	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Audit of Human Subjects Research Activities	**#10.1**

The purpose of this SOP is to provide detail on the conditions and steps for conducting an audit of human subjects research.

I. General Requirements

At times, audits of ongoing studies are necessary to confirm compliance with approved procedures, to ensure subject safety, and/or to ensure that subject privacy is protected.

The full IRB or the IRB chair may request an audit of any activity that is subject to or appears to be subject to UNCW IRB oversight. The UNCW Internal Audit office or the chancellor may also initiate an audit randomly, as part of an investigation, or for any other reason.

The IRB can use the following to determine which projects need verification from sources other than the principal investigator that no material changes have occurred since previous IRB review, that the study is being conducted as approved by the IRB, and/or the study is subject or not subject to IRB oversight.

A. randomly selected projects,
B. complex projects involving unusual levels or types of risk to subjects,
C. projects conducted by principal investigators who previously have failed to comply with UNCW policies, SOPs or federal regulations, or
D. projects where concerns have been raised during the continuing review process or other sources about conducting human subjects research without IRB approval, making material changes to approved human subjects research without IRB approval, or other concerns.

II. Scope

This SOP can be applied to any activity that has either been reviewed and/or approved by the UNCW IRB as human subjects research at any level of review, or any other activity conducted by UNCW faculty, staff and/or students that appears to be subject to UNCW IRB policies, SOPs and related federal regulations.

III. Applicable Definitions

A. Audit

For the purposes of this SOP, an audit is a review conducted by one or more objective parties designated by the IRB, Office of Internal Audit, or chancellor, for the purpose of confirming compliance with applicable policies and regulations and ensuring subject safety and protection.

B. 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 IRB staff or an IRB member's objectivity in conducting an audit of a human subjects research study.

C. Noncompliance

Failure to comply with applicable regulations, laws, UNCW policies, UNCW IRB SOPs, and/or the requirements or determinations of the IRB or provisions of the approved research study.

C. Serious Noncompliance

Instances of noncompliance that pose an actual or potential increased risk to the safety, rights and/or welfare of human research subjects. Examples of serious noncompliance include but are not limited to:

- Conducting human subjects research without UNCW IRB review, a determination of exemption and/or approval;
- Enrollment of subjects that fail to meet the inclusion or exclusion criteria of the approved study;
- Enrollment of subjects while study approval has lapsed;
- Failing to provide all relevant sections of the informed consent form to subjects;
- Major deviations from approved methods and procedures that may place subjects at risk from the research.

IV. Procedures

A. Appointment of an IRB Audit Team

1. When the IRB determines that an audit of one or more human subjects research studies is necessary, the research compliance manager will conduct the audit with one or more IRB members.
2. An IRB co-chair will appoint the audit team for all studies other than those reviewed at the full board level.
3. The full board will appoint the audit team for studies reviewed at the full board level.
4. The IRB co-chair or full board must refrain from appointing IRB members who may have a real or perceived conflict of interest related to the audited study or studies.

B. Cooperating with Audit

All members of the research team must fully cooperate with the IRB audit team, Internal Audit staff, or a chancellor-assigned audit team.

C. Audit Procedures

When conducting an audit of one or more human subject research studies, the audit team:

1. may conduct interviews of knowledgeable sources, including but not limited to the principal investigator, research team members, and subjects;
2. may observe the methods and processes used;
3. may review any related research documentation, including but not limited to consent forms, survey instruments, subject identification logs, or other study materials;
4. shall ensure that the audit procedures used are limited to those that are deemed reasonable and necessary in order to produce relevant, reliable, and sufficient detail that will enable the IRB chair or full board to determine if the study has been conducted in a compliant manner; and
5. shall make a recommendation based on the documentation collected.

D. Findings of Serious Noncompliance

If at any time an auditor finds a serious noncompliance or practice that may jeopardize the welfare of human subjects or others, the auditor must notify the IRB at the earliest possible opportunity upon identifying the problem.

D. Audit Report

Following audit, the audit team will write a report based on the documentation collected that includes recommendations as to whether the study or studies were found to be operating in compliance. The audit team will provide the report to:

1. the principal investigator of the study;
2. the IRB co-chair or full board, depending on the review level of the study; and
3. the Director of Sponsored Programs, if the study received external funding.

E. Determination of Compliance or Non-compliance

For all activities other than those reviewed by the full board, an IRB co-chair will review the recommendations contained in the report to determine if the audit team found the study to be compliant. The full board will make this determination for studies reviewed at the full board level. If the co-chair or full board determines that the study was found to be non-compliant, the co-chair or full board will refer to SOP 11.1, Findings of Noncompliance.

V. References to Other Applicable SOPs

Title	SOP #
Expedited Review Procedures	5.2
Full Board Review Procedures	5.3
Conflict of Interest Evaluation Procedures	9.1
Findings of Noncompliance	11.1

VI. Responsibilities

Title	Responsibility
Full Board	Responsible for designating audit team members for studies originally approved by the full board. Responsible for reviewing the recommendations included in the audit report and making a determination as to whether the audited study has been conducted in accordance with UNCW IRB policies, SOPs and related federal regulations.
IRB Co-chair	Responsible for designating audit team members for studies originally approved by the full board. Responsible for reviewing the recommendations included in the audit report and making a determination as to whether the audited study has been conducted in accordance with UNCW IRB policies, SOPs and related federal regulations.
Research Compliance Manager	Responsible for leading audit teams designated by an IRB co-chair or the full board.
Audit Team Members	Responsible for conducting audits in a fair, unbiased and timely manner. Responsible for making recommendations based on audit findings to assist an IRB co-chair or full board in determining if the audited study has been conducted in accordance with UNCW IRB policies, SOPs and related federal regulations.
Principal Investigator	Responsible for conducting human subjects research in accordance with IRB policies, SOPs and related federal regulations. Responsible for cooperating fully with audit teams.
Research Team Members	Responsible for conducting human subjects research in accordance with IRB policies, SOPs and related federal regulations. Responsible for cooperating fully with audit teams.

VII. Resources

A. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html
B. 45 CFR 46 ("Common Rule"): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
C. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
D. UNCW Conflict of Interest Website: http://uncw.edu/sparc/integrity/COI.html
E. UNCW Office of Internal Audit Website: https://uncw.edu/ia/