Issuing Department: Human Subjects Protection Program
Policy Number: 2011-012.1
Policy Title: Conflict of Interest – IRB members

Purpose

The purpose of this policy is to set forth requirements that must be followed for disclosing and managing a conflict of interest in human subject research for IRB members.

Definitions

See policy 2011-007 for definitions of:

Human Subject	Financial Interest Related to Research	Immediate Family Member

See Institutional Policy 2006-01 for definitions of:

Financial Conflict of Interest	Investigator	Significant Financial Interest (SFI)

See Guidance Document for Policy 2006-01 for elaboration of the following terms:

Conduct	Design	Investigator
Reporting		

Policy

On an annual basis IRB members will be asked to disclose known significant financial interests (SFIs) and board or executive relationships that may relate to their review of research. Annual disclosures will be used to aid in proper assignment of reviewers to studies (e.g. an IRB member who owns a significant amount of stock in a pharmaceutical company will not be assigned to review research sponsored by that company). An IRB member may also not participate in the review of research for which s/he or an immediate family member has any involvement in the design, conduct or reporting of the research. This policy pertains to all levels of review (i.e. full board, expedited, exempt) and all types of reviews (e.g. initial, continuing, modification, unanticipated problems, non-compliance). Reminders will be incorporated on all IRB reviewer sheets and announced at the IRB meeting.

An IRB member may also not participate in the review of research for which the member believes he or she cannot objectively review the research.

- A subordinate / supervisor relationship, or someone's departmental or center affiliation with a project, does not necessarily create a conflict of interest. The IRB member is expected to exercise his/her judgment and is encouraged to solicit advice from the IRB and / or the Director of the HSPP, to determine whether or not to review / vote on a study.

Procedure

Near the beginning of each fiscal year the IRB Administrator will send an email to the IRB membership to solicit information about Significant Financial Interests and board or executive relationships.

- the IRB Administrator will record such disclosures on excel tracking file titled IRBCommitteesyy-yy (fiscal years inserted for yy-yy)
- the Regulatory Specialists (RS) may refer to excel file when making preliminary reviewer assignments to make sure that no member is assigned to review a study for which s/he has a known conflict.
    - the IRB chair gives final approval to reviewer assignments

- If erroneously assigned as a reviewer for a study in which the member has a conflict, the member is responsible for contacting the IRB Office so that the Chair may assign another reviewer.

At the beginning of each meeting the Chair will remind members to recuse themselves from the review of any study with which a conflict exists, regardless of the type of review (e.g. initial review, continuing review, modification review, discussion item).

- IRB members will determine if a conflict exists by reviewing the agenda which notes study personnel and study sponsors.

If a conflict is disclosed, when the study is reviewed the member with the conflict may provide information requested by the IRB but is required to leave the meeting for the deliberation and voting and does not count towards quorum. The RS will document any such recusals in the minutes.

This policy also pertains to reviews conducted through the expedited process and for exempt determinations. The reviewer of such studies is responsible for identifying conflicts and excusing him/herself from the review of any study in which s/he has a conflict. If necessary, the review will be reassigned to a qualified member of the IRB.

Related Content

2006-001 – Conflict of Interest in Research – University Policy
2009-003.0 – Imposing and Lifting Suspension of IRB Approval or Imposing Terminations of IRB Approval
2011-009.2 - Exemptions
2011-009.3 - Review by Expedited Procedures
2011-009.5 - Review by Convened Board
2011-009.6 – Institutional Review Board - Consultants

Basis

45 CFR 46107(e)
21 CFR 56.107(e)
The U. S. Public Health Service (PHS) Objectivity in Research
The National Institutes of Health (NIH) Office of Extramural Research: Conflict of Interest
The National Science Foundation (NSF) Investigator Financial Disclosure Policy
The Food and Drug Administration (FDA) Guidance for Clinical Investigators on COI Disclosure

Document Attributes:

Effective Date: 8/17/2017

Replaced Version: 1/1/2015

Reviewed and Approved By:

Richard H. Simon *17 August 2017*

Richard Simon, MD **Date:**
Director Human Subjects Protection Program