**General Instructions**

**Do not submit this page with your protocol request.**

1. Please refer to the IRB website for a way to submit a successful request – ualr.edu/irb
2. All submitted protocols must be signed and dated.
3. Student research must be reviewed, signed and dated by the advisor. The signature needs to be an electronic signature (typed or special electronic signature).
4. Proofread the protocol before submission. Spelling and grammar errors can make a difference in meaning.
5. Make sure all titles and labels are consistent.`
6. Attach all supporting documentation to the protocol by combining them with this document into a single digitized file. Please do not send multiple attachments. See ualr.edu/irb for instructions.
7. Include the IRB Approval statement in both the Informed Consent and Recruitment material.
“This study has been reviewed and approved by UA Little Rock's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies.  If you have questions or concerns regarding this study, please contact the Principal Investigator (Provide the name of one or more researchers who can be reached for assistance. If you are a student, provide your advisor’s name and contact information too. The IRB recommends that researchers not include home addresses, personal emails or private cell phone numbers). If you have any questions regarding your rights as a research participant, please contact the Office of Research Compliance at 501-916-6209 or [irb@ualr.edu.](file:///C%3A%5CUsers%5Ccncroswell%5CDownloads%5Cirb%40ualr.edu)”
8. Send completed electronic submission to irb@ualr.edu.
9. To maintain proper record keeping, all communication with the IRB or the IRB Administrator must be through irb@ualr.edu .
10. Questions may be addressed to the Director of Research Compliance at irb@ualr.edu or by telephone at 501-916-6209.



For office use only

**EDD:**

IRB Protocol #:
Date Received:

**The approval period for all protocols is one year. Eight weeks before the end of the approval period submit a continuation form (https://ualr.edu/irb/home/irb-forms/) to request approval to continue the research. We have updated other templates and forms. To avoid delay, use the most current form.**

**UA Little Rock Institutional Review Board**

**Request for Protocol Review**

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

The UA Little Rock Institutional Review Board (IRB) must review all projects that involve human participants. The IRB will determine whether the project meets federal guidelines and constitutes human participants research. **The project may not start until IRB approval is granted**. If the duration of the project exceeds the length of the approval period, submit a Request for Continuation two months before approval expires. Please fill out all appropriate fields on this form. Double click on yes/no boxes to select a response. Responsible Conduct of Research (RCR) and Human Research CITI reports (not certificates) are required.

**Note:** UA Little Rock policy requires that all persons listed on this document show successful completion of training in the protection of human participants in research. **Please attach the Group 1 Human Research and Responsible Conduct of Research (RCR) CITI training completion reports for all listed persons**. This protocol will not be reviewed until all CITI training records are attached. *Further instructions are in red.*

|  |  |
| --- | --- |
| **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 of thesis or dissertation committee** *(must be included* *if PI or Co-PI is a student)*:        |
| **Department:**       | **Email:**       |
| **Human Research CITI Expiration date:**       **RCR CITI Expiration date:**       | **Phone:**       |
| **Project Title:**  |
| **Is this project externally/internally funded?** | Choose Yes or No |
| **If so, please indicate the funding source:**       |
| **Is this project requested by a third party**? If so, please elaborate under item 1 below\* | Choose Yes or No |
| **If sponsored, will data be owned solely by the sponsoring third party?** | Choose Yes or No |
| **Is the data for this study already collected and available to the public?** If data is derived from a proprietary data set, secondary analysis or any other combination, please elaborate under Item 2 below. | Choose Yes or No |
| ***Description of Human Participants:*** |
| Are participants members of a protected class? * Under 18 years of age
* Confined in a correctional or detention facility
 | Choose Yes or No Choose Yes or No |
| Will personal records/data be collected without informed consent? | Choose Yes or No |
| If collected, will personal records/data be directly or indirectly identifiable? | Choose Yes or No |
| Is any of the research conducted at a location other than UA Little Rock? | Choose Yes or No |
| If yes, where:       |

 ***Provide the information requested below.***

|  |
| --- |
| **1. Describe the purpose of the project** |
| *Provide a brief 1-2 paragraph description and explanation of the purpose of this project, including the significance of the research, and the research question(s). \*(If a third party requested the project, also answer the following: Who is the requesting party? What is their request? What is the PI’s relationship with third party?)*       |

|  |
| --- |
| **2. Describe the methods and procedures** |
| *Describe the data collection procedures and what participants will have to do: If potentially sensitive information is collected in an interview or if there is concern about participants’ or the investigators’ safety, please address procedures to protect the participants’ confidentiality and/or participants’ and investigators’ safety during data collection. What happens to the data if a participant withdraws or skips questions?*       |
| *How long will this take participants to complete?*       |
| *Will follow-ups or reminders be sent? If so, explain (address the frequency, the modality, and attach a copy of the message):*       |

|  |
| --- |
| **3. Describe the recruiting procedures** *(Please attach copies of all recruitment material such as fliers, ads, phone scripts, emails, posts, etc.)* |
| *Who will be recruited? Who are the participants? How many participants will be recruited? Include the minimum necessary for the study and the maximum number that is desired. If this is an adult sample, how are the PI(s) verifying that participants are 18 or older? If applicable, how are PI(s) informing participants they must be 18 or older?*       |
| *How will participants be approached about participating in the study?*       |
| *How will the names and contact information for participants be obtained?*       |

|  |
| --- |
| **4. Describe compensation** |
| *Will compensation be provided to participants?* | *Choose Yes or No* |
| *If YES, please describe amount and type of compensation including money, gift certificates, extra credit, etc. If the study involves compensation through lottery, identify the odds of winning. If the study involves extra credit provide an explanation of the alternative activity participants are provided, and how much influence the extra credit might have on a student’s grade.*       |
| *When will compensation be given? How much participation is required to earn the incentive? What happens if the participant quits before completion or skips some questions? Compensation must be prorated.*       |
| *Will compensation be paid by UA Little Rock?* | *Choose Yes or No* |
| *What participant information is required?* *The consent form should cover the information that is required for payment and the length of time their information is retained by the payment system.*       |
| *How will you avoid compensation having a coercive effect on participants (i.e., that they will feel compelled to participate to earn compensation)? How will the participants’ identity be kept confidential while allowing for compensation or extra credit to be awarded?*       |

|  |
| --- |
| **5. Conflict of Interest** |
| *State any financial or other relationships that are held by you or any individuals or institutions involved in the research which could create perceived or actual conflict of interest*:       |
| *State whether you or any individuals or institutions involved in the research will receive any compensation other than a grant award:*       |
| *Describe what reasonable and appropriate actions you plan to take to protect participants from the influence of the above conflict of interest:*       |
|  |
| **6. Benefits and Risks** |
| *Explain the benefits to participants or to others. State benefits in probabilistic terms such as may or might (i.e., may lead to better services). There must be some benefits either to the participants (direct benefits) or to others (indirect benefits).*       |
| *Are there any known or anticipated risks to participants greater than those experienced in everyday activities? List any foreseeable physical and non-physical risks of participating in the study. Non-physical risks may include social, psychological, or economic harm; risks of criminal or civil liability; or damage to financial standing, employability, or reputation.* | *Choose Yes or No* |
| *In all cases, including those with minimal risk, explain any possible risks that could affect the participant(s).*      |
| *What will be done to minimize the risks? For projects that make a statement that counseling is not provided remember that there may be community resources available. Provide some examples. The Little Rock Community Mental Health Center is often a good solution.*       |
|  |
| **7. Informed Consent** (Please attach copies of informed consent /assent forms, emails, and/or letters. If participants are under 18 you must attach consent forms for parents or guardians.) Please describe your consent process, even if you believe this project is not human participants research and you have no formal consent form.  |
| *How will informed consent / assent be obtained?*       |
| *Are you requesting a* ***waiver of a signed consent?*** | *Choose Yes or No* |
| *If YES, justify your request.**If there is more than one consent form, provide a justification for each form. Identify each consent form to clarify which forms are included in the request for a waiver of signed consent.* *(Providing participants with informed consent information is always required. However, requesting a waiver of* ***signed*** *consent may be appropriate for situations such as:** *Low-risk, online, survey research, in which the participant consents to participate by checking a box; or*
* *Sensitive research, in which a signed consent form may put the participant at undue risk.)*

 |
| *Tell us how participants can get a copy of the Informed Consent Form* (i.e., screen shot, attached to recruiting e-mail, other. The methods may vary for different consent forms. Identify each method used to provide access to a copy of the consent form.).       |

|  |
| --- |
| **8. Confidentiality** (Anyone who will collect, see or have access to the raw data must attach their certification document [Group 1 CITI Completion Report] attached to this protocol.) |
| *How will participant confidentiality be maintained? Address how the participants’ identity and data will be protected during data collection, analysis and when the data is reported.*       |
| *How will confidentiality of records be maintained? Address how the participants’ identity will be protected when the data is reported. If you are using direct quotes, audio, or video clips, etc. these are identifying information and measures to protect confidentiality must be included.* *A non-exhaustive list of identifying information is at the end of this form. Combining categories will often identify an individual. Aggregating data may lower this risk when cell sizes are 5 or greater*.       |
| *Who will be collecting the data? In most cases these individuals will need CITI training.*       |
| *Who will be able to see or have access to the raw data? List everyone who has access to the raw data. This can include those who collect data, if they can see it, and those who analyze it. Submit CITI verification for anyone with access to the data.*       |

|  |
| --- |
| **9. Data Security**  |
| *How will data be reported? List all the ways the data will or might be disseminated. Also list whether the data will be reported individually or in aggregate. If aggregated, what is the smallest cell size that will be reported? If the project was requested by another party is the data reported by that party? If so how? To whom will data be reported? Are there plans to present at a conference or publish? Will data only be reported to a third party?*       |
| *Where will the records be stored during data collection and analysis?*       |
| *Records should be kept for a minimum of three years beyond the life of the study. Where will the records/data be kept and who will have access? If the PI is a student, the advisor must have access to the data.*       |
| *What security measures are in place to protect the data during data collection, data analysis, and the 3-year storage?*       |
|  |

|  |
| --- |
| **10. Attachment List:** |
|

|  |
| --- |
|  |

 | *CITI Training Records for all personnel. Do not send the certificate but rather the completion report that shows the completed modules. (The UA Little Rock policy on training in the protection of human participants can be found at* [*http://www.ualr.edu/irb*](http://www.ualr.edu/irb)*.)* |
|

|  |
| --- |
|  |

 | *Consent Forms and/or Assent Forms (See templates and guidelines at* [*https://ualr.edu/irb/home/irb-forms/*](https://ualr.edu/irb/home/irb-forms/)*)* |
|

|  |
| --- |
|  |

 | *Site Letter of Support or Permission (Students must include a signed letter from the appropriate functionary at each site indicating that they are aware of the plan to conduct a study and what the study entails. Others must include a draft of such a letter.)* |
|

|  |
| --- |
|  |

 | *Recruiting Materials- The following abbreviated IRB statement can be included.* “*This study has been reviewed and approved by UA Little Rock's Institutional Review Board (IRB).” Make sure to put the PI’s contact information on the recruitment materials.* |
|

|  |
| --- |
|  |

 | *Questionnaire, survey, etc. For online surveys attach a pdf or screen shots showing exactly what the participant sees. Make sure to include how the participant indicates consent.* |
|  |  |

|  |
| --- |
| **11. Required Signatures:** |
| **Principal Investigator (PI) Signature and Date:** |
| 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) |
| **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. |
| 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) |

**Non-exhaustive List of Identifying information.**

1. Names
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone and Fax numbers
5. Electronic mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers, including license plate numbers
12. Device identifiers and serial numbers
13. Web universal resource locators (URLs)
14. Internet protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images
17. Any other unique identifying number, characteristic or code

**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*).Please explain in the Role in Protocol column not only the role of the individual listed, but how UA Little Rock plays a role in the protocol.

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:**

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