Financial Conflict of Interest Policy
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Purpose:
To establish policies and procedures related to assuring that human subjects are adequately protected in research studies where a conflict of interest exists for one or more study team members.

Definitions:

1. Conflict of Interest means a divergence between an individual’s private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the professional actions or decisions of an individual is determined or influenced by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and on the character or actions of the individual. For the purposes of this policy, a conflict of interest exists when the University, through procedures described herein, reasonably determines that a significant financial interest could affect directly and significantly the design, conduct, or reporting of research involving human subjects.

2. Financial Conflict of Interest (FCOI) means a reasonable determination that an investigator’s significant financial interest is related to a research study involving human subjects and could directly and significantly affect the design, conduct or reporting of the research.

3. Significant Financial Interest means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, paid authorship); equity interests (e.g., stocks, stock options or other ownership interest); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights), whether or not the value is readily ascertainable, that reasonably appears to be related to the Investigator’s institutional responsibilities.

- With regard to any publicly traded entity, if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.
- With regard to any non-publicly traded entity, if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
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- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities, no matter the dollar level.

4. Study team means any person, including the project director, principal Investigator and/or co-investigator, who is responsible for the design, conduct or reporting of the research. A Study Team member’s spouse, domestic partner, and dependent children are also included for purposes of disclosure and conflict of interest review.

Policy:

1. Potential financial conflicts of interest related to human subjects research add an additional dimension of concern for the Institutional Review Board (IRB). Conflicts of interest are not always prohibited because not all interests cause conflicts that impact research. However, the IRB recognizes that some conflicts of interest in research may affect the rights and welfare of human subjects. Conflicts of interest which may affect the rights and welfare of human subjects must be managed or eliminated so that they do not adversely affect participants in research.

2. As part of the submission of a human subjects research protocol to the IRB, study team members must disclose any interest consistent with the definition of a significant financial interest, as set forth above. The disclosure must describe the nature of that interest and its relationship to the proposed protocol. In addition, study team members must disclose any significant financial interest on an annual basis during continuing review, and immediately as new conflicts arise. Excluded from this disclosure requirement are the following financial interests:

- Salary, royalties, or other remuneration from the institution if the Investigator is employed by the institution
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles even if higher than the $5,000 significant financial interest threshold;
- Income from seminars, lectures, or teaching assignments sponsored by a federal, state, or local government agency of the United States, an institution of higher education within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education within the United States;
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- Income from service on advisory committees or review panels for a federal, state, or local government agency of the United States, an institution of higher education within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education within the United States;
- Travel that is reimbursed or sponsored by a federal, state, or local government agency of the United States, an institution of higher education within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education within the United States;
- Intellectual property rights assigned to the University and agreements to share in royalties related to such rights;

3. Studies that are sponsored programs funded by a governmental agency must abide by the required procedures for disclosing and managing financial conflicts of interest as outlined in the Office of Sponsored Programs’ Financial Conflicts of Interest in Sponsored Programs policy (http://www.nova.edu/ogc/forms/compliance_conflict_interest.pdf). The IRB may request a copy of the disclosure forms and/or management plans to determine that the rights and welfare of the subjects are adequately protected. Following the IRB’s independent review of the disclosure forms and/or management plans received from the Office of Sponsored Programs, the IRB may require additional stipulations related to the protection of the human subjects to manage the financial conflict of interest.

4. It is the responsibility of the IRB to determine whether the disclosed significant financial interest may affect the rights and welfare of the human subjects and if so, what actions could be considered to protect those subjects. The IRB shall propose specific mechanisms to mitigate the conflict in order to protect the interests of potential research subjects.

5. Studies that involve a significant financial interest may be reviewed at the center level or at the expedited level as long as they meet the exempt or expedited criteria as defined by 45 CFR 46.

6. In general, if conflicts of interest are identified, the IRB shall make the determination of whether the person with the conflict shall be part of the study and/or if his/her participation should be limited or excluded. The IRB’s determination may include limitations on: design of the study, monitoring the study, obtaining the informed consent, adverse event reporting, and analyzing the data.
7. The process of informed consent requires that a potential research subject consider the risks, benefits, and alternatives to the proposed research intervention. They must be given all the information that would be reasonably relevant to their choice, including information about potential conflict of interest. As part of the informed consent process, potential subjects should be informed about financial conflicts of interest in language that conveys the nature of the conflict and facilitates comprehension. Therefore, if a significant financial interest exists, the investigator should include the following suggested language on the consent forms: “The principal investigator and/or co-investigator(s) of this research study have a significant financial interest as it relates to this study” or “An investigator on this study has a relationship with the company sponsoring the research as follows: [insert specifics].”

Procedures:

1. The Principal Investigator will report any potential conflict of interest related to the research study in section 1.H. of the Submission Form for Initial Review. The Principal Investigator is also responsible for reporting to the IRB whether any study team members identify or disclose a potential conflict of interest. The Principal Investigator is also responsible for ensuring that study team members comply with any measures put in place to manage the conflict.

2. For studies that are sponsored programs funded by a governmental agency, the IRB office will work in collaboration with the Office of Sponsored Programs to request a copy of the disclosure forms submitted by the investigator.

3. The Board will review the conflict of interest to evaluate if it may affect the rights and welfare of the human subjects participating in the research study. If the Board determines that the conflict of interest may affect the rights and welfare of the human subjects, the Board will determine what actions could be considered to protect those subjects, and propose specific mechanisms to mitigate the conflict in order to protect the interests of potential research subjects. Evaluation considerations may include whether disclosure in the consent form is adequate to protect human subjects or if additional safeguards are needed. The Board’s management plan for the conflict will be communicated to the principal investigator in writing and sent via electronic mail. For studies that are determined to be exempt from 45 CFR 46, the center representative, on behalf of the Board, will determine the mechanisms to mitigate the conflict (if any are necessary). For studies that meet the expedited criteria, the IRB Chair or his/her designee, on behalf of the Board, will determine the mechanisms to mitigate the conflict (if any are necessary).

Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate actual or potential conflicts of interest include but are not limited to:
Public disclosure of the relationship, significant financial interests, and/or intellectual property;
Disclosure of financial conflicts of interest directly to human subject participants (conflicted PI may not be permitted to consent human subjects);
Monitoring of research by independent reviewers;
Modification of the research plan;
Disqualification from participation in the portion of the governmental agency-funded research that would be affected by the significant financial interests;
Divestiture of significant financial interests; or
Severance of relationships that create actual or potential conflicts.

All management plans shall contain, at a minimum, the following elements:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator’s agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance.

Additionally,

- All relevant publications, proposals and presentations should contain a statement disclosing support received from, or financial interests in, any source outside of the University;
- The PI will not participate in any intellectual property negotiations, or other negotiations, between the University and the outside entity;
- PI must notify students of the presence of a Conflict of Interest if the student is to perform as a research assistant on the research along with notification to the student’s advisor.

4. If a study team member conflict of interest develops after IRB approval, the investigator should immediately notify the center representative (in the case of an exempt study), the IRB Director and/or IRB Chair, submit the change as an amendment to the approved protocol and include a revised consent form including a statement address any potential conflict of interest. For studies that require a full review, the IRB Director will place the amendment submission on the upcoming IRB agenda for discussion by the IRB.
5. For studies reviewed at the expedited level or by the full Board, study team members must also disclose any significant financial interest on an annual basis during continuing review via the Submission Form for Continuing Review.

**Noncompliance with the Policy**
Failure to comply with a determination of the IRB or to comply with this policy, including the failure to file timely disclosures; filing incomplete, erroneous, or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving conflicts of interest, will be addressed by the IRB and the appropriate dean.