	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Findings of Noncompliance Procedures	#11.1

The purpose of this SOP is to outline the steps for evaluating and investigating a report of noncompliance in a human subjects study.

I. General Information

Researchers conducting human subjects research are required to conduct the research in an ethical and responsible manner, in accordance with the methods and procedures approved by the UNCW Institutional Review Board (IRB). Failing to follow the approved methods and procedures is a violation of UNCW IRB policy.

II. Scope

The SOP pertains to all human subjects research conducted by UNCW faculty, staff and students, or external researchers collaborating with UNCW faculty, staff or students on research approved by the UNCW IRB.

III. Applicable Definitions

A. Allegation of Noncompliance
An unproven assertion of noncompliance.

B. Continuing Noncompliance
Repeated instances of noncompliance by the same investigator. "Repeated instances" can mean a noncompliant activity occurring multiple times within the same study, or a noncompliant activity occurring once in multiple studies. Such repetition if unaddressed may affect the protection of human research subjects.

C. Minor Noncompliance
Noncompliance that does not increase risk to subjects, such as an administrative inconsistency from the methods and procedures approved by the IRB. Examples of minor noncompliance include but are not limited to:
- Failing to use the official stamped consent form, but using a version otherwise identical to the official stamped version.
- Failing to submit continuing review forms prior to lapse in IRB approval when study was otherwise inactive.

D. Noncompliance
Failure to comply with federal regulations, state laws, or UNCW policies or SOPs related to the protection of human subjects, and/or the requirements or determinations of the IRB, or provisions of the approved research study.

E. Research Misconduct
Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. Noncompliance of IRB policies and/or SOPs generally does not constitute research misconduct.

F. 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. Upon finding that a PI or any member of the research team has not complied with federal regulations, state laws, or institutional policies and/or SOPs regarding the protection of human subjects, IRB staff will ask an IRB co-chair to determine whether the violation is minor or serious.

1. Minor Noncompliance

If the co-chair determines that an incident of noncompliance is minor, and it is the first noncompliance by a PI or research team member, IRB staff will send a notification of the minor noncompliance to the PI and/or researcher (if different from the PI). IRB staff will retain a copy of the notification in electronic format.

a. The researcher and/or PI will be asked to respond within a specified time period, and provide the IRB with a plan to correct the noncompliance.
b. The IRB co-chair will promptly conduct a review of the researcher's response and of the corrective action taken.
c. If the IRB co-chair finds that the researcher's response is acceptable, the IRB co-chair will send the researcher an acknowledgement. IRB staff will retain the researcher's response and IRB co-chair's acknowledgement in electronic format.
d. If the co-chair finds that the researcher has not adequately addressed the noncompliance, or if the researcher fails to respond within the specified time period, the IRB co-chair may:

i. Order the researcher to suspend research activities, if warranted;
ii. Notify the applicable department chair or other immediate supervisor of the researcher, and/or;
iii. Instruct the researcher to submit a plan to correct the noncompliance within a specified time period.
- The IRB co-chair will acknowledge the researcher's corrective action plan when found to be acceptable.
- If the researcher fails to respond, or submits an inadequate response, the IRB co-chair may treat the incident as serious noncompliance as outlined below.

2. Serious Noncompliance

If the chair determines that an incident of noncompliance is serious, or if the IRB finds a significant number or repeated minor infractions, such activities will be reported promptly to the Institutional Official (IO) and forwarded to the full IRB for action. The IRB can vote to require any of the following actions or combination of actions:

a. Take no action

When the IRB votes to take no action, the PI/researcher, his/her immediate supervisor, and the IO will be notified in writing. IRB staff will file a report in electronic format.

b. Open an in-depth investigation

When the IRB votes to open an in-depth investigation, the IRB will designate two or more members of the committee who do not have conflicting interests in the study and are not in the role of lead chair to conduct the investigation under the coordination of the Research Integrity Office director (RIO director).

c. Suspend the protocol

When the IRB votes to suspend the protocol, the RIO director will notify the PI, his/her immediate supervisor, and the IO in writing on behalf of the IRB of the date the suspension must commence. When a protocol is suspended, no new subjects can be recruited or enrolled into the study. The researcher may also be required to phase-out existing enrolled subjects. The IRB may instruct the PI to provide the IRB with a plan to phase out subjects, which must be accepted by the IRB, and must contact the IRB when all subjects have been phased out. The study may resume only when the IRB votes to lift the suspension of the protocol.

d. Terminate the protocol

When the IRB votes to terminate the protocol, the RIO director will notify the PI/researcher, the PI's immediate supervisor, and the IO in writing on behalf of the IRB of the date the termination must commence. When a protocol is terminated, all research activities related to the protocol must cease. The IRB may direct the PI as to how to terminate the protocol. Typically, the PI may not recruit or enroll new subjects into the study, must notify all enrolled subjects of the termination of the project, and must cease all data collection, analysis and dissemination. The study may not resume until the IRB votes to lift the termination of the protocol or to allow some parts of the study to continue.

e. Prevent the researcher/PI from conducting research at UNCW

In extreme cases, the IRB may decide to no longer permit a researcher to conduct research at UNCW. When the IRB votes to prevent a researcher from conducting research, the RIO director notifies the PI/researcher, the PI's immediate supervisor, and the IO in writing on behalf of the IRB. When the IRB votes to prevent a researcher from conducting research at UNCW, all relevant research activities must cease.

f. In addition to or in lieu of the above-mentioned actions, the IRB can vote to require the researcher to complete additional training in the protection of human subjects, require more frequent than annual review of protocols, place a researcher on temporary probation from conducting human subjects research, require the researcher to destroy data already collected, or take any similar disciplinary action appropriate to the magnitude of the noncompliance.

g. The IRB, IO or Chancellor may take any of the above actions when it is determined a research protocol is not being conducted according to federal or local regulations or UNCW policies and procedures, has deviated from its approved protocol, or raises concerns about the risks to human subjects.

B. Conducting an In-Depth Investigation

1. When the IRB determines that an in-depth investigation is required to obtain detailed information regarding the conduct of a human subjects research study, the investigation team may:
   a. Conduct interviews of knowledgeable sources, including but not limited to the principal investigator (PI), research team members, and subjects;
   b. Request from the PI a written response to questions;
   c. Observe the methods and processes used; and

d. Collect and review any related documentation, including but not limited to correspondence, consent forms, completed survey instruments, subject identification logs, or other study materials.

2. The investigation team shall ensure that the investigation is conducted in a timely manner, is thorough, and the 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 further actions needed, if any. They should establish and communicate deadlines for interviews, responses, and document collection, and make available extensions for good cause.

3. Upon conclusion of the investigation, the investigation team shall prepare a written report to the IRB detailing the investigation process, the investigation findings, and the investigative team's recommendations for further actions to be taken, which may include, but are not limited to:
   a. Require no further action;
   b. Accept and approve a proposed corrective action plan provided by the PI or the Institution;
   c. Require that the PI modify the protocol to minimize risk, such as modifying the recruitment and/or consent procedures or revising the consent document;
   d. Require the interval at which continuing review is conducted to be modified to less than one year as appropriate to the degree of risk;
   e. Require observation of the research or the consent process;
   f. Require submission of status reports on a defined set schedule to the IRB;
   g. Require additional education and training for the PI and/or other research team members;
   h. Require that random audits be performed of studies conducted by the PI to ensure study procedures are followed as approved by the IRB;
   i. Require that previously and/or currently enrolled subjects be notified of the noncompliance and reconsented with the additional relevant information, if applicable, such as information that may relate to a subject's willingness to continue participation in the research;
   j. Replace the PI of the study with an experienced human subject investigator with a clean research compliance record, selected by the IRB;
   k. Issue a letter of reprimand to the PI and/or other research team member(s) and copying as appropriate the department chair, faculty advisor (if a student PI), dean, provost, institutional official, or other administrator;
   l. Require the PI to destroy or decommission data collected by noncompliant methods or during a lapse in IRB approval;
   m. Refer the PI or all of the researcher team to another University entity (i.e., Institutional Official, Sponsored Programs and Research Compliance, Institutional Risk Management, Human Resources);

n. Refer the matter to the appropriate UNCW office(s) that handle(s) research misconduct and/or whistleblowing activities.
o. Suspend any or all components of the research (i.e., new enrollment, treatment, follow-up and data analysis) until a corrective action plan can be developed and implemented or until additional review can occur;
p. Terminate the research; and/or
q. Revoke the privilege of the PI and/or members of the research team to conduct human subjects research or serve as a faculty advisor on a human subjects research study.

4. The IRB will review the investigation report at the next scheduled full board meeting and will consider the recommendations made by the investigation team. The IRB chair will issue a final determination letter to the PI to convey the final decisions of the board. The letter shall also describe the PI's appeal rights.

C. Appeals and Reporting Procedures

1. Appeal
The PI may appeal any action by the IRB in writing to the IO within 10 business days of receiving notification of the decision. The IRB's decision will stand until the appeal can be properly evaluated. The IO's decision is final. The only grounds for requesting an appeal are if the researcher believes that the IRB's decision is due to inadequate, or inaccurate information, or noncompliance with university policy, state law or federal regulation. Mere disagreement with the IRB's decision does not constitute grounds for an appeal. The RIO director will report the IO's decision to the IRB at the next scheduled meeting and will record the decision in the meeting minutes.

2. Reporting to Federal Agencies
a. As required by applicable law, regulation or UNCW policies, the IO shall report, in writing, the finding of serious or continuing noncompliance and the action(s) taken by UNCW to address such noncompliance to regulatory agencies, the study sponsor, and UNCW officials as appropriate.
b. In accordance with 45 CFR 46.103(a) and (b)(5) and UNCW's Assurance to the Office of Human Research Protections (OHRP), the IRB must report to OHRP when the following occurs on human subjects research supported by any agency that has adopted the Common Rule:
   i. Any unanticipated problems involving risks to subjects or others;
   ii. Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
   iii. Any suspension or termination of IRB approval.

3. Findings of Research Misconduct

If the IRB co-chair or full board determines that the incident of noncompliance involves research misconduct, the IRB co-chair will advise the RIO director, who will refer the matter to appropriate institutional officials in accordance with UNCW's Research Misconduct policy.

V. References to Other Applicable SOPs

VI. Responsibilities

Title	Responsibility
Full Board	Responsible for taking actions on findings of serious noncompliance, for reviewing investigation reports, and for making final decisions on the investigation team's recommendations.
IRB Co-chair	Responsible for determining the level of noncompliance, corresponding with the researcher, and determining if a corrective action plan is acceptable for findings of minor noncompliance.
IRB Staff	Responsible for assisting co-chairs with policy and SOP interpretation, drafting correspondence on behalf of co-chairs, providing relevant information to the full board, and retaining correspondence related to noncompliance.
RIO director	Responsible for informing researchers of suspensions and terminations, coordinating investigations, providing guidance to the full board, and coordinating with Sponsored Programs for notifying funding agencies as appropriate.
Principal Investigator	Responsible for conducting human subjects research in compliance with federal regulations, state laws, and UNCW policies and SOPs, cooperating with IRB instructions on submitting corrective action plans, and complying with suspensions, terminations or other determinations by the full board.

VII. **Resources**

A. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html

B. UNCW Research Misconduct Policy: http://uncw.edu/sparc/documents/ResearchCompliance/03.300_Reserach_Misconduct_PolicyJan07FINAL.pdf

C. U.S. Department of Health & Human Services, Office of Human Research Protections, Guidance on Reporting Incidents to OHRP: https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/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