

| Wayne State University Human Investigation Committee | |
|---|---|
| SUBJECT | Conflict of Interest: Principal Investigator/Key Personnel |
| Section | |
| Form Date | 08-18-06 |
| Approvals | Steering Committee: 12/07/06 , General Counsel : 11/20/06, Administrative Approval 12/18/06 |

Background

Wayne State University (WSU) is committed to the promotion of the highest level of integrity and ethics in all research endeavors at 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 employees in identifying 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. There is a distinct possibility of conflict of interest involving considerations among the investigators, key personnel and others directly, or indirectly, involved with the conduct and/or oversight of human participant research in the institution. Any compromise in the objectivity of decisions involving the welfare of research participants well defines the core problem imbedded within these conflicts.

Individual Financial Conflict of Interest and Institutional Financial Conflict of Interest are addressed in the WSU Research Policy on Financial Conflict of Interest and Commitment Policy. The Human Investigation Committee (HIC) Policy and Standard Operating Procedure compliments the Research Policy and specifically addresses communication between the University's Conflict of Interest Committee and the Institutional Review Boards (IRBs), the role the HIC plays in providing additional oversight in conflict of interest issues, as well as when the HIC may want to inform the research participant about a real or perceived financial conflict of interest. Together, these measures are designed to ensure that no real or perceived conflict of interest will adversely affect the objectivity in the conduct of research that involves human participants.

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

Scope

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

1. Principal Investigator (PI) and Key Personnel: As a result of submitting a research protocol to an IRB, all investigators and key personnel with any potential and/or real conflict of interest with a sponsor must submit a disclosure to the WSU Financial Conflict of Interest (FCOI) Committee.²

For investigators and key personnel who are not faculty, employees, or students of WSU, the policies and procedures of their institution or the WSU FCOI Committee may be used. If individuals who are not faculty, employees, or students of WSU chose to use their home institution's reporting requirement, a report on their financial conflict of interest must be submitted to the WSU HIC as part of the review of a research protocol.

2. Faculty, Staff & Sponsors: To allow for institutional COI to be reviewed adequately, this policy and procedure also applies to faculty, staff, and sponsors who have signature authority over research protocols prior to protocols being submitted to the HIC.

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 modification,
6. Review of unanticipated problems involving risks to participants or others
7. Review of non-compliance with the regulations or the requirements of the IRB

Definitions

Employee -- An Employee is any person possessing either a full-time or part-time appointment at WSU.y. 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 WSU 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.

² See Financial Conflict of Interest and Commitment Policy

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.

Principal Investigator/Key Personnel 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. ³

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.

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

Investigator/Key Personnel Conflict of Interest Disclosure

At the time that the PI completes either the Protocol Summary Form, the Continuation Form, the Exempt Protocol Summary Form, or the Amendment form, he/she will be prompted to answer whether or not they, their spouse or domestic partner or any dependent children have a conflict of interest with the sponsor of the project. All key personnel will be asked to answer the same question. If the answer is “Yes”, the individual will be directed to complete the “Individual Financial Conflict of Interest Detailed Disclosure Form”. If disclosures have not been made prior to the submission of the research protocol to the IRB, investigators and key personnel will be required to report these relationships to the FCOI Committee. The investigator must accept the FCOI Management plan before the protocol can be approved by the IRB. The FCOI disclosure must be updated on an annual basis and more frequently when significant changes have occurred.

Institutional Conflict of Interest Disclosure

Persons with institutional responsibilities (i.e., Department Chairs, individuals acting on their behalf, faculty, supervisors) at the time that they sign off on a Protocol Summary Form are prompted whether they, their

³ WSU Financial Conflict of Interest and Commitment Policy, section 3.4.

spouse or domestic partner or any dependent children have a potential conflict of interest with the sponsor of the project. If the answer is "Yes", the individual will be directed to complete the "Individual Financial Conflict of Interest Detailed Disclosure Form." If disclosures have not been made prior to the submission of the research protocol to the IRB, investigators and key personnel will be required to report these relationships to the FCOI Committee and the FCOI Management Plan must be accepted before the protocol can be approved by the IRB. The FCOI disclosure must be updated on an annual basis and more frequently when significant changes have occurred.

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. The FCOI Committee will communicate to the IRB the level of the conflict of interest and the subsequent management plan to the IRB. 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.

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 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 investigators and key personnel will be required to complete the FCOI module provided at the Responsible Conduct in Research web site, when the FCOI module become available.

Related References:

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/members/coitf/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/members/coitf/2002coireport.pdf>

Association of American Universities (AAU): Task Force on Research Accountability: Report on Individual and Institutional Financial Conflict of Interest
October, 2001. www.aau.edu

Food and Drug Administration (FDA): <http://www.fda.gov/oc/guidance/financialdis.html>

National Institutes of Health (NIH) Conflict of interest information:
<http://grants2nih.gov/grants/policy/COI/index.htm>

National Science Foundation: Policies (NSF): Conflicts of Interest Information:
<http://www.nsf.gov/home/pubinfo/conflicts.htm>.

Office of Human Research Protection (OHRP):
<http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm>

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.dhhs.gov/html/policies/fedreg42cfr50.asp>