14.1 Executive Summary
Conflicts of interest (COI) in research can adversely impact the integrity of research results and the confidence of prospective participants in research. The University seeks to identify, disclose, and avoid or manage conflicts to avoid these negative repercussions. In this document you will find information about NC State University’s IRB’s policy and standard operating procedure regarding Conflicts of Interest. This process is supplemental to the required NC State University COI disclosure.

14.2. Policy
All NC State University researchers are expected to comply with the NC State University regulation 01.25.01 Conflicts of Interest and Commitment and they are expected to submit a COI Disclosure to NC State University at least annually and, if applicable, comply with provisions made in their written management plan. NC State University researchers completing research with human subjects must disclose all Conflicts of Interest (financial and otherwise) related to a specific research study involving human subjects through the IRB application.

14.3. Standard Operating Procedure (SOP)
Upon submitting an IRB application, the principal investigator and all researchers involved in the study must assert that their current COI Disclosure and any necessary management plan(s) are up to date and executed. Within the IRB application, the researchers must address any conflicts of interest (financial or otherwise) that may affect the rights and welfare of participants, participants’ understanding of the purpose of the research, and issues related to data integrity.

All management plans must be considered and properly accounted for within the study design. The IRB is authorized to access the COI Disclosure forms for all individuals involved in the study protocol. The IRB has final authority as to if human subjects research may proceed, irrespective of the independent supervisory authorization of a COI disclosure and management plan.

14.3.a Conflicts of Interest
14.3.a.i. Financial Conflicts of Interest. Conflicts of interest arise when a researcher could financially benefit from their research, causing or appearing to cause potential bias in its design, conduct, or reporting (See Appendix A)

14.3.a.ii. Other Conflicts of Interest. Other conflicts of interest may include the desire to obtain and publish research findings that lead to recognition and career advancement, vindication of one’s intellectual biases, support for friends and colleagues, or access to people or information due to roles and relationships. These can represent secondary interests that may have meaningful or even greater impact on professional judgment.

1. Indirect benefits with a financial element include support for the time and salaries of the investigator(s) and their staff. While not providing financial gain beyond the institutional paycheck and the operating budget of the research endeavor such support defines the nature of the potential investigator’s professional position, identity, and activities, and thus, may have potential impact on professional judgments and actions.
2. Conflicts related to personal relationships or as a result of access and role often cause both real and perceived conflicts of interest while also possibly creating a culture of undue influence (See Appendix C)

3. When there is a perceived conflict of interest an observer cannot know with confidence that there is no real conflict of interest. As a result, there is no meaningful difference to participants between real, perceived, and potential conflicts of interest. The failure to effectively manage conflicts results in risk of personal and public mistrust, in reduced confidence in research results, and in risks leading to diminished public support for research.

14.3.b. Disclosing a Conflict of Interest to the IRB

14.3.b.i. Notifying the IRB

1. If the conflict exists or will exist at the time of IRB review, a researcher must disclose a real or perceived conflict of interest within the initial application to the IRB and ensure that it is reflective of the COI Disclosure on record with NC State

2. If a conflict arises once IRB approval has been granted, a researcher must disclose the real or perceived conflict of interest to the IRB via an Amendment request to the approved study. You must also update your COI Disclosure with NC State University as required by regulation 01.25.01

14.3.b.ii. Notifying Stakeholders: In addition to all parties identified in your COI management plan, when the conflict is determined to be allowable by the IRB, the following stakeholders must be informed of the conflict of interest:

1. Research subjects and their legally authorized representative, guardians, or advocates: Information regarding the conflict must be included in the Informed Consent Process.

2. External regulatory authorities (e.g. the state or federal agencies or as required by statute)

14.3.c. Timing of COI Disclosures

All NC State employees must file a COI disclosure with North Carolina State University at least annually in order to adhere to University regulations. If circumstances change, they must file a revised COI disclosure within 30 days of the change to notify the University accordingly. New employees must file a COI disclosure within 30 days of their start date.

Any conflicts of interest related to human subjects’ research must be reported to the IRB at initial submission of the IRB application or submitted as an Amendment to a study within 30 days of the conflict being in effect.

14.3.d. Information That Needs to be Disclosed

In addition to what must be disclosed in your NC State University COI Disclosure, your IRB application/protocol must include information regarding conflicts of interest and how the conflict may affect participants and the study design. Additionally information about mitigating the conflict must be included in the IRB application.

14.3.d.i Participants Rights and Welfare

1. You must disclose any conflict that affects participants’ perception of their role in the research and how their role will or will not benefit others (and who those other people are).

2. You must disclose any conflict that affects participants’ perception of voluntariness as a study participant, specifically addressing undue influence related to participant circumstance, environment, personhood, or status.
14.3.d.ii. Study Design and Outcomes
1. You must disclose when the conflict affects study design in a way that influences who is eligible to be in the study as a result of the selected inclusion/exclusion criteria.
2. You must disclose when the conflict affects the risks/benefits ratio to participants as a result of being a part of the study with a conflict of interest. This includes affecting study design by unduly influencing methods, products, and locations selected.
3. You must disclose when the conflict affects the data and findings from the project as related to bias in analysis and reporting.

143.3d.iii. Information regarding mitigating the conflict
1. A management plan is a document that outlines and implements safeguard measures to reduce, mitigate, or eliminate an actual, potential, or perceived conflict of interest held by a covered NC State affiliated individual (e.g. employee, graduate student, postdoc). It details the actions and measures you and your department head and/or associate dean for research will undertake to ensure your objectivity is maintained while performing research and other duties at NC State. Guidance on management plans can be found here.
2. In your IRB application, you will be asked to define procedures within the study that will be implemented to mitigate any real or perceived conflicts of interest.

14.3.g. Reporting to the IRB
Any identified conflict of interest related to human subjects' research must be reported to the IRB through the Human Subject Protocol System (eIRB) in a timely fashion. COIs can be reported at the initial submission or through an amendment if circumstances change.

14.3.h. IRB Risk/Benefit Analysis
The IRB has access to COI management plans established for researchers listed on the IRB application. IRBs include COI risk in their risk/benefit analysis and may place additional restrictions on the conflicted individuals or the research in its entirety, up to and including disapproving participation of a conflicted individual or disapproving the research. IRBs have final authority to determine whether any disclosed interest and its management allows the research to be approved. The IRB requires disclosure to potential subjects in the informed consent document if a key investigator, study team members, or the institution itself has a financial interest in the research.

14.3.h.i. Managing Conflicts of Interest
1. Regulation of the individual. This includes disclosure of financial interests, prohibition of products where the researcher has an equity interest, removal of processes where the researcher has problematic power dynamics with participants, abstention on behalf of the researcher regarding certain activities or access to information.
2. Design and Regulation of the Research Process. This includes optimization of research processes including researcher education around influence of bias, rigorous oversight by research supervisors, IRB review and approval of research projects, COI management plans, public registration of studies, proper analytic techniques, and avoidance of conflicts of interests on behalf of decision makers in management roles.
3. Critical Assessment of the Research Product. This includes a non-conflicted review of the study outcome, product, evaluation, and findings which can occur via peer review.
14.3.i. Failure to Comply

In accordance with the NC State University IRB policy for noncompliance, failure of investigators to comply with the requirements of the COI management plan could result either in termination of the study or in suspension of some or all study activities by the NC State IRB.

14.3.j. Conflicts of Interest of IRB Members, Consultants and Staff

14.3.j.i. An IRB member or a consultant with the IRB will recuse themselves from a review if they (and/or their spouse, domestic partner, close friend, research partner, or dependents):

1. Is an investigator or a team member of the study
2. Has a significant financial interest in the research
3. Has other conflicts that the member/consultant, the IRB, or the COI Committee believes might hamper that individual's ability to perform an impartial review.

14.3.j.ii. IRB members and consultants are also prohibited from participating in the following activities in which they have a conflict of interest:

1. Board review of the applicable IRB application, including meeting attendance, quorum count, deliberations for, and the vote on the disposition of the application
2. Review by expedited procedure
3. Review of unanticipated problems involving risks to subjects or others
4. Review of non-compliance with the regulations or the requirements of the IRB
5. The member or consultant may, however, be invited by the IRB meeting to provide information relevant to the IRB’s consideration of the application.
Appendix A
Significant Financial Interest (SFI)

Significant Financial Interest on COI disclosures
An SFI is defined as “a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities”

With regard to any publicly traded entity, an SFI exists 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. For the purposes of this definition, “remuneration” includes:

- Salary
- Any payment for services not otherwise identified as salary, such as:
  - consulting fees
  - honoraria
  - paid authorship
- Equity interest, which includes:
  - stocks
  - stock options
  - other ownership interests as determined through reference to public prices or other reasonable measures of fair market value

With regard to any non-publicly traded entity, an SFI exists 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) in the entity.

Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

NOTE: If the entity sponsors projects requiring the use of human subjects and approval from the Institutional Review Board, the above minimum remuneration and equity thresholds do not apply. In such cases, the disclosure threshold is any amount of payment and any equity.

On the COI disclosure, Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities.

- If the aggregate value of any sponsored or reimbursed travel by any single entity meets or exceeds $5,000 in the prior 12 months, then the following must be reported on your COI disclosure:
  - Purpose of the trip
  - Identity of the sponsor
  - Destination and duration of the trip
  - Total monetary value of the trip

NOTE: The above requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education.
Appendix B
Examples of Conflicts of Interest

- Any relationship you have with a third party that does business (such as sponsoring research or providing goods and services) with the University.

- Any relationship with a third party in which you hold a Significant Financial Interest (See Appendix A).

- Any External Professional Activity for Pay (EPAP) in which you receive $5,000 or more in remuneration of any kind (Salary, etc.).

- Any intellectual property (Patents, trademarks, licensing agreements, etc.) contractually obligated to you or the University in which you are the author or owner.

- Any relationship that you have with potential participants that may involve real or perceived power dynamics, issues of authority, possibility of reputational harm (teacher/student, doctor patient, supervisor/employee, parent/child, siblings)

- Researchers serving as participants in their own research project (see IRB guidance)

- Participating in University research involving Intellectual Property (IP) owned by or contractually obligated to a business in which the individual or their immediate family has a consulting relationship, has a Significant Financial Interest, or holds an executive position (For example, start up companies)

- Requiring students to purchase the textbook or related instructional materials of the employee or members of their immediate family, which produces compensation for the employee or family member

- Serving on the board of directors or scientific advisory board of an enterprise that provides financial support for the employee or their immediate family to conduct University research

- Having a Significant Financial Interest in a business which sponsors the employee’s research

- Family members working together on a sponsored project

- Having a Significant Financial Interest in a business that hires an NC State student whom the employee serves in a supervisory or mentoring capacity

- Having a Significant Financial Interest in a business which sells merchandise or services to the University while simultaneously working in the University business unit that makes purchasing decisions
Appendix C
Undue Influence

Undue influence occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. In addition to undue influence that can arise with the offering of rewards, undue influence also can be subtle because influence is contextual. Undue influence is likely to depend on an individual’s situation.

1. Undue influence may come about due to the participant’s environment.
   a. Consent/Assent may only be sought under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate in the research.
   b. This includes considering time, researcher role, and place where participants are recruited, consented, and engaging in research activities.

2. Undue influence may come about due to people with real and perceived authority over the possible participant.
   a. Undue influence may come from people such as parents and guardians, teachers, principals, administrators, medical professionals, case workers, service providers, coaches, religious leaders, siblings, and public figures such as police, fire fighters, government officials.
   b. When considering the recruitment, consent, and data collection methods, researchers must design their research to manage any aspects of undue influence as a result of power dynamics.

3. Undue influence may come about due to peer and familial relationships resulting in the feeling of pressure to participate in the research.
   a. This may manifest situations like when groups of friends are participating in research, or if an entire class is participating in research, if other family members are participating in research or when the research requires 2 parties from one group.
   b. This may manifest if the researcher is a family member of the potential participant

4. Undue influence may come about due to compensation. These issues range from type of compensation for participation, amount of compensation participation, and to whom the compensation is given.

5. Unless there is a scientific justification, researchers should not perform research where the participants are their family, their students, their friends, their employees, their partner, etc