

To promote objectivity in the design, conduct and reporting of NDSU research, an investigator's actual and apparent conflicts of interest require disclosure and management to minimize the potential for biased judgments, including those affecting the rights and welfare of human participants.

1.0 Potential impact to research participants.

Personal, financial, or political interests may conflict with an investigator's primary concern for the rights and welfare of NDSU research participants. These conflicts may bias decisions in various stages of the research, such as:

- study design (selection of design to favor a desired outcome);
- subject enrollment (awarding recruitment bonuses or using undue influence to increase participation);
- eligibility determinations (non-objective application of inclusion and exclusion criteria);
- informed consent (use of coercion, failure to discuss alternatives);
- evaluation of study endpoints (use of subjective criteria);
- data analysis (selective analysis to show a desired outcome); or
- adverse event reporting (failure to recognize and/or report adverse events and unanticipated problems related to the research).

2.0 Disclosure of actual and apparent conflicts of interest.

In accordance with NDSU conflict of interest (COI) policies (NDSU Policy 151.1, *External Activities and Conflicts of Interest*, and 823, *Financial Disclosure – Sponsored Projects*), NDSU employees disclose any external activities and significant financial interests that are related to, and may conflict with their NDSU responsibilities, including research. These interests, including those of an investigator's immediate family members (spouse, parents, siblings and children) are disclosed to the administrative head of the unit in which they are employed.

2.1 Applicable personnel.

For the purposes of IRB review of non-exempt human subjects research, NDSU investigators (faculty, staff and students) involved in design, conduct and reporting of the project disclose on the IRB protocol form any personal, financial, and political interests related to, and potentially affected by the outcome of the research. Non-NDSU investigators involved in a collaborative research project may be subject to similar policies at their home institution, but also must disclose any related conflicts of interest to the PI of the project.

2.2 Financial interests.

For the purposes of IRB review, financial interests related to the research (the sponsor, product or service being tested, or a competing product or service) may constitute a COI with the potential for bias in decisions related to research, including subject protections. As described in NDSU COI policies, disclosure and review is required for significant financial interests in an external entity related to the research.

Significant financial interest is defined as:

- 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); or
- intellectual property rights (e.g., copyrights, trademarks, patents, and royalties for such rights).

The term does not include:

- salary, royalties, or other remuneration from NDSU or the NDSU Research Foundation, if such payments have not originated with the sponsoring agency;
- income for seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committee or review panels for public or nonprofit entities; or
- financial interest in business enterprises or entities if the value of such interests (industry equity interest, salary, fees, or other continuing payments) does not exceed \$10,000 per annum or represents more than 5% ownership interest for any one enterprise or entity when aggregated for the investigator, their spouse, and children.

For the purposes of human subjects research, significant financial interests would also include recruitment or enrollment incentive payments, as well as payments based on a favorable outcome.

2.3 Personal or political interests.

For the purposes of IRB review, non-financial relationships with external entities that are related to the research (the sponsor, product or service being tested, or a competing product or service) also may constitute a COI with potential for bias in decisions related to research, including the protection of subjects. As part of NDSU COI policies, disclosure and review is required for personal or political interests in an external entity related to the research, such as:

- executive or administrative responsibilities;
- board memberships;
- consulting activities;
- membership in a political party potentially impacted by the research; or
- any relationship that may influence the research, resulting in improper advantage for the investigator or immediate family.

3.0 IRB review of human research involving conflicts of interest.

As part of the expedited and full board review process, the IRB determines whether an investigator's personal, financial, and political interest has the potential to bias judgments and compromise the rights, safety and welfare of research participants. Conflicts of interest are not considered when research is certified as eligible for exemption.

3.1 IRB protocol application.

The investigator provides information on any financial, personal or political interests to the IRB by responding to relevant questions on the protocol submission form (new review,

amendment or continuing review), and attaching documentation of NDSU COI determination and any management plan, as applicable. The PI is responsible for conferring with co-investigators and key personnel on the project to ascertain any interests related to the research.

3.2 IRB evaluation criteria.

In review of the protocol submission and COI determination, the IRB considers the potential impact of the COI on research participants. The evaluation may include criteria such as:

- whether the COI is actual or merely apparent;
- a conflicted investigator's role in human subjects interactions and decisions;
- the extent to which an external interest may introduce bias into decisions;
- the potential for adverse effects to participant's rights and welfare; and
- level of risk in the research.

The IRB may determine that the COI:

- represents no potential adverse impact to participant's rights and welfare;
- is adequately addressed by the NDSU COI determination or management plan to minimize potential for bias in decisions regarding research participants; or
- requires additional conditions or restrictions to minimize potential for bias in decisions regarding research participants.

3.3 Additional conditions or restrictions.

In order to approve research, any COI that may impact research participants must be sufficiently minimized or managed to avoid compromising the rights and welfare of subjects. Where the applicable administrative head or Vice President has already imposed conditions or restrictions to manage the COI the IRB may not eliminate or alter the management plan, but may impose additional stipulations when appropriate to address human subject protection issues.

The IRB may direct that participants be informed of an investigator's COI. In addition, any of the following strategies may also be required to minimize the potential for bias in the research:

- removal of a conflicted investigator's decision-making authority in:
 - study design;
 - subject recruitment;
 - eligibility determinations (applying inclusion/exclusion criteria);
 - informed consent process;
 - research interventions;
 - clinical evaluation of subjects;
 - monitoring adverse events; or
 - data analysis or reporting;
- use of blinding or randomization in the study design;
- removal of a conflicted investigator as principal investigator;
- involvement of an independent third party or subject advocate; or
- other terms, limitations or restrictions as necessary to protect subjects.

In accordance with procedures for expedited and full board review, the IRB documents any stipulations for approval of research involving a COI. Refer to SOPs 7.3 *Expedited Review* and 7.4 *Full Board Review* for more information.

4.0 Ongoing review and monitoring.

Conflicts of interest require ongoing review and monitoring as necessary to maintain objectivity in the design, conduct and reporting of research.

4.1 Changes in external interests.

As described in NDSU COI policies, investigators are responsible for prompt notification of changes in financial, personal or political interests related to their University obligations. The investigator also notifies the IRB when such changes involve human subjects research, including any new COI determination and/or applicable management plan.

4.2 Continuing review of research.

At the time of continuing review, the investigator includes information on related financial, personal or political interests in the IRB report, along with a summary of the research, including enrollment, withdrawals, complaints, adverse events, and unanticipated problems not previously reported. The IRB considers whether any changes in the previously approved protocol are necessary to ensure continued protection of the rights and welfare of participants.

4.3 Review of protocol amendments.

When submitting an amendment request, the investigator also includes information on any related financial, personal or political interests. This would include any related interests for new members of the research team. The IRB considers whether any additional changes are necessary to protect participants against bias in the conduct of the research.

5.0 Violations and noncompliance.

As described in NDSU COI policies, the University applies sanctions for failure to comply with requirements for disclosure and review of external interests, as well as any restrictions or conditions imposed to manage the COI. In addition, where the violation involves a human research project and compromises the rights, safety or welfare of participants, IRB noncompliance procedures, as described in SOP 12.3 *Complaints or Allegations of Noncompliance*, will apply.

DEFINITIONS:

Conflict of interest (related 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

1. An investigator has an actual conflict of interest when he or she has personal, financial, or political interests that undermine his or her ability to meet or fulfill his or her primary professional, ethical, or legal obligations to the human research subjects or the university.

2. An investigator has an apparent conflict of interest when he or she has personal, financial, or political interests that do not undermine his or her ability to meet or fulfill

his or her primary professional, ethical, or legal obligations to the human research subjects or university, but that create the perception of a conflict.

Immediate family: includes spouse, parents, siblings and children

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

REFERENCES:

[Financial Relationships and Interests in Research Involving Human Subjects](#): Guidance for Human Subject Protection, Dept. of Health and Human Services
[21 CFR Part 54](#) Financial Disclosure by Clinical Investigators, Food and Drug Administration
Researcher Conflict of Interest, Chapter 3-2 in *Institutional Review Board Member Handbook*, 2nd Ed., R. Amdur and E. Bankert, 2007
[NDSU Policy Section 823](#): Financial Disclosure – Sponsored Projects
[NDSU Policy Section 151](#): Code of Conduct
[NDSU Policy Section 151.1](#): External Activities and Conflicts of Interest

RELATED FORMS:

IRB Protocol Form – [COI section](#)
Protocol Amendment Request Form
Continuing Review or Completion Report Form
[Proposal Transmittal Form \(PTF\)](#)
[NDSU Conflict of Interest Form](#)

RELATED HRPP SECTIONS:

6.1 Conflict of Interest: IRB members
7.2 Criteria for IRB Approval
7.3 Expedited Review
7.4 Full Board Review
7.5 Protocol Amendments
7.6 Continuing Reviews