

UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-023
AAHRPP:	Element I.6.A., Element II.1.C. & Element II.1.D.
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Procedure Title:	IRB Member, IRB Staff, and Organizational Conflicts of Interest

1.0 Objective

- 1.1. To describe the policy and procedure associated with conflicts of interest which may be applied to human subject research covered by the University of Southern Maine (USM) Human Research Protection Program (HRPP).

2.0 General Description

- 2.1. The primary goal of this policy is to prevent conflicting interests from interfering with the review process either by competing with an Institutional Review Board (IRB) member's or consultant's obligation to protect participants or by compromising the credibility of the review process.
- 2.2. The IRB review process should be free of conflict of interest so that the IRB member's obligation to protect participants or ensure the integrity of the review process is not compromised by competing business interests.
 - 2.2.1. Competing business interests can influence the review process when individuals responsible for business development serve on the IRB.
 - 2.2.2. Organizational conflict of interest situations must also be considered for the same reasons.
- 2.3. No USM IRB Member, IRB Staff, consultant, or institutional leader may participate in the IRB's initial or continuing review of any project in which that individual has a non-financial or financial conflicting interest, except to provide the information requested by the IRB.
 - 2.3.1. This prohibition includes review by a convened IRB, by an expedited procedure of unanticipated problems involving risks to participants or others, or review of non-compliance with regulations or laws or the requirements of the IRB.

3.0 Definitions

- 3.1. Conflict of Interest: “Situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's judgment in conducting or reporting research.” *See Association of American Medical Colleges (AAMC), 1990*
 - 3.1.1. “A conflict of interest in research exists when the individual has interests in the outcome of the research that may lead to a personal advantage and that might, therefore, in actuality or appearance, compromise the integrity of the research.” *See National Academy of Sciences, Integrity in Scientific Research*
- 3.2. IRB Member or IRB Staff Conflict of Interest includes, but is not limited to, conflict situations related to review of initial applications, renewals, revisions, unanticipated problems involving risk to subjects or others, non-compliance investigations, or suspension/termination decisions. The following examples are illustrative and not exhaustive of non-financial and financial conflicts of interest. Other situations that may create conflicts of interest must be disclosed by IRB Members or Staff.
 - 3.2.1. Conflict situations include but are not limited to reviewing or managing a project involving:
 - 3.2.1.1. An IRB Member’s involvement in the design, conduct, supervision, oversight or reporting of the research, other than oversight for IRB purposes;
 - 3.2.1.2. An IRB Member who serves as an investigator or provides support on a project being reviewed;
 - 3.2.1.3. A graduate student for which the IRB Member serves on the thesis or dissertation committee;
 - 3.2.1.4. An IRB Member’s or IRB Staff Member’s service as the (direct or higher-level) supervisor or manager of the principal investigator, co-investigator, or research staff for the project being reviewed;
 - 3.2.1.5. Funding that would augment or accrue to program, research group or project budgets managed or overseen by the IRB Member or IRB Staff Member;
 - 3.2.1.6. An IRB Member’s or IRB Staff Member’s immediate family (spouse, domestic partner, dependent children, and other) who serves as a principal investigator, co-investigator, or research staff for the project being reviewed;
 - 3.2.1.7. An IRB Member or IRB Staff who has a significant financial interest in the research being reviewed;
 - 3.2.1.8. An IRB Member’s or IRB Staff Member’s immediate family (spouse, domestic partner, dependent children, and others) who has a significant financial interest in the research being reviewed; and
 - 3.2.1.9. Funding by or that affects a company that has provided or offered gifts of goods, property, or services, like airline tickets, resort or hotel

accommodations, or other recreational or personal amenities to an IRB Member or IRB Staff or member of their immediate family.

- 3.2.2. The judgment about what to report as a conflict of interest lies first and foremost with the IRB (or Staff) Member. Holding an appointment in the same departmental unit as the person whose project is being reviewed, does not, in most cases, constitute a conflict of interest.
- 3.3. Financial Interest: A financial interest is anything of monetary value, whether or not the value is ascertainable, including but not limited to:
 - 3.3.1. Payments for services such as consulting fees, salary, honoraria, or commissions;
 - 3.3.2. Equity interests like stock and stock options;
 - 3.3.3. Other ownership interests, like being a partner in a partnership or operating an unincorporated business;
 - 3.3.4. Beneficial interests, e.g., being the beneficiary of a trust or estate or a trustee of a trust or estate benefitting a family member;
 - 3.3.5. Indebtedness;
 - 3.3.6. Intellectual property rights, like the right to receive royalties or licensing fees as a result of a patent or copyright;
 - 3.3.7. Gifts of goods, property, or services, like airline tickets, resort or hotel accommodations, or other recreational or personal amenities; and
 - 3.3.8. Service on a corporate board or as a corporate officer, or on the scientific advisory board of a company, if payment is received for the service. But, even unpaid service as a corporate director or officer or as a corporate advisor can be an opportunity for tangible personal benefit that can form the basis for a conflict of interest.
 - 3.3.9. A financial interest can arise from any kind of legal entity including but not limited to a corporation or limited liability company; a partnership, limited partnership, or joint venture; a trust or estate; a firm, franchise, “dba” (doing business as), sole proprietorship, unincorporated association, or other business.
- 3.4. Significant Financial Interest: A significant financial interest includes, but is not limited to, a financial interest in the sponsor, product, or service being tested or researched, or in a competitor of the sponsor or product or service being tested or researched. This includes interests of the Investigator and those of the Investigator’s spouse and dependent children that reasonably appear to be related to the Investigator’s institutional responsibilities.

3.4.1. The following are deemed to create a “significant financial interest”:

- 3.4.1.1. Income or receipt of payments of any kind totaling more than \$5,000 over the last calendar year from a single entity;
- 3.4.1.2. Ownership interests in a single entity of greater than one percent (1%) or of an amount exceeding \$5,000;
- 3.4.1.3. Intellectual property rights or licenses with an established fair market value exceeding \$5,000 or which generate income of any value;
- 3.4.1.4. Unvalued stock options or other options for ownership in a privately held company of any value;
- 3.4.1.5. Paid or unpaid service on a governing or advisory board, or in a fiduciary or managerial role, for, or as a general partner of, an entity;
- 3.4.1.6. Serving as a trustee for a trust or estate, or having a beneficial interest in a trust or estate, whose value exceeds \$5,000;
- 3.4.1.7. Indebtedness to or from a single entity in an amount exceeding \$5,000;
- 3.4.1.8. Receipt of gifts of goods, property, or services, like transportation, resort or hotel accommodations, or other recreational or personal amenities; and
- 3.4.1.9. Other opportunities for tangible personal benefit.
- 3.4.1.10. The following financial interests are excluded from consideration and do not need to be reported:
 - 3.4.1.10.1. USM salary, remuneration by USM, or other payments at USM’s behest;
 - 3.4.1.10.2. Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels paid by:
 - 3.4.1.10.2.1. Federal, state, or local U.S. or international government
 - 3.4.1.10.2.2. U.S. or international institutions of higher education;
 - 3.4.1.10.2.3. U.S. or international academic teaching hospitals and medical centers;
 - 3.4.1.10.2.4. U.S. or international research institutes affiliated with an institution of higher education;
- 3.4.1.11. Financial interest arising solely by means of investment in a mutual, pension, or other institutional investment funds over whose management and investments neither the individual nor any immediate family member has control; and
- 3.4.1.12. Indebtedness from a bank, credit union, or other commercial lenders.

3.5. Organizational Conflict of Interest: An organizational conflict of interest exists for research involving human subjects when USM’s financial interests, or those of its “institutional leaders,” which may affect or reasonably appear to affect institutional processes with which the IRB and the ORIO carry out their responsibilities in reviewing a

proposed human research protocol and/or managing a human research project once it has been approved by the IRB.

3.5.1. Financial interests creating an organizational conflict arise in research on drugs, devices, biologics, or other questions of potential value from:

3.5.1.1. Protected intellectual property, licenses for commercialization of patented intellectual property, or receipt of royalties or other fees from licensed intellectual property, and/or

3.5.1.2. Gifts exceeding \$50,000 from organizations or individuals that would stand to benefit, or reasonably expect to benefit, as a result of the research.

3.6. Institutional Leaders means Deans, Separately Reporting Directors, and Executive Managers who have direct authority for faculty appointments, allocation of institutional resources, assurance of institutional compliance, application of disciplinary standards, and other similar administrative tasks.

3.6.1 Obligations regarding conflicts of interest related to institutional responsibilities address the following:

3.6.1.1. Use of confidential information;

3.6.1.2. Outside influence through personal gifts;

3.6.1.3. Use of authority, University resources;

3.6.1.4. Conflicting or incompatible service; and

3.6.1.5. Competition with the University.

4.0 Responsibility

4.1. It is the responsibility of the ORIO staff, Research Protections Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this SOP.

5.0. Procedure:

5.1. IRB Staff Member Conflict of Interest: If an IRB Staff Member has been assigned to a project with which they have a potential conflict of interest, the IRB Staff Member will notify the IRB Chair. The IRB Staff Member shall be recused (excluded) from reviewing the project.

5.2. Consultant Conflict of Interest

5.2.1. Non-IRB Members can be solicited for their additional expertise pursuant to the policy on *HRPP 022 IRB Use of Additional Expertise*.

5.2.2. Consultants will be queried as to whether they have a conflict of interest.

- 5.2.3. Consultants to the IRB must not have a conflict of interest when reviewing a protocol.
 - 5.2.3.1. If the individual or a member of his or her immediate family has a conflict of interest, they will be excluded from consideration as a consultant on the project.
- 5.2.4. When consultants have a conflict of interest at a convened IRB meeting, they may remain in the room to provide the information requested by the IRB but will leave the room before deliberation and voting.

5.3. IRB Member Conflict of Interest:

- 5.3.1. IRB Members will not participate in any review of the discussion of or voting on any protocol in which they have a conflict of interest except to provide the information requested by the IRB.
 - 5.3.1.1. Such conflicts are satisfactorily managed by the IRB Member's recusal from participating in or contributing to, the review. In an exceptional situation where the number of IRB members and alternates who are required to recuse themselves is so large as to deny quorum where a meeting is required, the conflict might be managed by securing review by an alternate IRB in a manner consistent with the regulations.
 - 5.3.1.2. When IRB members have a conflict of interest, they may remain in the room to provide the information requested by the IRB but will leave the room before deliberation and voting.
- 5.3.2. If an IRB Member (including the IRB Chair) has been assigned to review a project with which he or she has a potential conflict of interest, the IRB Member should alert the IRB Staff. The IRB Chair or staff will assign the project to another IRB Member.
- 5.3.3. At convened IRB meetings, IRB Members with a conflict of interest are not counted towards quorum when they leave the room.
 - 5.3.3.1. The IRB Staff will document in the IRB minutes that the IRB Member left the room during the discussion and voting on the proposal, with an indication that a conflicting interest was the reason for the absence.
- 5.3.4. Several mechanisms are used to remind IRB Members about conflict of interest. These include:
 - 5.3.4.1. Reminders on review checklists for exempt determinations, initial, renewal, and revision applications;
 - 5.3.4.2. A statement in the email sent to IRB Members for applications assigned for review; and

- 5.3.4.3. The IRB Chair will give a reminder at the beginning of a convened IRB meeting to disclose conflicts of interest on the protocols and actions being reviewed.
- 5.4. Individuals Responsible for Business Development: Individuals responsible for business development are prohibited from serving as members on the IRB or carrying out day-to-day operations of the review process.
 - 5.4.1. For example, the director of grants and contracts, the vice president for research, or deans of research who are responsible for raising funds or gaining support for research will not serve as IRB members or be involved in the daily operations of the IRB.
- 5.5. Financial Conflicts of Interest: USM and ORIO have systems in place to evaluate Financial Conflicts of Interest.
 - 5.5.1. USM's Research Service Center (RSC) includes ORIO in external funding requests and award notifications.
 - 5.5.2. ORIO verifies key personnel listed on the requests and awards are compliant with *HRPP-045 Financial Conflicts of Interest SOP*.
 - 5.5.2.1. Verify a Financial Conflict of Interest Disclosure form has been submitted to ORIO in the previous 12 months and their CITI conflict of Interest training is current within the past 4 years.
 - 5.5.2.2. If an individual is not compliant, reply back to grants management and the key individuals with instructions to be in compliance. Then notify the RSC when individuals are compliant.
 - 5.5.2.3. ORIO receives the Conflict of Interest Disclosure forms for review. The RSC is included in reminders to key individuals that disclose form and/or training is coming due.
 - 5.5.3. The online protocol submission platforms ask for funding source(s). The human subject research platform has a subsection to disclose any conflicts of interest.
- 5.6. Organizational Conflicts of Interest: USM and ORIO have systems in place to evaluate Organizational Conflicts of Interest.
 - 5.6.1. Annually, all institutional leaders are required to report individual financial interests with organizations that do business, or intend to do business, with USM.¹

¹ The UMS policy states "if an employee believes that they may have a conflict of interest, the employee shall promptly and fully disclose the conflict to the appropriate administrator (Chancellor or President's designee) and shall refrain from participating in any way in the matter to which the conflict relates until the conflict questions has been resolved,"

- 5.6.2. Disclosure of interest in an entity that reasonably appear to affect institutional processes with which the IRB and the ORIO carry out their responsibilities will be forwarded to the RCA by Human Resources for determining if any of the reported financial interests might significantly and directly influence or to be influenced by human subject research project(s).
 - 5.6.2.1. When such relationships are deemed to exist, the RCA will communicate this information to the IRB Chair.
- 5.6.3. When an organizational conflict of interest exists, the RCA will work closely with the IRB Chair to determine if the conflict could affect the rights and welfare of subjects participating in the project, the integrity of data collected, or objectivity. by which the human research protocol is managed.
 - 5.6.3.1. At a minimum, conflicted individual(s) will be excluded from the decision-making process and oversight of the research and will not be engaged to direct or take administrative actions.
 - 5.6.3.2. The evaluation criteria do not vary by funding agency or regulatory oversight.
 - 5.6.3.3. Evaluation considerations will include whether disclosure in the consent form is adequate to protect human subjects or if additional safeguards are needed.
 - 5.6.3.4. If the RCA and IRB Chair determine that an organizational conflict of interest could affect the rights and welfare of participants, the integrity of data collected, or objectivity by which the human research protocol is managed, then the conflict of interest must be eliminated or a management plan implemented so that the rights and welfare of participants and integrity of the research projects are not affected by the interest.
- 5.6.4. The RCA will communicate with the Provost to assure that conflicted institutional leaders are relieved of administrative oversight of related human research protections when necessary.
 - 5.6.4.1. The key to avoiding these situations is awareness of what constitutes such conflicts, disclosure of potential situations before activity is undertaken, and a review of the situation.
- 5.6.5. A determination may be made by the RCA to, in certain cases, permit an activity, which may otherwise be considered a conflict, if it is:
 - 5.6.5.1. Purely personal to the individual or beneficial to USM, and
 - 5.6.5.2. Performed in full compliance with all legal, regulatory, and other requirements.

5.6.6. Details of organizational financial conflicts will be reported in the IRB minutes, including details of deliberations related to the conflicting interest.

6.0 References

- 6.1. Association of American Medical Colleges (AAMC), 1990;
- 6.2. National Academy of Sciences (NAS), Integrity in Scientific Research;
- 6.3. 45 CFR part 46.107 d;
- 6.4. 45 CFR 46.107(e);
- 6.5. 21 CFR 56.107(e);
- 6.6. Financial Conflict of Interest: HHS Guidance 2004;
- 6.7. Institutional Review Board Written Procedures: Guidance for Institutions and IRBs – OHRP and FDA (2018);
- 6.8. 42 CFR Part 50 and 45 CFR 94 Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (2011)
- 6.9. University of Maine System Policy Manual –Section 410 Conflict of Interest (1998)