Individual Investigators

I. DEFINITIONS

Individual Investigator: A collaborating investigator who does not work at an institution with an FWA.

Collaborating independent individual investigators: are not otherwise an employee or agent of Birmingham-Southern College; are conducting collaborative research activities outside the facilities of Birmingham-Southern College; and are not acting as an employee of any institution with respect to his or her involvement in the research being conducted under the auspices of BSC.

Collaborating institutional investigators: are not otherwise an employee or agent of Birmingham-Southern College; are conducting collaborative research activities outside the facilities of Birmingham-Southern College; are acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted under the auspices of Birmingham-Southern College; and are employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

Individual Investigator Agreement: An agreement allowing an institution with an FWA to extend the applicability of its FWA to cover a collaborating investigator who may be an employee of an institution that does not routinely engage in research and therefore does not hold an active FWA or is not working as an employee or agent of any institution. The BSC IRB will extend assurance under its FWA only in compliance the Birmingham-Southern College Institutional Review Board Policy and when the specific conditions set forth below are met.

II. PROCEDURES

Birmingham-Southern College may extend its FWA to cover a collaborating independent or institutional investigator provided all of the following conditions are satisfied

1. The principal investigator employed by Birmingham-Southern College will direct and appropriately supervise all of the collaborative research activities to be performed by the collaborating individual investigator under the auspices of BSC, either on campus or at off campus sites.

2. The extension of the coverage of the Birmingham-Southern College FWA to a collaborating individual investigator occurs only when the BSC IRB approves a BSC IRB Individual Investigator Agreement (IIA) and all conditions specified by BSC are met. A separate individual investigator agreement must be approved for each collaborating individual investigator. IIAs will be approved only for collaborating individual investigators engaged in research being conducted by a principal investigator or co-principal investigators from BSC. The BSC IRB will maintain the BSC IRB Individual Investigator Agreement on file and provide copies to OHRP upon request.

3. A collaborating institutional investigator must provide documentation from their employing institution that proposed research has been approved to be conducted by and/or at his/her institution.

4. Birmingham-Southern College through the BSC IRB extends assurance under BSC’s FWA only when a completed BSC IRB Individual Investigator Agreement has been approved by the BSC IRB; the agreement is signed by the responsible parties; and supporting documentation is on file with the BSC IRB Administrator.
5. Collaborating individual investigators must be familiar with: (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; (b) the HHS regulations for the protection of human subjects at 45 CFR part 46 or other procedural standards designated by a non-U.S. institution under its FWA (see section B.3. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions on the OHRP website); (c) the FWA and applicable Terms of the FWA for Birmingham-Southern College; and (d) the relevant institutional policies and procedures for the protection of human subjects of Birmingham-Southern College.

6. Collaborating individual investigators must understand and accept the responsibility to comply with the standards and requirements stipulated in the documents referenced in the preceding paragraph (5. above) and to protect the rights and welfare of human subjects involved in research conducted under the BSC IRB Individual Investigator Agreement.

7. Collaborating individual investigators must agree to comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protections for human subjects participating in research conducted under the BSC IRB Individual Investigator Agreement.

8. The collaborating individual investigator must agree to abide by all determinations of the Birmingham-Southern College Institutional Review Board. Collaborating individual investigators must accept the final authority and decisions of the BSC IRB, including but not limited to directives to terminate participation in designated research activities conducted under the BSC IRB Individual Investigator Agreement.

9. Collaborating individual investigators must complete Collaborative Institutional Training Initiative (CITI Program) modules as required by the BSC IRB in accord with BSC policy. Collaborating individual investigators must submit satisfactory completion reports of CITI training to the BSC IRB Administrator before a BSC IRB Individual Investigator Agreement can be approved and accepted by the BSC IRB.

10. Collaborating individual investigators must agree not to enroll subjects in research under the BSC IRB Individual Investigator Agreement prior to the research being reviewed and approved by the BSC IRB.

11. Collaborating individual investigators must agree to report promptly to the BSC IRB any proposed changes in the research conducted under the BSC IRB Individual Investigator Agreement. The collaborating institutional investigators must agree not to initiate changes in the research without prior BSC IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

12. Collaborating individual investigators must agree to report immediately to the BSC IRB any unanticipated problems involving risks to subjects or others in research covered under the BSC IRB Individual Investigator Agreement.

13. Collaborating individual investigators, when responsible for enrolling subjects, must agree to 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 in the FWA for the institution referenced above) and stipulated by the BSC IRB.

14. Collaborating individual investigators must acknowledge and agree to cooperate with the BSC IRB in its initial and continuing review, record keeping, reporting, and certification for the research covered by the BSC IRB Individual Investigator Agreement. Collaborating institutional investigators must agree to provide all information requested by the BSC IRB in a timely fashion.