

For office use only

IRB Protocol #:
Date Received:

**UA Little Rock Institutional Review Board**

**Request for Review of Modification or Amendment to Approved Research**

*This form is to be used for ALL new protocols.*

Any modification or amendment to an approved protocol must be reviewed and approved by the IRB before implementation. Use additional pages as necessary. Responsible Conduct of Research (RCR) and Human Research CITI reports (not certificates) are required. Please fill out all fields appropriately on this form. To make selections, double click the box. Attach any revised materials with changes highlighted and send ONE signed PDF to irb@ualr.edu. For questions, contact the Office of Research Compliance at 501-916-6209 or irb@ualr.edu.

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| **Principal Investigator:**       | **Email:**       |
| **Department:**       | **Phone**:       |
|  **Human Research CITI Expiration date:**       **RCR CITI Expiration date:**       |
| **Co-Principal Investigator:**       | **Email:**       |
| **Department:**       | **Phone:**       |
| **Human Research CITI Expiration date:**       **RCR CITI Expiration date:**       |
| **Co-Principal Investigator:**       | **Email:**        |
| **Department:**       | **Phone:**       |
| **Human Research CITI Expiration date:**       **RCR CITI Expiration date:**       |
| **Co-Principal Investigator:**       | **Email:**        |
| **Department:**       | **Phone:**       |
| **Human Research CITI Expiration date:**       **RCR CITI Expiration date:**       |
| **Faculty Advisor/Chair or thesis or dissertation committee***(must be included if PI or Co-PI is a student)*:       | **Email:**        |
| **Department:**       | **Phone:**       |
| **Human Research CITI Expiration date:**       **RCR CITI Expiration date:**       |
| **Project Title:**       |
| **Is this project externally/internally funded?** | Choose Yes or No |
| **If so, please indicate the funding source:**       |
| **Approved IRB Protocol #:** | **Date of most recent IRB approval:**       | **Anticipated end date:**       |

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| **Section 1. Check any modifications that apply** |
| [ ]  Change in project title[ ]  Change in investigators (include names in Section 3)[ ]  Change in research personnel (include names in Section 3)[ ]  Change in study design[ ]  Change in participant cost or compensation [ ]  Change in participant population[ ]  Change in materials or instruments[ ]  Change in risks and benefits[ ]  Change in location of research[ ]  Change in participant activity[ ]  Change in recruitment method[ ]  Change in consent or assent form [ ]  Change in method and/or materials for advertisement[ ]  Change in sponsor[ ]  Change in advisor[ ]  Other changes - describe:       |

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| **Section 2. Current Study Information** |
| 1. **Has this research been conducted according to the most recently approved IRB protocol for this study?**  [ ]  **Yes** [ ]  **No If no, please explain**:
2. **Have participants enrolled in this study?** [ ]  **Yes** [ ]  **No****If yes, does the modification affect participants currently enrolled, or in follow-up, including their willingness to continue in this study?** [ ]  **Yes** [ ]  **No****If yes, how will you notify them of changes?**      **If no, explain why the modification will not affect previously enrolled participants.**
3. **Has the funding for the protocol changed?** [ ]  **Yes** [ ]  **No** **If yes, list new sponsor**
4. **Has the title of the study been revised?** [ ]  **Yes** [ ]  **No** **If yes, you will need to update the protocol and consent forms if affected.**
5. **Do proposed changes pose additional risks to participants?** [ ]  **Yes** [ ]   **No** **If yes, please describe risks and any procedures proposed to address them**.
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| **Section 3. Modification(s)** |
| 1**. Describe the proposed modification in detail**.      2. **Explain why the modification is necessary.**      3. **Explain any change in consent form or process**.      4. **Attach copies of any revised materials**.       |

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| **Section 4. Required Signatures:** |
| **Principal Investigator (PI) Signature and Date:** |
| By typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and UA Little Rock IRB policies and procedures on research with human participants. |
| **Signature of Principal Investigator:       Date:** Click for date.(Re-sign and date for every revision) |
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| **Advisor/Committee Chair Signature and Date (If PI is a student): Advisor:** After reviewing, please send completed protocol package from your UA Little Rock e-mail account to irb@ualr.edu. |
| By typing or signing my name and date below, I certify that I have reviewed and approve this student submission. I agree to supervise the research conducted by the student and I am aware that I am the responsible party for this research. I certify that this research will be the conducted in accordance with federal regulations and UA Little Rock IRB policies and procedures on research with human participants. |
| **Signature of Faculty Advisor/Committee Chair:** **Date:** Click for date.(Re-sign and date for every revision) |

**UA Little Rock**

**Key Research Personnel Form**

**Instructions:** In the grid below, list the names and roles of all Key Research Personnel *(principal investigators, co-investigators, faculty advisors, anyone involved in project design, anyone with access to the data, anyone who obtains consent, and/or anyone who collects data*).

For questions about personnel to include, consult irb@ualr.edu.

Please complete only **one form** per protocol. If necessary, add more rows to the grid if your Key Research Personnel exceeds the boxes provided.

**Principal Investigator:**

**Project Title:**

**Date:**

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| **Name** | **Student, Faculty, or Other** | **Affiliation** | **Role in Protocol** |
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