

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

The purpose of this SOP is to outline the steps for 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 a member of the committee who does not have a conflicting interest in the study who will 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.

3. Findings of Research Misconduct

If the IRB co-chair 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.

4. Notification of Agencies

The RIO director will coordinate with the director of Sponsored Programs regarding any required notification of outside agencies based on federal regulations and the policies of the funding agency.

5. Appeals

The researcher/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.

V. **References to Other Applicable SOPs**

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VI. **Responsibilities**

Title	Responsibility
IRB Co-chair	Responsible for determining the level of noncompliance, corresponding with the researcher, and determining if a corrective action plan is acceptable.
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 Misc
onduct PolicyJan07FINAL.pdf](http://uncw.edu/sparc/documents/ResearchCompliance/03.300%20Reserach%20Misc%20onduct%20PolicyJan07FINAL.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](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=pt45.1.4
6&rqn=div5](https://www.ecfr.gov/cgi-bin/text-idx?SID=75addf8360492a28075e3a218631fcdc&pitd=20180719&node=pt45.1.46&rqn=div5)
- E. Belmont Report: [https://www.hhs.gov/ohrp/regulations-and-policy/belmont-
report/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)