**LaGrange College Institutional Review Board (IRB)**

**Application for Research Involving Human Subjects**

**Part A – Research Team Information**

Before beginning, please review the *IRB Policy on the Use of Human Participants in Research*

document found on *myLC* for valuable information that will help you complete your application.

Please check which of the following you are requesting that the IRB consider with this application:

 A Human Subjects Research Project conducted by a member of the LaGrange College community, utilizing LaGrange College resources, and overseen by the LaGrange College IRB

 A request to create and maintain a recruitment registry and/or data or specimen repository.

**If this is a request that LaGrange College rely on the approval provided by an external IRB, please complete the remainder of Form A and append a copy of the application submitted to and the approval letter provided by the external IRB.**

**Investigators**

Name of Principal Investigator:

Email:

Phone:

Title of Project:

Role of Principal Investigator at LaGrange College:

 Student

 Faculty Member

 Staff Member

If Principal Investigator is a student, the Faculty Supervisor is:

Name:

Department:

Email:

Phone:

I (We) intend to begin the project on and end the project on .

This research will take place at (specify location, e.g., LaGrange College or other location):

Will this project receive external funding of any kind? Yes No

If yes, please specify source and how the funds will be spent:

Are there any external (*i.e*., non-LaGrange College-affiliated) researchers who will be involved in human research subject activities?

Select "**yes**" below if individuals at other institutions will be involved as researcherson the project who may:

* Direct recruitment of research participants,
* Obtaining informed consent from research participants,
* Interacting with research participants to collect data,
* Administering any research interventions, tests, procedures, etc., or
* Access to identifiable research data.

Select “**yes**” below if you wish to have an IRB at another institution oversee the project.

Select "**no**" below if you are conducting only with LaGrange College researchers; or if you will be conducting research at a collaborating site, but the only role of persons at that site is to serve as research participants,or activities of collaborating researchers do not involve interaction with human subjects *(e.g.*, contributing to methodology, analysis of deidentified data).

Yes No

Please list all members of the research team and identify:

* their role in the research (*e.g.*, Co-PI, faculty survey),
* their relevant qualifications to participate on the research team, and
* whether they will collect participant data, be involved in recruiting or obtaining consent, or have access to identifiable research data.

**Other Approvals**

Are there any other approvals which have been or will be obtained (*e.g.*, from school districts or cooperating institutions) before you begin the research? Other approvals may also be required to access confidential records, including medical, educational, or employment records.

Yes No

If yes, please identify how these approvals will be obtained and records maintained.

**Translation**

Will you require the translation of research materials into a language other than English? Yes No

If yes, please explain who will translate the documents and their qualifications for doing so.

**Part B – Research Methods and Procedures**

**Objectives**

In language *understandable to a layperson*, please explain the purpose and goals of the study.

**Broader Impact**

In language *understandable to a layperson*, please explain why this research is important and how information gained will advance knowledge in the field.

**Benefits**

Are there direct benefits to the participants from this study? If so, what are they? Compensation for participation (in any form) *does not* constitute a benefit.

**Future Publication**

Will any potential project publications (as appropriate) require the identification of individual subjects? Yes No

If yes, please explain why and how you will obtain consent for this from your participants.

**Anonymity and Confidentiality**

Describe the procedures used to assure the anonymity of subjects and confidentiality of subject data, including the following:

* What identification markers, especially names and contact information, will you collect from participants? If you are not collecting any identification markers, please explain why that is unnecessary.
* How will your data be protected from non-project personnel?
* What will happen to the data when it is no longer needed?

**Sample Population**

Briefly describe:

* the specific characteristics of the participants to be included in your study.
* the specific characteristics of the participants who will be excluded from your study
* Why these inclusions or exclusions are necessary and appropriate
* How many people you anticipate participating in your study (distinguishing between the number of people you will invite as well as the minimum number needed for viability)
* Your relationship to the participants, if any

**Compensation**

Do you intend to compensate your participants in any way? If so, how? Please be sure to review the participant compensation guidelines in the IRB Policy for Human Subject Research.

**Risk**

Yes No

Will the participant experience any **pain or physical danger**?

Will the participant experience any **emotional arousal or psychological stress** (*e.g.,* anxiety, discomfort, frustration) *beyond the levels normally expected in daily life?*

Will the project induce or attempt to induce **long-term, significant change in the participants’ behaviors** (including attitudes toward self and others)?

Will the data **embarrass or socially disadvantage the participant *beyond the levels normally expected in daily life* if confidentiality was to be violated**? (Note: A project involves more than minimal risk if the information would embarrass the subject were confidentiality to be violated. Survey research involving sensitive material is not exempt, even when confidentiality is maintained, because it involves more than minimal risk.)

Will there be **concealment or misinformation** such that the participant might choose to not participate in the research had they been aware of the true state of affairs?

Will participants be members of **prisoners, those with disabilities, minors, non-native English speakers, other vulnerable populations, or in an international setting**?

Is there *any* **foreseeable discomfort or risk** to participants from taking part in your research? Why or why not?

**If you answer yes to any of the prior questions, your research cannot be considered for exempt review.**

**Exempt Research**

Do you believe your study qualifies for **Exempt** status? Yes No

If yes, please provide justification as to why your study falls into one or more of the categories for exempt research. If not, please explain why not.

Research that qualifies for exemption falls into one of the following categories:

* 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.

**Research Protocol (for Expedited and Full Review Applications only)**

*In language understandable to a layperson*, please describe in detail your plans for collecting data from participants. Include a description of *all* procedures, tasks, or interventions participants will be asked to complete during the research (*e.g.*, random assignment, mail survey or interview procedures, observation protocols, sensors to be worn). If your research includes any type of recordings that will capture confidential or identifying information, please describe these in detail. *Please ensure that references to materials attached throughout the application are clear. We recommend that attachments (e.g., s*urveys, interview protocols*) are clearly named and when mentioning them in this section those names are used.*

**Additional Information**

* Non-exempt research applications must include informed consent documentation, recruitment narratives, additional approvals, survey instruments, and all other documents utilized in the research.
* **All students** must submit their certificates of completion of *Lesson 1: When HHS Regulations Apply* and *Lesson 2: What is Human Subjects Research* from the [Human Research Foundational Training](https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html) as part of their application.

**Part C**

**Investigator Assurance of Informed Consent**

Although exempt research may be freed from many regulatory requirements, it is not exempt from important ethical considerations such as informing potential participants about the research and allowing that they voluntarily agree to take part. Use of a formal informed consent document containing all the elements of consent *is not required* for exempt research.

The LaGrange College IRB expects *all* investigators to provide, *at minimum*, the following information to prospective participants (and their parent or legal guardian, if a minor) prior to enrollment in the study:

* A statement that the project involves research;
* A general description of the study procedures and time commitment;
* A description of any plans to audio or video record participants;
* A description of any discomfort or risk (such as discomfort with responding to sensitive or personal questions);
* A statement that participation is voluntary;
* A statement that the participant may skip any questions they do not feel comfortable answering in an interview or survey; and
* The measures that will be used to ensure the confidentiality of data collected in the research, including how audio or video recordings will be used.

A template for an approved Informed Consent document is provided on *myLC*.

The IRB understands that obtaining informed consent may not be feasible in some situations, such as obtaining large data sets from existing records where contacting persons is not possible or practicable. However, researchers should be aware that research that involves obtaining existing data, documents, specimens, etc., may require informed consent if the information is protected by regulation (*e.g.* FERPA, HIPAA) and includes any type of identifier (as defined by either FERPA or HIPAA regulations).

**EXEMPT REVIEW APPLICANTS**

Please affirm that you will implement a consent process that indicates that participants will receive the information above in a manner that facilitates their voluntary consideration, and participants will have an opportunity to agree before research procedures begin.

Yes No

**EXPEDITED AND FULL REVIEW APPLICANTS**

Please ensure that your informed consent document conforms to the requirements above and is attached to your application.

**Investigator Affirmation of Ethical Obligations of Researchers**

I have read the study protocol and agree to the following conditions: I understand that as Principal Investigator and/or Co-Investigator, I share the responsibility for the ethical performance of the project, the protection of the rights and welfare of the participants, and strict adherence to any stipulations imposed by the Institutional Review Board (IRB). I agree to comply with all applicable regulations, laws, and policies regarding the protection of participants in research, including, but not limited to:

* Obtaining the legally effective informed consent from the IRB or its legally responsible representative;
* Making no changes to the approved protocol or consent form without first having submitted those changes for review and approval of the IRB;
* Promptly reporting significant or untoward adverse effects experienced by participants to the IRB chair;
* Promptly and completely complying with a decision to suspend or withdraw its approval for the project;
* Promptly providing the IRB with any information requested relative to the project.

**All principal and co-investigators must electronically sign below. LaGrange College regards any infringement of IRB policies and procedures as a serious breach of professional standards. In making this application, I certify that I have read and understood the LaGrange College policy for projects that involve human subjects and that I intend to comply. I understand that a violation of IRB policies and procedures may result in the termination of my approval and/or in charges of academic dishonesty and violation of LaGrange College’s Honor Code.**

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Principal Investigator Date

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Co-Investigator Date

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Co-Investigator Date

**Faculty/Staff Sponsor: With my signature below, I affirm that I have reviewed this student research application and approve its contents and validity as undergraduate research. I agree to monitor the work of this (these) student(s) and to provide guidance in the ethical treatment of human subjects.**

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Faculty/Staff Sponsor Date

**Please submit this completed application and all related documentation in a single email to** **IRB@lagrange.edu****.**