

AdvancedCPR Solutions

Financial Conflict of Interest Policy

(Promoting Objectivity in Research)

Purpose

This policy is designed to disclose and ensure appropriate management of any Financial Conflict of Interest (FCOI) as a result of an Investigator or senior personnel planning to participate in or currently is participating in a NIH funded project. ACS requires FCOI training for all personnel who are applying for NIH funding prior to proposal submissions.

ACS requires financial interest listings from Principal Investigators (PIs) & Key Personnel on all sponsored projects as well as those of spouse & independent children to prevent potential bias' to design, conduct and reports or projects. All PIs and Co-PIs listed in a proposal for external funding must include a completed disclosure form before expenses can be charged to an award.

Required Training

All investigators must complete FCOI training prior to engaging in any research related grant. Investigators are required to renew training processes every 4 years. Training is provided by NIH & certificate of completion is to be submitted by PI to ACS'S admin.

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Disclosure Procedures

1. At time of Application: Each Investigator, including subrecipient Investigators, if applicable, planning to participate in PHS-funded research must submit a completed Financial Conflict of Interest Disclosure Form (attachment A below) to ACS's Grant Administrator.

2. Updates:

- *Annual:* The Investigator, including subrecipient Investigators, if applicable, must submit an updated disclosure of SFI at least annually, during the period of the award, beginning with the anniversary date of the award.
- *Within 30 days:* The Investigator, including subrecipient Investigators, if applicable, must submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review of Disclosure Forms

The Grant Administrator of ACS will review all PHS disclosure forms and determine whether an Investigator's SFI is related to the PHS-funded research, i.e. whether the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. If not, there is no financial conflict of interest. If it appears that the SFI is related to the PHS-funded research, the Grant administrator will determine whether a financial conflict of interest exists.

Management of FCOIs

1. Where an FCOI has been identified, the Grant Administrator will work with the personnel to develop a resolution plan to manage, reduce, or eliminate any actual or potential financial conflict of interest presented by a significant financial interest. Possible approaches include, but are not limited to the following:

- Public disclosure of significant financial interests;
- Appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the related project or research;
- Reduction or elimination of the significant financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create actual or potential financial conflicts.

2. Whenever ACS identifies a significant financial interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the Company, within 60 days the Grant Administrator will: review the significant financial interest; determine whether it is related to the Investigator's institutional responsibilities; determine whether a financial conflict of interest exists.

Reporting of FCOIs

1. Prior to ACS's expenditure of any funds under a PHS-funded research project, ACS is required to provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by ACS to be conflicting and ensure that ACS has implemented a management plan in accordance with the FCOI policy. If ACS identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, then ACS is not required to submit an FCOI report to the PHS Awarding Component.
2. For any significant financial interest that ACS identifies as conflicting subsequent to its initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), within sixty days ACS must provide to the PHS Awarding Component an FCOI report regarding the financial conflict of interest and ensure that ACS has implemented an FCOI management plan. If the FCOI report involves a significant financial interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed by ACS, then ACS must complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, ACS is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
3. FCOI reports will be submitted to the PHS Awarding Component according to PHS regulations.
4. For any FCOI previously reported by ACS with regard to an ongoing PHS-funded research project, ACS shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. ACS must provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Subrecipient Monitoring

When ACS carries out any PHS-funded research through a subrecipient, ACS will take reasonable steps to ensure that any subrecipient Investigator complies with PHS FCOI regulations by:

1. Incorporating terms as part of a written agreement with the subrecipient that establish whether ACS's FCOI policy or the subrecipient's policy will apply to the subrecipient's Investigators.

2. If the subrecipient's Investigators are to comply with the subrecipient's FCOI policy, the subrecipient must certify that its policy complies with the PHS FCOI regulations and the agreement will specify the time period(s) for the subrecipient to report all identified FCOIs to ACS. If the subrecipient cannot provide such certification, its Investigators must comply with ACSI's FCOI policy.

Records

ACS shall maintain records of all financial disclosures and all actions taken to resolve FCOI for at least 3 years from the date the final expenditures report is submitted to the federal agency, or until the resolution of any federal action involving those records, whichever is longer.

1. FCOI policy, the agreement will specify the time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to ACS.

Public Disclosure of PHS-Funded FCOIs

Pursuant to PHS FCOI regulations, prior to spending any funds under a PHS-funded research project, ACS will ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to ACS that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by the senior/key personnel;
2. ACS determines that the significant financial interest is related to the PHS-funded research; and
3. ACS determines that the significant financial interest is a financial conflict of interest.

Attachment A

Financial Interest Disclosure Form

This Disclosure Form is to be completed by the Investigator pursuant to the AdvancedCPR Solutions Policy on Financial Conflicts of Interest in Public Health Service-Funded Research.

1. Research Project Title and number:

2. Name of Investigator making this report about his/her financial interest(s):

3. Check which of the following you are submitting:

- A. _____ Initial Disclosure Form: Before the time of application for PHS-funded Research
- B. _____ Update Disclosure Form: Within 30 days discovering or acquiring a new Significant Financial Interest during a PHS-funded Research award
- C. _____ Update Disclosure Form: Required Annual Update during a PHS-funded Research award

4. Indicate whether you, the Investigator, have any Significant Financial Interests related to the work to be conducted under the PHS-funded Research project(s):

- A. _____ I have no Significant Financial Interest as that term is defined in the Policy (stop completing this Disclosure Form here and submit it).
- B. _____ I do have Significant Financial Interest(s) to report (continue completing rest of this Disclosure Form)

5. For each Significant Financial Interest (use additional pages if necessary):

A. Provide the name of each entity in which the Investigator has a Significant Financial Interest:

B. Provide the nature of the financial interest (for example, equity, consulting fee, travel reimbursement, or honorarium):

C. Indicate the value (dollar amount) of the Significant Financial Interest:

D. For Reimbursed or Sponsored Travel required to be reported by the Policy, indicate all of the following:

1. The purpose of the trip:

2. The identity of the sponsor/organizer:

3. The destination:

4. The duration:

E. Describe how the Significant Financial Interest relates to the PHS-funded Research:

F. Do you believe that the Research project(s) could be directly and significantly affect by the Significant Financial Interest(s) you are reporting?

Signature: _____

Name: _____

Title: _____

Date: _____