	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Conflict of Interest Evaluation	**#9.1**

The purpose of this SOP is to explain how real or perceived conflicts of interest in human subjects research will be evaluated and managed by the IRB.

I. General Requirements

The regulations protecting human research subjects are based on the ethical principles described in the Belmont report: respect for persons, beneficence, and justice. Researchers conducting human subjects research should not compromise Belmont Report principles by financial interests or other relationships that may create real or perceived conflicts of interest. The bias that such conflicts may impart can affect many human subject research activities, including decisions about who serves on the research team, where supplies or equipment are purchased, how data is collected, analyzed and interpreted, and which statistical methods are used. Openness and honesty are indicators of respect for persons, characteristics that promote ethical research and can only strengthen the research process.

II. Scope

This SOP pertains to all human subjects research reviewed by the UNCW Institutional Review Board (IRB).

III. Applicable Definitions

A. Conflict of Interest

Relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising a researcher's objectivity in conducting human subjects research.

B. Belmont Report

A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

IV. Procedures

A. IRB Member Conflicts

1. IRB members may not vote on agenda items if doing so creates a real or perceived conflict of interest.

a. When sending meeting agendas to IRB members, IRB staff include a statement asking IRB members to notify IRB staff of any real or perceived conflict of interest in reviewing or voting on agenda items.
b. If concerned, the Research Integrity Office director (RIO director) may inquire during meeting proceedings if any members have real or perceived conflicts of interest on agenda items.
c. IRB members must recuse themselves from review and approval of studies in which they have a conflicting interest.

B. Investigator Conflicts

1. The IRB will not approve an application if any personnel on the study subject to the UNCW Conflict of Interest or Commitment policy (UNCW Policy 03.230) do not have current annual conflict of interest disclosures on file in the AIR system.

2. The RIO director will confirm that research team members subject to UNCW Policy 03.230 either do not have conflicts relevant to the study under review, or that there is a current management plan for the conflict on file in the department or in Academic Affairs.

3. If the RIO director is unable to clear the application due to potential conflicts of interest, the RCM will notify the IRB co-chairs and the Institutional Official (IO). If the co-chairs and IO concur that a potential conflict exists with no appropriate management plan in place, the RIO director will coordinate conflict management plan meetings between the investigator, his or her supervisor, and General Counsel's office, as appropriate, to determine how or if the conflict can be managed.

4. As indicated in UNCW Policy 03.230, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

   a. Public disclosure of significant financial interests;
   b. Monitoring of research by independent reviewers;
   c. Modification of the research plan;
   d. Disqualification from participation in all or a portion of the research;
   e. Divestiture of significant financial interests; or
   f. Severance of relationships that create actual or potential conflicts.

V. References to Other Applicable SOPs

SOP Title	SOP #

VI. Responsibilities

Title	Responsibility
IRB Members	Responsible for notifying IRB staff at the earliest opportunity if the review of any agenda item or expedited study creates a real or perceived conflict of interest.
IRB Staff	Responsible for reminding IRB members of their obligation to recuse themselves if a real or perceived conflict of interest exists as a result of their review of human subjects research.
RIO Director	Responsible for determining if personnel listed in IRBIS applications under review have outstanding annual conflict of interest disclosures and notifying them that approval may not occur until disclosures are submitted. Responsible for coordinating meetings to develop management plans for investigators.
Investigators	Responsible for cooperating with IRB staff in resolving or managing conflicts of interest prior to conducting human subjects research.

VII. Resources

A. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html
B. UNCW Conflict of Interest Website: http://uncw.edu/sparc/integrity/COI.html
C. U.S. Department of Health & Human Services, Office of Human Research Protections Guidance on Financial Conflict of Interest: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html
D. 45 CFR 46 ("Common Rule"): https://www.ecfr.gov/cgi-bin/text-idx?SID=75addf8360492a28075e3a218631fcdc&pitd=20180719&node=pt45.1.46&rgn=div5
E. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html