LAGRANGE COLLEGE
INSTITUTIONAL REVIEW BOARD
AUTHORIZATION # ______________________

A COMPLETE SET OF ALL PROTOCOL INFORMATION MUST BE SUBMITTED TO THE INSTITUTIONAL REVIEW BOARD FOR REVIEW – SUBMIT ONE COPY WITH SIGNATURES IN ADDITION, AN ELECTRONIC COPY OF ALL MATERIALS MUST BE SUBMITTED

*****ONLY TYPEWRITTEN OR WORD PROCESSED PROTOCOLS WILL BE ACCEPTED*****

________________________________________________________________________________________

NAME OF PRINCIPAL INVESTIGATOR        TITLE        DEPT
PHONE

PROPOSED DATES OF STUDY: ____________________ THROUGH _____________________

PROJECT TITLE:________________________________________________________________________________________

SOURCE OF FUNDING: ____________________________________________________________________________

________________________________________________________________________________________

NAME OF CO-INVESTIGATOR        TITLE        DEPT
PHONE

DEPARTMENT HEAD 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 course of 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 Advisor Signature ___________________________ Date ____________

CHECK TYPE OF APPLICATION

EXEMPT _______ EXPEDITED _________ FULL REVIEW ________

1. PURPOSE OF STUDY. Please provide a complete statement of objectives for conducting this research project. (What do you hope to learn?)

2. PARTICIPANT POPULATION. Describe the criteria you have established for participant selection.

Can these participants be described as a vulnerable population? ______Yes ______No
If Yes, provide additional, acceptable justification for use of these participants.

What is the:
Maximum number of participants you need to validate the study? ________
Maximum number of potential participants you plan to recruit? __________

Maximum number you will include in the study? __________

How will you recruit participants? (If you are advertising or using flyers, please attach a copy.)

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.

LCIRB Protocol

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3. EXPERIMENTAL METHODS AND STUDY DESIGN. Please provide a description of all procedures you plan to use during the course of this research in lay language. (Without a complete description of all procedures, the LCIRB will not be able to review the protocol.)

4. BENEFITS. Describe realistic benefits to participants and general population.
5. **RISKS.** Identify which 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 (Specify): __________
- None: __________

Describe the risks that are associated with this protocol.

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**LCIRB Protocol**

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6. **PRECAUTIONS.** Describe all precautions you have taken to eliminate or reduce reasonable risks. If you are using deception in this study, please justify why and be sure to attach a copy of your debriefing form.

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7. **LOCATION OF RESEARCH.** Please be as specific as possible.

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8. **PROTECTION OF DATA.**

Will data be confidential? _____Yes _____No
Anonymous: _____Yes
_____No
Will data be coded in any way? _____Yes _____No

If Yes, explain reason (e.g. ensure confidentiality of sensitive information, to follow-up initial contacts, collate data, etc.) and describe the method you will use for coding data.

Will you be videotaping participants? _____Yes _____No

Will you be audiotaping participants? _____Yes _____No

Where will identifiable information (e.g., coded data, pictures, tapes, etc.) be stored? (If not applicable, please indicate N/A.)

Who will have access to identifiable information? (If not applicable, please indicate N/A.)

Where will code lists be stored? (If not applicable, please indicate N/A.)

How is the location(s) secured during your absence? (If not applicable, please indicate N/A.)

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How will identifying information (e.g., code lists, pictures, tapes, etc.) be destroyed? (If not applicable, please indicate N/A.)

What is the latest date on which identifiable data (e.g., code lists, pictures, tapes, etc.) will be destroyed? (If not applicable, please indicate N/A.)

NOTE: Research data which cannot be linked in any way to an individual participant of the project may be retained indefinitely.
9. A. If the research is being done in collaboration with research at other institutions or agencies, has this information been submitted for approval at that institution?

What other institution(s) are involved?

_____ Yes  _____ No  _____ No approval process at this institution(s).

B. Has approval for this research been obtained from this institution(s)?

_____ Yes  _____ No  _____ In Process

If this approval has not yet been obtained, you must file a copy of this approval with the IRB before the research can begin.

10. ATTACH A SAMPLE OF ALL INSTRUMENTS, SURVEYS, DRAWINGS, ETC. you will use in this study. If you are (or will be) developing the questionnaire, etc., please provide a general description of the instrument. If you are using interview procedures, please include a general script of the interview.

11. ATTACH A COPY OF ALL INFORMED CONSENTS AND/OR INFORMATION DOCUMENTS you have developed for use in this study. Be sure each form is applicable to the proposed procedures and that the form contains all of the requirements for compliance with the regulations regarding informed consent.