This set of guidelines is intended to assist students and other first time applicants with the Human Subjects Review Board (HSRB) request for review.

1. **What is the HSRB?**

   The Birmingham-Southern College Human Subjects Institutional Review Board (BSC HSRB) was established to safeguard human subjects in research by protecting their rights and promoting the ethical and responsible treatment of research subjects.

   BSC HSRB policy requires that all research involving human subjects conducted under the auspices of BSC must be reviewed and approved by the HSRB before the data gathering phase may commence. The BSC HSRB upholds and applies the ethical principles of the Belmont Report and operates in compliance with federal law outlined in the Code of Federal Regulations Title 45 Part 46 (45 CFR 46), in compliance with state laws and College policies.

   **Completion of the appropriate training course at The Collaborative Institutional Training Initiative (CITI Program) is a prerequisite for HSRB review.** Complete the training course before working on the Request for Review.

2. **How do I know if I should submit an application to the HSRB?**

   The HSRB reviews proposals that constitute research, as defined by the U.S. Department of Health and Human Services, Code of Federal Regulations and the Belmont Report. Research, according to the **Belmont Report**, “designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to
generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.” In the Code of Federal Regulations (45 CFR 46.102) research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subjects, sometimes referred to as participants, are living individuals about whom an investigator or investigators (whether professional or student) in the course of research obtain: (1) data through intervention or interaction with the individual or (2) identifiable private information.

3. You may be wondering why your research needs to be reviewed. Birmingham-Southern College is committed to the ethical conduct of research and has adopted the ethical standards of the Belmont Report. The principles and applications found in the Belmont Report excerpted below provide context for understanding the need for review. The report articulates ethical principles to be applied in the human subjects research setting and explains in a general way how the principles apply.

Guiding Principles and Applications from the Belmont Report

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 subjects, 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.

**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 subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate. Furthermore, this benefit must outweigh the risks.

**Principle: Justice** requires that people be treated fairly. Researchers should not take from research participants without giving back.

**Application: Selection of Subjects.** 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 subjects.
4. **What is taken into account in the review process?**

Based on the principles and applications of the Belmont Report and 45 CFR 46, a wide array of factors is considered by the BSC HSRB during a review of proposed research. You will be asked to provide documentation regarding informed consent and the selection of subjects. One of the most important factors, related to the principle of beneficence, is the design or protocol of the research project. **A key factor in the approval/disapproval decision by the BSC HSRB is based on weighing the benefits of the research (as defined above) against the risks to participants.** All research projects pose some risk of harm to participants so the weight assigned to risk in any review is never zero. However, if the design of the research project is flawed then hypotheses cannot be tested, research questions cannot be answered and no contribution to generalizable knowledge is possible. The benefit side of the benefit to reward ratio is given a weight of zero. In this circumstance, even though risk to subjects is minimal, the proposed research will not be approved.

It is important that research proposals submitted for review clearly articulate the potential benefits of the research, provide sufficient information regarding the design of the research so that the capacity of the research to provide the benefit is established, and that risks to subjects are clearly identified and addressed.

5. **What about the population under study?**

Different rules apply to research with the general population versus research that may involve vulnerable populations including children, pregnant women, prisoners and the cognitively impaired. Contact the HSRB Chair if your research involves a vulnerable population.
6. **What are the different levels of review?**

The levels of review are **exempt**, **expedited**, and **full**.

**Exempt Review**

Certain research projects may be exempt from review. An experienced member of the HSRB 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.

1. 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.
2. The research must be classified into at least one of the exempt categories defined by federal regulations and listed below.
   1. Education research
   2. Surveys, interviews, educational tests, public observations (that 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 you believe your research satisfies one of the exempt categories above, you may submit a request for exemption by completing the appropriate form. The HSRB will review requests for exemption and decide if exemption is warranted. If exemption is not granted, it will be necessary to apply for expedited or full review.

**Expedited Review**
Expedited review as defined by federal regulations allows the HSRB chairperson (or an experienced member or a subcommittee of the HSRB designated by the chairperson) to evaluate and approve specific types of research. Reviewers conducting an expedited review may exercise all of the authority of the HSRB except that they may not disapprove a study. When a board member or subcommittee cannot approve the research under expedited review, the study is referred to the full Committee 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; and (2) it must fall into at least one of the expedited categories defined by the federal regulations. An expedited review procedure is not applicable for research projects where identification of the subjects and/or their responses is reasonably construed to place them at risk of criminal or civil liability or be damaging to the subjects 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.

**Federally-defined Expedited Categories:**

- Clinical studies of drugs and medical devices only when certain conditions are met
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts
- Prospective collection of biological specimens for research purposes by noninvasive means
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes
- Collection of data from voice, video, digital, or image recordings made for research purposes
• 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

• Continuing review of qualified research previously approved by the BSC HSRB

**Full Committee Review**

Proposed human subject research which does not fall into either the exempt or expedited review categories must be submitted for full committee review. Contact the HSRB Administrator for submission deadlines and meeting dates for the HSRB.