|  |  |  |
| --- | --- | --- |
|  | **University of North Carolina Pembroke****Institutional Review Board** | **Standard Operating****Procedure** |
| **Findings of Noncompliance Procedures** |  |

The purpose of this Standard Operating Procedure (SOP) for the University of North Carolina Pembroke (UNCP) sets forth the definition of non-compliance and the Institutional Review Board (IRB) processes for assessing non-compliance and issuing corrective actions in human subjects research.

**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 UNCP IRB or as mandated by state laws and federal regulations. As per the Faculty Handbook, the UNCP IRB has the jurisdiction to determine whether an act or omission by a researcher constitutes noncompliance of IRB policy or violation of state law or federal regulations.

All university personnel conducting research involving human subjects are expected to comply with the highest standards of ethical and professional conduct in accordance with both federal regulations and institutional policies and procedures. As per the Faculty Handbook, any research team member (*i.e*., faculty, students, staff, or anyone conducting generalizable human subjects research) may be subject to allegations or inquiries into non-compliance.

**II.** **Definitions**

**A. Human Subjects**

According to [45 CFR 46,](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) *Human subject* refers to a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**B.** **Research**

According to 45 CFR 46.102(I), research is “a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (Protection of Human Subjects 2017).

**C. Noncompliance**

Noncompliance is defined as a failure to adhere to laws, regulations, policies, and procedures during the course of human subjects research. Noncompliance may range from relatively minor administrative violations to serious violations that pose risks to human subjects or violate the subject’s rights.

**D. Allegation of Noncompliance**

Allegation of noncompliance is defined as an unproved assertion of noncompliance.

**E. Continuing Noncompliance**

Continuing noncompliance is defined as repeated instances of noncompliance by the same investigator. *Repeated instances* refers to either a noncompliant activity occurring multiple times with the same study or a noncompliant activity occurring once in multiple studies. Such repetition, if unaddressed, may affect the protection of human research subjects.

**F. Minor Noncompliance**

Minor noncompliance is defined as 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:

1. Failing to use the official IRB-approved (stamped) consent form, but using a version otherwise identical to the official stamped version. We anticipate introducing a stamped consent form in January 2023.
2. Failing to submit continuing review forms prior to lapse in IRB approval when study was otherwise inactive.

**G. Serious Noncompliance**

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

1. Conducting human subjects research without UNCP IRB review.
2. Enrollment of subjects that fail to meet the inclusion or exclusion criteria of the approved study.
3. Enrollment of subjects while study approval has lapsed.
4. Failing to provide all relevant sections of the informed consent form to subjects.
5. Major deviations from approved methods and procedures that may place subjects at risk from the research.

**IV.** **Procedures**

**A.** Upon finding that a Principal Investigator (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, the IRB Chair and IRB members will determine whether the violation is minor or serious.

**A1.** **Minor Noncompliance**

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

A1a. 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.

A1b. The IRB Chair will promptly conduct a review of the researcher’s response and of the corrective action taken.

A1c. If the IRB Chair finds that the researcher’s response is acceptable and adequately addresses the noncompliance, the IRB Chair will send the researcher a written acknowledgement. The IRB Chair will retain the researcher’s response and IRB Chair’s acknowledgement in electronic format.

A1d. If the IRB 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 Chair may:

* Order the researcher to suspend research activities until the IRB finds the researcher’s response acceptable
* Notify the researcher’s Departmental Chair, or other immediate supervisor
* Notify the Office of Research and Sponsored Programs, as needed
* Instruct the researcher to submit a plan to correct the noncompliance within a specified time period.

A1e. The IRB 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 Chair may treat the incident as serious noncompliance as outlined below.

**A2**. **Serious Noncompliance**

If the IRB 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 Office of Research and Sponsored Programs and forwarded to the full IRB for action. During the live IRB meeting, the IRB will review the research protocol, discuss appropriate actions to take, and vote on a plan of action. The appropriate actions and/or vote may include, but is not limited to:

**A2a**. **Take No Action**

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

**A2b.** **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 who are not in the role of lead chair to conduct the investigation under the coordination of the Office of Research and Sponsored Programs.

**A2c.** **Suspend the Protocol**

When the IRB votes to suspend the protocol, the IRB Chair will notify the PI, his/her immediate supervisor, and the Office of Research and Sponsored Programs 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.

**A2d.** **Terminate the Protocol**

When the IRB votes to terminate the protocol, the IRB Chair, in coordination with the Office of Research and Sponsored Programs, will notify the researcher, and the researchers’ supervisors, 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, data analysis, and dissemination of research. 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.

**A2e**. **Prevent the Researcher from Conducting Research at UNCP**

In extreme cases, the IRB may decide to no longer permit a researcher to conduct research at UNCP. When the IRB decides to prevent a researcher from conducting research, the IRB will convene a meeting consisting of at least 51% of IRB members, the researcher(s), the Director of the Office of Research and Sponsored Programs, and the Provost. The serious noncompliance will receive a thorough discussion at the meeting, and then the IRB, Director of the Office of Research and Sponsored Programs, and the Provost will meet in private to discuss, and possibly vote, on whether to prevent the researcher from conducting research at UNCP. If a decision is made to prevent the researcher from conducting further research, then all relevant research must cease immediately.

**A2F. Possible Additional Actions**

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.

The IRB, Office of Sponsored Research Programs, or Provost 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 UNCP policies and procedures, has deviated from its approved protocol, or raises concerns about the risks to human subjects.

**B. Conducting an In-Depth Investigation**

**B1**. 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:

1. Conduct interviews of knowledgeable sources, including but not limited to the principal investigator (PI), research team members, and subjects;
2. Request from the PI a written response to questions;
3. Observe the methods and processes used; and
4. Collect and review any related documentation, including but not limited to correspondence, consent forms, completed survey instruments, subject identification logs, or other study materials.

**B2**. An investigation team will be appointed by the IRB Chair and will consist of three IRB members who do not have a conflict of interest with the research in question. 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 information that will enable the IRB Chair, or the full board, to determine further actions needed. The investigation team will establish and communicate deadlines for interviews, responses, and document collection, and make available extensions for good cause.

**B3**. 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:

* 1. Require no further action.
	2. Accept and approve a proposed corrective action plan provided by the PI or the Institution.
	3. Require that the PI modify the protocol to minimize risk, such as modifying the recruitment and/or consent procedures or revising the informed consent.
	4. Require the interval at which continuing review is conducted to be modified to less than one year as appropriate to the degree of risk.
	5. Require observation of the research or the consent process.
	6. Require submission of status reports on a defined set schedule to the IRB.
	7. Require additional education and training for the PI and/or other research team members.
	8. Require that random audits be performed of studies conducted by the PI to ensure study procedures are followed as approved by the IRB.
	9. As possible, 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.
	10. Replace the PI of the study with an experienced human subject investigator with a clean research compliance record, selected by the IRB.
	11. Issue a letter of reprimand to the PI and/or other research team member(s), copying as appropriate, the Department Chair, faculty advisor (if a student PI), Dean, Provost, Office of Research and Sponsored Programs, or other administrator.
	12. Require the PI to destroy or decommission data collected by noncompliant methods or during a lapse in IRB approval.
	13. Refer the PI or all the researchers to other UNCP entities (*e.g*., Office of Research and Sponsored Programs, Provost’s Office, and Human Resources).
	14. 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.
	15. Terminate the research.
	16. 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.

**B4.** 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. Allegations of Non-Compliance**

Reports or complaints of non-compliance may be submitted to the IRB or to the Office of Sponsored Research Programs verbally or in writing. Reports may arise internally (*e.g*., from faculty, staff, investigator self-reports, Office of Sponsored Research Programs staff, and IRB members) or from external constituents (*e.g*., participants and regulators). The Office of Sponsored Research Programs and the IRB will fully maintain the confidentiality of submitter, as permitted by law.

**D.** **Appeals and Reporting Procedures**

**D1.**  **Appeal**

Any decision by the IRB may be appealed in writing to the Office of Research and Sponsored Programs no later than ten (10) business days from receipt of the IRB’s decision by the party appealing the decision. The Office of Research and Sponsored Programs' decision is final. The only grounds for appeal are: 1) If the IRB’s decision lacks factual basis, or 2) If the IRB’s decision runs counter with university policy, state law, or federal regulation. Mere disagreement with the IRB’s decision does not constitute grounds for an appeal. The Office of Research and Sponsored Programs’ decision will be reported to the IRB at the next scheduled meeting and will be recorded into the meeting minutes.

**D2.** **Reporting to Federal Agencies**

**D2a.** As required by applicable law, regulation, or UNCP policies, the Office of Research and Sponsored Programs shall report, in writing, the finding of serious or continuing noncompliance and the action(s) taken by UNCP to address such noncompliance to regulatory agencies, the study sponsor (if any), and UNCP officials (*e.g*., the Provost, Departmental Chairs, or research supervisor), as appropriate.

**D2b.** In accordance with 45 CFR 46.103(a) and (b)(5) and UNCP’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:

1. Any unanticipated problems involving risks to subjects or others.
2. Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB.
3. Any suspension or termination of IRB approval.

V. **Resources**

**A.** UNCP IRB Website: <https://www.uncp.edu/academics/research/institutional-review-board>

A1. All the IRB materials can be found on this website under the link, Forms and Guidelines. This document can be found at this location.

**B.** 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-](https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html) [incident/index.html](https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html)

**C.** 45 CFR 46 (“Common Rule”):<https://www.ecfr.gov/cgi-bin/text-> [idx?SID=75addf8360492a28075e3a218631fcdc&pitd=20180719&node=pt45.1.4](https://www.ecfr.gov/cgi-bin/text-idx?SID=75addf8360492a28075e3a218631fcdc&pitd=20180719&node=pt45.1.46&rgn=div5) [6&rgn=div5](https://www.ecfr.gov/cgi-bin/text-idx?SID=75addf8360492a28075e3a218631fcdc&pitd=20180719&node=pt45.1.46&rgn=div5)

**D.** Belmont Report: [https://www.hhs.gov/ohrp/regulations-and-policy/belmont-](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) [report/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)

**E.** Protection of Human Subjects, 45 CFR § 46 (2017).