THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
Individual Investigator Agreement (Institutional)

A. This Agreement is entered into by and between The University of North Carolina at Chapel Hill ("UNC-Chapel Hill") for its Office of Human Research Ethics and Institutional Review Boards ("IRB") and on behalf of one or more of its employees or agents (hereafter collectively designated as "**COLLABORATING INSTITUTION**").

UNC Chapel Hill holds a Federalwide Assurance (FWA#4801) approved by the federal Office for Human Research Protections (OHRP) and has established one or more IRBs (the "UNC-Chapel Hill IRB") pursuant to the federal regulations at 45 CFR 46 governing human subjects research.

One or more investigators at the **COLLABORATING INSTITUTION** named above desire to collaborate with UNC-Chapel Hill in the conduct of the research described in **Section B**, are not covered by an FWA, and are acting as employees of the collaborating institution in the conduct of this research. Therefore, UNC-Chapel Hill has agreed to extend its FWA to cover this **COLLABORATING INSTITUTION** for the purposes of this research.

B. Both UNC-Chapel Hill and **COLLABORATING INSTITUTION** agree that the UNC-Chapel Hill IRB will provide initial review and continuing oversight of the human subjects research protocol described below pursuant to 45 CFR 46 and the terms of UNC-Chapel Hill's FWA:

Name of Research Project:
IRB Study #:
Principal Investigator at UNC-Chapel Hill:
Investigator(s) at Collaborating Institution:
Sponsor or Funding Agency:

C. **COLLABORATING INSTITUTION** agrees that:

(1) Investigators at the **COLLABORATING INSTITUTION** have reviewed: 1) *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 Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) UNC-Chapel Hill's FWA (FWA #4801) (copies available upon request); and 4) the relevant policies and

procedures of UNC-Chapel Hill for the protection of human subjects (copies available online and upon request).

(2) The **COLLABORATING INSTITUTION** understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above-referenced documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement. Investigators at the **COLLABORATING INSTITUTION** will personally conduct or supervise performance of the research conducted under this Agreement. The **COLLABORATING INSTITUTION** will ensure that all collaborators, students, and employees conducting research under this Agreement will comply with the terms of this Agreement.

(3) The **COLLABORATING INSTITUTION** 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 **COLLABORATING INSTITUTION** will abide by all determinations of the UNC-Chapel Hill IRB and will accept the final authority and decisions of the UNC-Chapel Hill IRB including, but not limited to, directives to terminate performance of designated research activities.

(5) The **COLLABORATING INSTITUTION** and all individuals who will have contact with human subjects during the performance of the research will complete any educational training required by UNC-Chapel Hill and/or the UNC-Chapel Hill IRB prior to initiating research covered under this Agreement.

(6) The **COLLABORATING INSTITUTION** shall provide accurate and complete information to the UNC-Chapel Hill IRB in all applications for review and other communication with the UNC-Chapel Hill IRB. The **COLLABORATING INSTITUTION** will report promptly to the UNC-Chapel Hill IRB any proposed changes in the research conducted under this Agreement. The **COLLABORATING INSTITUTION** will not initiate changes in the research without prior UNC-Chapel Hill IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The **COLLABORATING INSTITUTION** will report immediately to the UNC-Chapel Hill IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The **COLLABORATING INSTITUTION**, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR 46 or stipulated by the UNC-Chapel Hill IRB.

(9) The **COLLABORATING INSTITUTION** acknowledges and agrees to cooperate with the UNC-Chapel Hill IRB for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The **COLLABORATING INSTITUTION** will provide all information requested by the UNC-Chapel Hill IRB in a timely fashion.

(10) In conducting research involving FDA-regulated products, the **COLLABORATING INSTITUTION** will comply with all applicable FDA regulations (including 21 CFR 50 & 56) and fulfill all investigator responsibilities (or investigator-sponsor responsibilities), where appropriate.

(11) The **COLLABORATING INSTITUTION** will not enroll subjects in research under this Agreement prior to its review and approval by the UNC-Chapel Hill IRB.

(12) Emergency medical care may be delivered without UNC-Chapel Hill IRB review and approval to the extent permitted under applicable federal and state law. However, data and information obtained as a result of emergency medical care may not be included as part of federally-supported or-conducted research.

(13) This Agreement does not preclude the **COLLABORATING INSTITUTION** from taking part in research not covered by this Agreement. The **COLLABORATING INSTITUTION** understands that the purview of the UNC-Chapel Hill IRB extends only to the research protocol(s) specified in **Section B** and not to any other research protocol(s).

(14) The **COLLABORATING INSTITUTION** acknowledges that it is primarily responsible for safeguarding the rights and welfare of each research subject and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

(15) The **COLLABORATING INSTITUTION** and its investigators will not use, nor authorize others to use, the name, symbols, or marks of UNC-Chapel Hill in any advertising or publicity material or make any form of representation or statement in relation to the research protocol(s) specified in **Section B** which would constitute an expressed or implied endorsement by UNC-Chapel

Hill except for factual representation of UNC-Chapel Hill's performance of research pursuant to this Agreement.

D. Both UNC-Chapel Hill and **COLLABORATING INSTITUTION** agree to the following general provisions:

(1) The term of this Agreement shall begin upon full execution by the parties and shall continue in effect until expiration or termination of UNC-Chapel Hill IRB approval of the research covered under this Agreement.

(2) Each party will be responsible for its own negligence in connection with its performance of this Agreement and the research protocol(s) specified in **Section B**.

(3) This document must be kept on file by both parties and provided to OHRP or other regulatory agencies upon request.

(4) This Agreement shall be governed by North Carolina law.

(5) Correspondence for the parties shall be sent to the individuals listed below.

Signature of Signatory Official (or authorized designee) at UNC-Chapel Hill:

_____ Date: _____

Name:
Institutional Title:
Phone:
Email:

Signature of Signatory Official (or authorized designee) at Collaborating Institution:

_____ Date: _____

Name:
Title:
Phone:
Email: