Claflin University Institutional Review Board
Vice Provost of Research
400 Magnolia Street
Orangeburg, South Carolina 29115
Email: IRB@Claflin.edu and vpr@claflin.edu

Investigator's Checklist for IRB Submission

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

Submit application to IRB@claflin.edu, with a single signed hard copy sent to the Office of the 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 application, which must be submitted two weeks before the desired decision date. Final approval will not be granted before receipt of the aforementioned hard copy.

Application:

☐ Completed and signed Proposal Submission Form
☐ Protocol Summary (5 page limit: identifies research question; describes methods)
☐ Data collection instruments (must coincide with parts of study described in protocol)
☐ Recruitment materials (as applicable)
☐ Consent document (or rationale for deviation from written consent if research is not exempt)
☐ Certificate of training in protection of human subjects: http://phrp.nihtraining.com/users/login.php

Consent Form: (Written for a lay audience)

☐ Identification of researcher's position, institution
☐ Consent 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

a) Explain use of recording
b) Explain plan for storage
c) Explain how information will be disseminated, if applicable

☐ Contact 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 Vice Provost of Research, whose office oversees the protection of human research participants at (***803-535-5544, 5176, 5177***)
☐ Signatures and date

Claflin University Institutional Review Board
Proposal Submission Form

Vice Provost of Research
400 Magnolia Street
Orangeburg, South Carolina 29115
Email: IRB@Claflin.edu and vpr@claflin.edu

DATE OF SUBMISSION

FOR OFFICE USE ONLY			
Number			
Review Type:	Exempt ☐	Expedited ☐	Full☐
PR			

Proposal type: ☐ Original ☐ Revised

Proposal Title	36T
Proposed start date	36T
Anticipated of duration of research	36T

Type of Research:

☐ Claflin Student Classroom project
☐ Claflin Student Thesis project
☐ Claflin faculty project
☐ Claflin staff project
☐ External researcher project

Investigators (please attach additional investigators as necessary):

Principal Investigator (for student research, faculty advisor is the PI**)**
Name: 36T
Department: 36T
Phone: 36T
Email: 36T
University Affiliation: 36T

Co-Investigator (including student researchers**):**
Name: 36T
Department: 36T
Phone: 36T
Email: 36T
University Affiliation**: 36T**

Co-Investigator (including student researchers**):**
Name: 36T
Department: 36T
Phone: 36T
Email: 36T
University Affiliation**: 36T**

Claflin Sponsor (If the researcher is not affiliated with Claflin**):**
Name: 36T
Department: 36T
Phone: 36T
Email: 36T
University Affiliation: 36T

Data Sources

Number of participants: 36T

How this number was determined (e.g. power analysis). 36T

Does this project require the collection of new data? ☐ Yes ☐No

If Yes: How will participant be selected or recruited?36T

Will subjects participate on a fully voluntary basis? ☐ Yes ☐ No

Will subjects be compensated for their participation? ☐Yes ☐No

If yes: Please describe briefly the compensation:
36T

Does this project make use of human tissue or cell lines? ☐Yes ☐No

Briefly describe the research methodology(ies) to be used in this study(e.g. focus group, participant observation, survey, experiment).
36T

Does this project use data that have already been collected for a non-research purpose or by another researcher? ☐Yes ☐No

If yes: What is the source of the data?
36T

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:
36T

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, 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:
36T

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:
36T

Potentially Vulnerable Populations

Will this research involve:

Physically/Mentally Challenged	☐Yes	☐No
Young children (ages 0-13)	☐Yes	☐No
Older children (ages 14-17)	☐Yes	☐No
Senior Citizens (over age 65)	☐Yes	☐No
Pregnant Women	☐Yes	☐No
Prisoners	☐Yes	☐No

If yes to any of the above: Please briefly explain how the rights of this (these) population(s) will be protected:
36T

Informed Consent, Continued

Will participants be fully informed about:

The voluntary nature of participation and the freedom to skip questions and/or withdraw without penalty	☐Yes	☐No
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 treatments available if injury occurs	☐Yes	☐No
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:
36T

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 PI is not affiliated with Claflin University)
☐Other
☐Not applicable

Please insert your protocol summary in this space (5 pages maximum)
36T

Please paste your recruitment materials (as applicable) in this space:

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

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: At what institutions(s)?
36T

What is its status? ☐Approved ☐Rejected ☐Pending (or provisionally approved)

Has this protocol been submitted for Federal Funding? ☐Yes ☐No

If yes: Agency or Organization: 36T
Submission date: 36T
Funding Start date: 36T ☐Anticipated ☐Actual
Contact Person: 36T
Contact's Phone**: 36T**

Has this protocol been submitted for any other types of funding? ☐Yes ☐No

If yes: Agency or Organization: 36T
Submission date: 36T
Funding Start date: 36T ☐Anticipated ☐Actual
Contact Person: 36T
Contact's Phone**: 36T**

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.

_____ 36T
PI Signature:

_____ 36T
Co-PI Signature

_____ 36T
Claflin Sponsor (if applicable)