Birmingham-Southern College

IRB Protocol # _____

REQUEST FOR IRB REVIEW OF EXEMPT RESEARCH INVOLVING HUMAN SUBJECTS

Please complete this Request for Review as thoroughly as possible.
FORM MUST BE TYPED. HANDWRITTEN DOCUMENTS WILL NOT BE ACCEPTED.

COMPLETE ONLY ONE EXEMPTION SECTION BELOW BEST DESCRIBING YOUR RESEARCH.

For further **detail on exemption categories**, consult
the US Department of Health and Human Services Code of Regulations, Title 45, Part 46, Section 101(b).

EXEMPTION I: FOR PROTOCOLS INVOLVING ESTABLISHED OR COMMONLY ACCEPTED EDUCATION SETTINGS AND NORMAL EDUCATIONAL PRACTICES [CFR 46.101(b)(1)]

Ia. Where will the research activity take place? *(Check all that apply.)*
☐ Established educational setting ☐ Other, please explain below.

Ib. What type(s) of activities will be used? *(Check all that apply.)*
☐ Research on regular and special education instructional strategies
☐ Research on the effectiveness of instructional techniques, curricula, or classroom management methods
☐ Research comparing instructional techniques, curricula, or classroom management methods
If the research involves other activities, it is not eligible for this exemption. Do not proceed.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

EXEMPTION II and III: FOR PROTOCOLS INVOLVING TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR [CFR 46.101(b)(2)] WITH ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE [CFR 46.101(b)(3)]

IIa. What type(s) of instruments/activities will be used *(Check all that apply.)*
☐ Educational (cognitive, diagnostic, aptitude, achievement)
☐ Tests *Type of test:* ☐ *published/standardized or* ☐ *researcher-created*
☐ Questionnaire Survey *Type of survey:* ☐ *paper* ☐ *telephone* ☐ *online*
☐ Interviews *Type of interview:* ☐ *face-to-face* ☐ *telephone* ☐ *e-mail/chat room*
☐ Observation of public behavior
If the research involves other activities, it is not eligible for this exemption. Do not proceed.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

IIb. Will information be recorded in a manner that participants can be identified? ☐ Yes ☐ No

IIc. Would disclosure of information obtained put participants at risk for civil or criminal liability or damage to their financial standing, employability, or reputation? ☐ Yes ☐ No
If the answer to "b" and "c" is "Yes," the research is not eligible for this exemption. Do not proceed.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

EXEMPTION IV: FOR PROTOCOLS INVOLVING THE COLLECTION OR STUDY OF EXISTING DATA, DOCUMENTS, RECORDS, OR SPECIMENS [CFR 46.101(b)(4)]

IVa. What will be collected or studied? *(Check all that apply.)* ☐ Existing data ☐ Existing documents
☐ Existing records ☐ Existing pathological specimens ☐ Existing diagnostic specimens
If the research involves other types of data, it is not eligible for this exemption. Do not proceed.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

IVb. Is this information publicly available? ☐ Yes ☐ No

IVc. Will information be recorded in a manner that research subjects cannot be identified, directly or through identifiers? ☐ Yes ☐ No
If the answer to "b" and "c" is "No," the research is not eligible for this exemption. Do not proceed.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

Exemption categories continue on the next page.

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EXEMPTION V: FOR PROTOCOLS INVOLVING RESEARCH AND DEMONSTRATION PROJECTS THAT ARE CONDUCTED BY OR SUBJECT TO THE APPROVAL OF DEPARTMENT OR AGENCY HEADS, AND THAT ARE DESIGNED TO STUDY, EVALUATE, OR OTHERWISE EXAMINE PROGRAMS OR BENEFITS [CFR 46.101(b)(5)]

V. What is the purpose of this study? *(Check all that apply.)*

- ☐ To evaluate public benefit or service programs
- ☐ To evaluate procedures for obtaining benefits or services under programs
- ☐ To determine possible changes in or alternatives to programs or procedures
- ☐ To assess possible changes in methods or levels of payment for benefits or services under those programs

If none of these apply, do not proceed. The research is not eligible for this exemption.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

EXEMPTION VI: FOR PROTOCOLS INVOLVING TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES [CFR 46.101(b)(6)]

VIa. What is the purpose of this study? *(Check all that apply.)*

- ☐ To evaluate the taste or quality of food
- ☐ To test consumer acceptance of a food

If neither of these apply, do not proceed. The research is not eligible for this exemption.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

VIb. What type of food will be consumed during the research? *(Check all that apply.)*

- ☐ Wholesome food without additives
- ☐ Food that contains an ingredient at or below the level and for a use found to be safe by the FDA or approved by the EPA or Food Safety and Inspection Service of the USDA
- ☐ Food that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or Food Safety and inspection Service of the USDA

If the food to be consumed is not in one of these categories, it is not eligible for this exemption. Do not proceed.
You must complete the Request for IRB Review of Non-Exempt Research Involving Human Subjects.

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1. Research Project ***(This section to be completed for ALL exemptions.)***	☐ **New** ☐ **Modification**
Protocol Title:	
Date of Submission:	
Research project start date*: _____ **The project start date cannot be earlier than the protocol's approval date. If you want to start your research as soon as your protocol is approved, you may put "upon approval" for the project start date.*	Research project end date*: _____ ***The project end date should be the date after which you will no longer be working with human subjects data collected for this project.*
☐ Unfunded	
☐ Internal Funding (BSC award)	Source:
☐ External Funding *(provide grant title and award # below)*	Sponsor/Agency:
Grant Title:	Grant Award #:

2. Principal Investigator (PI) ***(This section – 2a OR 2b – to be completed for ALL exemptions.)***		
2a. STUDENT PI*		
Name:	Telephone:	E-mail:
Course # and Name**:		
***Use "Independent Student Research" for course name if research is not for specific course.**		
Faculty Sponsor:	Faculty Sponsor E-mail:	
***ALL** student investigators must have a faculty sponsor for their project. Faculty sponsor needs to review and approve the protocol before it is submitted. The faculty sponsor will indicate their approval by signing and submitting a Faculty Sponsor Assurance Form to irb_administrator@bsc.edu.*		
2b. FACULTY/STAFF PI (Do not complete this section if you are a student.)		
Name:	Department:	E-mail:
☐ Class Research Project	☐ Independent Research Project	
Course # and Name:		

3. Co-Investigators ***(This section to be completed for all exemptions, if applicable.)***	
Name: E-mail:	Institution *(if not BSC)*:
Name: E-mail:	Institution *(if not BSC)*:
Name: E-mail:	Institution *(if not BSC)*:
Name: E-mail:	Institution *(if not BSC)*:

Section 3 continues on the next page.

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Name: E-mail:	Institution *(if not BSC)*:
Name: E-mail:	Institution *(if not BSC)*:

4. Cooperating Institutions *(This section to be completed for all exemptions.)*

4 (a) Will the research be conducted on the BSC campus? ☐ Yes ☐ No
If "no," please indicate the location(s):

4 (b) If applicable, have you obtained permission to conduct the research at the off-campus location? ☐ Yes ☐ No
If "yes," please attach a copy of the documentation of permission if it was provided.

4 (c) Is this research being done in cooperation with any institutions, individuals, or organizations not affiliated with BSC? ☐ Yes ☐ No If "yes," please list:

4 (d) Have you received IRB approval for this study from an IRB at another institution? ☐ Yes ☐ No
If "yes," please attach a copy of the IRB approval.

5. Research Project Description *(This section to be completed for all exemptions.)*

5 (a) Rationale: In the boxes, below, provide (in lay terms) a concise statement of the project's general aims in relation to the broader field of research. **Please limit your rational to the space below.**

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For protocols involving tests, surveys or interviews: ☐ **N/A**

5 (b) What type(s) of instruments/activities will be used *(Check all that apply.)*

☐ Educational (cognitive, diagnostic, aptitude, achievement)

☐ Tests *Type of test:* ☐ *published/standardized or* ☐ *researcher-created*

☐ Questionnaire Survey *Type of survey:* ☐ *paper* ☐ *telephone* ☐ *online*

☐ Interviews *Type of interview:* ☐ *face-to-face* ☐ *telephone* ☐ *e-mail/chat room*

Please attach a copy of any tests, questionnaires, interview questions, surveys, scripts, etc. that will be used.*

5 (c) Reason for research: ☐ Faculty/Staff Research ☐ Undergraduate Research ☐ Graduate Research

5 (d) Does your research involve any of the following topics?

☐ Alcohol Use ☐ Drug Use ☐ Sexual Habits/Orientation ☐ Illegal Activities ☐ Emotional Stress

6. PARTICIPANTS

6(a) Participant Population

Research involving study participants who are likely to be vulnerable to coercion or undue influence (such as minors under the age of 19 (45 CFR 45 Subpart D), prisoners (45 CFR 47 Subpart C), pregnant women, human fetuses, neonates (45 CFR 45 Subpart B), persons with mental disabilities, or persons whose economic status would leave them susceptible to coercion) is not eligible for exempt status.

How many participants are needed for the study?	What will the ratio of males to females be?

Target Populations Include:

☐ Athletes
☐ Children 0-12 (Parental Consent Required)
☐ Children 13-18 (Parental Consent Required)
☐ Developmentally disabled
☐ Elderly
☐ Mentally ill
☐ Military personnel
☐ Persons convicted of a crime or on parole
☐ Persons over the age of 19 ONLY
☐ Persons with English as a second Language
☐ Physically impaired
☐ Pregnant women
☐ Teachers
☐ BSC staff
☐ BSC students
☐ College students (Non-BSC)
☐ Victims of crime

6(b) Participant Recruitment

Describe how participant recruitment will be performed. Include how and by whom potential participants are introduced to the study. *Check all boxes below that apply.*

☐ BSC College directory ☐ Postings, flyers ☐ Radio, TV

☐ E-mail solicitation. Indicate how the e-mail addresses will be obtained and describe the sampling technique that will be used.

☐ Web-based solicitation. Specify sites.

☐ Participant Pool. Specify what pool (ex. PY 101 students).

☐ Other. Please specify.

Please attach any recruiting materials and/or the text of e-mail or web-based solicitations you will use.*

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6(c) Participant Compensation and Costs

Are participants to be compensated for the study? ☐ Yes ☐ No If "yes," what is the amount, type, and source of funds.
Amount: Source: Type (ex. gift card, cash, etc.):

Will participants who are students be offered class credit? ☐ Yes ☐ No ☐ N/A
If you plan to offer course credit for participation, please describe what alternative assignment(s) students may complete to get an equal amount of credit should they choose not to participate in the study.

Are other inducements planned to recruit participants? ☐ Yes ☐ No If yes, please describe.

6(d) Participant Risks and Benefits

What are the benefits to participants in this study?

What are the risks (physical, social, psychological, legal, economic) to participants in this study?

Describe how confidentiality will be protected.

Describe how the research will be explained to participants. If applicable, attach the script that will be used to tell participants about the study, their right to withdraw, how confidentiality will be protected, and the risks and benefits of the study.

Indicate the degree of risk (physical, social, psychological, legal, economic) you believe the research poses to human subjects (**the one** which applies).
☐ **MINIMAL RISK**: a risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
☐ **GREATER THAN MINIMAL RISK**: Great than minimal risk is where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

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7. Confidentiality and Data Security *(This section to be completed for Exemption I, II and VI.)*

Will personal identifiers be collected? ☐ Yes ☐ No Will identifiers be translated to a code? ☐ Yes ☐ No
Will recordings be made (audio, video)? ☐ Yes ☐ No If "yes," please describe.

If any type of audio or video recordings will be made of your participants (including photographs), please describe how you will obtain the participants' consent to obtain these recordings, and how you will maintain a record of this consent.

Who will have access to data (surveys, questionnaires, recordings, interview records, etc.)?

Describe how you will protect participant confidentiality and secure research records.

8. Confidentiality and Data Security *(This section to be completed for Exemption IV ONLY.)*

8a. Data/Documents/Records/Specimens

From where will the data/documents/records/specimens be obtained?

Is de-identified information being provided to the investigator? ☐ Yes ☐ No
Is the information being recorded by the investigator? ☐ Yes ☐ No
If "yes," describe how the investigator will record data without identifiers.

Is the information related to the provision of healthcare? ☐ Yes ☐ No
Does the data meet the HIPAA de-identification requirements? ☐ Yes ☐ No ☐ Don't know ☐ N/A
Describe the information being used in the research.

8b. Confidentiality and Data Security

Describe how you will protect anonymity and secure research records.

9. Food *(This section to be completed for Exemption VI ONLY.)*

Specify what food(s) will be provided to participants.

How will the food be prepared?

How will the food be stored?

Describe your plan to deal with food allergies.

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10. MODIFICATIONS ONLY

What has been changed?

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SUBMISSION CHECKLIST (This section must be FULLY completed.):

For submission to be complete, all applicable documents must be sent as attachments to irb_administrator@bsc.edu. Incomplete protocol submissions will not be sent out for review and will be returned to the investigator.

My submission contains the following documents (IF APPLICABLE, DOCUMENT MUST BE ATTACHED):

Attached	N/A	
☐	☐	This Request for Review form, fully completed and signed by researcher.
☐	☐	(#4b) Documentation of permission to conduct research in a location other than BSC.
☐	☐	(#4d) IRB approval documentation from another institution.
☐	☐	(#5a) Research project description (check N/A if typed on form).
☐	☐	(#5b) Tests, questionnaires, interview questions, surveys, scripts, etc.
☐	☐	(#6b) Recruiting materials, text of e-mail or web-based solicitation.

ADDITIONAL SUBMISSION REQUIREMENTS FOR ALL STUDENT PRINCIPAL INVESTIGATORS (including students conducting independent research projects):

☐ Request for IRB Review and all other related documentation has been reviewed by faculty sponsor.

☐ **Faculty Sponsor Assurance Form** has been completed by student and forwarded to faculty sponsor for their signature and submission to irb_administrator@bsc.edu.

STUDENT PI protocol submissions will be sent out for review after the following requirements are met:

1. **Request for IRB Review and supporting documentation has been reviewed and approved by the faculty sponsor designated in 2(a) and then submitted to irb_administrator@bsc.edu.**
2. **The IRB has received a completed Faculty Sponsor Assurance form sent from the BSC e-mail account of the faculty sponsor.**

Principal Investigator's* Assurance Statement for Using Human Subjects in Research

I certify that the information provided in this Request for IRB Review is complete and accurate.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of IRB-approved studies, the ethical performance of protocols, the protection of the rights and welfare of human participants, and strict adherence to the study's protocol and any stipulations imposed by the Birmingham-Southern College Institutional Review Board.

If applicable, I understand that it is my responsibility to ensure that the human participants' involvement as described in the funding proposal(s) is consistent in principle, to that contained in the Request for IRB Review. I will submit modifications to the IRB as necessary.

I agree to comply with all Birmingham-Southern College policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human participants in research.

_____ _____

Principal Investigator Name and Signature** Date

***** Please type in name and date. If e-mailed from the PI's BSC College e-mail account, a handwritten signature is not needed.***

Questions? Please contact the IRB chair (irb_chair@bsc.edu) or IRB administrator (irb_administrator@bsc.edu).

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COMMENTS:

Links to the policies and Federal regulations for the protection of human research subjects (including the Code of Federal Regulations [CFR] Title 45 CFR Part 46 and Title 21 CFR Parts 50 and 56) are available on the BSC College IRB web page.

(For office use only) IRB Protocol #: _____

☐ New Protocol ☐ Revision ☐ Renewal Date Received: _____

Date Faculty Advisor Assurance form received: _____

Distribution Date: _____ Reviewer(s): _____

Date Reviewer Comments Due: _____

Comments: