**AUBURN UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM (HRPP)**

**REQUEST for MODIFICATION**

 For Information or help completing this form, contact: **The Office of Research Compliance (ORC)** Phone: **334-844-5966** E-Mail: **IRBAdmin@auburn.edu**  **- Federal regulations require IRB approval before implementing proposed changes.
- Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the investigator’s
 Brochure, questionnaires, surveys, advertisements, etc.). See Item 4 for more examples.**

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| **1. Today’s Date** | Click or tap to enter a date. |

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| **2. Principal Investigator (PI) Name:** Click or tap here to enter text. |
| **PI’s Title:** | Click or tap here to enter text. | **Faculty PI (if PI is a student):** | Click or tap here to enter text. |
| **Department:** | Click or tap here to enter text. | **Department:** | Click or tap here to enter text. |
| **Phone:** | Click or tap here to enter text. | **Phone:** | Click or tap here to enter text. |
| **AU-E-Mail:** | Click or tap here to enter text. | **AU E-Mail:** | Click or tap here to enter text. |
| **Contact person who should receive copies of IRB correspondence (Optional):** | Click or tap here to enter text. | **Department Head Name:** | Click or tap here to enter text. |
| **Phone:** | Click or tap here to enter text. | **Phone:** | Click or tap here to enter text. |
| **AU E-Mail:** | Click or tap here to enter text. | **AU E-Mail:** | Click or tap here to enter text. |

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| **3. AU IRB Protocol Identification** |
|  **3.a. Protocol Number:** Click or tap here to enter text. |
|  **3.b. Protocol Title:** Click or tap here to enter text. |
|  **3. c. Current Status of Protocol – For active studies, check ONE box at left; provide numbers and dates  where applicable** |
|[ ]  **Study has not yet begun; no data has been entered or collected** |  |
| [ ] [ ]  | **In progress If YES, number of data/participants entered:** Click or tap here to enter text.**Is this modification request being made in conjunction with/as a result of protocol renewal?** [ ]  **YES** [ ]  **NO** | **Current Approval Dates****From:** Click or tap to enter a date. |
|[ ]  **Adverse events since last review If YES, describe:** Click or tap here to enter text. | **To:** Click or tap to enter a date. |
|[ ]  **Data analysis only** |  |
|[ ]  **Funding Agency and Grant Number:** Click or tap here to enter text. | **AU Funding Information:** Click or tap here to enter text. |
|[ ]  **List any other institutions and/ or AU approved studies associated with this project:** Click or tap here to enter text. |  |

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| **4. Types of Change** **Mark all that apply, and describe the changes in item 5** |
|[ ]  **Change in Key Personnel**List the name(s) of personnel being added to or removed from the study and attach a copy of the CITI documentation for personnel being added to the study.  |
|[ ]  **Additional Sites or Change in Sites, including AU classrooms, etc.**Attach permission forms for new sites. |
|[ ]  **Change in methods for data storage/ protection or location of data/ consent documents** |
|[ ]  **Change in project purpose or project questions** |
|[ ]  **Change in population or recruitment**Attach new or revised recruitment materials as needed; both highlighted version & clean copy for IRB approval stamp |
|[ ]  **Change in study procedure(s)**Attach new or revised consent documents as needed; both highlighted revised copy & clean copy for IRB approval stamp |
|[ ]  **Change in data collection instruments/forms (surveys, data collection forms)**Attach new forms as needed; both highlighted version & clean copy for IRB approval stamp |
|[ ]  **Other**(BUAs, DUAs, etc.) Indicate the type of change in the space below, and provide details in the Item 5.c. or 5.d. as applicable. Include a copy of all affected documents, with revisions highlighted as applicable.Click or tap here to enter text. |

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| **5. Description and Rationale** |
| **5.a. For each item marked in Question #4 describe the requested change(s) to your research protocol, and the  rationale for each.** |
| Click or tap here to enter text. |
| **5.b. Briefly list** (numbered or bulleted) **the activities that have occurred up to this point, particularly those that  involved participants.** |
| Click or tap here to enter text. |
| **5.c. Does the requested change affect participants, such as procedures, risks, costs, benefits, etc.** |
| Click or tap here to enter text. |
| **5.d. Attach a copy of all “IRB stamped” documents currently used. (Information letters, consent forms, flyers,  etc.)** |
| Click or tap here to enter text. |
| **5.e. List all revised documents and attach two copies of the revised documents – one copy which highlights the revisions and one clean copy of the revised documents for the IRB approval stamp.** |
| Click or tap here to enter text. |

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| **6. Signatures** |
| **Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Faculty Advisor PI, if applicable: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Version Date:** Click or tap to enter a date.