



INDIVIDUAL INVESTIGATOR AGREEMENT

Protocol Certification for Collaborating Individuals (No Home IRB)

For use of this form, see UNCA IRB SOP-020 *Research Collaborations and Multiple Research Sites*

Institution Providing IRB Review: **University of North Carolina at Asheville**
Federal-wide Assurance Number: **00013541**
FWA Expiration Date: **12/12/2022**
IRB Review Number: **00006169**

Individual Investigator's Name: _____

Individual Investigator's Organization: _____

Research Covered by This Agreement: *(to be completed by UNC Asheville Principal Investigator)*

UNC Asheville Principal Investigator: _____

UNC Asheville IRB Protocol Title: _____

UNC Asheville IRB Protocol Number: _____

Sponsor or Funding Agency: _____

Award Number, if any: _____

Funding Start and End Dates: _____

Title and investigator of funding proposal (if different from above): _____

1. The above-named Individual Investigator has reviewed:
 - a. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; See section B.1. of the Terms of the Federal-wide Assurance (FWA) for International (Non-US) Institutions);
 - b. the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-US) Institutions);
 - c. the FWA and applicable Terms of the FWA for the institution referenced above; and
 - d. the relevant institutional policies and procedures for the protection of human subjects.
2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this Agreement.
4. The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to the directives to terminate participation in the designated research activities.
5. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
6. The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

8. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.
9. The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continued review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.
10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
12. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
13. The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject, and the subject's rights and welfare must take precedence over the goals and requirements of the research.

Signatures:	
<p><i>Authorized Official of UNC Asheville:</i></p> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%; border-bottom: 1px solid black; text-align: center;">(signature)</div> <div style="width: 45%; border-bottom: 1px solid black; text-align: center;">(date)</div> </div> <p><i>Name:</i></p> <p><i>Title:</i></p> <p><i>Address:</i></p> <p><i>Phone:</i></p> <p><i>Email:</i></p>	<p><i>Individual Investigator</i></p> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%; border-bottom: 1px solid black; text-align: center;">(signature)</div> <div style="width: 45%; border-bottom: 1px solid black; text-align: center;">(date)</div> </div> <p><i>Name:</i></p> <p><i>Title:</i></p> <p><i>Address:</i></p> <p><i>Phone:</i></p> <p><i>Email:</i></p>

INSTRUCTIONS

The UNC Asheville PI should submit the printed version of the partially executed agreement, signed by the Individual Investigator, with a modification of the UNC Asheville application if adding the investigator to the UNC Asheville Study. After the agreement has been signed by the UNC Asheville IRB Chair, copies of the fully executed agreement will be distributed as follows:

- Original to UNC Asheville IRB files
- Electronic copy uploaded into the UNC Asheville protocol management system
- Electronic copy to the unaffiliated Individual Investigator sent by email
- Electronic copy to the Principal Investigator sent by email