LaGrange College Institutional Review Board IRB Approval # _____

*******NO HANDWRITTEN APPLICATIONS WILL BE ACCEPTED*******

_____

NAME OF PRINICPAL INVESTIGATOR TITLE DEPT PHONE

PROPOSED DATES OF STUDY: _____ THROUGH _____

PROJECT TITLE: _____

_____

NAME OF CO-INVESTIGATOR(S)

_____

PROGRAM COORDINATOR SIGNATURE DATE

INVESTIGATOR'S ASSURANCE

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

I understand that as Principal Investigator, 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 participants, and strict adherence to any stipulations imposed by the LCIRB.

I agree to comply with all LC policies and procedures, as well as with all applicable federal, State, and local laws regarding the protection of human participants in research, including, but not limited to the following:

- Perform the project by qualified personnel according to the approved protocol,
- Implement no changes in the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human participants),
- Obtain the legal effective informed consent from human participants or their legally responsible representative and use only the currently approved, stamped consent form with human participants,
- Promptly report significant or untoward adverse effects to the IRB in writing within 5 working days of occurrence,
- If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person will be named as co-investigator in this application, or I will advise the IRB, by letter, in advance of such arrangements.

_____

Principal Investigator Signature Date

FACULTY SPONSOR'S ASSURANCE

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

- I agree the project will be performed by qualified personnel according to the approved protocol.
- I agree to meet with the investigator on a regular basis to monitor study progress.
- Should problems arise during the study, I agree to be available, personally, to supervise the investigator in solving them.
- I assure that the investigator will promptly report significant or untoward adverse effects to the IRB in writing within 5 working days of occurrence.
- If I will be unavailable to supervise this study, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the IRB by letter of such arrangements.
-

_____

Faculty First Name Faculty Last Name Faculty Email Address

_____

Faculty Advisor Signature Date

1. **Check the type of application –** Please see the IRB policy posted at www.lagrange.edu/academic/irb for a full description of each type of application

   Exempt ☐ **Expedited** ☐ **Full Review** ☐

2. **Location of Project**: ☐ LaGrange College Facility ☐ Other (If other, give more detail below)

3. **Is the researcher receiving financial support or applying for funding?**

   ☐ No

   ☐ Yes

   If Yes, please complete the following:

   List the source(s) of funding: _____

   Funding will be used for:

   ☐ Paying participants (provide further details in compensation section of application)

   ☐ Researcher Expenses (postage, copies, equipment, travel, etc.)

   ☐ Other: _____

4. **Previous literature and project objectives –** Please describe the specific scientific objectives (aims) of this research and any previous relevant research. If you need more space and would like to submit a separate document instead, please type SEE PREVIOUS LITERATURE AND OBJECTIVES ATTACHMENT below and submit that document along with your application

5. **Description of Project –** Please provide a brief summary of this project, using non-technical terms that would be understood by a non-scientific reader. Please limit this description to no more than one page. Specific details should be provided in the methodology section below. If you need more space and would like to submit a separate document instead, please type SEE DESCRIPTION OF PROJECT ATTACHMENT below and submit that document along with your application.

6. **Methodology –** Please describe the procedures (sequentially) that will be performed/followed with human participants. Without a complete description of all procedures, the LCIRB will not be able to review the protocol. If you need more space and would like to submit a separate document instead, please type SEE METHODOLOGY ATTACHMENT below and submit that document along with your application

7. **Instruments** – Please list all questionnaires, instruments, standardized tests, interview protocols, etc. below with a brief description of each.

8. **You should also provide a copy of all instruments to be used. All instruments can be included in a single attachment. If you are utilizing a survey instrument, you should upload the exam instrument that participants will see. If this is an online survey, please provide a PDF web printout of that survey so that reviewers can see exactly what participants will see.**

9. **Characteristics of participants** – Check as many as appropriate

- ☐ Minors
- ☐ Adults
- ☐ Prisoners
- ☐ Pregnant
- ☐ Disabled (physically or mentally)
- ☐ Legally incompetent
- ☐ Cognitively impaired
- ☐ Non-English speaking
- ☐ Elementary school students
- ☐ Middle school students
- ☐ High school students
- ☐ University/College students

10. **Briefly describe the criteria for selection of participants (inclusion/exclusion). Include such information as age range, health status, etc.**

11. **If using minors, please include an attachment of the procedure/form for parental consent and for the assent of the minor.**

12. **Describe how you will determine group assignments (random vs. criteria) and number of participants to be assigned to each group, the number of groups needed, provisions for controls, or any other clarifying information regarding participant population you feel is appropriate. If participants will not be assigned to groups, please respond N/A.**

13. **Maximum number of participants to be enrolled** – If screening occurs, include total number that will need to be screened.

14. **Describe your relationship to the potential participants (i.e., instructor of class, classmate, coworker, etc.). If no relationship, state no relationship.**

15. **Can these participants be described as a vulnerable population?**

- ☐ No
- ☐ Yes

If yes, provide additional, acceptable justification for the use of the proposed vulnerable population.

16. **REPS usage** – Will you use the LaGrange College Research & Experiment Participation System (REPS) to recruit participants?
☐ No
☐ Yes

If yes, please see the REPS Researcher user guide (https://docs.google.com/document/d/1ivNTp6iV4YwuhjL7TUUjVyTmSikg0APMGFL3eOwwqCU/edit) to review how to use REPS.

If yes, please provide an attachment including a screenshot of the participant view of your study in the REPS system.

17. **If not using REPS, describe how you will identify and recruit participants. Be specific.**

18. **If you are using a flyer, social media post, or other advertising to recruit participants, please submit an attachment of a copy of the exact advertisement to be used.**

19. **Informed consent process** – Which of the following informed consent processes will you be using (choose only one)?

☐ **I am obtaining a signed consent for this study**

Include an attachment with the informed consent form to be used. If conducting an electronic survey, please provide a PDF web printout of the informed consent that participants will see. Use the template provided on the IRB website (www.lagrange.edu/academics/irb/forms).

☐ **I am requesting a waiver or alteration of informed consent**

Why are you requesting a waiver of a signed informed consent?

- ☐ Exempt study
- ☐ Waiver needed to protect the privacy of the participants
- ☐ Waiver needed due to cultural norms (e.g., wary of forms needing signatures)
- ☐ Impractical (online or phone study)
- ☐ Other : _____

Below, provide any details you feel necessary to explain your choice above.

Include an attachment with all information that will be provided to participants regarding the study (email, cover letter, etc.). If completing an online or phone study, please see the templates for informed consent on the IRB website (www.lagrange.edu/academics/irb/forms**).**

☐ **I am requesting to use deception (incomplete disclosure)**

Why are you using deception?

- ☐ Necessary to avoid participants altering behavior (e.g., not informing of 2-way mirror, providing a cover story, etc.)
- ☐ Other: _____

Include an attachment with the informed consent form to be used. If conducting an electronic survey, please provide a PDF web printout of the informed consent that participants will see. Use the template provided on the IRB website (www.lagrange.edu/academics/irb/forms).

☐ **I am requesting a complete waiver of consent**

Provide justification for why you request a complete waiver of informed consent.

20. **Consent process** – How and where will the consent process occur? Who will be discussing consent with participants? Will participants have an opportunity to ask questions and have them answered? What steps will be taken to avoid coercion or undue influence? (If requesting a complete waiver, you may skip this question).

21. **Records** – Are you accessing private (e.g., medical, educational, employment) records?

☐ No

☐ Yes

If yes, describe the process for obtaining approval for the use of the records or for securing consent from participants

If yes, include an attachment of a letter of support from the holder or custodian of the records (e.g., primary physician, therapist, public school official, etc.).

22. **Participant benefits** – Describe the realistic anticipated benefits to the individual participants. NOTE: compensation is NOT a benefit but should be listed in the compensation section of the application.

23. **Society benefits –** Describe the realistic and anticipated benefits to society and/or the scientific community in lay language. There must be some benefit to justify the use of human subjects.

24. **Risks** – Are there risks or discomforts to participants associated with the proposed protocol? (Note: This may include physical risks, psychological risks, social risks, or deception).

☐ No

☐ Yes

Identify why of the following risks participants might encounter if they decide to participate in this research. Please check all that apply.

☐ Physical
☐ Psychological
☐ Deception
☐ Social
☐ Other

Describe the risks/discomforts that are associated with this protocol.

Describe all precautions you have taken to reduce these risks to participants. If you are using deception in this project, justify why and be sure to include an attachment of your debriefing form; a debriefing form template can be found on the IRB website (www.lagrange.edu/academics/irb/forms).

25. Confidentiality – Please indicate which of the following describes the anonymity of the data you will collect.

☐ **Data is collected anonymously** (e.g., anonymous online survey, etc.)

☐ **Data will be recorded without possibility of identification** (e.g., participants are not anonymous [i.e., come into the lab] but no identifying information is recorded)

☐ **Data will be recorded with a code replacing identifiers and a master list connecting the code and the identifier exists for some period**

Provide details, such as how/where the code list is securely stored, when it will be destroyed, etc.

☐ **Data will be recorded with identifying information** (e.g., name, SSN, LC ID, etc.)

Provide justification for why identifiable information will be used.

Provide details on how data will be stored securely (e.g., locked cabinet, password protected device, etc.), who will have access to the data, as well as a time frame of when data will be de-identified/destroyed and how.

☐ **Nature of data makes it potentially identifiable** (e.g., material with DNA, photographs/video, etc.)

Are you videotaping participants? ☐ Yes ☐ No

Are you audiotaping participants? ☐ Yes ☐ No

Provide justification for why identifiable information will be used.

Provide details on how data will be stored securely (e.g., locked cabinet, password protected device, etc.), who will have access to the data, as well as a time frame of when data will be de-identified/destroyed and how.

26. Course Credit – Will participants receive course credit for participation?

☐ No

☐ Yes

Please describe non-research alternatives to earn the credit, the number of points awarded and what percentage of total points for the course it represents. If you are using REPS, which has already established guidelines that provide these details to the IRB, simply write REPS.

27. Monetary Compensation – Will participants receive monetary compensation (including gift cards)?

☐ No

☐ Yes (be sure to speak with the business office to ensure compliance with college policy on payments)

Detail the amount per session and total compensation possible. Additionally, describe what compensation amount is paid to participants who discontinue participation prior to completion.

28. Gifts – Will participants receive a gift or token of appreciation?

☐ No

☐ Yes

List the item(s) and the approximate value

29. Other compensation – Will participants receive services, treatment, or supplies that have monetary value?

☐ No

☐ Yes

Describe and provide approximate value

30. Other institution – Is this project being conducted in collaboration with research at other institutions or agencies?

☐ No

☐ Yes

What other institution/agency is involved?

Has this project been submitted for approval at that other institution?

☐ Yes, approved

☐ Yes, denied

☐ Currently under review

☐ Not submitted

☐ No approval process at this institution/agency