Policy on the Use of Human Participants in Research

**Fall 2023**

*The decision to undertake research rests upon a considered judgment by the individual researcher about how to contribute to knowledge and human welfare. Having made the decision to conduct research, the investigator considers alternative directions in which research energies and resources might be invested. On the basis of this consideration, the researcher carries out the investigation with respect and concern for the dignity and welfare of the people who participate and with cognizance of federal and state regulations and professional standards governing the conduct of research with human participants.*

From the *American Psychologist*, June 1981, 637-638

**General Information**

**What is the Institutional Review Board?**

The LaGrange College Institutional Review Board (IRB) exists as a safeguard for ethical and responsible treatment of human participants in research. The IRB oversees all research conducted by LaGrange College faculty, staff, and students that involves work with human subjects, whether funded or not.

The National Research Act of 1974, recognizing the need for safeguard regulations concerning the use of human participants in social and behavioral science research requires institutional review, letters of assurance, and documentation thereof for such research. The Federal Policy for the Protection of Human Participants, known as the **Common Rule,** represents the latest Federal regulations for protection of human participants.

LaGrange College abides by the [**World Medical Association’s Declaration of Helsinki**](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/), as well as the US Department of Health and Human Services’ [**Belmont Report**](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)**,** bothstatements of ethical principles regarding research using human subjects; in its protection of human research participants. The research application process detailed below conforms to the changes to the **Common Rule**, effective January 21, 2019.

**Definitions**

**How does the IRB define “human subject research”?**

Per the Code of Federal Regulations, [Title 45, Part 46](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.102), Protection of Human Subjects under the United States Department of Health & Human Services, **research** is, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

A **human subject** *is* a “living individual about whom an investigator (whether professional or student) conducting research either obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

Under federal regulations, research involving human participants is classified into three distinct categories requiring different levels of review: exempt, expedited, and all other research.

**What are the primary concerns of the IRB at LaGrange College?**

The IRB seeks to document that:

* risks to subjects are minimized using procedures consistent with sound research design and do not unnecessarily expose subjects to risk;
* risks to subjects are reasonable in relation to anticipated benefits;
* the selection of subjects is equitable and appropriate;
* informed consent is sought from each prospective subject and documented to the extent required;
* there is adequate provision for monitoring the data collected to ensure the safety & confidentiality of subjects; and
* there is adequate protection of the anonymity of subjects.

**Who must file an application for IRB approval?**

The federal government mandates that all research involving human participants be reviewed for its potential harm to the research subjects. Any faculty, staff, or student engaging in research on or with human participants to gain additional knowledge, or with the intention of sharing their results with a larger audience, whether internal or external to the college, needs to submit a proposal of the research project to the IRB. The IRB maintains final determination whether the proposed research is exempt from review, qualifies for approval under an expedited administrative review process, or requires the convening of the full IRB for approval.

If you are engaging in research on or with humans, and:

* your work is a *systematic investigation designed to develop or contribute to generalizable knowledge* [45 CFR 46.102(d)];
* you intend to present this to a larger audience as part of a conference or symposium (*e.g.*, disciplinary conference, undergraduate research project); and/or
* you intend to seek publication of your work in a scholarly journal; then

you **are required to** submit an application.

If you are engaging in research on or with humans, but:

* do NOT intend to use this as anything beyond an example of how to engage in research-related work in your discipline;
* do NOT intend to present your work to a larger audience beyond the group being surveyed;
* do NOT intend to seek publication of your work; and
* do NOT consider your work to be the creation of “generalizable knowledge,” but rather a summary of what you have learned; then

you **are not required** to submit an application.

As an example of the distinction, suppose you are working on a survey instrument as part of an in-class assignment. If the assignment requires the student to ask questions of other students for the purpose of learning how the survey process works, and the information learned by the student will not go beyond the completion of the assignment, then the student does not need to complete an IRB application to be able to complete the in-class assignment. However, if the student creates a survey instrument as part of an in-class assignment and the instrument will be a component of a larger research project that may be presented at an undergraduate research conference later, then the student must complete an IRB application prior to utilizing the survey in the larger research project.

**Do I need special training to file an application?**

Beginning Spring 2024, any student who serves as a researcher on a project and intends to submit an application for IRB approval must first complete Human Research Foundational Training provided by the Department of Health and Human Services. Available on the website of the [Office of Human Research Protection](https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html), students must submit certificates of completion of *Lesson 1: When HHS Regulations Apply* and *Lesson 2: What is Human Subjects Research* as part of their application.

Faculty and staff members are highly encouraged to complete this training as well, but are not similarly required.

# General Ethical Guidelines for Research Involving Human Participants

In planning a study, the investigator has the responsibility to make a careful evaluation of its ethical acceptability. To the extent that the weighing of scientific and human values suggests a compromise of any principle, the investigator incurs a correspondingly serious obligation to seek ethical advice and to observe stringent safeguards to protect the rights of human participants. Considering whether a participant in a planned study will be a "participant at risk", according to recognized standards, is of primary ethical concern to the investigator.

The investigator always retains the responsibility for ensuring ethical practice in research. The investigator is also responsible for the ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom, however, incur similar obligations.

Except in minimal-risk research, the investigator establishes a clear and fair agreement with research participants, prior to their participation, that clarifies the obligations and responsibilities of each. The investigator has the obligation to honor all promises and commitments included in that agreement. The investigator informs the participants of all aspects of the research that might reasonably be expected to influence willingness to participate and explains all other aspects of the research about which the participants inquire. Failure to make full disclosure prior to obtaining informed consent requires additional safeguards to protect the welfare and dignity of the research participants. Research with children or with participants who have impairments that would limit understanding and/or communications requires special safeguarding procedures.

Methodological requirements of a study may make the use of concealment or deception necessary. Before conducting such a study, the investigator has a special responsibility to:

* + determine whether the use of such techniques is justified by the study's prospective scientific, educational, or applied value;
	+ determine whether alternative procedures are available that do not use concealment or deception;
	+ ensure that the participants are provided with sufficient explanation as soon as possible.

The investigator respects the individual's freedom to decline to participate in or to withdraw from the research at any time. The obligations to protect this freedom require careful thought and consideration when the investigator is in a position of authority or influence over the participant. Such positions of authority include, but are not limited to, situations in which research participation is required as part of employment or in which the participant is a student, client, or employee of the investigator.

The investigator protects the participant from physical and mental discomfort, harm, and danger that arise from research procedures. If risks of such consequences exist, the investigator informs the participant of that fact. Research procedures likely to cause serious or lasting harm to a participant are not used unless the failure to use these procedures might expose the participant to risk of greater harm, or unless the research has great potential benefit and fully informed and voluntary consent is obtained from each participant. The participant should be informed of procedures for contacting the investigator within a reasonable time following participation should stress, potential harm, or related questions arise.

After the data are collected, the investigator provides the participant with information about the nature of the study and attempts to remove any misconceptions that may have arisen. Where scientific and human values justify delaying or withholding this information, the investigator incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant. Where research procedures result in undesirable consequences for the individual participant, the investigator has the responsibility to detect and remove or correct these consequences, including long-term effects.

Information obtained about a research participant during the course of an investigation is confidential unless otherwise agreed upon in advance. When the possibility exists that others may obtain access to such information, this possibility, together with the plans for protecting confidentiality, is explained to the participant as part of this procedure for obtaining informed consent.

**Participant Compensation**

If you intend to compensate subjects for their participation in your study, please note the following:

* Best practice is to compensate all participants or compensate none of them. To include participants’ names into a drawing for prize may be considered gambling and should be discouraged.
* Any compensation (including the use of gift cards) is regarded as income and may be subject to appropriate taxation. If this is offered to LaGrange students, faculty, or staff because of their participation in a LaGrange College project, you must send their names, amount, and reason for the compensation to the LaGrange Business Office.

**Types of Review**

**Exempt Review**

Exempt research involves little or no risk to participants and fits one of the categories listed below. More detail on each can be found under [Title 45, Part 46](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.101) in the Code of Federal Regulations pertaining to Protection of Human Subjects. Exempt projects include

* Research into normal educational practices or the assessment of educators who provide instruction;
* Research involving educational tests, survey procedures, interview procedures, or observation of public behavior;
* Research involving benign behavioral interventions;
* Secondary research for which consent is not required;
* Research and demonstration projects that are conducted or supported by a Federal department or agency;
* Taste and food quality evaluation and consumer acceptance studies;
* Storage or maintenance for secondary research for which broad consent is required; or
* Secondary research for which broad consent is required.

**Expedited Review**

Expedited research involves no more than minimal risk to human subjects according to the [Office of Human Research Protections Expedited Review Categories](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/). Please refer to the parent document for details, but research of the type listed below fall into this category:

* Clinical studies of drugs or medical devices with certain restrictions;
* Collection of blood samples from healthy, non-protected classes;
* Collection of biological samples by non-invasive means;
* Collection of data through non-invasive means;
* Research involving materials which have (or will be) collected for non-research purposes;
* Collection of data from voice, video, digital or image recordings for research; or
* Research on individual or group characteristics or behavior that is not considered benign.

In an exempt or expedited administrative review, a limited review of confidentiality and anonymity will be done, ensuring that appropriate safeguards for the subjects are met.

**Full Review**

Research not eligible for an exempt or expedited review or that involves *more than minimal risk* to the subject requires a full review by the IRB. Some examples that may require full review include, but are not limited to:

* Projects that are personally intrusive, stressful or potentially traumatic;
* Research on minors (under 18 years) or populations unable to make informed decisions;
* Research involving deception; or
* Research conducted outside the United States.

**How long does it take to get IRB approval?**

Carefully prepared proposals that do not require additional information and meet the criteria for either exempt or expedited review processes should be approved within 3 – 5 business days of submission. Carefully prepared proposals that do not require additional information or require full board approval may take up to two weeks approval. Review times will increase if additional information is needed before approval can be provided.

Please submit your project well in advance of your actual start date in the event modifications to your proposal are required to secure approval. **Data collection may not begin until IRB approval is fully secured, and an IRB approval number is granted.** Failure to seek IRB approval prior to beginning your data collection may result in nullification of results received up to that point. Approval WILL NOT be provided retroactively.

Applications are to be emailed to IRB@lagrange.edu, and an assessment will be made as to the type of review to be received. Members of the IRB will review the application and get back to the applicant(s) as soon as possible.

**Submission Checklist**

**Before requesting IRB Approval:**

* Carefully review your proposed research plan;
* Complete Part A, the relevant portions of Part B, and Part C;
* Complete your informed consent document;
* Attach all relevant documents (*e.g.*, surveys, email correspondence);
* For student projects, ensure that the certificates of completion of Lessons 1 and 2 from the Office of Human Research Protection Foundational Training is attached to your application;
* For student projects, make sure faculty and staff supervisor(s) review all documents, and sign Part C; and
* Submit the proposal forms with all required signatures and supporting documents by email to IRB@lagrange.edu.

**After securing IRB Approval:**

* Include the project approval date and approval number on all written correspondence with participants or with the IRB;
* Notify the IRB immediately of any significant or unexpected adverse effects experienced by participants during your research project; and
* As appropriate, request permission from the IRB for all modifications to the approved research project.

**IRB Composition**

The LaGrange College IRB is composed of up to five faculty and staff members and one member from the LaGrange community appointed by the Vice President for Academic Affairs. IRB members serve three-year terms, and IRB chairs must have served at least one year on the Board prior to assuming that role. Pursuant to the regulations [45 CFR 46.107], the committee shall consist of:

* + Individuals with varying backgrounds who are sufficiently qualified by experience and expertise to evaluate research proposals involving human participants;
	+ At least one member whose primary concerns are in scientific areas;
	+ At least one member whose primary concerns are in nonscientific areas;
	+ One member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
	+ Equitable representation across multiple demographic groups.

The IRB consists of up to five faculty and staff members and one non-College-affiliated member from the local community, all appointed by the vice president for academic affairs. As the IRB is an institutional body, it is answerable to the president. IRB members serve three-year terms. Board members for 2023-24 and their terms include:

* **Sandy Blair, MSN, RN, CNS,** associate professor of nursing (2024)
* **Colleena Collins, D.C.,** assistant professor of exercise science (2025)
* **John Cook, Ph.D.,** professor of religious studies (2025)
* **Marci DeRamus, Ph.D.**, assistant professor of psychological science (2026)
* **Richard Ingram, M.D., nephrologist, LaGrange Internal Medicine Clinic** (2024)
* **Kelli Tolbert, assistant director of housing (2026)**
* **Brian Peterson, Ph.D.,** chair, vice president for academic affairs (2026)

IRB Members must complete *Lesson 4: IRB Review of Human Research* and *Lesson 5: Institutional Oversight of Human Research* prior to the start of their term on the IRB. Both are part of the Human Research Foundational Training on the [Department of Health and Human Services Office of Human Research Protection website](https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html).

**IRB Application/Review Procedures**

The IRB will meet as needed to review proposals requiring full Board review, to review progress reports, to generate committee activity reports, or to conduct business as deemed appropriate by the members of the committee. Minutes will be kept at all IRB meetings. All records and all correspondence between the IRB and investigators shall be retained for a minimum of three years following completion of the research project.

# Review Procedures

**Exempt** and **Expedited** applicationsshall be assigned for review by the chair of the IRB to a member of the Board. These projects will be considered as they are received. **All other research applications** shall be reviewed/approved by the full IRB committee. Applications requiring full IRB review should allow for at least two weeks for deliberation.

**Risk Incident Report**

Investigators are responsible for immediate notification of the IRB Chair in the event of any injury or psychological harm to a participant enrolled in a research activity at LaGrange College.

# Continuing Review

**Expedited** projects and projects requiring **full IRB review** shall be reviewed annually by the IRB. Investigators are required to complete and submit a progress report requesting continuing IRB approval. All projects deemed to be **Exempt** will not require a yearly review if there are no changes in research design or methodology.

# Final Report

When the study is complete, the principal investigator will submit a final report to the IRB.

# Acknowledgements

LaGrange College gratefully acknowledges the assistance of Institutional Review Boards at Auburn University, Bryn Mawr College, Central College, Georgia Department of Human Resources, Iowa State University, Jacksonville State University, and University of Georgia for their assistance in this document.