

UNIVERSITY OF LOUISIANA MONROE

POLICIES AND PROCEDURES MEMORANDUM

<i>Title:</i>	Research Involving Students
<i>Effective Date:</i>	11/06/2019
<i>Update Responsibility:</i>	Academic Affairs
<i>Revised Date:</i>	NONE
<i>Cancellation Date:</i>	NONE

1. Subject of Policy

This document sets forth the requirements for obtaining University of Louisiana at Monroe's (ULM) Institutional Review Board (IRB) approval for research involving ULM students. Student is defined as any individual who is enrolled in an undergraduate, graduate, doctorate, or post-doc program at ULM. The intent of this policy is not to over-reach its authority and restrict student participation in research at other institutions. ULM students have the right to choose or not choose to participate in face-to-face and online research, surveys, polls, and questionnaires conducted or sponsored by other institutions. This policy applies solely to research being conducted at or sponsored by ULM, its affiliates and partnerships and involves ULM student participation

There are no federal regulations that specifically address the inclusion of students in research protocols. However, these participants are vulnerable to being unduly influenced by the expectation that participation or non-participation in a protocol may place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming "uncooperative," not part of the scientific community).

Students may also be vulnerable to undue influence to participate in research; from being approached multiple times for participation in research because their presence on campus makes convenient their recruitment and participation as controls. Potential educational and other benefits of participation in research must be balanced against the possibility that students are potentially vulnerable to undue influence to participate from researchers and the researcher's collaborators and student peers. Confidentiality and security of data also may be of special concern to potential student participants, especially in light of the closeness of the university community.

The IRB, therefore, will pay special attention to ensuring that the research protocol and associated recruitment methods and informed consent avoid coercion or the appearance of coercion when including ULM students in research.

While special attention by the IRB is warranted, students have the same rights as any other potential participants to participate in an IRB-approved protocol, regardless of the degree of risk.

Finally, certain ULM students may be members of another vulnerable population (*e.g.*, [pregnant students](#), [students who are under the age of 18](#), *etc.*). In these instances, the Principal Investigator (PI) and the IRB should carefully apply, as appropriate, not only this policy, but also the policies pertaining to the additional vulnerable populations of which the ULM student is a member.

Scope of Policy

This Policy applies to all on-going and future human participant research projects conducted by ULM faculty, staff, or students or by anyone conducting a research activity supported by ULM or on property maintained by ULM. See ***Subject of the Policy*** stated earlier for further clarification on the boundaries and reach of this policy.

2. Terms and Definitions

All parties to whom this policy applies (*e.g.*, faculty, students, staff, IRB members) should consult the IRB Glossary at <http://www.irb.ulm.edu/glossary/>. (Glossary to be added to the website)

3. See Also

Affected researchers and students should also consult:

4.1 University of Louisiana Monroe Federal-wide Assurance Registration:
<https://www.ulm.edu/research/ulminfo.html>

4. Regulations Applicable to Informed Consent

5.1. The Belmont Report

5.2. [45 CFR 46.109\(b\), \(c\), & \(e\)](#): IRB Review of Research, stating that (1) “[a]n IRB shall require that information given to subjects as part of informed consent is in accordance with [§46.116](#). The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects;” (2) “[a]n IRB shall require documentation of informed consent or may waive documentation in accordance with [§46.117](#),” and (3) “[a]n IRB shall have the authority to observe or have a third party observe the consent process and the research.”

5.3. [45 CFR 46.111\(a\)\(4\), \(a\)\(5\), & \(b\)](#): Criteria for IRB approval of research, mandating that (1) informed consent “will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by §46.116,” and “appropriately documented, in accordance with, and to the extent required by §46.117;” and (2) “[w]hen some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as [children](#), [prisoners](#), [pregnant women](#), [mentally disabled persons](#), or [economically or educationally disadvantaged persons](#), additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

5.4. [45 CFR 46.116: General requirements for informed consent](#)

5.5. [45 CFR 46.117: Documentation of informed consent](#)

5. Requirements for IRB Approval of Research Involving ULM Students

6.1. Recruitment—Protecting Against Coercion

- A PI may offer extra credit as an incentive to students to participate in a research project. However, the PI would not offer extra credit for a research project where data was collected in his or her personal classes. Collecting research data from one's own classes would be considered unethical and undue influence. The amount of such credit, however, cannot be so significant so as to be coercive. This limitation on extra credit applies to an amount offered from an individual study as well as the aggregate amount of extra credit offered for a particular course. Investigators are discouraged from directly recruiting individuals they supervise or selecting participants on such basis.
- To avoid the appearance of coercion or undue influence, the IRB may elect to require that the PI take one or more of the following measures:
 - Offer the same amount of extra credit for non-participating students who complete an assignment requiring equivalent time and effort such as a short paper or presentation or attendance at a research colloquium.
 - Advertise for subjects generally (*e.g.*, through notices posted in the school or department) rather than to recruit individual students directly or individually.
 - Allow students to withdraw from participation at any time without losing the extra credit.
 - Give students several studies to choose from, rather than requiring them to volunteer for a particular study, especially where participation is a course requirement.
 - Provide justification for including student volunteers from courses for which they are the instructor.
 - Indicate that the extra credit will not be made part of the grading curve, but will be taken into account for each individual.
- Documentation is always welcomed from the PI when securing collaboration or agreement with a colleague on (within and across disciplines) and off campus, especially in those incidences when bonuses or extra credit incentives are offered to student participants. For instance, if the PI's proposal, informed consent, and any attachments to the proposal states that extra credit or that bonus points will be offered to student participants then the PI must be able to follow through with that incentive and ensure student participants do in fact receive the offered incentive. The PI's proposal, informed consent form and attachments to the proposal should not obligate or

offer bonus points on behalf of a collaborating colleague (within, across and outside campus disciplines). That is, a PI cannot in his or her proposal, informed consent form, and attachments to the proposal state or even suggest (such as use the word, "may offer") bonus points or extra credit will be offered for a collaborating colleague within and across his or her discipline and off campus. Only the student participant's instructor can offer extra points or bonus points to students enrolled in his or her classroom not the PI.

- In light of the limited financial resources of most students, PIs should be cautious about offering excessive monetary compensation to students. The IRB may deem that other appropriate incentives be offered instead of money. However, in those research situations where the PI is offering monetary rewards to student participants, the PI will need to ensure that the student participants are compensated at a fair-market value for time outside of class, especially if the student participants are not getting class credit.

6.2. Informed Consent

- The IRB may need to give special consideration as to who is responsible for obtaining consent from students, in order to avoid the appearance of coercion by a faculty member of a student.
- Depending on the risk level of the project, the IRB may consider whether a member of the IRB or some other third party affiliated or unaffiliated with ULM should observe/monitor the consent process

6.3. Confidentiality of Data

- The IRB may require extra precautions to ensure the confidentiality and security of data files for ULM participants. As with research involving human subjects generally, IRBs should be aware that research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they should be made aware and from which they should be protected, to the greatest extent possible.
- Because ULM is a relatively closed community, the IRB may also require that the data collection process be designed to be equally sensitive to the privacy of individuals. For instance, a study on sensitive topics as described above should not have participants waiting in a public space where fellow students may readily deduce their participation in the study.