



POLICY STATEMENT
REGARDING CONFLICT OF INTEREST
PERTAINING TO DUHS IRB MEMBERS AND CONSULTANTS
06/25/2008

Conflict of Interest Pertaining to DUHS IRB Members and Consultants

DUHS IRB Members and Consultants are responsible for making known any potential or perceived conflict of interest (COI) concerning protocols reviewed by the IRB. This would include the IRB member's/consultant's service in any of the following categories with respect to the study in question:

- Principal Investigator
- Co-Principal Investigator
- Investigator receiving funding from the study, as listed in the study budget
- In a supervisory role over the PI of the study, or
- Family member of PI (spouse and each dependent child)

An IRB member or consultant is considered to have a conflicting interest when the member/consultant or the member's or consultant's immediate family has any of the following:

- Involvement in the design, conduct, or reporting of the research with the following exception:
 - An IRB member who is listed on an IRB protocol as a member of the study's Key Personnel but whose study-related activities are limited to (i) the performance of commercial services for the investigator (or performing other genuinely non-collaborative services meriting neither professional recognition nor publication privileges), while (ii) adhering to commonly recognized professional standards for maintaining privacy and confidentiality, is not considered to have a conflicting interest on this basis.
- Supervisory role over the principal investigator of the research.
- Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
 - The value of the interest does not exceed \$10,000 when aggregated for the immediate family.

- The interest is publicly traded on a stock exchange.
 - The value of the interest does not exceed 5% interest in any one single entity when aggregated for the immediate family.
 - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
- Compensation related to the research unless it meets two tests:
 - The value of the compensation does not exceed \$10,000 in the past year when aggregated for the immediate family.
 - No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, regardless of compensation.
- Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

Board members and consultants should make known any conflict of interest prior to the beginning of the Board's discussion of the protocol under review. They must leave the meeting room prior to the Board's deliberation and vote.

Additionally, IRB members are responsible for self-identifying any conflicting interests before conducting review using the expedited procedure, so as to remove themselves from involvement in the review of the research.

COI Query by Chair or Vice Chair

The chair or vice chair will read or paraphrase the statement below at the beginning of each convened meeting:

"Does anyone have a conflict of interest with any investigator or protocol that is under consideration today? If you do, you will be expected to leave the room unless the IRB requests you to stay temporarily to answer questions about the study, but you must leave the room during the IRB's deliberations and vote on the protocol."

"Should you realize at any time during today's meeting that you have a conflict of interest regarding a protocol under review, please promptly declare it as so."

This COI query by the chair will be recorded in the minutes, along with any declarations of COI made by the members.

Conflict of Interest Pertaining to Investigators

All Investigators are to follow the Duke University School of Medicine (DUSOM) Conflict of Interest (COI) policy. Investigators must identify for resolution under that policy's specific procedure any conflict of interest associated with a study, including but not limited to their personal investment in, or other financial relationship with, a company that might profit from the study. If the Investigator is to be permitted by the DUSOM COI Committee to proceed with the study following review under that policy, the Committee will evaluate and develop a management plan for the financial interests of the investigator. The convened IRB will be informed of the results of this evaluation, including the details of the management plan. The IRB may not limit or reduce the conditions imposed by that management plan, but may impose a higher standard if necessary in order to find that the regulatory criteria for approval of the research have been met. The research consent form provided to subjects must include an appropriate description of any relationship that might be perceived as a potential conflict of interest., The convened IRB has the final authority to decide whether the interest and its management, if any, and its form of disclosure allow the research to be approved.

NIH requires grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought." That subpart promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator.

The signature of the authorized organizational official on the face page of the grant application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F. Under those requirements the organization (and thus, the investigator) must do the following:

- Before spending any NIH funds awarded under a new award, inform the funder's Chief Grants Management Officer (CGMO) of the existence of any conflicting financial interests it identified of the type covered by 42 CFR 50.605.
- Continue to make similar reports to NIH on subsequently identified conflicts within 60 days of identifying them.

If the Conflict of Interest status of an individual changes during the course of a study, the individual is required to declare this to his/her Department Chair, the IRB Executive Director, and the Director of the Grants & Contracts Office.