



Birmingham-Southern College

## Collaborating Individual Investigator Agreement

**Birmingham-Southern College FWA #:** \_\_\_\_\_

**Collaborating Individual Investigator:** \_\_\_\_\_

**Research Project:** \_\_\_\_\_

**Effective Dates: From:** \_\_\_\_\_ **to** \_\_\_\_\_

Dates should coincide with periods of IRB approval. Individual Investigator Agreements must be renewed on the same schedule as IRB approvals.

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- (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; 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 part 46](#) (or other procedural standards; see section [B.3. of the Terms of the FWA for International \(Non-U.S.\) Institutions](#)); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.
  - (2) The Individual 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 Individual 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 Individual Investigator will work under the direction and supervision of the principal investigator or co-principal investigators employed by Birmingham-Southern College in the conduct of the collaborative research activities to be performed by the collaborating individual investigator.

- (5) The Investigator will abide by all determinations of the BSC IRB designated under the above FWA and will accept the final authority and decisions of the BSC IRB, including but not limited to directives to terminate participation in designated research activities.
- (6) The Investigator will complete BSC IRB designated training modules at the Collaborative Institutional Training Initiative (CITI Program) prior to initiating research covered under this Agreement.
- (7) The Investigator will report promptly to the BSC IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior BSC IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
- (8) The Investigator will report immediately to the BSC IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
- (9) 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 (or any other international or national procedural standards selected on the FWA for Birmingham-Southern College) and stipulated by the BSC IRB.
- (10) The Investigator acknowledges and agrees to cooperate in the BSC IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research project referenced above. The Investigator will provide all information requested by the BSC IRB in a timely fashion.
- (11) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
- (12) Emergency medical care may be delivered without BSC IRB review and approval to the extent permitted under applicable federal regulations and state law.
- (13) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
- (14) 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.

**Investigator**

Name: \_\_\_\_\_  
*(Last)* *(First)* *(Middle Initial)*

Degree(s): \_\_\_\_\_

Address: \_\_\_\_\_ Phone #: \_\_\_\_\_

\_\_\_\_\_  
*(City)* *(State/Province)* *(Zip/Country)*

Signature: \_\_\_\_\_ Date \_\_\_\_\_

**FWA Institutional Official (or Designee)**

Name: \_\_\_\_\_  
*(Last)* *(First)* *(Middle Initial)*

Institutional Title: \_\_\_\_\_

Address: \_\_\_\_\_ Phone #: \_\_\_\_\_

\_\_\_\_\_  
*(City)* *(State/Province)* *(Zip/Country)*

Signature: \_\_\_\_\_ Date \_\_\_\_\_