

Conflicts of Interest in Human Research	Effective Date	5.14.2014
	Revised Date	1.15.2021

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for the handling of Conflicts of Interest (COI) reported to the UMCIRB.
- 2.0 Persons Affected:**
- 2.1 Individuals engaged in human research activities
 - 2.2 UMCIRB Chairperson (or designees) and members
 - 2.3 UMCIRB staff and administrators
- 3.0 SOP:** The UMCIRB requires full disclosure of any financial, professional, personal, and/or intellectual property interests, relationships, and affiliations by any study team member associated with the human research activity. Any new COI that arises after the research begins and any changes in an existing COI shall be reported to the UMCIRB at that time. A COI management plan will be developed by the ECU conflicts of interest officer (COIO) (or the appropriate institutional office from which the study team member is affiliated) and uploaded within the human research application. An approved management plan does not obligate the UMCIRB to approve a human research study. The UMCIRB retains the final authority on whether a human research study may proceed.
- 4.0 Definitions:**
- 4.1 Conflicts of Interest (COI): 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 Covered Employee’s objectivity in fulfilling University duties or responsibilities, including research, service and teaching activities, and administrative duties.
- 5.0 Responsibilities:**
- 5.1 **Investigators/Study team members** are responsible for:
 - 5.1.1 Disclosing any COI within the human research application.
 - 5.1.2 Providing a management plan that has been approved by the proper institution.
 - 5.1.3 Incorporating any required management plan procedures into the proposed research study plan and/or informed consent.
 - 5.1.4 Updating the IRB about any new COI or changes to an existing COI or management plan.
 - 5.2 **UMCIRB staff** are responsible for:
 - 5.2.1 Confirming the COI section of the human research application has been completed and any necessary management plan (developed in conjunction with the appropriate institutional office) for a reported COI has been uploaded.
 - 5.2.2 Reviewing COI management plans to ensure any requirements set forth

in that plan have been included in the human research study design.

5.2.3 Ensuring the UMCIRB approval letter is not sent to the Principal Investigator and study team until all COI documentation is provided and UMCIRB approval has been secured.

5.3 **UMCIRB/UMCIRB Chairperson (or designee)** is responsible for:

5.3.1 Reviewing COI information and management plans provided by the study team.

5.3.2 Assessing whether the plan approved by the study team member's institution has been incorporated and is acceptable in relation to human subject protection.

5.3.3 Requesting more information, if needed, to make a determination regarding issuing UMCIRB approval.

Revision History

Date	Change	Reference Section(s)
4.25.2016	Updated	
5.31.2019	Update office name	Section 2.0, 5.2
1.15.2021	Corrected the hyperlink to the UNC Systems Policy manual; added new footer	References; all

References

University of North Carolina Systems policy on COI (Contained within the policy manual):

https://www.northcarolina.edu/apps/policy/index.php?tab=policy_manual

ECU Regulation on Conflicts of Interest, Commitment, and External Professional Activities for Pay.
REG01.15.03:

<http://www.ecu.edu/prr/01/15/03>