



Human Research Protection Program / Institutional Review Board
Standard Operating Procedure
Pre-2018 Common Rule

**For Studies Initially Approved on
or Before January 20, 2019**

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1 Conflict of Interest in Research

It is MaineHealth policy to preserve public trust in the integrity and quality of research by reducing actual or perceived conflict of interest in the conduct of research.

Conflicts of interest (COI) in research can be broadly described as any interest that competes with an organization's or individual's obligation to protect the rights and welfare of research subjects, the integrity of a research study, or the credibility of the research program. Conflicts of interest can be financial or non-financial.

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

1.1 Researcher Conflicts of Interest

Pursuant to the Policy on Conflict of Interest in Research ("COI Policy"), MaineHealth maintains a Research Conflict of Interest Committee (RCOIC) Committee). MaineHealth IRB collaborates with the RCOIC to ensure that COI of investigators and research team members are identified and managed before the IRB completes its review of any research application.

1.1.1 Procedures

1.1.1.1 Disclosure of Researcher COI

In addition to other triggers for reporting disclosures (e.g., time of funding application, annual institutional requirements), investigators must disclose their significant financial interests (SFI-as defined in the COI policy) each time a human subject proposal on which they are named is submitted to the IRB or to a Central IRB for research to be conducted at MaineHealth or under the auspices of MaineHealth. Specific triggering events involving human research are: new study submissions, continuing reviews, additions of a new investigator, and whenever an investigator updates their MaineHealth COI disclosure indicating a new or changed interest.

All research disclosures are made via an electronic financial disclosure form to be maintained by the ORC. The ORC will perform an initial review of submitted disclosures and will determine the presence of an SFI as defined in the COI Policy. Where an SFI is deemed present, and there is possible or probable potential for the SFI to influence the design, conduct and/or reporting of a research study (i.e., an FCOI exists), the Investigator and their Department Chief (or direct supervisor) will be contacted by an RCOIC delegate and asked to provide, for RCOIC review, one or both of the following:

- Documentation, to include specific detail, addressing factors that may contribute to, or negate, a potential finding by the RCOIC of an actual (or perceived) conflict of interest.
- A proposal to include actions or methods to be taken to prevent, or manage, an actual (or perceived) conflict of interest.

The case with all supporting documents will be reviewed a convened meeting of the RCOIC. If an FCOI is found, a conflict management plan (CMP) is drafted and submitted to the IRB for further review and

consideration. When the research is under an external IRB, any conflicts identified as the result of COI review and any CMP are provided to the external IRB in accordance with the IRB reliance agreement.

1.1.1.2 Evaluation of COI

The IRB will review COIs and CMPs to determine:

1. Whether the COI affects the rights or welfare of research subjects;
2. Whether the COI might adversely affect the integrity or credibility of the research or the research program; and
3. Whether the CMP effectively protects research subjects and the integrity and credibility of the research and the research program.

In evaluating COIs and CMPs, among other factors the IRB will consider:

1. How the research is supported or financed;
2. The nature and extent of the conflict;
3. The role and responsibilities of the conflicted individual in the design, conduct, and reporting of the research; and
4. The ability of the conflicted individual to influence the outcome of the research.

1.1.1.3 Management of COI

The IRB has final authority to determine whether the research, the COI, and the CMP, if any, allow the research to be approved. With regard to the CMP issued by the RCOIC, the IRB may include additional requirements and may also make modification requests. The IRB can require additional measures to manage a COI so that the research may be approved. However, the IRB cannot weaken a CMP approved by the RCOIC.

For example, in addition to the CMP, the IRB may require:

1. Disclosure of the COI to subjects through the consent process;
2. Modification of the research plan or safety monitoring plan;
3. Monitoring of research by a third party;
4. Disqualification of the conflicted party from participation in all or a portion of the research;
5. Appointment of a non-conflicted PI;
6. Divestiture of significant financial interests; and/or
7. Severance of relationships that create actual or potential conflicts.

In the event the conflict cannot be effectively managed, the IRB may disapprove the research.

A research project will not be approved unless and until the CMP has been approved by the IO, the RCOIC, and the IRB.

1.2 IRB Member Conflict of Interest

No IRB member or alternate may participate in the review of any research project in which the member has a COI, except to provide information as requested. It is the responsibility of each IRB member to disclose any COI related to a study submitted for review and recuse himself or herself from the deliberations and vote by leaving the room.

All members and alternate members of the IRB complete a conflict disclosure when first appointed and annually thereafter or sooner when their circumstances change. These forms are submitted to the Office of Research Compliance. Disclosures of COI are reviewed by the IRB Chair who will work with the member to eliminate or manage the disclosed COI. To protect the privacy of members, the specific details of the conflict will not be given to staff or other members; however, the type of research where a COI exists will be provided (e.g., studies from X sponsor; studies using X device/drug; studies involving X investigator). The RRC staff, in turn, ensures that IRB members and alternates are not assigned to conduct reviews of studies for which the member has a conflict and reminds members of conflicts at convened meetings as needed to ensure recusal. IRB staff may consult with the IRB Chair to clarify whether a specific study involves a member COI.

IRB members, alternates, or consultants may be considered to have a conflicting interest requiring recusal when they, or an immediate member of their family, have any of the following:

1. Involvement in the design, conduct, and reporting of the research;
2. Significant financial interests (see COI Policy for a definition of significant financial interests) related to the research being reviewed; or
3. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a study.

The IRB Chair will remind IRB members at the beginning of each convened meeting that if any members have a COI regarding any of the items to be reviewed, they must recuse themselves by leaving the room during the discussion and vote of the specific research study. If a conflicted member is participating by conference call, videoconference or web meeting, the member's participation (connection) is terminated for discussion and voting.

If an IRB member is conflicted on an agenda item for review by the convened board, the conflicted member will not have access to the committee review in IRBNet.

IRB members with a conflicting interest are excluded from being counted towards quorum. Recusals of members with COIs are recorded in the minutes.

1.3 Institutional Conflict of Interest

As an organization that conducts and reviews research involving human subjects, MaineHealth recognizes its obligation to protect the rights and welfare of those subjects, and ensure the integrity of the research and the human research protection program. Toward this end, the financial interests of MaineHealth or its senior administrative officials must be identified, evaluated, managed, and minimized or eliminated in order to ensure that meeting that obligation is not jeopardized.

1.3.1 Definition of Institutional Financial Conflicts of Interest

An “Institutional Financial Conflict of Interest” arises in human subjects’ research when a financial interest of MaineHealth may affect or appear to affect the design, conduct, reporting, review, or oversight of the human subjects’ research. Institutional financial conflicts of interest are of significant concern when they create the potential for inappropriate influence over a human subjects’ research project, particularly to the integrity of the research and the safety and care of subjects enrolled in the research. All forms of potential Institutional Financial Conflicts of Interest in human subjects’ research require disclosure, evaluation, and either management or elimination under this Policy.

Note that it is MaineHealth’s policy to prohibit receipt of gifts or gifts in kind from a potential commercial sponsor of human subjects research or a company that owns or controls products being studied or tested in human subjects research.

An “Institutional Financial Conflict of Interest” (IFCOI) exists when:

1. MaineHealth receives or might reasonably be expected to receive royalty income from the sale of a product covered by any patent, license or copyright, whether issued or pending, held by, and is proposed to be used in human subjects’ research projects, at MaineHealth;

2. MaineHealth holds or proposes to hold, directly or indirectly, any equity interests of any amount (or entitlement to the same), in research sponsors of human subjects’ research projects, whether such research sponsor is public or non-public, through its technology licensing activities or investments related to such activities;

and/or

3. MaineHealth Senior Administrative Officials with direct responsibility for human subject research (or their spouse, dependent children), as defined in Section II below:

a. Hold positions such as an officer, trustee, director, employee or consultant in commercial research sponsors, or any company that owns or controls products being studied or tested in human subjects

b. Receive remuneration from commercial research sponsors, or any company that owns or controls products being studied or tested in human subjects. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);

c. Hold any equity interest (e.g., stock, stock option, or other ownership interest) in commercial research sponsors, or any company that owns or controls products being studied or tested in human subjects

d. Hold Intellectual property rights and interests (e.g., patents, copyrights), royalties from such rights, etc. relating to products being studied or tested in human subjects

1.3.2 Reporting

The ORC, in consultation with the RCOIC, will be advised of any annual disclosures from individuals in which significant financial interests relating to human research are identified. The ORC will, in turn, contact the affected individuals to receive confirmation that they will not be involved in the scientific

merit, resource review, or any other review relating to research with which they have an SFI. Such confirmation will constitute the management plan that mitigates the potential COI (see also 'Conflict Management Plan' section below).

1.3.3 Review and Evaluation

IRB proposals submitted in IRBNet will be assessed (in advance of IRB review and approval) by an RRC for potential IFCOI by assessing applicability of information contained within the reports referred to above. As a matter of policy, MaineHealth will not participate in a human subjects' research project when it has an IFCOI. An exception to this policy may be made only when the Institutional Review Board, in consultation as deemed necessary with the RCOIC determines that:

- Circumstances exist to justify MaineHealth's participation in the project while still maintaining the protection of human subjects, and
- A conflict management plan is adopted to maintain research integrity and serve the best interests of subjects enrolled in the research. These circumstances and conflict management plans will be documented.

1.3.4 Conflict Management Plan

If MaineHealth's participation in a project is permitted notwithstanding the IFCOI, MaineHealth's participation will be subject to a conflict management plan developed and approved by the IRB as above. In the case of senior administrative officials, the conflict management plan shall be agreed to by the conflicted individual. The IRB has the final authority to determine whether any IFCOI and its management allows the research to be approved. Options for managing institutional conflict of interest, include but are not limited to the following:

- Disclosing the institutional conflict of interest to research subjects in the consent process and documents.
- Disclosing the institutional conflict of interest to any journals or other publications for which the results of the research will be submitted.
- Recusing of conflicted senior administrative officials from scientific merit review of human research
- Having an external, independent IRB review the research in question
- Monitoring of research by independent reviewers
- Divestiture of financial conflicts of interests
- Severance of relationships that create actual or potential conflicts.
- Prohibition of the conduct of the research at the MaineHealth.

1.3.5 Timing

The review, evaluation, and where applicable, management of an IFCOI shall be completed prior to the account establishment of an award for the human subjects' research project or any commencement of the project (including enrollment of any research subjects), whichever comes first. IRB proposals will remain unapproved, pending approval by IRB of the conflict management plan.

1.4 Recruitment Incentives

Payment arrangements between or among sponsors, organizations, investigators, research personnel, and those referring research participants present a conflict of interest and may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective participants (finder's fees) is not permitted. Similarly, payments designed to accelerate recruitment that is tied to the rate or timing of enrollment (bonus payments) are also not permitted. Bonus payments do not include payments for bona fide items or services.