# IRB Protocol #

**REQUEST FOR IRB REVIEW OF NON-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.

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| **1. Research Project ☐New ☐ Modification**  **(This section to be completed for ALL exemptions.)** | | | | | |
| 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*](http://www.bsc.edu/academics/irb/) *to* [*irb\_administrator@bsc.edu.*](mailto: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: |  |  | Institution *(if not BSC)*: | | |
| E-mail: |  |  |
| Name: |  |  | Institution *(if not BSC)*: | | |
| E-mail: |  |  |

*Section 3 continues on the next page.*

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| Name: | Institution *(if not BSC)*: |
| E-mail: |
| Name: | Institution *(if not BSC)*: |
| E-mail: |
| Name: | Institution *(if not BSC)*: |
| E-mail: |
| Name: | Institution *(if not BSC)*: |
| E-mail: |
| **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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| **5 (b) Specific Aims:** Identify the variables to be manipulated and/or measured, and describe their expected relationships.  **Please limit your response to the space below.** |
| **5 (c) Procedure**: Describe the activities in which the participants will be engaged. You will want to provide as many specifics as possible, including the actual materials participants will see and/or specific questions that will be asked, if possible. If this level of detail is not possible, provide an idea of the types of questions and the reason that greater specificity would not be possible at the point of submission. Be sure to reference previous research that might use the same methodology, when using a methodology that might put the participants at risk. |
| **5 (d) Use of Deception:** Describe in detail any deception used and explain why deception is critical to the research. When using a methodology that might put participants at risk , be sure to reference previous research that might use the same methodology. |
| **5 (e) Training**: Describe any supervision or training that will occur for research personnel involved in this study, including both CITI training and any additional training. For student investigators, please include previous research experience and/or coursework that might be relevant. |

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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* ☐ t*elephone* ☐ *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*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd)*), prisoners (*[*45 CFR 47 Subpart C*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc)*), pregnant women, human fetuses, neonates (*[*45 CFR 45 Subpart B*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb)*), 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. If deception is involved, please explain (see section 5d, above). | | |
| 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. Consent** | | | |
| **8a. Informed consent** | | | |
| Do you plan to use consent forms? ☐ Yes ☐ No  **If “no,” you must complete Section 8b below on waiver of written informed consent.**  If “yes,” describe how consent will be obtained and by whom. | | | |
| If the participants are minors, will assent forms be used? ☐ Yes ☐ No If “no,” please explain. | | | |
| Will the consent form be presented on paper or online? ☐ Paper ☐ Online | | | |
| *If you do not have a previously approved consent form, please choose the appropriate* [*consent form template*](http://www.bsc.edu/academics/irb/) *to prepare your consent form.*  ***\*\*Please attach the consent form(s) that the participants and/or parent/guardian will be required to sign.\*\**** | | | |
| **8b. Waiver of written informed consent** | | | |
| Are you requesting a waiver of written documentation (signed) of informed consent? ☐ Yes ☐ No If “yes,” please answer the following questions: | | | |
| **8b(1)** Will the only record linking the participant and the research be the consent document and the principal risk to the participant would be from breach of confidentiality? ☐ Yes ☐ No | | | |
| **8b(2)** Do you consider this a minimal risk study that involves no procedures for which written consent is normally required  outside of research? ☐ Yes ☐ No | | | |
| **8b(3)** Explain how you plan to obtain consent. | | | |

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| **8c. Retention of signed consent forms** |
| **8c(1)** How and where will the written, signed consent forms be stored? |
| **8c(2)** For how long? |
| **8c(3)** If these forms will later be destroyed, specify how and when (**consent forms must be retained for at least three years following completion of the research [**[45 CFR 46.115(b)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)]): |
| **9. MODIFICATIONS ONLY** |
| What has been changed? |
| **10. RENEWALS ONLY** |
| Please provide a statement of results to date. |

# 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.](mailto: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**

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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.

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(#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. (#8a) Consent and/or assent form(s).

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(#8a) **If using oral consent,** researcher must provide a copy of the consent document that will be read to research participants and, if required, the name and address of the individual

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who will witness the oral consent. The oral consent document should include a statement indicating that completion of the research exercise will confirm the participants’ consent to participate.

# ADDITIONAL SUBMISSION REQUIREMENTS FOR ALL STUDENT PRINCIPAL INVESTIGATORS

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**(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**](http://www.bsc.edu/academics/irb/) has been completed by student and forwarded to faculty sponsor for their signature and submission to [irb\_administrator@bsc.edu.](mailto: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.**](mailto:irb_administrator@bsc.edu)
  2. **The** [**IRB**](mailto:irb_administrator@bsc.edu) **has received a completed** [**Faculty Sponsor Assurance form**](http://www.bsc.edu/academics/irb/) **sent from the BSC e-mail account of the faculty sponsor.**

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| **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. | | |
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| 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](mailto:irb_chair@bsc.edu)) or IRB administrator ([irb\_administrator@bsc.edu](mailto:irb_administrator@bsc.edu)).

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| **COMMENTS:** |
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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](http://www.bsc.edu/academics/irb/) [page.](http://www.bsc.edu/academics/irb/)

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| **(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:** |