

To promote objectivity in the review of NDSU human subjects research, an IRB member is prohibited from participating in the review of any protocol in which financial, personal or political interests may conflict with their responsibility to protect research participants.

1.0 Protocol-related conflicts of interest.

An IRB member, staff or consultant may have financial, personal or political interests that are related to a protocol under review, which may bias consideration for the protection of subjects.

1.1 Financial interests.

Financial interests related to the research (the sponsor, product or service being tested, or a competing product or service) may constitute a conflict of interest (COI) with the potential to bias IRB review of the research. Protocol-related financial interests of an IRB member, staff or consultant (including their immediate family members) may include:

- compensation related to the research;
- ownership interest of any value related to the research (excluding publicly-traded funds); or
- proprietary interests (e.g., patent, trademark, copyright or licensing agreement).

1.2 Personal or political interests.

Personal or political interests of an IRB member, staff or consultant (or interests of immediate family members) may also constitute a COI with the potential to bias review of the research. Examples of personal or political interests related to a research protocol may include:

- involvement in the design, conduct or reporting;
- supervisory relationship with PI;
- executive or administrative responsibilities for a sponsor or an external entity associated with the research;
- consulting activities;
- membership in a political party that may be positively or negatively impacted by the research under review; or
- any other reason for which a member feels they may lack objectivity in review of the protocol.

2.0 Identification of COI.

A member of the IRB may not participate in the deliberation or review of any protocol for which they have a COI, except to provide information. While some conflicts may be readily apparent (e.g., involvement as PI or co-investigator), each member is responsible to disclose any COI as they become aware of a protocol submitted for IRB review.

2.1 Expedited review or exempt determinations.

Protocol review assignments are made with the intention of avoiding protocol-related conflicts of interest. In the event a member is assigned to review a protocol for which they,

or a member of their immediate family has a conflicting interest, it must be disclosed to the IRB Chair or HRPP staff to allow re-assignment to another experienced member.

2.2 Full board review.

Primary review assignments are made with the intention of avoiding protocol-related conflicts of interest. In the event a member is assigned as primary reviewer for a protocol for which they, or a member of their immediate family has a conflicting interest, it must be disclosed to the IRB Chair or HRPP staff to allow for re-assignment to another experienced member. At the beginning of each convened meeting, all IRB members disclose any COI related to protocols to be reviewed by the full board. A conflicted member may answer questions and provide information related to the study, but must recuse themselves from review and leave the meeting during deliberation and voting on the protocol.

2.3 Consultants.

An individual with expertise in a particular area may be invited as a consultant to provide information related to a protocol under review by the IRB. Although a consultant does not vote, regardless of the existence of a COI, they must disclose any COI related to a protocol prior to providing information or responding to questions from the board.

DEFINITIONS:

Conflict of interest (relating to human subject protections): an interest in the outcome of the research that conflicts with, or has the potential to create a bias in, consideration for the rights, safety and welfare of research participants

Immediate family: spouse and dependent children

Investigator: project director, principal investigator and any other person responsible for the design, conduct, or reporting of research (for purposes of financial interests, also includes immediate family members)

REFERENCES:

[45 CFR 46.107\(e\)](#) and [21 CFR 56.107\(e\)](#) IRB membership

[Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection](#), Dept. of Health and Human Services

[NDSU Policy Section 151:](#) Code of Conduct

[NDSU Policy Section 151.1:](#) External Activities and Conflicts of Interest

RELATED FORMS:

IRB Protocol Form

Protocol Amendment Request Form

Continuing Review or Completion Report Form

RELATED HRPP SECTIONS:

4.1 IRB Membership

4.2 IRB Meeting Procedures

6.2 Conflict of Interest: Investigator and research team

- 7.3 Expedited Review
- 7.4 Full Board Review