IRB No. _____
(to be assigned)

COTTEY COLLEGE
CREATORS OF INCREDIBLE FUTURES

Institutional Review Board
Application for Research Approval

1. **Name of Investigator(s):**

   Email address:

   Phone number:

2. **Faculty Sponsor:**

   Department:

3. **Title of Research Study:**

4. **Anticipated Starting Date for the Research Study:**

5. **Anticipated Ending Date For the Research Study:**

6. **Individuals other than those named above that are involved in conducting this research:**

7. **Certifications:**

   By submitting this application I am certifying that I have read, understand, and will comply with the policies and procedures of Cottey College regarding human subjects in research. I subscribe to the standards and will adhere to the policies and procedures of the IRB, and I am familiar with the published guidelines for the ethical treatment of subjects associated with my particular field of study.

   Date Human Subjects Training Certification Received:

   Signature of Principal Investigator:

   Signature Date:

All applications must include copies of recruitment announcements, consent forms (or a request for exemption from informed consent with justification), instructions for participants, and surveys or interview questions to be used and any additional materials that will assist the Board in completing its review. Please combine all components into one document in PDF (portable document format) and submit to Sarah Quick, IRB Chairman, squick@cottey.edu

8. ***REVIEW CATEGORY FORM***

Indicate the review category for which you are applying.

☐ **APPLICATION FOR EXEMPT REVIEW (**Check all categories that apply)

- ☐ Research conducted in established or commonly accepted educational setting and involving normal educational practices.
- ☐ Research involving the use of educational tests, if information from these sources cannot be linked to the participant.
- ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, where these sources are publicly available and data cannot be linked to the participant.
- ☐ Research involving observation of public behavior where the participant's behavior is not linked to their identity.
- ☐ Research involving survey or questionnaire procedures where responses are not linked to the participant.

☐ **APPLICATION FOR EXPEDITED REVIEW (**Check all categories that apply)

- ☐ Collection of voice video, digital, or image recording made for research purposes.
- ☐ Research on group or individual behavior or on characteristics of behavior (including, but not limited to, research on perception, cognition, motivation, communication, cultural beliefs, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- ☐ Collection of hair and nail clippings in a non-disfiguring manner.
- ☐ Collection of deciduous teeth at the time of exfoliation, or of deciduous or permanent teeth if routine patient care indicates a need for extraction.
- ☐ Collection of excreta and external secretions (including sweat), saliva, skin cells, sputum, placenta removed at delivery, or amniotic fluid at time of rupture of the membrane prior to or during labor.
- ☐ Recording of data from adult participants (18+ years of age) using noninvasive procedures (not involving general anesthesia or sedation) routinely used in clinical practice, excluding procedures involving x-rays or microwaves. Examples: physical sensors that are applied either to the surface of the body or at a distance; weighing or testing sensory acuity; moderate exercise, muscular strength testing.
- ☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from adult participants (18+years of age) who are in good health, not pregnant and weigh at least 110 pounds.
- ☐ Collection of supra- and sub-gingival dental plaque and calculus in a routine manner.
- ☐ Study of existing data, documents, records, pathological specimens, or diagnostic specimens that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- ☐ Continuing review of research previously approved by the convened IRB where no new participants will be recruited.
- ☐ Research on drugs or medical devices that are not new investigations.

☐ **APPLICATION FOR FULL REVIEW (**Check all categories that apply)

- ☐ Research that utilizes deception of participants.
- ☐ Research that involves the manipulation of participants' behavior, with or without the participants' knowledge.
- ☐ Research that involves new and/or untested procedures.

9. ***CHARACTERISTICS OF THE SUBJECTS*** (check as many boxes as appropriate.)

☐ Minors	☐ Disabled	☐ College/University Students
☐ Adults	☐ Pregnant	☐ Secondary School Students
☐ Prisoners	☐ Legal Incompetents	☐ Elementary School Students
☐ Others (specify) _____		

A. ***Further description of the subjects***
Please write a brief description of your proposed participants, including any population parameters, also explaining, if need be, how the characteristics of the proposed participants are relevant or necessary to your research question(s).

B. ***Further describe how the subjects are to be selected***. Please indicate how you will gain access to, and recruit these subjects for participation in the research. That is, will you recruit participants through word-of-mouth, fliers or poster, newspaper ads, public or private membership or employee lists, etc.

C. ***Estimated Number of Human Subjects Involved in the project:*** _____

D. ***Estimated length of time the subjects will be involved in the project:*** _____

10. **ETHICAL CONSIDERATIONS and CONSENT**

A. ***Respect for Persons:***
☐ Consent obtained from individuals; and/or
☐ Consent obtained from legally authorized representatives

B. ***Informed Consent Method***
☐ Written (attach copy)
☐ Oral (attach a copy of the script)

C. ***Risks and Beneficence***
Please write a brief description of any risks (physical, economic, psychological, social, legal, or others) to the subjects that your research may cause:

Please write a brief description of any benefits (physical, economic, psychological, social, legal, or others) to the subjects from your research directly and/or indirectly based on significance of the research:

11. ***PROJECT DESCRIPTION***

Research Title:_____

A. Please write a ***general description***, including the focus and purpose of the proposed research as well as any resources required to conduct the research.

B. Please write a ***detailed description of the methodology and procedures*** to be used, especially as they relate to human subjects.

C. Please write a ***description of the personnel,*** including the principal investigator, who will participate in the project and their qualifications for participation.

D. Please include as supporting evidence copies of ***recruitment announcements, consent forms, instructions, and surveys or interview questions*** to be used; and any additional materials that will assist the Institutional Review Board in completing its review. (Supporting documentation listed above should be collated into one document if possible and saved as a PDF submitted for review.)

E. Please describe the steps you are taking to protect the confidentiality and anonymity of the subjects if these subjects desire their identities remain confidential and anonymous. Please note these steps in your informed consent process as well.

12. **PREVIOUS APPROVAL**

If this or a similar research protocol has been approved by the Cottey College IRB or any other college/university IRB, provide the information below:

13. **AGREEMENTS**

By signing this form, the project director (and, if the director is a student, her faculty advisor/instructor) agrees to the following:

A. The project director will comply with Cottey College policies on research and investigation involving human subjects.
B. The project director will provide documentation of selection and informed consent procedures upon request by the IRB.
C. The project director will inform the IRB of any planned changes in procedures which involve human subjects, giving the IRB sufficient time to review and approve such changes before they are implemented, and to supply IRB with such progress reports or annual assessments as it may require.
D. It is understood that any approval granted by the IRB applies to this project only and only under the conditions and procedures described in the application. Any change in the protocol or conditions set forth will require separate approval.
E. ***It is understood that the identification of human subjects in any publication or medium (print or electronic) is an invasion of privacy and requires the execution of a consent form***. Informed consent must be obtained from each subject or the subject's legally authorized representative. Documentation of the informed consent must be retained, in a secure environment, for a minimum of four years after termination of the project.

Date _____ Signature _____

If the project director is an undergraduate student, the student's instructor or advisor for this research proposal must sign the form.

Date _____ Signature _____

The Board chair will provide feedback regarding required modification(s), if appropriate, within ten working days of the submission date. The principal investigator will be expected to respond to the feedback within five working days of when the feedback is given. The Board will make a decision on an application within five working days of when the Board chair shares an application with the Board. The principal investigator will be informed in writing of the Board's decision by the Board chair, with an IRB protocol number (to be comprised of the month, date, and year of approval within five working days of the date the decision is made.

_____Approved for exemption from review _____Approved after expedited review

_____Approved after full review _____Not approved (Explanation attached)

_____ _____

Signature of the IRB Chair **Date**