Birmingham-Southern College Institutional Review Board
Charter

Birmingham-Southern College (also referenced as "BSC" or "the College") has expressed its commitment to research in its mission statement and in the Faculty Handbook. As part of this commitment, the College embraces its ethical obligation to protect the rights, health, and privacy of individuals who participate in College-sponsored research. Toward this obligation, and in compliance with the Federal guidelines set forth by the **Office of Human Research Protection (OHRP)** and **Code of Federal Regulations Title 45 Part 46, Protection of Human Subjects,** the College has established an Institutional Review Board (IRB) for human participant protection. The IRB is charged with reviewing **all** proposed research conducted under the auspices of the College involving the use of human participants. To fulfill the ethical obligation to protect human participants, the College has adopted the three principles of The Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Participants of Research": *respect for persons, beneficence*, and *justice*. This charter establishes the authority and jurisdiction of the BSC IRB to encompass projects involving the collection and analysis of human participant data intended primarily for research purposes. The BSC IRB has the authority to approve, require modification, or disapprove all research involving human participants conducted under the auspices of BSC. The BSC IRB has authority to observe, or have a third party observe, the consent process and the research procedures of any project or protocol it approves.

No officer or entity of the College may override an IRB disapproval of proposed research. The Birmingham-Southern College President or Provost may, however, disapprove research that has received IRB approval.

I. BSC IRB Guiding Principles and Applications from The Belmont Report

Birmingham-Southern College has adopted the principles of The Belmont Report as the basis for ensuring the ethical treatment of human participants in research. These principles and their application are presented below in abbreviated form as they, along with the Code of Federal Regulations Title 45 Part 46, shape the policies and procedures of the BSC IRB.

A. Principle: **Respect for Persons** incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
Application: Informed Consent. Respect for persons requires that participants, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

B. Principle: Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of

beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.
Application: Assessment of Risks and Benefits. The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to participants are justified. For prospective participants, the assessment will assist the determination whether or not to participate. Furthermore, the benefit(s) must outweigh the risks.

C. Principle: Justice requires that people be treated fairly. Researchers should not take from research participants without giving back.
Application: Selection of Participants. Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research participants.

II. DEFINITIONS

A. Research

The type of research that the BSC IRB is charged with reviewing is defined in the relevant federal regulations *(**45 CFR 46.102**)* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

B. Research Participant

The BSC IRB is charged with protecting human participants. A human participant is defined as a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual and /or (2) identifiable private information.

In the Birmingham-Southern College Institutional Review Board Charter and in its Policies and Procedures the terms *human participant(s)* and *human subject(s)* both refer to research participants as defined above.

At BSC research with human participants is frequently conducted by the disciplines of biology, business, economics, education, political science, psychology, and sociology. However, any scholarly discipline may involve human participant research. All research conducted by BSC faculty, staff, and/or students falling under the definition above in which data are obtained from human participants, is subject to BSC IRB review.

C. Intervention

Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for

research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

D. Private Information

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

III. Persons Required to Submit a Research Protocol to the IRB for Approval

The following persons must complete a request to the BSC IRB for approval of human subject research:

Anyone formally affiliated with BSC (faculty, staff, or students) who engages in scholarly research involving human participants, either on or off campus. See Addendum 1 regarding students who are conducting research as part of a course or class project.

Researchers who are not affiliated with BSC but who want to conduct research with human participants on BSC's campus, or want to collect data specifically from BSC faculty, students, or staff.

Anyone using data from human participants that was collected at BSC under the provisions of BSC's IRB. For example, this includes graduates who intend to continue working with data that was originally collected as a student at BSC.

BSC faculty, staff, and students who plan to conduct research reviewed and approved by an IRB other than the BSC IRB and for which the Birmingham-Southern College IRB will not be the IRB of record should refer to Addendum 3 regarding appropriate procedure regarding an IRB Authorization Agreement.

Investigators from institutions other than BSC who wish to conduct research at BSC or cooperate in research conducted under the auspices of BSC should refer to Addendum 3 regarding the policy for IRB Authorization Agreements.

Individual investigators should refer to Addendum 4 regarding investigators unaffiliated with an institution with FWA.

IV. General Principles

"The Common Rule" is a shorthand reference to "The Federal Policy for the Protection of Human Subjects," which was adopted in 1991 and codified in separate regulations by 15 Federal departments and agencies. BSC's IRB policy adheres to the Common Rule as set forth in 45 CFR part 46, Subpart A. Under 45 CFR part 46, the BSC IRB also provides additional protections for vulnerable populations as specified in Subpart B, for pregnant women, human fetuses, and neonates; Subpart C, for prisoners; and Subpart D, for children (See Addendum 2). Birmingham-Southern College will adhere to The Common Rule and Department of Health and Human Services regulations to ensure compliance in all research

conducted by BSC regardless of the funding source, including research that is internally funded and collaborative research across institutions.

All individuals conducting original research are responsible for protecting their participants from the risk of unreasonable harm. The principal investigator has initial responsibility for determining whether such a risk exists. In assessing risk, the principal investigator should follow the guidelines of his or her relevant professional organization(s) and, where appropriate, the guidelines of governmental funding and regulatory agencies. Individual researchers should be aware of any state laws or local regulations governing the proposed research. If there are any doubts about risks, the principal investigator or his/her faculty supervisor should contact the IRB Chair for assistance.

The expressed documented support and signed approval of a faculty supervisor (See BSC Faculty Sponsor Assurance Form) is required before any BSC student may conduct human participant research. All research involving human participants conducted by students at BSC must be reviewed by the BSC IRB. Faculty members supervising student research are responsible for introducing students to BSC's IRB policies and ensuring compliance with BSC IRB approved research protocols. The faculty member is also responsible for supervising research undertaken by students in the context of his/her courses. See Addendum 1 for research conducted in the context of a course.

At a minimum, research activities at the College should conform to the following standards:

A. **Protection of Human Participants Training**: All researchers involved in a study, even if they will not be directly involved in working with human participants, must have a completion report on file with the IRB demonstrating that they have successfully completed the appropriate module of the Collaborative Institutional Training Initiative (CITI) Program. The BSC IRB has provided a document with guidance regarding CITI training. If questions remain after reviewing the CITI training guidelines, please contact the Chair of the IRB with substantive questions or the IRB Administrator with technical matters such as difficulty logging in. See BSC's New Learner Account Registration Document to get started.

B. **Informed Consent:** Prior to an individual's participation in the study, the principal investigator must explain the objectives of the research, the procedures to be followed, the associated risks, and the potential benefits. Investigators may not use individuals as participants unless the participants or their legal guardians freely consent to participating in the study and fully understand the consequences. This consent is typically indicated by a written signature on the Informed Consent sheet.

   There are exceptions to written informed consent. In the case of electronic or online surveys, the participants may indicate their agreement by making an electronic entry (e.g., check box, radio button) in response to the statement "I have read the consent form and willingly agree to participate," or other similar statements. The requirement for written or electronic consent may be waived by the IRB if the research involves no risk or only minimal risk, or if the consent form will be the only evidence linking the subject to the research and the primary risk of harm is to the subject's privacy.

   Some research protocols involve obtaining oral consent from the participants. When oral consent is utilized, the following information is required to be communicated to the participant: the study purpose and procedures involved, what will be asked of the participant in the study,

the amount of time participation will require, that participation is voluntary, that the participant is free to withdraw at any time, and that the data collected will remain confidential. The IRB may request that additional information be offered to the participants. Participants should always be offered contact information for the researcher and/or the IRB. For surveys conducted by telephone, oral informed consent may be obtained after the information listed above is read to each participant and explicit verbal agreement to participate is obtained.

Anonymous surveys do not require written consent, though the explanations of the research protocol that are standard on written consent forms should be included at the beginning of the survey. Consent to participate is implied when a subject completes and returns the survey. Anonymous data can be obtained by using questionnaires that are returned by mail (in envelopes with no return address or other identifying markers), by ballot box, by the collection of surveys that are returned to the researcher as a group and at the same time, or internet surveys using software that renders it virtually impossible to connect answers with respondents.

Research involving deception compromises a participant's ability to give true informed consent. The IRB will consider requests to waive some of the requirements for informed consent for research that intentionally involves deception, but only if **all** of the following criteria are met:

1. The research cannot be done without the deception.
2. The potential value of the research outweighs any potential risks to the subject.
3. The participants are informed of the true nature of the research as soon as possible.
4. The research involves no more than minimal risk.

In some cases, revealing the purpose of the study prior to participation may undermine the study's design. In these cases, the researchers must provide a mechanism for debriefing the participants on the purpose of the study and allow them to have their questions regarding the study answered.

See Addendum 2: Special Protections for Children as Research Subjects for consent procedures regarding children as research participants

C. Confidentiality: Investigators must respect the privacy of their participants. Investigators must protect confidential information and must advise participants in advance of any limits on their ability to ensure that the information will remain confidential.

If the data gathered by a student researcher is not anonymous, the IRB recommends that the data be turned over to the faculty supervisor, who will then become responsible for either properly storing the data for three years, or ensuring that the data are destroyed. If a student plans to continue the research or use the data in future projects, he or she may request permission from the IRB to retain the data. Permission is contingent upon the student's capacity and agreement to protect the confidentiality of the data.

D. Coercion: Participants, including students who are participating in classroom experiments or faculty scholarship, may not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participating in research, some other mechanism to earn that credit must be made available to students who choose not to participate in research. Alternative mechanisms for earning credits and the rewards for

participating in research should be in line with the burden imposed by participating in the research to avoid presenting an undue influence on a person's ability to freely choose to participate (or not).

Researchers must inform participants that they are free to withdraw from participation in the research at any time. Participants who indicate a desire to withdraw must be allowed to do so promptly and without penalty or loss of benefits to which he/she is otherwise entitled. This condition must be clearly stated as part of the informed consent statement. In the case where participation is linked to a student's earning course credit, the participants must be given an alternative option to earn the course credit that is equivalent in time and effort so that they do not feel unduly pressured to continue to participate in the research.

E. Disclosure: Upon request by any participant, an investigator must disclose the source of financial and/or institutional support for the research to the participant.

Birmingham-Southern College Institutional Review Board
Policies and Procedures

I. Composition of the IRB

A. IRB as Committee of the College
The Institutional Review Board (IRB) is a Committee of the College with a minimum of five members. IRB members shall be appointed by the Provost and may be renewed annually. The IRB must include:

1. At least one representative from the public without active ties to the college or organization sponsoring the research (45 CFR 46.107 b)
2. To be eligible for participation on the IRB as an unaffiliated member, neither the member nor any member of his/her immediate family may otherwise have a direct affiliation (for example, as an employee, contractor, student in a degree program, or active emeritus faculty member) with the College. The fact that an individual is an alumnus or former faculty or staff member of the College, or contributes to College fundraising drives, does not necessarily constitute a direct affiliation.
3. In cases where a community member without active ties to the college may have a potential conflict of interest with a submitted request for review, that person will be temporarily replaced by another community member.
4. A member whose primary concerns are in non-scientific areas (45 CFR 46.107 c)
5. A member qualified to address the validity of scientific experimental designs (45 CFR 46.107 c)
6. Additional members as necessary to provide a balanced representation of disciplines that conduct research with human participants (45 CFR 46.107 b)
7. IRB Alternate Members: All Alternates for IRB members must complete the same training as new IRB members prior to serving as an Alternate and through their expertise, training, and/or affiliation are designated to serve as an Alternate for one or more IRB members.
8. The IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB (45 CFR 46.107 f).

The IRB will strive to be sensitive to the composition and concerns of the community, in both its makeup and its decisions. Membership shall be made up of a balanced representation of gender and include members from a variety of professions and academic disciplines (45 CFR 46.107 b). No IRB member may participate in the initial or continuing review of any project in which the member has a conflict of interest except to provide information requested by the IRB (45 CFR 46.107 e).

B. Conflict of Interest
Any IRB member with a vested interest in a project being reviewed will recuse him- or herself from participating in the review and decision

C. IRB Chair
The provost appoints the Chair of the BSC IRB.

D. Alternate Members
The provost may appoint one or more alternate members of the BSC IRB. Alternate members must be of the fit the categories of membership of membership, and meet the training and/or professional requirement for IRB membership.

E. IRB Oversight
The Provost, or the Provost's designee, is responsible for ensuring that the IRB is completing its duties in a timely and appropriate manner. The Chair of the IRB shall submit an annual report detailing the activities of the BSC IRB to the Provost and the faculty.

II. TRAINING

IRB members must meet the following minimum training requirements before reviewing any research protocols:

1. Read The Belmont Report.
2. Read the Birmingham-Southern BSC Policy on Protection of Human Participants.
3. Read the Common Rule and B, C, and D of the U.S. Department of Health and Human Services (HHS) regulations 45 CFR part 46.
4. Complete the IRB Member Training at https://www.citiprogram.org/.
5. Completion reports must be submitted to the IRB Administrator (irb_administrator@bsc.edu).

III. BSC IRB LEVELS OF REVIEW

The levels of review, established in the relevant federal regulations and guidelines, are **exempt**, **expedited**, and **full**. Some research involving human participants poses little potential for harm and may be found exempt from further review. At the other end of the spectrum, research may pose a substantial risk of harm to participants and necessitate a full and thorough review of the research protocol before a decision regarding approval or disapproval is rendered by the IRB. The levels of review are defined in the section below. Special guidelines apply to research being conducted as part of a class, see Addendum 1: Human Participant Research Conducted as Part of a Course or Class Project.

A. Exempt Review

Certain research projects may be exempt from review. An experienced member of the IRB will conduct a review of the request for exemption and determine if the proposed research qualifies. There are two criteria the proposed research must satisfy in order to qualify for review via exempt procedures.

The research must not pose greater than *minimal risk* of harm defined as the probability and magnitude of physical or psychological harm that is normally encountered in daily life, or in the routine medical, dental, or psychological examination of healthy persons.

The research must be classified into at least one of the exempt categories defined by federal regulations and listed below. (See 45 CFR 46.101 (b).)

1. Education research
2. Surveys, interviews, educational tests, public observations (as long as they do not involve children)
3. Studies of public officials
4. Analysis of previously-collected, anonymous data
5. Public benefit or service program
6. Consumer acceptance, taste, and food quality studies

If a researcher believes his or her research satisfies one of the exempt categories above, a request for exemption may be submitted by completing the appropriate form. The IRB will review requests for exemption and decide if an exemption is warranted. If an exemption is not granted, it will be necessary to request an expedited or full review.

B. Expedited Review

Expedited review, as defined by federal regulations (45 CFR 46.110), allows the IRB Chairperson to evaluate and approve specific types of research. The BSC IRB Chair may designate an experienced IRB member or a subcommittee of the IRB to evaluate and approve specific types of research eligible for expedited review. Reviewers conducting an expedited review may exercise all of the authority of the IRB except that they may not disapprove a study. When the BSC IRB Chair or designated member or subcommittee cannot approve the research under expedited review, the study is referred to the full Board for review.

In order to qualify for review via expedited procedures two criteria must be met:

1. The research must not pose greater than minimal risk to participants.
2. It must fall into at least one of the expedited categories defined by the federal regulations, which are listed below:
    a. Clinical studies of drugs and medical devices only when certain conditions are met
    b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts
    c. Prospective collection of biological specimens for research purposes by noninvasive means
    d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves
    e. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes
    f. Collection of data from voice, video, digital, or image recordings made for research purposes
    g. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
    h. Continuing review of qualified research previously approved by the BSC IRB

An expedited review procedure is not applicable for research projects where identification of the participants and/or their responses is reasonably construed to place them at risk of criminal or civil liability or be damaging to the participants financial standing,

employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk. See 45 CFR 46.110 (a) (b)

C. Full Board Review

Proposed human subject research that poses greater than minimal risk to participants and does not fall into either the exempt or expedited review categories must be submitted for full IRB review.

IV. Review of Proposals

A. Types of Reviews

1. Exempt Review

The Chair, or an IRB member designated by the Chair, will review requests for exemption from further review.

2. Expedited Review

If the investigator indicates on the Request for Review of Research Involving Human Participants that the proposed project involves minimal risk to participants, and if the Chair of the IRB agrees with that assessment, then the review will be carried out by the IRB Chair or will be conducted by an experienced committee member or a subcommittee who is designated by the Chair.

The IRB Chair or committee member conducting review may offer approval with the provision that minor procedural changes be made in the protocol. If the investigator agrees to implement the suggestions, it will not be necessary to convene the Board to discuss them. However, the investigator should resubmit his or her proposal incorporating those changes for the purpose of a permanent record.

Requests for a waiver of informed consent documentation or a waiver of informed consent can be considered in both full board reviews and expedited reviews by the members of the IRB.

3. Full Board Review

For the following circumstances, the IRB Chair will distribute copies of the plan of investigation to all Board members and will add the request for review to the agenda of the next scheduled full IRB meeting:

a. If the investigator indicates on the Request for Review of Research Involving Human Participants that the proposed project involves putting the participants at risk or if the IRB Chair disagrees with the investigator's assessment that the project involves minimal risk to participants.
b. If the research is conducted with a vulnerable population (e.g., children [see Addendum II and Alabama Code, Section 26-1-1 Age of Majority Designated as 19 Years], cognitively impaired persons, prisoners, and elderly/aged persons).
c. If a Board member disapproves of a project sent through Expedited Review. All reviewing members of the IRB shall be sent materials pertaining to the proposal and

shall be given timely notice of all meetings. No decision regarding approval or disapproval shall be made unless a quorum is present.

B. Criteria Applied in Review

In order for research to be approved by the BSC IRB all of the following requirements must be satisfied.

1. Risks to subjects must be minimized:
    a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk
    b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the proposed research. In evaluating risks and benefits, the BSC IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The BSC IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects must be equitable. In making this assessment the BSC IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent must be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
5. Informed consent must be appropriately documented, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data must be adopted and practiced.

The BSC IRB will ensure additional adequate safeguards to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, are included in any research project that is approved.

C. Timeline Regarding Proposal Review

A decision regarding approval of a request for exemption will typically occur within five business days of submission of the request.

For projects that pose minimal risk to participants and can be evaluated using Expedited Review, it will typically take five business days for researchers to receive feedback. If the IRB suggests any changes, researchers will typically be requested to respond to the suggested changes within one week of receiving the IRB feedback.

For projects that place participants at risk, a Full Board Review must be conducted. The schedule of meetings is published on the BSC IRB website. Researchers must submit proposals requiring full IRB review at least ten business days prior to a scheduled IRB meeting. If the IRB suggests any changes, researchers will typically be requested to respond to the suggested changes within one week of receiving the IRB feedback.

These timelines are the time for review after **all** required materials are submitted. If an initial proposal does not include all required materials, the committee will wait until all materials have been submitted for review before the timeline for approval starts.

D. Decisions Regarding Proposals

The IRB Chair shall notify all investigators of the Board's decision regarding their requests. Approval of requests will generally last for one calendar year; investigators will be given an expiration date when they receive approval. Research projects that pose greater than minimal risk may be approved for a period of six months. In the event that the IRB does not approve an request, the Chair will explain to the investigator why approval was not granted and will specify the changes, if any, that would be necessary for the request to be approved.

V. MEETINGS SCHEDULE AND DEFINITION OF QUORUM

A. Meetings Schedule

The IRB shall hold meetings as necessary for the timely and effective review of proposed research projects. The IRB Chair shall schedule and preside over the meetings. Each academic year the Chair of the IRB shall set and publish monthly meetings dates on which the full IRB convenes.

B. Quorum

Meetings shall only proceed when a quorum exists. A quorum exists when a majority of the IRB members are present and voting. For a quorum to exist, at least one IRB member whose primary concerns are in a non-scientific area shall be present and voting.

VI. IRB DECISIONS

A. Approval

Approval is the determination of the BSC IRB upon review that the research described in the request for review may be conducted by BSC faculty, staff, or students under the auspices of BSC and within the constraints set forth by the BSC IRB and by other institutional, local, state and federal requirements.

B. Conferring Approval

Proposed research projects shall be deemed approved by the IRB when:

1. In the case of requests for exemption, the Chair of the IRB, or the IRB member designated by the Chair, determine that an exemption is warranted and inform the investigator proposing the research in writing of the decision.
2. In the case of expedited reviews, the designated IRB member or subcommittee conducting the review and the Chair both confer approval, and the investigator proposing the research is informed in writing of the decision.

3. In the case of all other reviews, a simple majority of the IRB members present at an IRB meeting (and comprising a quorum) vote to confer approval, and the investigator proposing the research is informed in writing of the decision.
4. Except where required by federal state, local or agency regulation notice of approval in writing shall be provided by e-mail. When required, notice of approval will be provided in hard copy to the principal investigator.

C. Conferring Disapproval

Full IRB meetings are required for the disapproval of proposed research projects even if such proposals were initially subjected to expedited review. Such disapprovals shall be the result of the vote of a simple majority of the IRB members present at the meeting and comprising a quorum. In the communication of the disapproval to the investigator, the IRB shall state the reasons the proposed research project was disapproved.

D. Resubmission of a Request to the IRB

Some projects submitted for review may be disapproved with the need for substantial and extensive modifications beyond the capacity of the IRB to make recommendations. Investigators proposing research projects that have been disapproved by the IRB where the IRB is unable to suggest modifications may resubmit a Request for Review and Approval at any time after substantial modifications have been made to the project design.

VII. Responsibilities of Principal Investigators in the Conduct of BSC IRB Approved Research

1. Know and apply ethical guidelines and federal, state, local, and institutional regulations regarding the protection of human participants from research risks.
2. Conduct the research according to the approved protocol.
3. In the case of research approved with a requirement of written informed consent, use the approved consent form for each and every study participant as required by the BSC IRB. In cases where written informed consent is not required use the consent procedures as stated in the request for review and approved by the BSC IRB for all study participants.
4. Immediately report to the BSC IRB and your immediate administrator any unanticipated effects or adverse events on participants that become apparent during the course or as a result of study procedures. Include the actions taken as a result.
5. Obtain prior review from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form.
6. Maintain documentation of consent forms and progress reports for three years in a secure location.
7. Ensure that all personnel conducting the research have completed the necessary training, including appropriate CITI training as specified by the BSC IRB. Completion reports for all personnel must be on file with the IRB Administrator.
8. Cooperate with the IRB in the continuing review of and final reporting on the project as required by Federal regulations and the BSC IRB.

VIII. Record of IRB Work

The IRB Administrator shall take and maintain minutes in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving

research; and a written summary of the discussion of controverted issues and their resolution for all BSC IRB meetings in a permanent file . The minutes shall be shared with all IRB members within a reasonable period following each meeting. The IRB Administrator will maintain an accurate list of IRB members and ascertain that member training requirements are current for all members. All research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects and unexpected and adverse event reports will be maintained and archived by the IRB Administrator.

Actions of the IRB that take place outside of regular meetings (conferring approvals through expedited reviews and exemptions) shall be shared with all IRB members within a reasonable period following each such action. Approvals conferred by expedited reviews and exemptions will be recorded in the minutes of full IRB meetings. The IRB Administrator shall place all correspondence with Board members, correspondence with investigators, statements of significant new findings provided to subjects and records of continuing review activities in a permanent file. All records shall be retained for at least three years after completion of the research in the Office of the Provost. All records shall be accessible for inspection and copying by authorized representatives of a funding department or agency, or OHRP at HHS, at reasonable times and in a reasonable manner

IX. APPEALS

The Institutional Review Board will deny a research request if they believe the risks outweigh the benefits of the research. If the principal investigator disagrees with the Board's disapproval decision, the researcher may make an appeal. The principal investigator may either submit a new request or re-submit the same request form with a letter of appeal presenting the researcher's arguments for approval and any other pertinent information in support of the appeal.

The appeal request should be submitted via email to the Chair of the IRB. Requests submitted for appeal are considered by the entire Board. The decision of the IRB is delivered via email to the investigator. If the appeal request is not approved, the research cannot be conducted.

No limitations are placed on the appeal process, allowing investigators to appeal decisions and resubmit additional information as frequently as warranted.

X. MODIFICATIONS TO APPROVED PROTOCOLS

All modifications to an existing approved protocol (including study-related procedures, personnel, or duration of the study) must **FIRST** be approved by the IRB, unless said changes are necessary to avoid undue harm or increased risk to the participants. Changes made in response to adverse effects or events must be reported to the IRB immediately. Modifications are to be documented in the appropriate section on the originally approved request (Section 9. MODIFICATIONS ONLY).

A. **Modifications eligible for expedited IRB review** (Exempt or expedited)
    1. Changes in protocols for studies that have had no adverse effects or events reported, and that will not result in a change in risk to participants
    2. Changes in personnel or duration of the study that will not result in a change in risk to participants

B. Modifications requiring full IRB review

1. Changes in protocols, personnel, or duration for studies that have had adverse effects or events reported
2. Changes in protocols, personnel, or duration that may result in increased risk for the participants
3. Changes in protocols that involve the addition of vulnerable populations (e.g., fetuses, infants, children, prisoners, or those with diminished cognitive abilities)

C. Modifications to existing protocols must be submitted for approval and include the following:

1. A copy of the approved protocol with requested changes highlighted and an accompanying explanation or justification for said changes.
2. Changes that involve increased risk to participants must address how this risk will be managed.
3. Changes that involve the addition of vulnerable populations must address what measures will be taken to ensure the protection of these participants.
4. A copy of the current and/or new consent form.
5. If the researcher is a student, a letter or email from the supervising professor stating their approval of the revision.

D. Modifications to existing protocols involving only changes in personnel or duration of study:

1. Addition of personnel: submit the name of the individual(s), their completion reports for the appropriate CITI training, level of involvement or role in the study, and qualifications.
2. Removal of personnel: submit the name of the individual(s) and a brief explanation for why he/she is no longer involved in the study.
3. Change in duration: submit a status report explaining how much of the project has been completed, how much remains, the new estimated duration, and a justification for the proposed change in the duration of the study.

XI. RENEWALS

A research project is subject to renewal review by the BSC IRB if it extends beyond the approval period. Approval of a human participant research request is generally for one year, unless the project has acceptable but significant enough risk that the committee elects to extend approval for only a shorter time period. If the project continues beyond the approval period, the principal investigator must submit a status report of the project to date, including:

1. The number of participants accrued
2. A summary of adverse events and any unanticipated problems involving risks to participants or others, including the number and any reason given for the withdrawal of participants from the research or complaints about the research since the last review
3. A summary of any relevant amendments or modifications to the research not necessitating review at the time of amendment or modification.
4. Any other relevant information, especially information about risks associated with the research
5. A copy of the current informed consent document and any newly-proposed consent document

The IRB will follow procedures for the appropriate level of review in light of the status report and will either extend or withhold renewed approval. If renewed approval is withheld, data collection must cease on the date of the expiration of the prior term of approval.

XII. Audits

The BSC IRB is responsible for auditing approved human participant research conducted under the auspices of BSC. Research projects may be randomly selected for auditing, or a decision to audit may be made by the IRB based on the complexity of the project, potential risk to participants, or a history of non-compliance with IRB regulations.

XIII. Project Closure

At the end of a BSC IRB-approved research project, researchers must submit a Project Closure Form.

XIV. Reporting of Unanticipated Problems, Serious or Continuing Non-Compliance, and Suspensions or Terminations of IRB Approval

Investigators must immediately report to the IRB any adverse effects, events, or unanticipated problems involving risks to participants or others. The IRB Chair must report such events to the Provost, the sponsors of the research, and OHRP.

Upon receiving knowledge of adverse effects, events, other unanticipated problems involving risks to participants, or serious non-compliance, the IRB Chair will inform the Provost, who will determine the next immediate course of action.

In cases where there is significant risk of injury to participants, the IRB Chair has the authority to suspend the research until a more thorough review can take place. The Provost will notify OHRP as soon as possible after the verification of a report of adverse event or non-compliance.

Following the immediate response to reports of adverse effects, events, serious non-compliance, or other unanticipated problems involving risks to participants noted above, the BSC IRB may take one or more of the following actions:

1. Suspend the study pending further investigation
2. Terminate IRB approval and require the study to be closed (with appropriate protections for avoiding harm to enrolled participants)
3. Require further training for the investigator as a condition of review for future research

XV. Misconduct

Issues regarding misconduct by researchers or IRB members should be reported to the Provost. The Provost, or the Provost's designee, will review and address any alleged misconduct.

Addendum 1

Human Participant Research Conducted as Part of a Course or Class Project

I. Faculty Teaching/Research and Related Activities

This section is intended to provide guidance to faculty regarding course activities that are research-related and present issues regarding whether or not the course activities fall under the jurisdiction of the Institutional Review Board (IRB). What follows is guidance *only.*

Review by the IRB should be sought if a project uses methods designed to develop or contribute to generalizable knowledge, involves human participants, and any of the following apply:

1. The student intends to disseminate the results beyond the classroom (e.g., presentations at local, regional, and national conferences; publications; blogs and websites). Dissemination at Senior Conference or Honors Day, on campus, does not necessitate IRB review unless one or more of the conditions described in points 2 through 5 below apply.
2. The project involves greater than minimal risk, meaning the probability and magnitude of physical or psychological harm is greater than what is normally encountered in the daily lives of the participants.
3. The project collects sensitive information that is recorded in such a way that the respondent can be linked with their responses (either through collected identifiers or demographic data). Sensitive information may include information about drug use, sexual preferences, family violence, and similar topics.
4. The project collects data from people unable to provide informed consent due to their age, incarceration, or limited mental capacity.
5. The research involves deception.

II. Class and Course Research Exceptions to Review Requirements and Research Requiring review

Faculty are encouraged to consult with the IRB Chair or committee members if they have questions. The federal definition of research as "a systematic investigation (i.e. the gathering and analysis of information) designed to develop or contribute to generalizable knowledge" is the key concept defining IRB jurisdiction. The following three categories illustrate how applying the concept to activities combining teaching and research may or may not require IRB review.

1. **Demonstrations**

   Classroom projects that are for the primary purpose of teaching a student about research, to illustrate scientific principles, or to conduct statistical analysis, and are not for dissemination beyond the instructor and other students in the class, do not constitute human subjects research because they are not designed to develop or contribute to generalizable knowledge. The following sections provide additional guidance regarding circumstances where classroom projects do or do not require review by the IRB.

   Data are collected from students enrolled in a course for the purpose of demonstrating principles of science and/or behavior firsthand or to provide data for learning statistical analysis. Such demonstrations are public only within the context of the class, the risks are known to be minimal, and students are able to choose not to participate and are provided alternate means of earning participation credit. The data are not collected for publication in scholarly journals or

disseminated outside the course. There are no restrictions about how long the demonstration lasts (one or more class periods), where the data are initially collected (during or outside class time), or how "well-known" the principle being demonstrated is. The primary components of these types of class activities are that the **risk of harm to students is minimal and gathering and dissemination of the data is confined within the class setting.** If the activities in a class conducted by faculty are as described in this section, IRB review is not required.

2. **Students Learning About Research or How to Do Research in a Class**
   This category differs from the first in that students may be asked to be participants in research projects as a credit earning class activity, but the research is not confined to one just one class. An example is joining a participant pool of students enrolled in introductory social science classes or students conducting human participant research as a component of a research methods class.

   If students are enrolled in a course where, as a component of the course, they are offered the opportunity to participate in research as subjects, this should be clearly stated in the course syllabus. Faculty teaching courses where credit is offered for participating in research should seek a single, global informed consent for participation from the students (or students' parents or legal guardians if they are under 19 years of age) for all participation opportunities throughout the term. Researchers should then obtain assent from the subject pool participants for each project in which an opportunity to participate is offered.

   In other cases students may be enrolled in classes designed to develop research capacity and skill. Students in these classes may individually or jointly conduct several research projects in one term. Faculty instructing these classes should request IRB approval for all projects to be conducted in the class at the beginning of the term. The faculty member must stipulate that none of the projects will be disseminated beyond the classroom or BSC campus setting, involve greater than minimal risk, collect sensitive information that is recorded in such a way that the respondent can be linked with their responses, or collect data from people unable to provide informed consent.

   When students are asked to serve as researchers with non-class participants serving as subjects, then the interests of these non-class members takes precedence. If the project would readily fit under the exemption categories of the IRB, then the professor may seek "blanket" IRB approval in advance, based on a generic description of topics and/or methods that the professor will subsequently allow students to pursue. Otherwise, the project should be submitted under standard IRB procedures.

3. **Students Doing Research under Faculty Guidance**
   Students doing individual or group research under faculty guidance (e.g., senior project, independent study, Honors projects, etc.) are not conducting classroom projects and may or may not require IRB review. Consultation with the IRB is recommended.

III. Change in Status of Research Approved for Instructional Purposes

If the original project is primarily for instructional purposes but researchers wish to disseminate the results publicly at a later time, the researchers or course instructor may file for IRB review of the archival data analysis at that time. Similarly, if the investigator finds that demonstration or instructional research

conducted and/or approved under the principle of minimal risk of harm to participants poses a greater than minimal risk of harm the research must stop. Full IRB review and approval is required before the research may continue.

Addendum 2

Special Protections for Children as Research Subjects

I. Definition of a Child for Purpose of Consent

By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in research, under applicable law of the jurisdiction in which the research will be conducted. Under Alabama law, a minor is a person younger than 19 years old, unless such a person has been emancipated (Code of Alabama, Section 26-1-1).

II. Obtaining Consent and Assent to Participate

Research conducted under the auspices of BSC in which children, as defined above, are participants will be reviewed by the IRB in accordance with 45 CFR 46, Subpart D, which generally requires the consent of at least one parent or a legal guardian and the assent of the child.

III. Definition of a Parent or Guardian

A parent, for purposes of consent, means either a child's biological or adoptive parent. A guardian is an individual who is authorized under applicable state or local law to exercise the powers and responsibilities of a parent regarding the minor's health, support, education, or maintenance and to consent to the general medical care of the minor.

IV. Research in a State Other Than Alabama

If the proposed research involves children in another state as participants, the laws of the state where the research occurs will apply. Researchers should specify the location of research and, if conducted in a state other than Alabama, assure compliance with relevant state laws and local ordinances.

V. Obtaining Consent from College Students Who Have Not Reached Age of Majority

Investigators need to be aware that the age of majority in Alabama places many college students in the legal category of minor children unable to provide informed consent to participate in research. Where students are offered the opportunity to participate in multiple research projects as a component of a class or classes at BSC the IRB will consider approval of consent procedures where a single, global consent to participate in any of the research opportunities presented during a term is obtained from parents or guardians. All research projects for which such global consent is obtained must pose no more than a minimal risk of harm to participants. Assent must then be obtained from minor students for each individual research project in which the opportunity to participate is offered and accepted. No student legally classified as a minor will be a participant in research unless both the consent of a parent or guardian and the assent of the student are obtained.

Addendum 3
IRB Authorization Agreements

I. Definitions

IRB Authorization Agreement: A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying Institution. Agreements are generally used to cover a single research study, categories of research studies, or research studies within a research program.

Federalwide Assurance (FWA): A formal, written, binding attestation in which an institution ensures to the Department of Health and Human Services (HHS) that it will comply with applicable regulations governing research with human subjects.

IRB of Record: A reviewing IRB that assumes IRB responsibilities for another institution and is designated to do so through an approved Federalwide Assurance on file with the federal Office for Human Research Protections.

IRB Reliance and Relying Institution: IRB reliance is a term to describe partnerships or agreements among different IRBs to rely on each other to provide IRB oversight for research studies. The relying institution accepts the review of the IRB of record.

II. Scope

IRB Authorization Agreements apply only to research that requires review at the expedited or full IRB levels of review. As a relying institution, the BSC IRB will only enter in Authorization Agreements with IRBs with Federalwide Assurance.

III. Procedures

A. BSC IRB as IRB of Record: Authorization Agreements with the BSC IRB as the IRB of record will generally be submitted by principal investigators. Approval from the Chair of the BSC IRB must be obtained before submitting the agreement for approval.

B. BSC as the Relying Institution: The Authorization Agreement shall be submitted to the Chair of the BSC IRB for review and approval. The BSC IRB Chair, or the Chair's designee, shall review and approve or disapprove submissions for authorization agreements where BSC is the relying institution. Investigators seeking an IRB Authorization Agreement where BSC will be the relying institution shall complete the BSC IRB Authorization Agreement form and supply supporting documentation as required. If the agreement is approved by the Chair of the BSC IRB or the Chair's designee, it will be forwarded to the Provost for final approval or disapproval. Only agreements with IRBs having Federalwide Assurance will be approved.

If the BSC IRB is the IRB of record or if BSC is the relying institution, no research covered by an agreement shall commence until the agreement is formally approved by the cooperating institutions. The Chair of the BSC IRB shall inform the full BSC IRB of all Authorization Agreements, and the IRB Administrator shall record the approval of all Authorization Agreements in the minutes of a regular full IRB meeting.

Addendum 4
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.

Addendum 5
International Research Review

Research conducted in foreign countries under the auspices of Birmingham-Southern College remains under BSC IRB purview and guidelines. The standards for ethical conduct of research or for a meaningful consent process may be adapted to cultural and/or religious norms as appropriate with justification provided with the request for review. Requests for waivers of written consent should also be justified in terms of adaptation to the norms of the locale where the research will be conducted. The "International Compilation of Human Research Protections" is a resource that may be consulted for known international research protections. When a country or institution abroad has an equivalent to an IRB, research projects must have been approved by that local equivalent board **before** they are presented to the BSC IRB. Where there is no equivalent board or group, investigators must demonstrate that they have obtained approval from local experts or community leaders. The IRB requires documentation of this "local approval" before it approves a project. Principal investigators and research assistants for international research must complete CITI training modules in Cultural Competence in Research and International Studies in addition to the appropriate basic courses in either Social & Behavioral Research or Bio-Medical Research.