- Findings of the review.
- Conclusions of the review.

## **16. PROJECT SPECIFIC CERTIFICATION FORM SUBMISSION**

The Principal Investigator or Project Director involved with a funding submission is required to enter a Project Specific Certification Form (**see Appendix 2**) to the CURE Epilepsy Conflict of Interest Committee one week prior to submitting a sponsored research application requesting an amount greater than \$5,000 from a federally funded agency to confirm the PI/PD's continued compliance with the Investigator Conflict of Interest policy.

The basic information needed to complete the Project Specific Certification Form is as follows:

- Name of the Principal Investigator or Project Director.
- Name of the funding organization.
- The funding opportunity announcement.
- Submission deadline.
- Project title.
- Names of personnel who are responsible for the design, conduct or reporting on any of the proposed research, including non-CSHL Investigators (domestic and foreign) such as collaborators, sub-recipients, or subcontractors proposed for funding.

The Project Specific Certification Form then confirms the following:

- That the Principal Investigator or Project Director has read the Investigator Conflict of Interest Policy and submitted an Annual Disclosure Form in the last 12 months.
- That the Principal Investigator or Project Director does not have any new or changed Significant Financial Interest information to disclose.
- Whether any Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the research.
- The project's involvement in a clinical trial.
- The involvement of any foreign component.

CURE Epilepsy's Research Operations Coordinator will contact any Principal Investigator or Project Director who fails to submit a Project Specific Certification Form. Upon receipt of an award notice of \$5,000 or more, CURE Epilepsy's Research Operations Coordinator will verify that a Project Specific Certification Form was submitted and stored on the Research Shared Drive, and if not, the Principal Investigator or Project Director must complete the Project Specific Certification Form for the award to be submitted for funding.

## **17. FOREIGN RESEARCH COMPONENTS**

CURE Epilepsy values its international collaborations, but the federal government remains concerned about foreign threats to the research infrastructure in the U.S. As such, CURE Epilepsy Principal Investigators or Project Directors are asked to disclose on the Project Specific Certification Form (**See Appendix 2**) any scientific element or segment of the project that is being conducted outside of the U.S., regardless of whether the foreign component will receive funding from the sponsored research application. In addition, the Principal Investigator or Project Director is asked to disclose if a foreign component provides the Principal Investigator or Project Director or any of their laboratory members with any resources or financial support, access to, or in-kind support for laboratory space, research materials, supplies, equipment or staff participation. Federal funding agencies may request additional information regarding a foreign research component, and if needed, institute specific corrective actions to comply with the NIH Grants Policy statement. Refer to **Section 20, *Additional Resources***, for a link to the federal regulation.

Activities that meet the definition of a foreign component include, but are not limited to the following:

- The involvement of human subjects or animals from or in a foreign entity.
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling and similar activities.
- Any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.
- Collaborations with Investigators at a foreign site anticipated to result in co-authorship.
- Use of facilities or instrumentation at a foreign site.
- Receipt of financial support or resources from a foreign entity.

**Note:** Foreign travel for consultation is not considered a foreign component but requires disclosure as Sponsored/Reimbursed Travel. Refer to **Section 5, *What Should be Disclosed***, for more information.

## **18. SUBRECIPIENT CONFLICT OF INTEREST COMPLIANCE**

A subrecipient relationship is established when federal funds flow down from or through CURE Epilepsy to another individual or entity and the subrecipient will be conducting a substantive portion of a federally funded research project and is accountable to CURE Epilepsy for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to CURE Epilepsy's terms and conditions, and as such, CURE Epilepsy will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. CURE Epilepsy will incorporate as part of a written agreement with the subrecipient, terms that establish whether CURE Epilepsy's Investigator Conflict of Interest Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with CURE Epilepsy that it is in compliance with the federal FCOI regulation and that the institution's portion of the project is in compliance with the federal conflict of interest policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to CURE Epilepsy's Investigator Conflict of Interest Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for CURE Epilepsy. CURE Epilepsy will, if applicable, submit an FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to CURE Epilepsy. Such time period must be sufficient to enable CURE Epilepsy to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to CURE Epilepsy's Investigator Conflict of Interest Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to CURE Epilepsy. Such time period shall be sufficient to enable CURE Epilepsy to comply with its review, management, and reporting obligations under the regulation. CURE Epilepsy will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

Other funding agencies outside the NIH may have a different process as it pertains to subrecipients, and CURE Epilepsy will meet their requirements as instructed.

## **19. RECORD RETENTION**

Records relating to conflict-of-interest matters covered under this Investigator Conflict of Interest Policy for NIH-funded research must be maintained for a minimum period of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation or claim, whichever is longer. Records for conflict-of-interest matters relating to other funded research will be maintained in accordance with CURE Epilepsy's Record Retention Policy.

## **20. ADDITIONAL RESOURCES AND PHS POLICY LINKS**

Please contact CURE Epilepsy's Chief Science Officer to inquire about the Investigator Conflict of Interest Policy.

- See the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) ([click this link](#)) and 45 CFR Part 94 (contracts) ([click this link](#)).
- See the NIH's Office of Extramural Research Financial Conflict of Interest Web page: ([click this link](#)).
- See the NIH's training about FCOIs: ([click this link](#)).
- See the Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interests and Foreign Components to determine if additional disclosures should be made at JIT or in the next progress report: ([click this link](#)).
- See NIH Other Support Information Page: ([click this link](#)).
- See NSF Current and Pending Support FAQs: ([click this link](#)).

# CURE Epilepsy

## Appendix 1: Financial Conflict of Interest – Annual Disclosure & Acknowledgement Form

Investigator:

Date:

Please disclose & describe below Significant Financial Interests that meet the criteria/thresholds described in section 5 of CURE Epilepsy's Financial Conflict of Interest Policy. Report any Significant Financial Interests to the extent they reasonably appear to be related to the Investigator's CURE Epilepsy research responsibilities. In the interest of full transparency, Investigators should err on the side of disclosure. Note "No relevant financial interests to be reported" if that is the case.

Significant Financial Interest 1:

Entity:

Approximate Dollar Value:

Description:

Significant Financial Interest 2:

Entity:

Approximate Dollar Value:

Description:

Significant Financial Interest 3:

Entity:

Approximate Dollar Value:

Description:

Significant Financial Interest 4:

Entity:

Approximate Dollar Value:

Description:

Significant Financial Interest 5:

Entity:

Approximate Dollar Value:

Description:

Significant Financial Interest 6:

Entity:

Approximate Dollar Value:

Description:

Significant Financial Interest 7:

Entity:

Approximate Dollar Value:

Description:

Significant Financial Interest 8:

Entity:

Approximate Dollar Value:

Description:

*By signing below, I certify that I have received, reviewed and fully understand all requirements of CURE Epilepsy's Financial Conflict of Interest Policy. I have outlined all relevant Significant financial interests above.*

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Signature

---

Date

# CURE Epilepsy

## Appendix 2: Project Specific Certification Form – Use for Federally Funded Program requests more than \$5,000

Principal Investigator/Project Director:

Funding Organization:

Funding Opportunity Announcement:

Submission Deadline:

Project Title:

Names of personal responsible for design, conduct or research reporting:

Is there a “Foreign Research Component” (outlined in section 17 of the CURE Epilepsy Conflict of Interest Policy)? Please describe if yes:

*By signing below, as a Principal Investigator/Project Director I confirm all criteria & requirements noted in section 16 of the CURE Epilepsy Financial Conflict of Interest Policy have been met or updated as required.*

\_\_\_\_\_

Signed

\_\_\_\_\_

Date

