



PRINCIPAL INVESTIGATOR AND FACULTY ADVISOR RESPONSIBILITIES

A. Conduct of the Research

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the Common Rule, and the ethical principles of my discipline.
2. I accept responsibility for the conduct of this research ensuring this research is conducted according to:
 - a. sound research design and methods;
 - b. the IRB approved protocol including the informed consent process;
 - c. the applicable terms of the grant, contract and/or signed funding agreements;
 - d. applicable laws and regulations, including those for protecting the rights, safety, and welfare of human subjects.
3. I certify that I am or my faculty advisor is sufficiently qualified by education, training, and/or experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that members of this research team, including study staff and trainees, are appropriately qualified, trained and supervised.
4. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research for which they are responsible.

B. Ensuring and Maintaining Compliance

1. I will comply with relevant regulatory and institutional requirements, including those relating to conflicts of interest.
2. I understand it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct, and reporting of research declare any potential conflicts of interests related to the research and to maintain current records. I will ensure changes in conflicts of interest are promptly disclosed to the IRB.
3. I will ensure that informed consent is obtained as approved by the IRB and a copy is provided to participants, unless the IRB waives these requirements.
4. I will obtain initial IRB approval prior to implementing human subject research activities as well as prior approval for any amendments to this research.
5. I will conduct this research within the approval period issued by the IRB. I agree to submit a request for continuing review of this research at least 45 days in advance of the expiration date.
6. I will submit a closure report form prior to protocol expiration or within 45 days of completion of all activities involving human subjects or identifiable participant data.
7. I will maintain approval, as applicable, with collaborative entities including approvals from other countries or jurisdictions.
8. I will promptly report to the IRB any instances of noncompliance with the approved protocol or requirements of the IRB and any unanticipated problems.



Investigator Agreement

9. I will assist in the facilitation of any monitoring and/or auditing of study activities and/or records as required by the IRB, funding entities, sponsors, and any federal and state regulatory agencies.

C. Investigator Records, Reports and Documentation

1. I will maintain research records, all protocol materials, and any other documents associated with this research (e.g., research plan, signed consent forms, and IRB correspondence).
2. I will submit written reports to the IRB and permit inspection of the research records as required by the IRB.
3. I will ensure the safe and secure storage of this research data (whether in paper or electronic formats) and for protecting the confidentiality of the data in accordance with the approved protocol.
4. I will maintain records for at least three years after this research ends, or for the length of time specified in applicable regulations or institutional or sponsor requirements, whichever is longer. I will take measures to prevent accidental or premature destruction of these documents.