

**CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES**

**By signing below I agree/certify that:**

1. I have reviewed this protocol submission in its entirety and I state that I am fully cognizant of, and in agreement with, all submitted statements and that all statements are truthful.
2. This application, if funded by an extramural source, accurately reflects all procedures involving human participants described in the proposal to the funding agency previously noted.
3. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
  - a. I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
  - b. I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.
4. I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) anonymity and/or confidentiality assurances promised when securing informed consent (d) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (e) adverse event reporting requirements; (f) data and record-keeping requirements; and (g) the current IRB approval status of the research study.
5. I will not enroll any individual into this research study: (a) until such time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of this research study has lapsed; (c) during any period wherein IRB approval of the research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of the research study or following sponsor/principal investigator termination of research study enrollment.
6. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.
7. I will submit the research study in a timely manner for IRB renewal approval.
8. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent ).
9. I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.
10. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
11. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.
12. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.
13. I will notify the IRB within 24 hours regarding any unexpected study results or adverse events that injure or cause harm to human participants.
14. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
15. I will notify the IRB prior to any change made to this protocol or consent form (if applicable).
16. I will notify the IRB office within 30 days of a change in the PI or the closure of the study.

<p>_____</p> <p><b>Principal Investigator Name (typed)</b></p>	<p>_____</p> <p><b>Principal Investigator Signature</b></p>	<p>_____</p> <p><b>Date</b></p>
<p>_____</p> <p><b>Faculty Advisor Name (typed)</b></p>	<p>_____</p> <p><b>Faculty Advisor Signature*</b></p>	<p>_____</p> <p><b>Date</b></p>

**\*Faculty signature indicates that he/she has reviewed the application and attests to its completeness and accuracy**