

Principal Investigator Certification

Project or Study Title:	
Principal Investigator (PI) Status:	Select one option: ☐ Student Principal Investigator (complete sections A & B below) ☐ Faculty/Staff Principal Investigator (complete Section C below)

Section A: Student Principal Investigator Certification

(Required if PI is a student)

By signing below, I certify that the information contained in this application, the research proposal/protocol, and any associated materials accurately reflects how the research will be conducted. I understand that I may not initiate research activities until official IRB approval or exemption have been granted.

As Student Principal Investigator, I agree to:

1. Conduct the day-to-day implementation of the research in accordance with applicable institutional policies, procedures, and regulatory requirements governing human subjects research, under the oversight of my Faculty Advisor.
2. Complete required CITI training prior to engaging in research activities and maintain current certification throughout the study.
3. Adhere to the IRB-approved protocol and consult with my Faculty Advisor prior to implementing any modifications, ensuring that required IRB approval is obtained in advance (unless necessary to eliminate an apparent immediate risk of harm, which will be reported promptly to the IRB).
4. Conduct informed consent processes (as applicable) in accordance with IRB approval and applicable regulations, with guidance from my Faculty Advisor.
5. Protect participant privacy and maintain data confidentiality consistent with IRB-approved procedures and Faculty Advisor oversight.
6. Promptly report adverse events, unanticipated problems, protocol deviations, and participant complaints to my Faculty Advisor and assist in timely reporting to the IRB in accordance with requirements.
7. Maintain regular communication with my Faculty Advisor and seek guidance regarding study conduct, regulatory compliance, and participant protections.
8. Maintain accurate and complete study records and provide materials to my Faculty Advisor as needed for oversight and IRB submissions.
9. If I depart from the institution prior to study completion, notify my Faculty Advisor and the IRB and cease research activities unless and until the IRB approves a change in PI or other appropriate action.

I understand that, as Student Principal Investigator, I am responsible for the accurate and ethical execution of the research activities assigned to me and for complying with IRB requirements and applicable regulations in the conduct of the study. I further understand that I must conduct this research under the active supervision of my Faculty Advisor, who retains ultimate institutional, legal, and regulatory responsibility for oversight and compliance of the study.

**Student PI
Signature & Date:**

Section B: Faculty Advisor Certification and Oversight Responsibility*(Required for all student-led projects)*

I have reviewed and approve the proposed research plan. I affirm that the student is capable of conducting the research as described with appropriate supervision.

As Faculty Advisor, I acknowledge that although the student is designated as Principal Investigator (PI) for this project, I retain ultimate institutional, legal, and regulatory responsibility for the oversight, conduct, and compliance of the research.

As Faculty Advisor, I agree to:

1. Assume responsibility for ensuring that the research is conducted in compliance with all applicable federal, state laws, institutional policies, and IRB requirements.
2. Provide active, ongoing supervision of the research from initial development through study closure, consistent with institutional requirements for student-led research.
3. Complete required CITI training prior to serving as Faculty Advisor and maintain current certification throughout the study.
4. Ensure that all members of the research team, including the student PI and any co-investigators, are appropriately qualified, adequately trained, and have completed all required CITI or equivalent training prior to engaging in research activities, and maintain current certification throughout the study.
5. Provide mentorship and guidance regarding study design, ethical conduct, and regulatory requirements, while maintaining responsibility for ensuring these standards are met.
6. Review and formally approve all IRB submissions, modifications, continuing review/progress reports, and study materials prior to submission, and ensure their accuracy and completeness.
7. Oversee and monitor the conduct and progress of the research to ensure it is performed in accordance with the IRB-approved protocol, applicable regulations, and institutional policies.
8. Ensure all required communications with the IRB are completed appropriately and in a timely manner, including responses to IRB requests.
9. Ensure that adverse events, unanticipated problems, protocol deviations, and participant complaints are promptly identified, appropriately managed, and reported to the IRB in accordance with requirements.
10. Ensure that continuing review/progress report requirements are met and that the study is appropriately and timely closed.
11. Maintain availability to provide timely oversight, guidance, and decision-making related to participant safety and regulatory compliance.
12. Take appropriate and timely corrective action, including modification, intervention, suspension, or termination of research activities if necessary, to protect participants and ensure compliance.
13. If the student PI departs from the institution or is unable to continue, ensure that the study is either appropriately closed or that a change in PI is submitted to and approved by the IRB prior to continuation of research activities.

I acknowledge my responsibility to provide active oversight and supervision of this research and to ensure that appropriate safeguards are in place to protect the rights and welfare of participants. I understand that I am accountable

to the institution and the IRB for the regulatory compliance and ethical conduct of this research, and that I have the authority and obligation to intervene as necessary to ensure such compliance.

**Faculty Advisor
Signature & Date:**

Section C: Faculty/Staff Principal Investigator Certification*(Required if PI is faculty or staff)*

By signing below, I certify that the information contained in this application, the research proposal/protocol, and any associated materials accurately reflects how the research will be conducted. I understand that I may not initiate research activities until official IRB approval or exemption has been granted.

As Principal Investigator, I:

1. Accept full institutional, legal, and regulatory responsibility for the conduct of this research and for the oversight and supervision of all research team members.
2. Am responsible for ensuring that the research is conducted in compliance with applicable federal regulations, state laws, institutional policies, and IRB requirements.
3. Am responsible for ensuring that all research personnel are appropriately qualified and complete required CITI or equivalent training prior to engaging in research activities, and maintain current certification as required.
4. Will obtain IRB approval prior to initiating research and prior to implementing any modifications (unless necessary to eliminate an apparent immediate risk of harm, which will be reported promptly to the IRB).
5. Am responsible for ensuring that informed consent processes (as applicable) are conducted in accordance with IRB approval and applicable regulations.
6. Am responsible for protecting participant privacy and maintaining data confidentiality consistent with IRB-approved procedures.
7. Will ensure that adverse events, unanticipated problems, protocol deviations, and participant complaints are promptly identified, appropriately managed, and reported to the IRB in accordance with requirements.
8. Will ensure that all required communications with the IRB, including responses to IRB requests, are accurate, complete, and submitted in a timely manner.
9. Will comply with all applicable continuing review, progress reporting, record retention, and study closure requirements.
10. Will take appropriate and timely action, including modification, suspension, or termination of research activities if necessary, to protect participants and ensure compliance with IRB and regulatory requirements.
11. Will ensure that if I depart from the institution prior to study completion, the study is either appropriately closed or a change in PI is submitted to and approved by the IRB prior to continuation of research activities.

**Faculty/Staff PI
Signature & Date:**