Issuing Department: Human Subjects Protection Program
Policy Number: 2011-012.0
Policy Title: Financial Conflict of Interest – Research Personnel

Purpose

The purpose of this policy is to set forth requirements that must be followed by research personnel involved in human subject research for financial disclosures and, if applicable, for following a conflict of interest management plan.

Definitions

See policy 2011-007.0 for definitions of:

Human Subject	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

It is the policy of the HSPP that investigators, study coordinators, data managers and persons authorized to obtain consent (i.e. key personnel) disclose whether a SFI (as defined in Policy 2006-01) in the sponsor, product, service, and/or technology being researched exists. Disclosures are to be solicited from and made by key personnel when initial approval is sought, when continuing approval is sought, or when key personnel are added to a study.

Records of disclosures are to be kept with the study documents (e.g., with the regulatory binder). If a SFI is disclosed, the IRB Project-Specific Disclosure of SFI Form must be completed and routed to a designated person who supports the Financial Conflict of Interest Committee (FCIC) for review and sign-off. The signed form is then included in the submission to the IRB, along with any management plan that may have been developed. The form will list only the individual(s) who disclosed a SFI related to the project (e.g., a SFI in the sponsor, product, service, and/or technology).

When a SFI is disclosed, and it constitutes a Financial Conflict of Interest (FCOI), the FCIC develops a management plan if one is not already in place from the annual disclosure process. If a determination is/has been made by that committee that the SFI does not constitute a FCOI, a management plan is not required.

In all cases, the decisions of the committee are shared with the IRB and the IRB makes the final determination as to whether the conflict can be managed sufficiently to allow for approval of the research. The IRB may add to, but not remove from, the management plan developed by the FCIC. Restrictions that might be imposed by the IRB to manage a conflict of interest to prevent it from adversely affecting the rights and welfare of subjects and/or integrity of the data, include, but are not limited to:

1. Witnessing of the consent process;
2. Monitoring of the research by independent reviewers;
3. Modification of the research plan;
4. Disqualification of the PI or other research personnel from participation in all or a portion of the activities affected by the conflict (e.g. restricted from obtaining consent or analyzing data);
5. Divestiture of significant financial interests, or;
6. Severance of relationships that create the conflict.

Sanctions: Failure of an investigator to comply with the requirements of disclosure and/or a management plan may be considered serious and/or continuing noncompliance by the IRB and may also lead to sanctions identified in Institutional Policy for Individual Financial Conflicts of Interest in Research (2006-01).

Procedure

Principal Investigators, or their designee, will be responsible for obtaining information about SFIs related to a specific project from the investigators, coordinators, data managers, and persons authorized to obtain consent (i.e. key personnel). The information is to be retained with the study records (e.g., in the regulatory binder). For any individual who does disclose a SFI, the name(s) will be recorded on the IRB Project-Specific Disclosure of SFI form. This form will be submitted to the staff person who supports the Financial Conflicts of Interest Committee who will sign and date and return the form, and if applicable the management plan, to the PI or designee.

The signed form, and if applicable management plans, are then included as part of the IRB submission packet. If there is no SFI disclosed by any of the key personnel, the Project-Specific Disclosure Form is not required to be part of the IRB submission.

The IRB* reserves the right to impose management strategies in addition to those outlined by the FCIC.

- If a management plan has not been developed prior to the IRB meeting date
  - the IRB may defer the review until the plan has been developed or a determination has been made by the FCIC that the SFI does not constitute a conflict; or
  - the IRB may develop the initial plan, requiring at a minimum disclosure in the consent form and during the consent process.
  - upon receipt of the determination from the FCIC, if a management plan is required and it differs from what was required by the IRB, the PI will be required to follow both plans. If there is a conflict between the plans, the PI must submit a request for modification to the previously imposed IRB requirements. The Chair may elect to refer the FCIC's determination to the next convened board meeting for review.
    - The Chair will determine on a case by case basis whether the investigator may continue with the research or whether to restrict his/her involvement until the plan is reviewed by the convened board. Such restriction is not considered a suspension of study approval.

When plans are available at the meeting, the IRB will consider the disclosures and the measures in place to manage, reduce or eliminate the conflict. The IRB is responsible for taking the appropriate action(s), e.g.:

1. Reviewing the nature of the conflict and the management plan developed by the FCIC.
2. Determining whether the FCIC plan is sufficient to properly oversee and manage the conflict(s), or whether additional management strategies are required, taking into consideration the possible remedies as outlined in the policy section above.
3. Determining whether the conflict can be sufficiently managed to ensure protection of subjects is not affected and to allow for approval of the research.

*When the research qualifies for exempt status or expedited review, the assigned reviewer assumes the responsibility.

Related Policies

2006-001 – Individual Conflict of Interest in Research – University Policy

Basis

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

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Reviewed and Approved By:

Richard H. Simon *28 August 2017*

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