Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 211.1	TITLE: Principal Investigator Responsibilities	Date Effective: 07/12/2021 Last Revision Date: initial

I. Purpose

Principal Investigators (PIs) are ultimately responsible for the conduct of research. PIs may delegate tasks to appropriately trained and qualified members of their research team. However, PIs must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities. This sets forth the PI's responsibilities when conducting research using human subjects under the authority of the WCU Institutional Review Board.

II. Definitions

Principal Investigator: WCU full time Faculty or Staff Member responsible for the content of the IRB application and the conduct of the study.

Research Personnel: any individual who is involved in conducting human subjects research studies. Such involvement may include:

- obtaining information about living individuals by intervening or interacting with them for research purposes;
- obtaining identifiable private information about living individuals for research purposes;
- obtaining the voluntary informed consent of individuals to be subjects in research; and
- studying, interpreting, or analyzing identifiable private information or data for research purposes.

III. Responsibilities

Principal Investigators who conduct research involving human subjects must:

1. Develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
2. Develop a research plan that is scientifically sound and minimizes risk to the subjects;
3. Incorporate into the research plan a plan to ensure the just, fair, and equitable recruitment and selection of subjects;
4. When some or all of the subjects are likely to be vulnerable to coercion or undue influence (e.g. children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons), include additional safeguards in the study to protect the rights and welfare of these subjects;
5. Ensure that the research plan includes adequate provisions for the monitoring of subjects and data to ensure the safety of the subjects;
6. Ensure that there are adequate provisions to protect the privacy interests of subjects;
7. Ensure that there are adequate provisions to protect data confidentiality and interests of subjects, including an information security plan that considers the collection, storage, maintenance, analysis, and transmission of data and other identifiable information;

8. Have sufficient resources necessary to protect human subjects, including:
    a. Access to a population that would allow recruitment of the required number of subjects.
    b. Sufficient time to conduct and complete the research.
    c. Adequate numbers of qualified staff.
    d. Adequate facilities.
    e. Necessary equipment.
    f. A plan to ensure proper supervision of the research, including a plan for periods of absence or decreased availability;
    g. Availability of medical, psychological, or other support that subjects might require during or as a consequence of their participation in the research.
9. Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under the laws of North Carolina and the policies of Western Carolina University.
10. Assure that all study personnel are educated in the regulatory requirements regrading the conduct of research and the ethical principles upon which they are based;
11. Assure that all persons assisting with the research are adequately trained and informed about the protocol/research plan and their specific duties and function.
12. Promptly report any changes in, addition to, or department of investigators or research staff to the IRB for evaluation and approval;
13. Protect the rights, safety, and welfare of participants;
14. Ensure that when private health information is used, legally effective HIPAA authorization is obtained for each subject unless the IRB has approved a waiver of the requirement.
15. Ensure that the language in the consent form is consistent with that in the protocol/research plan and, when applicable, in the HIPAA authorization;
16. Obtain and document informed consent and ensure that no human subject is involved in the research prior to obtaining consent or consent/permission from their legally authorized representative, unless a waiver of the requirement has been approved by the IRB;
17. Have a procedure to receive questions, complaints, or requests for additional information from subjects and respond appropriately;
18. Ensure that all information provided to the IRB is accurate and complete so that the IRB may fulfill its responsibilities to review the research and make the required determinations;
19. Ensure that all research involving human subjects received IRB review and approval in writing or a determination of exemption before research begins;
20. Ensure that all research involving human subjects is reviewed by other experts and organizational components and committees as applicable to the research;
21. Comply with all IRB decisions, conditions, and requirements;
22. Ensure that studies receive timely continuing IRB review and approval;
23. Report unanticipated problems, deviations, complaints, non-compliance, suspensions, terminations, and any other reportable events to the IRB;
24. Notify the IRB if information becomes available that suggests a change to the potential risks or benefits of the research;
25. Obtain IRB review and approval before changes are made to the research unless a change is necessary to eliminate apparent immediate hazards to the subject(s);
26. Seek HRPP or IRB assistance when in doubt about whether proposed research requires IRB review;

27. Retain records for the time period and in the manner required by applicable regulations, contractual agreements, and organizational policies.

IV. Study Records

Principal Investigators must maintain the following records for at least three (3) years after completion of the research in accordance with 45 C.F.R. § 46.115:

Study Records

- Individual subject records
- Recruitment materials
- Documentation of consent process (who, what, when and how)
- Signed consent forms
- Unanticipated Problem and Reportable Event Reports
- Subject Complaint reports
- Results of all procedures conducted on the subject, including final visit

Regulatory Records

- Most recent IRB-approved protocol/research plan
- Previous versions of protocol/research plan
- All correspondence to and from the IRB
- All correspondence with the sponsor and others regarding the study
- Continuing review progress reports
- Modification Requests

Public Records Request

Some of this documentation may be subject to public access under the North Carolina Public Records Act. The Office of Legal Counsel should be consulted when a public records request is received.

V. Responsibilities
Principal Investigators

VI. References
45 CFR §§ 46.111, 46.115 - 46.117
University Policy 56 – Ethics in Research
University Policy 131 – Research Involving Human Subjects