



ACTC Policy on Financial Relationship Disclosure and Management

1.0 Overview

This document provides guidance on the reporting of ACTC members financial interests. Reporting a financial interest *does not* mean the interest is a conflict of interest. Disclosures will be reviewed by the ACTC Internal Ethics Committee (IEC) to determine whether a disclosure is an actual, potential or has the appearance of a conflict of interest, and, if it does, how to manage it. Whether a relationship presents an actual, potential or the appearance of conflict of interest and, the management are ultimately under the purview of the NIH/NIA.

Questions regarding specific relationships should be sent to the chair of the ACTC IEC (Jason Karlawish, Jason.Karlawish@uphs.upenn.edu).

This policy addresses the ACTC structure and function, in particular the roles of the Project Evaluation Committee (PEC) and Steering Committee (SC) in selecting projects, but the scope of this policy is for the duration of any project, through publication of results.

Key features:

Because the ACTC is a NIH funded entity and operates in a not-for-profit institution, NIH and not-for-profit research grants do not create a potential for conflict of interest and therefore should not be disclosed.

Research, DSMB, or adjudication committee support provided by a company or other private, for profit entity (calculated as the overall monetary value of grant) should be disclosed but is not counted towards calculating a significant financial interest.

Travel reimbursement is not considered a financial interest and so is not counted towards calculating a significant financial interest.

Disclosure of an individual's financial relationships is required from the following ACTC roles:

- ACTC members who are principal investigators
- Project Evaluation Committee (PEC)
- Steering Committee (SC) members (which includes Member Site PIs and Unit Leads)
- Project leaders
- Internal ethics committee members
- DSMB members
- Committee Chairs
- Anyone who will speak at an ACTC meeting (by teleconference, webinar, or in person)

Persons on PEC or SC who have a significant financial interest related to a project the ACTC is considering should contribute to the discussion but are recused from voting.

2.0 Policy

AN OVERVIEW OF DISCLOSURE

At the time of disclosure, all relationships in the categories listed below that currently exist, have existed within the past 12 months or are expected in the coming 12 months should be disclosed. It is important that each relationship and its monetary value are reported separately (for example, it is possible to have multiple relationships with one company, such as grant funding, consulting and intellectual property; each is distinct, and each has its own monetary value). In the event income or value are not known, the option exists to select “value unknown.”

Some useful guidelines for a relationship to disclose are:

The relationship involves something that could be used to diagnose, stage, treat or care for persons with the disease being studied (typically, but not always Alzheimer’s disease), even if the relationship is distinct from the proposed ACTC project.

The relationship is with an entity that could benefit from the results of the proposed study; for example, the study tests a novel mechanism and you have an IP holding on a separate intervention that uses that mechanism or for an accompanying diagnostic test that will be used in the study.

Annual disclosure is required, regardless of attendance the ACTC PEC or SC meetings. Disclosure is required to participate in a meeting.

This disclosure also applies to spouses and dependent children.

ACTC PEC and SC members who do not have up to date or complete disclosure on file with the ACTC cannot vote on submitted proposals.

Complete disclosure will be formally collected prior to live meetings, but is expected to be updated prior to each teleconference, web-based conference, or other ACTC related meetings for any new relationships that have developed since the last formal or interim disclosure.

Disclosure information will be kept confidential by the ACTC Coordinating Center. A summary report will be circulated at the beginning of the ACTC PEC and SC meetings that will list by Investigator and PEC and SC members, the nature of each relationship disclosed. To facilitate the review of disclosures, the reports will group members by their role in the ACTC: PI, PEC, Unit leads, DSMB, IEC, SC.

These summary reports will be collected at the end of the ACTC PEC and SC meetings to assure confidentiality. In the case of a web meeting, disclosures will be posted in a non-downloadable electronic format prior to the meeting and then taken down at the end of the meeting.

CATEGORIES OF RELATIONSHIPS TO DISCLOSE

Below are the categories of relationships that should be reported by investigators submitting proposals as well as ACTC PEC members:

Category 1. DSMB service / Adjudication committee / Grant / Research support provided by a company or other business entity: Please report the total monetary value of the grant for the relevant time period (i.e., do not limit disclosure to salary support only). Please do not report DSMB service/adjudication committee/grant/research support

from Federal (e.g. NIH, NSF, CDC) or other non-profit sources as these relationships do not present a potential for COI or SFI.

Category 2. (a) Honoraria payments for talks and lectures & (b) CME talks and lectures: Category 2 (a) includes talks paid for by a company, an intermediary for a company, or a for-profit CME group where the company directly or indirectly influences selection of the speaker. The 2 (b) CME subcategory is limited to CME talks through national professional organizations and non-profit academic institutions, where the sponsoring company does not select the speakers and has no relationship to the CME entity. In the disclosure, income received for 2 (a) counts towards a significant financial interest; 2 (b) CME talks are not so counted.

Category 3. 3 (a) Stock or other ownership rights, 3 (b) Stock Options & 3 (c) Company Ownership or Majority Stock Owner:

Category 4. (a) and (b) Intellectual Property rights such as copyrights, licenses, and patents: Intellectual property rights and interests are divided into two categories: "4a - Intellectual property rights with royalties" and "4b - Intellectual property rights without royalties." If the value of the property is unknown, the disclosure should indicate "unknown."

Category 5. Consultant or Advisory Role (examples include, but are not limited to, Consulting, Scientific Advisory Board, one-time consulting). (a) paid directly (payment is to the person), (b) paid indirectly (to a department or charity), (c) unpaid. Reimbursement for travel does not count as part of the reported income. The roles of DSMB or adjudication committee member are not considered consulting as they serve the science and the interests of the subjects.

Category 6. Other. The discloser will explain the relationship.

MANAGEMENT OF RELATIONSHIPS

The decision whether a relationship is an actual or potential COI or SFI depends on the nature of the relationship, including its value and the role of the person who has that relationship.

Stock, equity and other ownership in a company or product

Sponsoring Company:

ACTC members may not own or acquire stock, stock options, or other direct ownership interests in ACTC sponsoring companies, or in potential sponsoring companies that are under consideration for ACTC research engagement.

In the situation where an ACTC member already holds stock or other ownership interests in a company that becomes a sponsoring company or potential sponsoring company, the member has the following alternatives:

Immediately sell the stock or interest; or

Choose to retain the stock or interest, but

Not participate in closed discussion and voting in the PEC and SC meetings when the agenda includes the project with their relationship.

Recuse himself/herself from being a project PI or site PI on any study involving that company and its product(s);

Not be involved in other roles regarding such a study, including subject recruitment or evaluation of subject responses to study interventions, with the exception that the member may help to develop the study protocol; and

Agree not to buy/sell any stock in the sponsoring company or potential sponsoring company, or in a known competing company, until six (6) months after publication of the primary study paper from the ACTC trial involving the company.

Non-Sponsoring Company: ACTC SC members may hold stock and ownership interests in non-sponsoring companies, including known competitors of sponsoring companies.

Non-Sponsoring Companies that are Known Competitors of Sponsoring Company: Project leaders, the ACTC PI's, and PEC members may have stock and other ownership interests in known competitors of a sponsoring company, as long as such financial interests are annually < \$5,000.

Mutual and Sector Funds: Financial interests in companies through ownership of mutual funds, blind trusts, sector funds, or other investments in which the ACTC member has no direct control, are permitted and do not need to be disclosed.

Patent, Royalty and Intellectual Property Interests:

In general, intellectual property interests present a COI risk.

Sponsoring Company:

ACTC PI's, the ACTC statisticians, Unit leaders, PEC members, DSMB, the ACTC project leader, and ACTC SC members who serve as site PI may not have or acquire patent, royalty or other intellectual property interests in a sponsoring company, potential sponsoring company or have property interests that could benefit from the trial, such as a patent on the intervention or an assessment tool.

In the situation where the ACTC member already holds intellectual property interests in a company that becomes a sponsoring company or potential sponsoring company, or has property interests that could benefit from the trial, such as a patent on the intervention or an assessment tool, the member can either:

Assign the income to another person or institution who cannot directly benefit the member (such as a charity), or:

Do all the following:

Recuse himself/herself from the closed sessions when that involve the property in question; and

Recuse himself/herself from being a project PI or site PI on any ACTC study involving that company and its product(s); and

Not be involved in other roles regarding such a study, including subject recruitment or evaluation of subject responses to study interventions, with the exception that the member may help to develop the study protocol; and

Agree not to buy/sell any financial interests in the sponsoring company or potential sponsoring company, or in a known competing company, until six (6) months after publication of the primary study paper from the ACTC trial involving the company.

Non-Sponsoring Company: ACTC SC members may hold intellectual property interests in non-sponsoring companies, including known competitors of sponsoring companies.

Non-Sponsoring Companies that are Known Competitors of Sponsoring Company: Project leaders, ACTC PI's and PEC may have intellectual property interests in known competitors of a sponsoring company, as long as income from such interests is annually < \$5,000.

Employment Relationships:

ACTC members may not be employed by sponsoring companies or potential sponsoring companies, or by known, direct competitors of sponsoring companies.

Relationships with a sponsoring company that has study roles that exceed the provision of either funds or an intervention such as drug or device, or both:

The ACTC PI's, the ACTC statisticians, Unit leaders, PEC members, DSMB, and the ACTC project leader may not have:

Any paid relationship with the sponsoring company except as part of the grant or grants, Equity holdings with a sponsoring company, or Intellectual property with the sponsoring company, or concerning the intervention being used in the ACTC study.

The ACTC PI's, the ACTC statisticians, Unit leaders, PEC members, DSMB, and the ACTC project leader may have grants with the sponsoring company prior to ACTC approval of a project involving the sponsoring company. These grants between the sponsoring company and either the ACTC project leader or the ACTC PI should only address science necessary to develop and plan the project.

Once the ACTC PEC and SC have approved the project, the ACTC IEC will review any new grants between the sponsoring company and the project leader, statisticians, and/or the ACTC PI's. The IEC will provide initial recommendations regarding approval of such a grant to the ACTC PI's, who will make the final decision concerning whether the grant should be approved. Projects should have a scientific link to the ACTC study in question, and the relationship between work proposed and funding provided should be transparent and appropriate.

This guideline applies from the time of the planning of the protocol, through the course of the entire study, and until the publication of the paper reporting the study's primary endpoints.

Consultant or Advisory Role (examples include, but are not limited to, Consulting, Scientific Advisory Board, one-time consulting) either (a) paid directly (payment is to the person), (b) paid indirectly (to a department or charity).

An ACTC member whose relationship has a value that is not an SFI, may participate and vote in PEC and SC open and closed meetings. The member may designate an alternate from their site to represent the site in the closed meeting.

An ACTC PEC and SC member whose relationship has a value that is an SFI may not vote for approval/disapproval of actions related to the ACTC project for which the relationship exists. In the event the SFI is for the coming 12 months, the member may choose to end the planned relationship and then participate in PEC and SC voting.

3.0 Reference Documents

None

4.0 Definitions

ACTC: Alzheimer's Clinical Trial Consortium

PEC: Protocol Evaluation Committee

SC: Steering Committee

Project Leader: A person who proposed a protocol to the ACTC. This person has had a role in the design of the project. A project may have more than one leader.

Investigator: All persons involved in the design and conduct of a project. A useful rule to determine who is an investigator is this is a person who would either be a co-author or acknowledged on a publication of the project's results.

Site Investigator: The SC member who has overall charge of the execution of an ACTC project at a study site.

DSMB: Data Safety Monitoring Board

ACTC Member: Persons involved in the ACTC Committees or Units, project leader, investigator, DSMB member.

Open Discussion: A meeting where discussion of a project – its review, approval, monitoring and analyses of results – is attended by all ACTC members, including those with and without conflict of interest.

Closed discussion: A meeting where discussion of a project – its review, approval, monitoring and analyses of results – is attended solely by ACTC members without conflict of interest.

Financial Interest (FI): Any interest of monetary value, related to a company or other business entity, which would reasonably appear to affect, or be affected by, the research and activities of the ACTC. Such interests include, but are not limited to:

- Income or other payments for services not part of the member’s regular employment (eg., consulting, speaking fees, or honoraria)
- Equity interests (eg., stocks, stock options, or other ownership interests) that currently have value or could have value in the future.
- Intellectual property rights (eg., patents, copyrights, and royalties from such rights) that currently have value or could have value in the future
- Research, DSMB, or adjudication committee support provided by a company or other private, for profit entity (calculated as the overall monetary value of grant).
 - Because the ACTC is a NIH funded entity and operates in a not-for-profit institution, NIH and not-for-profit research grants do not create a potential for conflict of interest and therefore should not be disclosed.

Significant Financial Interest (SFI): An SFI involves salary for consulting or advising, directly owned equity interests, property, honoraria and other FIs (with the qualifications listed below) that, when aggregated for the ACTC member, and the ACTC member’s spouse and dependent children over the past 12 months, exceeded \$5,000 or over the next 12 months, are expected to exceed \$5,000.

- Research, DSMB, or adjudication committee work funded by a company or other business entity is not counted as a resource contributing to a SFI for an ACTC member. However, all research, DSMB, or adjudication committee work provided by a company or other business entity is considered to constitute a financial interest and must be disclosed.
- Travel reimbursement is not considered a financial interest.
- An equity and intellectual property interest by itself, irrespective of current cash value, is a SFI as this value could be influenced by ACTC activities and has the potential to become a SFI over the next 12 months.

Non-Significant Financial Interest: A financial interest as defined above that does not meet criteria for an SFI.

Product: The term “product” is construed broadly and includes, but is not limited to, drugs, devices, inventions, and assessment instruments.

Sponsoring Company: A company partnering with the ACTC on a particular study or trial.

Potential Sponsoring Company: A company with a product that is under consideration by the ACTC, or that has applied to the ACTC for consideration as a sponsoring company.

Non-Sponsoring Company: A company with a product or service in the area of Alzheimer’s diagnostics, drug development, assessment instruments, or intervention that is not currently partnering with the ACTC.

Known Competitor of Sponsoring Company: A company (1) which offers a product which is similar in terms of design, class, and/or mechanism of action to a product offered by a sponsoring company in an ACTC trial, and (2) which ACTC members could be reasonably expected to know about.

Research: A systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.

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Author:

Name	ACTC Role	Signature	Date
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As a publicly-funded consortium, all ACTC Policies are public documents. Current versions are maintained centrally by the ACTC Program Administrator. Copies of this controlled document are not considered controlled.

Reviewed and Approved by:

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