COTTEY COLLEGE

CREATORS OF INCREDIBLE FUTURES

GUIDE TO THE APPLICATION FOR RESEARCH APPROVAL

BACKGROUND

Before you embark on your research, it is important to understand the background related to ethical considerations in human subjects research. It begins with Public Law 93-348.

> ***National Research Act: Public Law 93-348, Sec. 474 (a):***
> The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurance satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the right of the human subjects of such research. (12 July 1974)

Although ethical questions surrounding the use of human subjects in research projects preceded Public Law 93-348, this is the legislation which served as a mandate for university and college Institutional Review Boards (IRBs). The Act specifies a concern with "funded" (or "sponsored") research. Universities and colleges have typically defined "sponsorship" as including use of university time, facilities, resources, etc. Thus, IRBs review not only work on federally funded projects, but also projects that involve the financial support of the university or college or that are conducted under the auspices of the university or college. This may include simply using a faculty member's title as a research credential or using the College's subscription survey software.

RATIONALE FOR COLLEGE POLICY

The Cottey College Institutional Review Board exists for several reasons. First, a college-wide policy reflects the College's commitment to basic ethical principles and provides a consistent application of those principles across disciplines involved in research with human subjects. Second, this policy provides an environment in which students directly learn and apply ethical principles. Third, federal funding agencies require that all grant applications be reviewed and approved by an Institutional Review Board that ensures ethical compliance.

Because the generally accepted guidelines for IRBs cover institutions from small liberal arts colleges to major research universities, some of the procedures outlined in this document will not be applicable to Cottey. Inclusion of these procedures, however, helps establish the large and complex environment in which academic research takes place.

WHEN TO SUBMIT AND HOW LONG THE PROCESS TAKES

Applications for IRB approval can be submitted at any time. During the academic year, the IRB considers applications on a rolling basis. [If necessary, the Board chair will provide feedback regarding required modification(s), 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.

Applicants will receive written notice of the IRB's review within one week of the meeting at which the application is reviewed.

The IRB recommends that lead-time for committee approval be figured into the schedule for the conduct of research, especially since committee action (i.e., discussion and vote on approval of the project) is not necessarily equivalent to or a guarantee of committee approval.

WHAT TO SUBMIT

Applications are submitted using the IRB application form. The form is available online at cottey.edu.

Part I: The IRB application consists of several pages: a cover page, a review category checklist, a few pages of research description, and an agreements page.

Part II: Supporting Documents

Most IRB applications require supporting documentation that should be submitted at the same time. Supporting documentation usually includes (but is not limited to) a copy of the Informed Consent form, copies of surveys, questionnaires, assessment materials, etc., that will be used in the conduct of the research. The Principal Investigator (PI) should feel free to include any materials that will assist the committee in evaluating the application.

Training/Certification (#7 on application)

Each researcher involved in the application is required to be certified for protecting human research participants within the past five years. Proof of certification is required with the application. Certification may be through a previous institution via CITI-training (Collaborative Institutional Training Initiative), the PHRP (Protecting Human Research Participants) program (https://phrptraining.com/), or an internal certification process. The researcher should contact the IRB chair for logistical and cost-related questions if they want to pursue PHRP, which other institutions will also accept, or internal training and certification. Cottey's internal training MAY NOT be transferrable to other institutional settings.

The application and supporting documents should be collected into one document and submitted for review as a PDF.

INSTRUCTIONS FOR COMPLETING THE IRB APPLICATION FOR RESEARCH APPROVAL

Cover Page (page 1)

The space for the IRB application number at the top right of the face page should be left blank.

1. Name(s) of Investigator(s). List the names of all persons conducting the research. For student research, list the names of all students involved in conducting the research. The first student listed should be the PI. The PI will ultimately be responsible for the proper conduct of the research with respect to the protection of human subjects.
2. Faculty Sponsor. All student research must list a Cottey College faculty member as the sponsor.
3. Title of Research Study. Give only the name of your study
4. Anticipated Starting Date. The date you plan to begin collecting information from your human subjects.
5. Anticipated Ending Date. The date you plan to end collecting information from your human subjects.
6. Individuals other than those named above that are involved in conducting this research. List other faculty or staff members that may be providing assistance to you in your research study, i.e., developing survey questions, etc.
7. Certifications. You will submit a copy of your human subjects training certificate and enter the date you received it here. The PI must sign the first page. Creating an electronic signature will make this easier. Otherwise, you should print out this page when it is complete and scan it into your final PDF document.

   This is an important step. The IRB cannot process applications that are not signed by the principal investigator. Please note that by submitting the application you are certifying that you have read, understand, and will comply with the policies and procedures of Cottey College regarding human subjects in research and that you subscribe to the standards and will adhere to the policies and procedures of the IRB.

Review Category Form (pages 2-3)

Please read each item carefully and check all those that may apply to your study. The checklist allows the IRB to rapidly screen applications for possible expedited or exempt conditions. Failure to do so accurately may result in delays in the processing or approval of your proposal. Note that the areas that apply to your study may require supporting information, i.e., a copy of your survey, copies of your recruitment materials, and a copy of your written or oral informed consent.

Because the generally accepted guidelines for IRBs cover institutions from small liberal arts colleges to major research universities, some of the procedures outlined in this document will not be applicable to Cottey. Inclusion of these procedures, however, helps establish the large and complex environment in which academic research takes place. The following are some notes to guide you.

Application for Exempt Review: The key to Exempt Review is that there is no risk to the participants, and the identity of the participants is not linked to the data collected. A survey with data analysis that is in group form and the respondents are not identifiable may qualify for exempt review.

Application for Limited Review: This review is required for any form of data collection where the identity of the participants is not linked to what is collected BUT has potential risk to participants in financial standing, employability, educational advancement, or reputation.

Application for Expedited Review: While some undergraduate research at Cottey does not fall into the Expedited Review category, if it does, it is usually in the first two categories listed. The reason these categories call for a higher level of review is that extra steps may be necessary to protect the identity of the subjects and to make sure that they are informed, willing participants. For example, research in which audio and/or video recording is intended, your consent form should explain who will have access to the tapes, security measures you will take to protect the privacy of subjects recorded, and what you will do with the tapes upon completion of your research (e.g. erase them, retain them for future research, etc.).

Application for Full Review: Research that involves more than minimal risk to participants, including research that utilizes deception, or research that involves particularly vulnerable populations as listed in the Review Category Form.

Characteristics of the Subjects and Ethical Considerations and Consent (pages 4-5)

Information about your proposed subjects and selection procedures helps the committee discern the potential benefits to be derived from the research, whether the proposed population is especially vulnerable or at risk, and whether the processes for subject selection are equitable and sensitive to issues of confidentiality and privacy.

1. Check the line in front of the listed characteristics (#9) that apply to your research subjects.

2. Further description of the subjects (9.A). Please indicate any special criteria for including or excluding subjects involved in the proposed research. For example, if subjects are to be included in the research only if they are from a particular age group, racial group, or gender, please indicate this here. Additionally, if there is some medical attribute (e.g., Alzheimer's Disease, heart disease, etc.) or physical (e.g., marathon runners, bicyclists, weight lifters) that characterizes the subjects to be included in the study, please indicate this here as well.

3. Describe how the subjects are to be selected (9.B). 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. If subjects are recruited by a flier or poster or newspaper ad, a copy of this should be included with your application. Estimate the number of subjects (9.C) and how long they will be

involved in the project (9.D). You should explain how long they will be actively involved (i.e., the minutes/hours a survey or interview will take) and the length of time you need access to them for your research (i.e., 3 times for one hour over a one month period.)

4. Ethical Considerations and Consent (#10). Indicate from whom you will obtain consent (10.A) and the method you will use. (10.B). Be sure you read in Cottey's *IRB Policies and Procedures* what must be included in the consent form according to the federal code of regulations (45 CFR 46).

5. Please write a brief description of any risks (physical, economic, psychological, social, legal or others) to the subjects that your research may cause. Also 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 (10.C)

Project Description and Previous Approval (page 5)

This should provide a general overview of the focus and purpose of the proposed research (11.A). It should include the procedures and the methodology you will use. (11.B.) Describe your procedures and methods without jargon, abbreviations, or technical terminology. If you must use technical terms, please define or explain them so that someone not knowledgeable about your field can understand them. Remember to include copies of recruitment announcements, consent forms, instructions, and surveys or interview questions. These will verify for the IRB that you are following human subjects research guidelines (11.D)

Please indicate if this or a similar research protocol has been approved by the Cottey College IRB or another college or university IRB.

Agreements (Page 6)

This page is where you will assure the IRB that you understand and will follow Cottey College 's Institutional Review Board Policies, which affirm the primary statement concerning ethical principles and guidelines for the use of human subjects as outlined in the Belmont Report (1979).

The IRB will pay close attention to particular aspects of the research proposal. The first and foremost concern is that risks to subjects are minimized. Other aspects of the proposal that the IRB will review closely include the following: that risks to subjects are reasonable in relation to anticipated benefits; that informed consent will be sought and documented from each subject (or the subject's legal representative); that adequate provisions are made to insure the safety of subjects; that adequate provisions are made to protect the privacy of subjects and maintain confidentiality; and that there are additional safeguards for subjects who are especially vulnerable.

Forms of Committee Action

The outcome of the IRB review can take several forms. Each of these particular actions is discussed below:

Disapproval. Research is disapproved when the committee judges the risk to human subjects participating in such experiments to be unacceptable. The acceptability of the risk is determined by the judgment of the cost/benefit ratio of the research. Thus, higher levels of risk will be tolerated for research in which the potential benefit is judged to be higher; the opposite is true for research that presents no obvious benefit.

Failure on the part of the applicant to adequately describe the research in the abstract portion of the application is often the cause for disapproval, since it is here that the applicant must describe screening, safety precautions, and contingency plans to meet adverse reactions from subjects to research procedures, as well as to describe the procedures in layperson's terms without technical jargon.

No Decision. In some cases, not enough information is provided to allow the committee to determine the degree of risk to which subjects will be exposed. This occurs when critical information is omitted from the application. Thus, the application does not describe the research in detail adequate to allow a judgment of either approval, contingency, or disapproval. Occasionally, the cause for a failure to approve lies in the use of technical jargon which neither reviewers nor prospective subjects may understand. In such a case, the applicant must submit the needed information so the proposal may be considered at the next IRB meeting.

Approval Upon Meeting Contingencies. The IRB may withhold approval of the application, contingent upon a request from the committee for clarification of some point concerning the research, or for changes to the consent form or materials involved in the research. The applicant then must respond to the request. Depending on the number of contingencies involved in the research, the determination of whether the response is adequate will be made by the chair or the opinion of other IRB members may be sought. If the response adequately meets the contingencies set by the committee, an approval is generated for the research.

Approval. The IRB may approve the application. Upon notification of approval, the applicant may begin the research. The approval notification will include an IRB number. The Cottey College IRB requests that your IRB number be listed in the corner of information use to recruit participants, e.g., posters, emails, or letters.