

Wayne State University Human Investigation Committee	
Subject	Conflict of Interest: Institutional Review Board Member and HIC Administrative Staff
Form Date	August 18, 2006 (Rev. 7/15/10)
Approvals	10/25/06 OGC Approval, 11/17/06 Steering Committee, 12/05/06 Administrative Approval, 9/30/10 Administrative Approval.

Background

Wayne State University (WSU) is committed to the promotion of the highest level of integrity and ethics in all research endeavors in the institution. In accordance with federal and state regulations and guidance from the Office of the Human Research Protections (OHRP) and other federal agencies, this policy has been developed to assist Institutional Review Board (IRB) members in identifying their own Conflict of Interest (COI) within research situations.

A conflict of interest is a situation, and not a behavior. The presence of conflict of interest is not necessarily an indictment of the individual, but rather an acknowledgement of a potentially challenging situation¹. Any compromise in the objectivity of decisions involving the welfare of research participants well defines the core problem imbedded within these conflicts.

Scope

This policy applies to the following groups of individuals associated with a research protocol involving human participants:

IRB Members, IRB Consultants, and Immediate Family Members: Because of the unique responsibilities in reviewing research protocols, IRB members, consultants, and immediate family members' financial relationships may appear to be a potential Financial Conflict of Interest (FCOI) with their institutional responsibilities.

Individuals responsible for Business Development: Because of the unique responsibilities of these individuals they are prohibited from serving as members or ex-officio members on the IRB's and from carrying out day-to-day operations of the review process.

¹ "Shared Responsibility, individual Integrity: Scientists addressing conflicts of interest in biomedical research": The Federation of American Societies for Experimental Biology, July 14, 2006

HIC Administrative Staff and selective WSU Senior Management: Because of their unique responsibilities in processing and providing institutional support, this policy applies to the administrative staff of the HIC and selective WSU senior management to allow for institutional FCOI to be reviewed.

This policy applies to all types of IRB review including:

1. Review by a convened IRB,
2. Review using the expedited procedure,
3. Initial Review,
4. Continuing Review,
5. Review of modifications,
6. Review of unanticipated problems involving risks to participants or others, and
7. Review of non-compliance with the regulations or the requirements of the IRB.

Definitions

Conflict of Interest – refers to situations in which the employee and or his/her immediate family has financial or personal interests that may compromise, or have the appearance of compromising, the employee's professional judgment in conducting or reporting research.

Conflicts of Interest may occur when:

- An employee or member of his/her immediate family has or will receive from the sponsor of the research financial or other forms of compensation, or
- An employee or member of his/her immediate family have a significant financial interest in the company/agency/firm that is sponsoring the research, or
- An employee or member of his/her immediate family serve in a corporate or for-profit leadership position with the company sponsor, such as executive officer board member, fundraising officer, agent or member of a scientific review committee, or member of a data safety and monitoring committee related to the company sponsor, regardless of compensation, or
- An employee or member of his/her immediate family discloses a conflict of interest to the Federal Drug Administration (FDA) or other agency.

Employee – An Employee is any person possessing either a full-time or part-time appointment at the University. These include the faculty ranks of professor, associate professor, assistant professor (and all of the foregoing whose appointments contain such terms as "Research," "Adjunct," "Visiting," or "Clinical,"), instructor, and lecturer, as well as academic professionals and postdoctoral associates. Employees, students, and other individuals identified as key personnel on grant applications, whether salaried or non salaried, who on behalf of the University are responsible for, or in a position to influence the design, conduct or reporting of the research, or other scholarly activity are also included in this definition.

Immediate Family – Immediate Family means the employee's spouse or domestic partner and dependent children.

Institutional Conflict of Interest – Institutional Conflict of Interest consist of two major types: (1) Conflict of Interest involving University equity holdings or a royalty arrangement related to sponsored programs, and (2) Conflict of Interest involving University officials who make decisions with institutional-wide implications, which can include department heads and center and institute directors, in addition to senior management.

Management Plan – A plan developed by the FCOI Committee that places requirements on a relationship to reduce or eliminate factors that may compromise objectivity in the conduct of the research.

Significant Financial Interest – Anything of monetary value, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options or other ownership interests) and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

HIC Policy/Procedures

Conflict of Interest (COI) disclosure is accomplished by self-report. The research community has been educated in the requirements of COI disclosure. Forms and instruction for disclosure are available on the HIC website. IRB members, in addition to completing a COI disclosure that is maintained in the HIC file, are queried at the beginning of each IRB meeting by the IRB Chairs to identify any COI that may not as yet been reported. This information is then reflected in the minutes. Within the HIC Office, reviewers/pre-reviewers of expedited research protocols, unanticipated problems, noncompliance issues, etc., report to the HIC Chair or his/her designee if a COI would prohibit their review of a specific proposal.

IRB Member Conflict of Interest Disclosure

IRB members are required to file a FCOI disclosure regarding all potential sponsors with the FCOI Committee within one month of their appointment to the HIC. The disclosure must be updated on an annual basis and more frequently when significant changes have occurred.

IRB consultants are required to file a FCOI disclosure regarding all potential sponsors with the FCOI Committee as soon as they agree to assist an IRB with the review of a research protocol. This disclosure must be updated on an annual basis and more frequently when significant changes have occurred.

HIC Administrative staff and selective WSU senior management are required to file a FCOI disclosure regarding all potential sponsors with the FCOI committee within one month of their appointment to their position. The disclosure must be updated on an annual basis and more frequently when significant changes have occurred.

IRB members and HIC administrative staff are required to leave the room during the discussion of research protocols involving sponsors with which they have a potential institutional FCOI. IRB members with a conflict of interest are not counted towards quorum.

Confidentiality of Information Provided in the FCOI Disclosure

Disclosures to the FCOI Committee are confidential and all employees of WSU who have been provided information from the FCOI database must maintain a high level of confidentiality. HIC administrative

personnel will not have access to the actual disclosures of other employees. However, select HIC administrative personnel will have administrative access to the summary report that indicates whether or not a potential FCOI might exist and the level of potential FCOI that has been assigned by the FCOI Committee.

Relationship between the IRB and the FCOI Committee

The FCOI Committee will have primary responsibilities to review relationships between investigators, key personnel and individuals who may have a FCOI. Based upon their review, they may require the implementation of a FCOI Management Plan to reduce and/or eliminate the potential FCOI. When a management plan has been established, the IRB will have the authority to review and add additional requirements to the FCOI Management Plan that pertain to the protection of human participants in the proposed research protocol. The IRB will not have the authority to remove a condition in the Management Plan that was approved by the FCOI Committee. However, if appropriate, the IRB may request that the FCOI Committee remove a condition that they have previously incorporated into the Management Plan.

The HIC administrative personnel have the authority to request a FCOI report on all IRB members, IRB consultants and individuals with Institutional FCOI.

When Wayne State University has a potential or real financial conflict of interest with a sponsor, the FCOI Committee will communicate this conflict and the resulting management plan to the HIC.

Additional Conditions that the IRB may Place on a Research Protocol

When the IRB is reviewing a research protocol in which the FCOI Committee has a management plan for the financial conflict, the IRB may require that a statement be added to the research consent and assent documents about the financial holdings of investigators and key personnel. As part of the IRB review, the IRB will determine if parts of the management plan should be disclosed to the research participants in the research consent and assent documents.

When it is determined that the integrity of the institution and the well-being of the research participants may be in question, the research may need to be conducted outside Wayne State University by independent investigators at sites that do not have a financial stake in the outcome.

A summary of all IRB discussions regarding FCOI shall be noted in the minutes of the IRB.

Education and Training

All IRB members and others involved with research are required to participate in training on actual or potential financial conflict of interest during their orientation and/or periodically thereafter as deemed necessary.

Policies for Managing COI of IRB Members and HIC Administrative Staff

1. The IRB Chair or his/her designee is not eligible to assign a protocol for which he/she is the Principal Investigator (PI) or Co-Investigator (Co-I) to their IRB. In these cases, the Chair of the HIC or his/her

designee will be responsible for making the protocol assignment to a specific IRB. The HIC Chair may then: a) assign the protocol to the very IRB of which the IRB Chair is the PI or Co-I for reason of a heightened level of scientific expertise extant on said IRB, as regards the review of protocol in question, compared to other IRBs, or b) identify another IRB that would be duly constituted to review that particular research protocol.

In the first case, the Chair of the IRB would be required to leave the room, and if a quorum is maintained, the IRB would discuss the protocol and vote to approve, request certain modifications, or otherwise disapprove the research submission. At the conclusion of all actions involving the protocol, he/she would rejoin the committee meeting.

The IRB Chair would retain the rights of all other investigators in that he/she may be asked to appear, or request to appear before the committee to answer questions regarding his/her protocol. Should the Chair appear before the committee, he/she can enter in the general discussion of the protocol but would be asked to leave the room prior to further IRB discussion and/or the voting procedure.

2. In situations wherein an IRB member is a PI or Co-I for a particular protocol, the IRB Chair may: a) assign the protocol to the IRB of which the potentially conflicted IRB member is assigned for reason of extant scientific expertise (as cited above), or b) identify another IRB duly constituted to review that particular research protocol. If the protocol is assigned to the IRB of the PI or Co-I, the IRB member would be requested to leave the room, a quorum re-established, and the IRB would discuss the protocol and vote to approve, make modifications, or disapprove. After the vote, the IRB member would be asked to rejoin the committee.

The IRB member retains the rights of all other investigators and may request to be heard before the IRB committee to answer questions regarding his/her protocol. If the IRB determines that Conflict of Interest cannot be managed by the IRB member/PI merely leaving the room, all review and approval activities by another WSU IRB may be required. In rare cases the use of a non-WSU IRB maybe an option.

When grant deadlines or other time constraints make it necessary for a PI who is also the Chair or member of an IRB to submit a protocol to their own committee, the assignment of the protocol to a particular committee member will be managed by the HIC Chair on a case-by-case basis.

3. If any members of an IRB have contributed to or have served as a co-investigator, a consultant, or key personnel on a protocol being reviewed at a convened meeting, they must disclose the relationship to the IRB before the protocol is discussed. The IRB member and the Chair of the IRB (together or independently) will make a determination as to whether or not the IRB members should leave the room for the discussion, and/or vote to approve, disapprove, or require modifications to the protocol. After the vote by the IRB they will be asked to rejoin the Committee.

The IRB member may, however, be called into the meeting if the IRB has questions about the protocol and have the same rights as all investigators to request to appear before the IRB committee.

4. Within WSU, various divisions, departments, and institutes vary in organizational size, location, and structure. Where possible, given the expertise of the members within a particular IRB, a protocol should be assigned to primary and secondary reviewers with membership outside of the PI's primary organizational unit. When expertise is not available for a duly constituted IRB to review a particular protocol and it is necessary to assign reviewers with membership inside the same primary organization unit, the reviewers should determine whether or not they have a Conflict of Interest. If this is the case, it is the responsibility of each reviewer to disclose the Conflict of Interest to the Chair of the IRB before he/she accepts the role of primary and/or secondary reviewer. The IRB member and Chair of the IRB (together or independently) will make a determination as to whether or not the IRB reviewer should leave the room for the discussion and/or vote to approve, disapprove, or require modifications to the protocol. The IRB reviewer may, however, be called into the meeting if the IRB has questions about the protocol. After the vote by the IRB they will be asked to rejoin the Committee.
5. When IRB members have other perceived Conflicts of Interest, it must be disclosed to the IRB before the protocol is discussed. The IRB member and the Chair of the IRB (together or independently) will make a determination as to whether or not the IRB members should leave the room for the discussion and/or vote to approve, disapprove, or require modification to the protocol. After the vote by the IRB they will be asked to rejoin the Committee.

If a member of an IRB is a spouse or family member of an investigator, a consultant, or key personnel for a particular research protocol, that IRB member must disclose the relationship to the IRB before the protocol is discussed. The IRB member and the Chair of the IRB (together or independently) will make a determination as to whether or not the IRB members should leave the room for the discussion, and/or vote to approve, disapprove or require modification to the protocol. The IRB member may, however, be called into the meeting if the IRB has questions about the protocol. After the vote by the IRB they will be asked to rejoin the Committee

Procedures for Handling COI of IRB Members or HIC Administrative Staff

1. Individual IRB members with Conflicts of Interest that have not been previously been identified shall disclose their Conflict of Interest so that they or the Chair of the IRB can made a decision (together or independently) about whether or not they should leave the room for the discussion and/or vote to approve, disapprove, or require modification to the protocol. After the vote by the IRB they will be asked to rejoin the Committee.
2. All disclosures regarding Conflict of Interest shall be noted in the minutes of the IRB.
3. All IRB members are required to participate in training on actual and potential Conflict of Interest during their orientation and periodically thereafter as deemed necessary.

Additional Resources

Wayne State University Research Policy Individual and Institutional Financial Conflict of Interest and Commitment

Association of American Medical Colleges (AAMC): Protecting Subjects, Preserving Trust, Promoting Progress - Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research

(<http://www.aamc.org/research/coi/firstreport.pdf>)

Association of American Medical Colleges (AAMC): Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research

(<http://www.aamc.org/research/coi/2002coireport.pdf>)

Association of American Universities (AAU): Task Force on Research Accountability: Report on Individual and Institutional

Financial Conflict of Interest October, 2001. (<http://www.aau.edu/research/COI.01.pdf>)

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/finreln/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>)

"Shared Responsibility, individual Integrity: Scientists addressing conflicts of interest in biomedical research": The Federation of American Societies for Experimental Biology, July 14, 2006