IRB SOP 105
Investigator

key research personnel is an integral part of the process for human subject's review and approval.

Procedures

1.0 Conflict of Interest Disclosure

Investigators, Co-Investigators and any study personnel are required to disclose Financial Conflicts of Interest or other interests that are, or may be perceived to be related to the study on the application for initial IRB review and approval. If there is a potential or perceived conflict related to the study, the Investigator is asked if the conflict has been disclosed and/or managed. Conflict of Interest disclosure forms are reviewed by the department chair/supervisor and forwarded to the Office of Research Compliance and Assurance. If warranted, the IRB will verify that a management plan has been executed. A management plan template for human subject's research may be used for documenting and identifying appropriate actions to eliminate reduce or resolve financial conflicts of interest or conflicts of commitment. In instances where a conflict of interest involving human subject's research is allowed, it is essential that research subjects and other interested parties be informed of the conflict of interest. If an investigator is participating in a multi-center trial and has been allowed to conduct human subject's research while possessing a financial interest, the fact should be made known to the Investigator or sponsor by the coordinating center. Notification of research subjects falls within the purview of the applicable IRB, which will determine whether and how the conflict of interest should be disclosed to the relevant human research subjects. This may include a description in the consent form of the conflict of interest.

1.1 Investigators and key research personnel submitting research applications to the IRB are required to:

1.1.1 Disclose financial conflicts of interest or other interests that are, or may be perceived to be related to the study on the application for initial IRB review and approval. If there is a potential or perceived conflict related to the study, the Investigator is asked if the conflict has been disclosed and/or managed.

1.1.2 Submit documentation of Conflict of Interest disclosure form in IRBNet.

2.0 IRB Review

It is not the purview of the IRB to reinterpret conflict of interest policies. Rather its function is to ensure that subject protection, the integrity of IRB review, and the conduct of a research are not jeopardized by an unidentified or unmanaged conflict of interest. IRB approval is not granted until the Office of Research Compliance and

Assurance completes its review and any management actions required are agreed to by the Investigator. A management plan template for human subject's research may be used for documenting and identifying appropriate actions to eliminate reduce or resolve financial conflicts of interest or conflicts of commitment. These matters may be referred to the Institutional Official, Human Subject's Protection Program.

The IRB shall concentrate on those aspects of any conflict of interest that may reasonably affect human subject protection and may require changes to the protocol or consent form that may include, but are not limited to the following:

2.1 The IRB may require an enhanced data safety monitoring plan.

2.2 Where applicable, the informed consent will disclose the nature of an investigator's conflict using language approved by the IRB.

2.3 In the event that additional protections are required to ensure human subjects protections that extend beyond those which have been incorporated in the management plan, a convened IRB will be required to review the plans for management and institute any required changes necessary to ensure that human subjects protections have been appropriately addressed and the study meets the criteria for IRB approval. In addition to individual investigator interests, any interests of the institution that could constitute a conflict of interest require review.

If the USA IRB has agreed to rely on an External IRB per an IRB authorization agreement, the process described above should still be followed. The researchers must disclose this conflict of interest to the IRB of Record according to the process agreed upon between the USA IRB and the IRB of Record and comply with any conflict of interest management plans that may result.

3.0 IRB Review of Conflicts of Interest at External Sites

If the USA IRB is serving as the IRB of Record for another organization through an IRB authorization agreement or under the conditions of an approved cooperative

management requirements more stringent or restrictive than proposed by the relying organization or University if necessary. However, the USA IRB will not modify or change any management plan or mandated disclosure to subjects without discussion with an acceptance by the relying organization or University.

University Related Documents

SOP 104: Conflict of Interest- IRB Members and Staff
University of South Alabama Conflict of Interest Policy

University Related Forms

Conflict of Interest Disclosure Forms

Guidance

Food and Drug Administration (FDA): Guidance for Industry - Financial Disclosure by Clinical Investigators (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm)

National Institutes of Health (NIH) Conflict of interest information (http://grants.nih.gov/grants/policy/coi/index.htm)

National Science Foundation: Policies (NSF): Conflicts of Interest Information (http://www.nsf.gov/policies/conflicts.jsp)

Office of Human Research Protection (OHRP): Final Guidance Document (http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf)

Office of Research Integrity (ORI): Policies/Regs/Statutes: PART 50: Subpart F—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought (http://ori.hhs.gov/policies/fedreg42cfr50.shtml)

HISTORY

Effective Date:
Revisions: November, 2018

Responsible Office:

Office of Research Compliance and Assurance