Title:	Individual Conflict of Interest in Research		
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1 Purpose

Consistent with the University of North Carolina at Chapel Hill's research, teaching and public service missions, the University encourages faculty, staff and students to engage in appropriate outside relationships, including but not limited to private industry and the nonprofit sector. Members of the University community are expected to avoid conflicts of interest that have the potential to directly and significantly affect the University's interests; compromise objectivity in carrying out University responsibilities; or otherwise compromise performance of University responsibilities, unless such conflicts are disclosed, reviewed, and managed in accordance with the Policy on Individual Conflicts of Interest and Commitment.

It is the University of North Carolina at Chapel Hill's (UNC-CH) policy on Individual Conflicts of Interest and Commitment to preserve public trust in the integrity and quality of research through the management, reduction or elimination of actual, potential or perceived conflicts of interest in the conduct of research.

2 Researcher Conflicts of Interest

Conflicts of interest (COI) in research can be broadly described as any interest that competes with the integrity of a research study, or the credibility of the research program or an individual's obligation to protect the rights and welfare of research subjects. At the University, conflicts of interest can be financial or non-financial; any type must be disclosed as applicable. In general, a "financial Interest related to the research" means a financial interest in the sponsor, product or service being tested but it can extend beyond this definition based on the context of the study.

Some of the general standards the University maintains regarding conflict of interest (COI) and research are:

- All individuals who engage in research are required to take and maintain COI training.
- Any individual in a role will be requiring COI disclosure will need to disclose, at minimum, their own activities, interests and relationships as well as those of a spouse/partner and dependent child(ren).
- A zero dollar threshold of disclosure is required so that even uncompensated relationships may need to be disclosed.
- Similar to any involvement in human studies research, there is a higher standard for conflict of interest review and possible management related to a human study.

For more detailed information, please consult the *Policy on Individual Conflicts of Interest and Commitment* as well as the associated Standard Operating Procedures on *Individual Conflicts of Interest and Commitment*.

For human studies, in the event the conflict of interest cannot be effectively managed to its satisfaction, the IRB retains the authority to disapprove the research. When the financial interest is directly related to the human subjects' research and may be substantially affected by it, the risk is greatest and the bar must be high.

3 Conflict of Interest Procedures

3.1 COI Disclosure

The IRB application requires certain key members of the study team who will be involved in the design, conduct or reporting of the human study to file Conflict of Interest (COI) disclosures. These individuals are required to disclose based on their role on the study, which are reflective of their institutional duties.

Disclosure requirements apply to any researchers and research staff who are subject to UNC-CH policies. Personnel subject to their home institution's COI policies (e.g., EPA, other universities) are not required to submit separate disclosures through the UNC-CH COI Program. Non-UNC study personnel are required to submit documentation of compliance with their home institution's COI policies for their work on the IRB study. Non-UNC study personnel who are not covered by a home institution's policies are expected to comply with UNC-CH policies related to research.

3.2 University review coordination with IRB

When a principal investigator initially submits a human subjects research study to the IRB for review, the electronic system automatically creates Conflict of Interest (COI) disclosures in the Activities, Relationships and Interests system (air.unc.edu) for all applicable persons named on a human subjects research study. These persons are notified immediately by email of the requirement to complete the COI disclosure.

Upon completion of a disclosure by the applicable research personnel, the COI system programmatically evaluates that disclosure for a potential COI. If a potential COI is identified by the system, the disclosure if flagged for review and routed to the COI Program office.

All specified personnel needing COI disclosure named on a human subjects research study are required to update their disclosures at least annually in conjunction with the annual renewal, or if newly added to the human study or if there is an additional sponsor. Individuals can also self-submit a disclosure through the electronic system to indicate any change in an external activity, interest or relationship and are required to submit if there is change in an interest or relationships within thirty (30) days.

When the COI Program receives a COI disclosure disclosing a potential conflict of interest in the human studies research, the staff at COI Program conducts a preliminary review and provides appropriate information to the applicable school conflict of interest committee chair(s) in accordance with its standard process. For further details, please see *Standard Operating Procedures for Individual Conflicts of Interest*.

In the case of human subject research, the UNC-CH IRB is also informed automatically through the electronic system of a pending conflict undergoing review for a particular individual. In the case of complex review, an IRB Chair and/or Analyst may be invited to attend a COI Committee meeting to partake in the analysis.

The applicable University conflict of interest review chair and/or committee provides to the IRB any written determination of the conflict of interest and its resolution, including any conditions or management plans that are put in place regarding the conflict(s) for the specific human subjects research study. These details are automatically visible to the IRB through the electronic system for each human research study.

Approval of a conflict of interest and its associated management plan by a University Conflict of Interest Chair and/or Committee does not obligate an IRB to approve an individual's involvement in a proposed human subjects research activity. The UNC Chapel Hill IRB retains the final approval and authority as to whether human subjects research may in fact proceed.

If the COI Committee has not completed its review, the IRB will not issue its approval for the research study or will prohibit participation by the researcher with a potential COI until the COI Committee review process is completed and the results are made available to the IRB for its consideration.

3.2 Evaluation of COI

The University's Policy on *Conflicts of Interest and Commitment* includes a rebuttable presumption that an investigator may not conduct human subjects' research that is related to a financial interest of the investigator (or immediate family) except in compelling circumstances.

Compelling circumstances are those facts that convince the reviewer that a covered individual who has a financial interest should be permitted to conduct human subjects' research, taking into account the following factors:

- The nature of the research,
- The nature and magnitude of the financial interest
- How closely the financial interest is related to the research
- The extent to which the interest may be affected by the research
- The degree of risk to the human subjects involved that is inherent in the research protocol
- The extent to which the investigator is uniquely qualified to perform a research study with important public benefit
- The extent to which the interest is amenable to effective oversight and management.

The applicable COI Chair and/or Committee takes into these criteria into account when reviewing any disclosed conflict of interest in the context of the human study. The COI Chair or Committee considers the following factors into their review:

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

The IRB has final authority to determine whether the research, the COI, and the related management plan, if any, allow the research to be approved.

3.4 Management of COI

With regard to the human study specific management determined by the applicable COI Chair or Committee, the IRB shall either accept or indicate changes to strengthen it. The IRB can require additional measures to manage a COI so that the research may be approved. However, the IRB cannot weaken a managed plan determined by a COI Chair or Committee.

Standard examples of items that can be included in a human study specific management plan from a COI Chair or Committee include:

- Disclosure of the COI to subjects through the consent process
- Modification of the research plan or safety monitoring plan
- Monitoring of research by a third party
- Disqualification of the conflicted party from participation in all or a portion of the research such as consenting, Adverse Event determination or data analysis
- Appointment of a non-conflicted PI
- Divestiture of significant financial interests or maintenance below a certain threshold in order to participate as the principal investigator
- Severance of relationships that create actual or potential conflicts

The IRB may also add any one of these standard elements to the management plan or decide upon additional restrictions to a conflicted individual's involvement in the proposed human study research.

The IRB will review the COI and associated management plan to determine whether:

- The COI affects the rights or welfare of research subjects,
- The COI might adversely affect the integrity or credibility of the research or the research program, and
- The management plan effectively protects research subjects and the integrity and credibility of the research and the research program

The IRB will convey any additional requirements for the human subject specific management plan to the COI Program for conveyance to the applicable COI Chair and/or Committee.

Monitoring of any conflicts and adherence to a management plan is maintained by the COI Program in conjunction with the applicable COI Committee and/or Dean of the School. For further information please see Standard Operating Procedures for *Individual Conflicts of Interest*. The OHRE monitors adherence of the human subject specific plan including such items as disclosure text in the informed consent and maintenance of study specific roles. If any items arise through a monitoring process which may have implications for any human study, the COI Program notifies the OHRE of the changed circumstance so that additional review can occur, if applicable.

3.5 Coordination with Other IRBs

If an investigator is participating in a multi-center trial and has been allowed to conduct human subjects research while possessing a financial or personal interest, that fact should be made known to the PI or

sponsor by the coordinating center. It is the responsibility of the investigator to convey the UNC COI Finalization letter which provides the overview of the conflict and project specific management details.

Notification of research subjects falls within the purview of the applicable reviewing IRB, which will determine how the conflict of interest should be disclosed to the relevant human research subjects. This may include a description in the consent form of the conflict of interest.

References:

University of North Carolina at Chapel Hill Policy on Individual Conflicts of Interest and Commitment
University of North Carolina at Chapel Hill Standard Operating Procedures on Individual Conflicts of Interest and Commitment
45 CFR 50 Subpart F and 45 CFR 94
21 CFR 54.1, 21 CFR 54.2, 21 CFR 54.4, 21 CFR 312.64(d), 21 CFR 812.110(d)
Department of Health and Human Services Final Guidance Document, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" May 5, 2004 (http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf)