

## INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

**APPLICATION**

**Proposals for review by the University of Louisiana Monroe (ULM) Institutional Review Board (IRB) may be submitted at any time. With the exception of expedited reviews, complete proposals submitted no later than one (1) week prior to a scheduled meeting will be reviewed at that meeting. Late proposals will be reviewed at the next scheduled meeting. The IRB meeting schedule is posted on the Office of Sponsored Programs and Research (OSPR)** [**website**](http://ulm.edu/research/irb.html)**. Incomplete proposals WILL NOT be reviewed until all missing information has been submitted. A response to all sections is required. If a section is not applicable (N/A), please respond as such.**

All materials related to this research project must be included in the submission packet. Information regarding the submission process can be found on the OSPR [**website**](http://ulm.edu/research/irb.html).

**Required materials include:**

* Completed application.
* Copies of all recruiting materials, including scripts, emails, letters, posters, advertising, etc.
* Copies of all measurements, instruments, surveys, interview questions being used, etc.
* All consent forms and assent forms or scripts (for children).
* Debriefing materials.
1. **Certifications (Principal Investigator must inform key personnel/research investigators about certifications):**

I am familiar with the [policies and procedures](http://ulm.edu/research/documents/irbhandbook.pdf) of University of Louisiana at Monroe (ULM) regarding human subjects in research. I subscribe to the university standards and applicable state and federal standards and will adhere to the policies and procedures of the IRB for the Protection of Human Subjects. I will comply with all instructions from the IRB at the beginning and during the project or will discontinue the project.

**AND**

I am familiar with the published guidelines for the ethical treatment of human subjects associated with my particular field of study.

# Statement of Agreement:

By signing and submitting this application packet, I certify that I am willing to conduct and/or participate in these activities in accordance with the guidelines for human subjects in research. Further, I certify that any changes in procedures from those outlined above or in the attached proposal will be cleared through the IRB.

I certify the information provided in this application is complete and correct.

I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations imposed by the IRB.

I agree to comply with all [ULM policies](https://webservices.ulm.edu/policies/document.php?i=17742), as well as all [federal](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html), state and local laws on the protection of human subjects in research, including:

* Ensuring all study personnel satisfactorily complete human subjects in research training
* Performing the study according to the approved protocol
* Implementing no changes in the approved study without IRB approval
* Obtaining informed consent/assent from subjects using only the currently approved form
* Protecting identifiable health information in accordance with [HIPAA Privacy rules](https://www.hhs.gov/hipaa/for-professionals/privacy/index.html)
* Promptly reporting significant or untoward adverse effects of participants to the IRB

I understand that data collection (including recruitment) is not permitted until final approval is granted by the IRB.

1. **Definitions:**

***“Conflict of interest”***occurs when an independent observer may reasonably question whether an individual's professional actions or decisions are influenced by considerations of the individual’s private interests, financial or otherwise.

Conflicting financial interests do not include:

* + Salary and benefits from ULM;
	+ Income from seminars, lectures, teaching engagements, or publishing sponsored by federal, state, or local entities, or from non-profit academic institutions, when the funds do not originate from corporate sources;
	+ Income from service on advisory committees or review panels for governmental or non-profit entities;
	+ Investments in publicly-traded mutual funds;
	+ Gifts and promotional items of nominal value; and
	+ Meals and lodging for participation in professional meetings.

***“Human subject”*** means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention and interaction, or (b) identifiable private information.

***“Minimal risk”*** means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

***“Principal investigator or other key personnel”***means the principal investigator and any other person, including students, who are responsible for the design, conduct, analysis, or reporting of research involving human subjects.

***“Private information”*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

***“Research”*** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. Activities, which meet this definition, constitute "research" whether or not they are supported or funded under a program, which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

# IRB Request for Review

1. **List all key personnel/collaborators/research investigators involved in research project:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Role** | **College** | **Email** | **Phone** | **Signature** |
|  | \*Principal Investigator (PI) | Click to select. |  |  |  |
|  | Supervisor of PI | Click to select. |  |  |  |
|  |  | Click to select. |  |  |  |
|  |  | Click to select. |  |  |  |
|  |  | Click to select. |  |  |  |
|  |  | Click to select. |  |  |  |
|  |  | Click to select. |  |  |  |

**\*Principal Investigator must be a ULM employee. (DO NOT DELETE)**

**Please tab on last line to add more rows as needed for additional individuals.**

1. **Project Title:**

Click here to enter text.

**Project Period:**

From: **Click to select start date.**

To: **Click to select end date.**

1. **Research Type and nature of the activity:** (Check all appropriate categories.)
2. Unfunded

Submitted for extramural funding to:

Click here to enter text.

Submitted for intramural funding to:

Click here to enter text.

Quality improvement/program evaluation

Quality assurance

Other (Please explain):

1. Undergraduate Research

Graduate Research Paper

Independent Study

Thesis/Dissertation Related

Specialist Field Study

Class Project (Please review [policy](http://ulm.edu/research/documents/class_guidelines.pdf).)

Click here to enter text.

 (Course Title/Course Number):

Other (Please Explain):

Other than faculty, staff, or student at ULM (Unaffiliated with ULM).

1. **Human Subjects Research Ethics Training:** All key personnel involved in the research project must have completed the appropriate [CITI](http://ulm.edu/research/compliance_training.html) training modules. If an individual researcher is not affiliated with ULM, documentation of CITI training must be provided. **All key personnel/research investigators have completed the ULM required** [**CITI Training**](http://ulm.edu/research/compliance_training.html)**:**  Yes No
2. **Description of Project**

Completely describe the research project below. Provide sufficient information for effective review, and define abbreviations and technical terms. Do NOT simply attach a thesis, prospectus, grant proposal, etc. If an item is not applicable, please provide justification.

1. Project purpose(s):

Click here to enter text.

1. Project significance (i.e., Is your study examining a new research question or phenomenon not addressed in previous research? Is there a gap in the literature and your study is filling that void in the literature? Has a population been neglected in previous research and your study is addressing that void?):

Click here to enter text.

1. Describe the proposed participants (number, age, gender, ethnicity, etc.)

Click here to enter text.

1. What are the criteria for including or excluding subjects? Are any criteria based on age, gender, race, ethnicity, sexual orientation, or origin? If so, provide justification.

Click here to enter text.

1. Population from which the participants will be recruited/obtained:

**General Populations:**

Adults (18 years or older)

**Special Considerations Populations:**

Children (under the age of 18)

Cognitively impaired

Elderly (65 years or older)

Fetuses

Mentally/physically impaired

Pregnant/Lactating Women

Prisoners

Wards of the State

None

**Other Vulnerable Populations:**

Vulnerable to influence or coercion

Economically disadvantaged

Educationally disadvantaged

Decisionally impaired

Non-English speakers

International research

None

1. Recruitment Procedures: Describe in detail the process to be used to recruit participants. Attach scripts, emails, letters, advertising and all marketing materials with your application. Provide a step-by- step description of how potential participants will be recruited for the study.

Click here to enter text.

1. Where will the data collection and data analysis procedures take place? (i.e., explain where you are distributing surveys, conducting interviews, etc.) **(Letter(s) of support from site of data collection must be included)**.

Click here to enter text.

1. Will the data derive from existing records on the participants? Yes No If yes, will the data be recorded in a fashion that will prevent the subjects from being identified? Please explain.

Click here to enter text.

1. Describe the benefits to the participants, discipline/field, and/or society for completing the research project. This description is necessary for determining if the risks are reasonable in relationship to anticipated benefits. Research that provides no benefit or potential for benefit will not be approved.

Click here to enter text.

1. Describe the potential risks to participants for completing the research project. A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risk categories include physical, psychological, social, economic and legal, and include pain, stress, and invasion of privacy, embarrassment, or exposure of sensitive or confidential information. All potential risks and discomforts must be minimized to the greatest extent possible by using appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event*.*

Click here to enter text.

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the 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.

More than minimal risk.

1. Describe the follow up efforts that will be made to detect any harm to subjects and how the IRB will be kept informed. Serious adverse or unexpected reactions or injuries must be reported to the IRB within 48 hours. Other adverse events should be reported within 10 calendar days.

Click here to enter text.

1. Describe **in detail** the procedures to be used in the research project. What will all participants experience during the research project?

Click here to enter text.

1. List all measures/instruments to be used in the project, include citations and permission to use (if measure/instrument is copyrighted) if needed or if it will be changed for this study. Attach copies of all measures, such as surveys, interview questions, instruments, etc. to the package.

Click here to enter text.

1. Describe **in detail** how confidentiality will be protected or how anonymity will be ensured before, during, and after information has been collected? Please note the difference between confidentiality (researcher knows identity of subjects and keeps information secret) and anonymity (researcher does not know identity of participants).

Click here to enter text.

1. Data Management: How will the data be stored? When will the data be destroyed? Who will have access to the data? If audio or video recordings are used, how will they be kept confidential?

Click here to enter text.

1. Informed Consent: Describe in detail the **process** for obtaining consent*. If non-English speaking subjects are involved, describe how consent will be obtained. If participants are not able to give legal consent (e.g. minors), explain how assent will be secured.*

Click here to enter text.

1. Explain Debriefing procedures/end of study information that will be given to all participants.

Click here to enter text.

1. Emergencies. How will emergencies or unanticipated adverse events related to the research be handled if they arise? Please note that this refers to an emergency situation associated with the research activity, not an emergency such as a fire alarm.

Click here to enter text.

1. Will information about the research purpose and design be withheld from subjects? Yes No If yes, justify the deception.

Click here to enter text.

1. If the research involves protected health information, it must comply with the [HIPAA Privacy Rule](https://www.hhs.gov/hipaa/for-professionals/privacy/index.html).

Select one:

The research does not involve protected health information.

Do you plan to use or disclose identifiable health information outside ULM? *If yes, the consent form must include a release of protected health information.*

Will the protected health information to be used or disclosed be de-identified or will a limited data set be used or disclosed? *Please describe*:

Click here to enter text.

1. Conflict of Interest: Each individual with a personal financial interest or relationship that in the individual’s judgment **could reasonably appear to affect or be affected by the proposed study** involving human subjects is required to disclose the existence of financial interests. It is unnecessary to report any financial interests or relationships that do **not** reasonably appear to affect or be affected by the proposed study.

Click here to enter text.