

Individual Investigator Agreement

Individual Investigator Information:

Name: _____ Degree(s): _____
(Last), (First) (Middle Initial)

Address: _____

Telephone: _____

Fax number: _____

Email address: _____

Describe the Specific Research Covered by this Agreement:

Specify Location(s) Where Research will be Conducted: _____

The Medical College of Georgia authorizes the designation of its IRB for review of protocols to be conducted under this Agreement at the investigator's site. This IRB is constituted under OHRP approved registration IRB 00000150. This institution and its IRB will abide by the provisions of this Agreement and of the Assurance cited above.

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; 2) 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; 3) 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 institution and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB and require all research staff to complete any educational training required by the Institution/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 such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by the IRB.

(9) The Investigator acknowledges and agrees to cooperate in the IRB responsibility for initial and continuing 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 and a fully executed contract.

(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's rights and welfare must take precedence over the goals and requirements of the research.

(14) The Investigator acknowledges that he/she is responsible for notifying the main site at this institution of all serious adverse events, adverse events, unanticipated problems, protocol deviations, protocol violations and other actions or incidents.

(15) The Investigator acknowledges that he/she is responsible for the safe and accurate accountability of the test article to include storage, dispensing, return or destruction.

(16) The Investigator acknowledges that the research staff should, and will be supported by the investigator to seek and obtain training as necessary to supplement or build new knowledge, skills and abilities as needed.

(17) The Investigator acknowledges that he/she is responsible for ensuring that adequate staff is available to meet the documentation requirements of research.

(18) The Investigator acknowledges that he/she is responsible for working with the primary site to determine all necessary source documents for each protocol and for providing that documentation in a timely and secure manner

Investigator Signature: _____ Date _____

Name: _____ Degree(s): _____

(Last) (First) (Middle Initial)

Address: _____

Phone #: _____

Email Address: _____

Fax Number: _____