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**Claflin University**

**Institutional Review Board (IRB)**

**Application for Approval for Conducting research**

400 Magnolia Street

Orangeburg, South Carolina 29115

Email: IRB@claflin.edu and vpr@claflin.edu

 **Application Submission Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Application Revised Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Application Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\*Please note that the Application Approval Date must pre-date the study/research data collection begin date.**

**\*Claflin University IRB Committee will meet quarterly during the academic year on the third (3rd) Thursday of October, January, and April to review the IRB applications.**

**Student Research Thesis IRB Submission:**

* **December Graduates: Submission should be by the 2nd week of September.**
* **May Graduates: Submission should be by the 2nd week of January.**

**TIMELINE RESPONSE OF THE IRB COMMITTEE FOR THE SUBMITTED APPLICATIONS FOR REVIEW**

|  |  |
| --- | --- |
| **REVIEW TYPE** | **RESPONSE TIMELINE**  |
| Exempt | 10 days |
| Expedited | 7 days |
| Full | Varies, see above IRB convening meeting dates. |
| Not Research | 7 days |

**THE Institutional Review Board (IRB) committee is required by federal law to protect the rights and welfare of human SUBJECTS BY participating in reseArch activities.**

University policies and federal regulations require that each project involving studies with human subjects be reviewed to consider:

1. The rights and welfare of the participant(s) involved.
2. The appropriateness of the methods used to secure informed consent from the participants.
3. The balance of risks, so there is minimal or no risk to the participant(s) and potential benefits of the investigation.

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| **FOR IRB OFFICE USE ONLY** |
| Number Assigned by IRB |  |
| Review Type: | Exempt [ ]  Expedited Review [ ]  Full Review [ ]  Not Research [ ]  |

**Proposal Type**: [ ]  Original [ ]  Revised

**How to complete your application and begin the IRB review process:**

1. This form should not be handwritten.
2. Answer all the questions on this form. Complete and attach appropriate appendices required by responses in this application.
3. Attach protocol.
4. Attach supporting documentation: informed consent form, survey/interview questionnaire, interview schedules, solicitation letters, advertisements, etc.
5. Complete the checklist that accompanies this form to assure all requirements for submission are completed so that review is not delayed.

**Checklist for SubmiTINg A Complete Application FOR IRB REVIEW**

Please make sure that your application is complete prior to submitting it to the IRB committee. Please be particularly careful that your informed consent form (or consent procedure) includes all the information listed below.

Submit electronic application to IRB@claflin.edu, and the Office of the Associate Vice Provost of Research, vpr@claflin.edu. The emailed application must be received no later than three weeks before an IRB meeting to be considered at that meeting, except for student research applications, which must be submitted on the specified dates (refer page 1) before the desired decision date.

**IF THE QUESTION IS NOT APPLICABLE, PLEASE INCLUDE YOUR RESPONSE AS “NOT aPPLICABLE (N/A).”**

**Application:**

[ ]  Project/Study Summary (250 to 300 words).

[ ]  Study Description/Research Plan (5 pages maximum). Categories part of Study Description/Research Plan:

[ ]  Background related to the Study.

[ ]  Objective of the Study.

[ ]  Significance of the Study.

 [ ]  Research Design, Methods, and Data Analysis.

[ ]  Data collection instruments (survey or interview questionnaire, tests used to analyze the data, must be provided, and should coincide with parts of study described in study description).

[ ]  Results of the preliminary studies if conducted.

[ ]  Anticipated outcomes of the study: publication, book chapter, or submission of preliminary data to funding agency for funding research.

[ ]  References (cited in the background of study).

[ ]  Detailed Recruitment Plan.

[ ]  Participants/subjects profile.

[ ]  Recruitment materials (as applicable: flyers, recruitment letters, printed ads, and e-mail solicitation).

[ ]  Informed Consent Form.

[ ]  Conflict of interest.

Certificate of training in protection of human subjects: <http://phrp.nihtraining.com/users/login.php> or http://www.citiprogram.org

[ ]  Vulnerable Population (if your study includes vulnerable populations, please provide CITI/ethics training certification). <https://about.citiprogram.org/?s=Vulnerable+Population>

[ ]  Children *(45CFR46, subpart D):* [*https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html)

[ ]  Pregnant Woman/Fetuses/Neonates/placenta/dead fetus or fetal material (45CFR46, subpart B): <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html>

[ ]  Prisoners (45CFR46, subpart C): <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html>

[ ]  Animal Subject (if your study includes animals, please provide CITI/ethics training certification). <https://about.citiprogram.org/series/animal-care-and-use-acu/>

[ ]  External IRB Approval (Provisional and Final, if applicable).

**Consent Form:** (Written or Online for a lay audience)

[ ]  Identification of researcher’s position, institution.

[ ]  Consent/assent form and date.

[ ]  Description of study (appropriate for lay audience).

[ ]  Description of procedure (activities, duration: audio or videotaping).

[ ]  Statement of benefits and risks (even if there are no direct benefits or known risks, explain precautions if there are risks, monetary payment does not constitute a benefit).

[ ]  Statement of voluntary nature of participation (including the right to skip questions).

[ ]  Statement of confidentiality (rationale if deviate from complete anonymity; may include waiver to use names of respondents; specify how data will be used).

[ ]  *Studies using audio, photographic, or video recordings,* explanation of use of recordings and release information required:

1. Explain use of recording.
2. Explain plan for storage.
	* + 1. Explain how information will be disseminated, if applicable.

[ ]  Contact information of key persons: PI, Claflin Sponsor (if external researcher).

[ ]  Copy of consent form given to respondent with included statement: “If you have questions about your rights as a participant in this study, you may contact the Office of the Associate Vice Provost of Sponsored Programs and Research, whose office oversees the protection of human research participants at (***803-535-5177***).

[ ]  Signatures and date.

1. **PROJECT IDENTIFICATION**
	1. **Project Title:** Click here to enter text.
	2. **Person Preparing This Document:**

|  |  |
| --- | --- |
| **Name:** |  |
| **Phone Number:** |  |
| **E-mail Address:** |  |

* 1. **Project Duration Time:**

|  |  |
| --- | --- |
| **Proposed Start Date:** |   |
| **Proposed End Date:** |   |

***\*Note that project cannot begin until AFTER your IRB Application has been approved and you have received written approval letter.***

**1.4 Type of Research:**

[ ]  Claflin Student Classroom Project

[ ]  Claflin Student Thesis/Capstone Project

[ ]  Claflin Faculty Project

[ ]  Claflin Staff Project

[ ]  External Researcher Project

**1.5 Investigators:**

**Please add additional investigators as necessary.**

**Principal Investigator (**for student research, faculty or staff advisor is the PI**):**

**Name:** Click here to enter text.

**Department:** Click here to enter text.

**Title:** Click here to enter text.

**Institution Phone Number:** Click here to enter text.

**Mobile Number:** Click here to enter text.

**Institution Email Address:** Click here to enter text.

**Institution Affiliation:** Click here to enter text.

**Institution Address:** Click here to enter text.

**Co-Investigator (**includingstudent researcher**):**

**Name:** Click here to enter text.

**Department:** Click here to enter text.

**Title (if student, list your Classification, e.g., sophomore):** Click here to enter text.

**Institution Phone Number:** Click here to enter text.

**Mobile Number:** Click here to enter text.

**Institution Email Address:** Click here to enter text.

**Institution Affiliation:** Click here to enter text.

**Institution Address:** Click here to enter text.

**Claflin Sponsor (**If the researcher is not affiliated with Claflin University but funding the study and the study is conducted by Claflin Faculty, Staff, or Students in collaboration at Claflin University, please provide the sponsor information below**):**

**Name:** Click here to enter text.

**Department:** Click here to enter text.

**Title:** Click here to enter text.

**Institution Phone Number:** Click here to enter text.

**Mobile Number:** Click here to enter text.

**Institution Email Address:** Click here to enter text.

**Institution Affiliation:** Click here to enter text.

**Institution Address:** Click here to enter text.

**Claflin Coordinator (**If the researcher is not affiliated with Claflin University but the study is coordinated by Claflin Faculty, Staff, or Students at Claflin University, please provide the Claflin contact individual information below**):**

**Name:** Click here to enter text.

**Department:** Click here to enter text.

**Title:** Click here to enter text.

**Institution Phone Number:** Click here to enter text.

**Mobile Number:** Click here to enter text.

**Institution Email Address:** Click here to enter text.

**Institution Affiliation:** Click here to enter text.

**Institution Address:** Click here to enter text.

1. **Human Subjects**

**Does the research involve human subjects?** [ ]  Yes [ ]  No

***If Yes***, **please complete the following specific to your study:**

**Does the research involve:**

Claflin University students as subjects? [ ]  Yes [ ]  No

***If Yes,*** how many? Click here to enter text.

Claflin University faculty/staff as subjects? [ ]  Yes [ ]  No

Faculty/staff or students from another college/institution as human subjects? [ ]  Yes [ ]  No

***If Yes***, provide the name and address of the institution(s).

**Name of the Institution(s):** Click here to enter text.

**Address(es) of the Institution(s):** Click here to enter text.

Human subjects from a population other than students or faculty. [ ]  Yes [ ]  No

Specify the population that will be used as non-academic human subjects.

Is this a vulnerable population? [ ]  Yes [ ]  No

Will this research involve a potentially vulnerable population? [ ] Yes [ ] No

***If Yes***, select the potentially vulnerable population from the list below.

**2.1 Inclusion/Exclusion of Potentially Vulnerable Populations:**

Physically/Mentally/Emotionally/Developmentally Challenged Individuals. [ ] Yes [ ] No

Children ages 0-7 years (Include parental consent form). [ ] Yes [ ] No

Children ages 8-17 (Include child’s assent form, parent consent form). [ ] Yes [ ] No

Senior Citizens (ages 65+) (Include consent form of the participant or the caretaker). [ ] Yes [ ] No

Pregnant Woman/Fetuses/Neonates/placenta/dead fetus or fetal material. [ ] Yes [ ] No

Prisoners [ ] Yes [ ] No

Minority Group(s) and non-English speakers [ ] Yes [ ] No

***If Yes,*** to any of the above, please briefly explain how the rights of this (these) population(s) will be protected:

Click here to enter text.

**2.2 For All Targeted Human Subjects:**

Will subjects be healthy (no known physical or mental illnesses)? [ ]  Yes [ ]  No

Will any subjects be incapacitated, incarcerated, or detained? [ ]  Yes [ ]  No

Will any subjects be adjudicated and under official supervision (i.e., probation, parole, court-ordered counseling?) [ ]  Yes [ ]  No

Will subjects be employees of the organization/profession related to the study? [ ]  Yes [ ]  No

1. **ANIMAL SUBJECTS**

**Does the research involve the use of animal subjects?** [ ]  Yes [ ]  No

***\*If research involves animal subjects, please complete Appendix A.***

1. **INFORMED CONSENT FORM**

***\*Note: Please make sure to attach the informed consent form. If the informed consent form is not provided, the application will be rejected.***

1. **SURVEY/INTERVIEW QUESTIONS**

***\*Note: If the study involves surveys administered online or in-person and interviewing participants, please make sure to attach the survey and interview questionnaire. If the questionnaire is not provided, the application will be rejected.***

1. **DATA ANALYSIS**

***\*Note: If the study does not include how the data will be analyzed, the application will be rejected. A few examples of statistical methods that can be used for data analysis: Chi-square test, t-test, ANOVA, Regression tests, Comparison tests, etc.***

1. **CONFLICT OF INTEREST**

**Do any of the investigators or personnel listed in this research have a potential Conflict of Interest (COI) associated with this study?**

 [ ]  Yes [ ]  No

***If Yes***, has this potential COI been disclosed as per the relevant policy?

[ ]  **Yes.** *Include a copy of the plan for IRB review.*

[ ]  **No.** *The IRB cannot review the study before a potential COI has been disclosed.*

**8. Project/STUDY Summary**

Please provide a 250- to 300-word summary of the research (including objective of the study, methodology(ies) to be used in this study, analysis of data, and dissemination of obtained data).

Click here to enter text.

**9. SUBJECTS/PARTICIPANTS PROFILE**

* 1. **Number of subjects/participants you plan to enroll in the study.**

Click here to enter text.

* 1. **How was this number determined (e.g., power analysis)?**

Click here to enter text.

* 1. **If this is a multi-site study, what is the total number of subjects/participants to be enrolled from each site? Please add study sites as needed.**

[ ]  N/A

Site 1: Name of the institution: Total Number:

Site 2: Name of the institution: Total Number:

Site 3: Name of the institution: Total Number:

Site 4: Name of the institution: Total Number:

 **9.4 Does this project require the collection of new data?** [ ]  Yes [ ] No

***If Yes***, how will participants be selected or recruited?

Click here to enter text.

If collecting new data: Will subjects participate on a fully voluntary basis? [ ]  Yes [ ]  No

If collecting new data: Will subjects be compensated for their participation? [ ] Yes [ ] No

***If Yes***, please briefly describe the compensation.

Click here to enter text.

**9.5 Does this project use data that has already been collected for a non-research purpose or by another researcher?** [ ] Yes [ ] No

***If Yes,*** what is the source of the data?

Click here to enter text.

Are the data accessible in the public domain? [ ] Yes [ ] No

***If No,*** are fields included that would allow identification of individuals, either directly or indirectly? [ ] Yes [ ] No

***If Yes,*** please explain briefly how participant confidentiality will be safeguarded:

Click here to enter text.

**10. HUMAN TISSUE OR CELL LINE**

**Does this project make use of human tissue or cell lines?**  [ ] Yes [ ] No

***If Yes***, please provide a brief description.

Click here to enter text.

**11. RECRUITMENT**

* 1. **Describe in detail the subject recruitment strategies you will use for each group of subjects.**

Click here to enter text.

***Attach a copy of all recruitment materials to be used, e.g., advertisements, bulletin board notices, flyers, brochures, letters, phone scripts, or URLs.***

* 1. **Explain who will approach the subjects to take part in the research and what will be done to protect subjects’ privacy in this process.**

Click here to enter text.

**12. RISKS AND BENEFITS**

**12.1 Participant Risks:**

**Will participants be exposed to any stresses (e.g. anxiety, pain, etc.) or physical harm (e.g. injury, infection, etc.) in connection with this research?** [ ] Yes [ ] No

***If Yes,*** please briefly explain what risks may be involved in the research and **justify the risks in relation to the anticipated benefits to the subjects. Explain** what specific steps will be taken to minimize and monitor the risk and what will be done to compensate and/or treat participants who are harmed by the research.

Click here to enter text.

**Does the research design require that participants be deceived?**  [ ] Yes [ ] No

***If Yes***, please briefly explain why deception is necessary and what steps will be taken to ameliorate potential harm from this deception.

Click here to enter text.

**12.2 Does the Research Involve:**

***Check all that apply:***

[ ]  Embryonic stem cells

[ ]  Blood draw

[ ]  Use of private records (medical or educational)

[ ]  Possible invasion of privacy of subject or family

[ ]  Any probing of personal or sensitive information in surveys or interviews

[ ]  Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading, specify:

Click here to enter text.

[ ]  Other risks, specify:

Click here to enter text.

1. **POTENTIAL BIOHAZARDS**

**Will this research include:**

[ ]  **Recombinant DNA/Human Gene Transfer**  [ ] Yes [ ] No

***If Yes***, please explain:

Click here to enter text.

[ ]  **Biologically Derived Toxins** [ ] Yes [ ] No

***If Yes***, please explain:

Click here to enter text.

[ ]  **Infectious Agents** [ ] Yes [ ] No

***If*** ***Yes***, please explain:

Click here to enter text.

1. **CARE OF SUBJECTS IN CASE OF ACCIDENT DURING THE STUDY**

Please provide a brief description of how the study subjects will be taken care of if there is an accident during the study.

Click here to enter text.

1. **Informed Consent**

 ***Will participants be fully informed about:***

The voluntary nature of participation and the freedom to [ ] Yes [ ] No

skip questions and/or withdraw without penalty?

The purposes and procedures of the research? [ ] Yes [ ] No

Any reasonably foreseeable risks or discomforts? [ ] Yes [ ] No

Any benefits to the participants or to others from the research? [ ] Yes [ ] No

The extent to which confidentiality will be maintained? [ ] Yes [ ] No

For research involving risks, a description of compensation and/or [ ] Yes [ ] No

treatments available if injury occurs?

Whom to contact for information about the research, participants’ [ ] Yes [ ] No

rights, and research-related injury?

**If the answer to any of the above is *No***, please briefly explain why the research requires an alteration of the standard elements of informed consent.

Click here to enter text.

**How will participants’ informed consent be documented? Please check all that apply:**

[ ]  Signature on written consent document.

[ ]  Signature on document to be read to the participants and witnessed by another party.

[ ]  Written documentation of informed consent will not be obtained because one or more of the following criteria is satisfied (check all that apply):

 [ ]  The only link between the subject and the research would be the informed consent documentation, and

 the primary risk is loss of confidentiality.

[ ]  The risks to participants (including risks to loss of privacy) are no greater than those ordinarily

encountered in daily life and the research involves no procedures for which written consent is normally required outside of the research context.

**Who will obtain the informed consent from the participants?**

[ ]  Principal Investigator.

[ ]  Co-Investigator.

[ ]  Claflin Sponsor (in cases where researcher/ PI is not affiliated with Claflin University but funds the study).

[ ]  Claflin Coordinator (in case where the researcher is not affiliated with Claflin University).

[ ]  Other

[ ]  Not applicable

**If this is a revised application, please describe the changes that you have made in response to the IRB’s comments.**

Click here to enter text.

1. **External Reviews and Funding**

Has this protocol been reviewed by an Institutional Review Board or Human Subjects Review Committee at another institution(s)? [ ]  Yes [ ]  No

***If Yes,*** please provide the name(s) of the institution(s)?

Click here to enter text.

**What is its status?** [ ]  Approved [ ]  Rejected [ ]  Pending (or provisionally approved)

***If the status is “Rejected”,*** please explain why:

Click here to enter text.

**If the IRB Application for this study has been approved, please attach a copy of the IRB Decision/Approval from your home/host institution/organization to this application.**

**If IRB approval is not required from your home/host institution/organization, please provide a letter, on organizational letterhead, with the name and contact information of the appropriate staff member indicating that said agency does not have formal IRB processes in place, or per said organization’s policies, IRB approval is not required. Attach a copy of said letter from your home/host institution/organization to this application.**

**Has this protocol been submitted for Federal Funding?** [ ]  Yes [ ]  No

***If Yes:*** Agency or Organization: Click here to enter text.

Submission date: Click here to enter a date.

Funding Start date: Click here to enter text.[ ]  Anticipated [ ]  Actual

Contact Person: Click here to enter text.

Contact’s Phone**:** Click here to enter text.

**Has this protocol been submitted for any other types of funding?**  [ ]  Yes [ ]  No

***If Yes:*** Agency or Organization: Click here to enter text.

Submission date: Click here to enter a date.

Funding Start date: Click here to enter text.[ ]  Anticipated [ ]  Actual

Contact Person: Click here to enter text.

Contact’s Phone**:** Click here to enter text.

1. **ASSURANCE**

**As Principal Investigator/Co-Investigator, I/we assure the IRB that the following statements are true:**

The information provided in this form is correct. I/we will seek and obtain prior written approval from the IRB for any substantive modification in the proposal, including changes in procedures, principal investigator or co-investigator, funding agencies etc. I/we will promptly report to IRB, adverse events (internal/external), unanticipated problems or incidents involving risk to subjects and noncompliance, during this course of the study within five business days. I/we will report in writing any significant new findings which develop during this study which may affect the risks and benefits to participation. I/we will not begin my/our research until I/we have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines. The grant submitted to funding agency will have the final IRB approval submitted along with the application. If these conditions are not met, I/we understand that the study could be suspended or terminated.

**Certificate of Agreement:**

I certify that I agree to comply with the requirements of both Claflin University and the Office for Human Research Protection (OHRP) of the United States Department of Health and Human Services as described in 45 CFR 46.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click here to enter a date.

PI Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click here to enter a date.

Co-PI Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click here to enter a date.

Claflin Sponsor (if applicable)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click here to enter a date.

Claflin Coordinator (if applicable)

**YOU HAVE REACHED THE END OF THIS IRB APPLICATION FORM. PLEASE MAKE SURE TO SUBMIT ALL DOCUMENTATION AND RESPOND TO EVERY QUESTION ON THIS APPLICATION.**

**Study Description/Research Plan**

**Please complete your detailed research proposal according to the categories specified on pages 2-3 and attach additional documents as applicable (5 pages maximum).**

**Background Related to the Study:**

**Objective of the Study:**

**Significance of the Study:**

**Research Design, Methods, and Data Analysis:**

**Data Collection Instruments:**

**Results of the Preliminary Studies if Conducted:**

**Anticipated Outcome of the Study:**

**References:**

**IRB APPLICATION PACKAGE**

**Appendix A**

**Application for Animal Subjects Application Addendum**

**Please complete the following information specific to your study:**

Does your study involve invasive procedures other than major recovery surgery (routine injections or withdrawal of blood samples are not considered invasive)?

 [ ]  Yes [ ]  No

If ***Yes***, how many? Single\_\_\_\_\_\_\_ Multiple\_\_\_\_\_\_

Will the animals have a serious natural or experimentally induced disease?

 [ ]  Yes [ ]  No

Will your research require/involve procedures which animals will perceive pain or discomfort either during or after the procedure?

 [ ]  Yes [ ]  No

Will the animals be subjected to prolonged restraint?

 [ ]  Yes [ ]  No

Does your study involve husbandry?

 [ ]  Yes [ ]  No

How will these services be afforded?

Have scientific, technical, and animal care personnel have been appropriately trained for use of your animal study?

 [ ]  Yes [ ]  No

