COTTEY COLLEGE

CREATORS OF INCREDIBLE FUTURES

INSTITUTIONAL REVIEW BOARD

POLICY ON THE USE OF HUMAN SUBJECTS: ETHICAL CONSIDERATIONS AND APPROVAL PROCEDURES

Revised September 2018

POLICY ON THE USE OF HUMAN SUBJECTS: ETHICAL CONSIDERATIONS AND APPROVAL PROCEDURES

BACKGROUND

> ***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 the Act cited above, 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 (e.g. Dr. John Doe, Professor of Slavic Languages, Ignota University) as a research credential.

RATIONALE FOR A 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.

THE BELMONT REPORT

Prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research, The Belmont Report (1979) is the primary statement concerning ethical principles and guidelines for the use of human subjects. The Cottey College Policy on the Use of Human Subjects incorporates the major points set forth in the Belmont Report and adapts the language of that and similar IRB protocols.
Reference: <http://ohsr.od.nih.gov/guidelines/belmont.html>

I. Three basic principles generally accepted as especially relevant to the ethics of research involving human subjects:

A. Respect for Persons
1. Individuals should be treated as autonomous agents; they have the right to decide for themselves about involvement or non-involvement in research.
2. Persons with diminished autonomy (children, prisoners, the infirm, etc.) are entitled to protection. These groups should not be subjects simply out of convenience; if they are the group of interest, then special care must be taken in protecting their rights.

B. Beneficence
1. Every effort should be taken to protect the well-being of the persons involved in research.
2. "Beneficence" is understood to cover acts of kindness and charity that go beyond strict obligation.
3. Two general rules reflect the concept of beneficence:
   a. Do not harm.
   b. Maximize possible benefits and minimize possible harms.

C. Justice
1. There is an injustice whenever some benefit to which a person is entitled is denied or when an undue burden is imposed.
2. It is not just or fair to select a particular group of people as research subjects simply because of their availability or manipulability rather than for reasons directly related to the research project.

II. Applications of the three principles to the conduct of research.

A. Informed Consent
1. Respect for persons requires that they be capable of making an informed decision about whether or not to be involved in a research project. Generally participants should be informed about:
   a. the research purpose
   b. the participant parameters
   c. the procedures
   d. the benefits
   e. the risks
   f. the participant's right to withdraw at any time

g. how confidentiality will be maintained
h. the participant's rights to ask questions

2. The researcher should consider what a reasonable person would need to know in order to make an informed decision. Informed decisions require information about both the risks and the benefits. Incomplete disclosure can be justified only if:
   a. incomplete disclosure is truly necessary to accomplish the goals of the research;
   b. there are no undisclosed risks to subjects that are more than minimal;
   c. there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them.
3. Comprehension: A person's ability to understand his or her rights is a function of intelligence, rationality, maturity, and language. It is the researcher's responsibility to be sure that information about the study is presented in a manner that can be understood.
4. Voluntariness: Consent to participate in research is valid only when it is voluntarily given. This requires conditions which are free of coercion and undue influence. Coercion exists when overt threat of harm is intentionally presented. Undue influence exists when there are offers of excessive, unwarranted, inappropriate or improper reward or other overtures in order to obtain compliance. Even inducements that would ordinarily be acceptable can be undue influences if the potential participant is especially vulnerable.

B. Assessment of Risks and Benefits

Members of the Institutional Review Board shall determine:

1. the validity of the presuppositions of the research
2. the nature, probability and magnitude of risk as well as the clarity with which the risk will be communicated to potential participants
3. the method by which the risks were ascertained (If a proposal claims there be no or little risk, the researcher must explain how he or she made this decision.)
4. the reasonableness of the estimates of probable harm and benefits
5. the appropriateness of involving vulnerable populations

C. Selection of Subjects

1. To ensure individual justice, researchers should not offer beneficial research only to the "desirable" and risky research only the "undesirable."
2. To ensure social justice, researchers should distinguish between groups of individuals that ought, and ought not, participate in any particular kind of research.

COMPOSITION OF THE INSTITUTIONAL REVIEW BOARD

In accordance with the federal Office for Protection from Research Risks (OPRR), which operates within the Department of Health and Human Services (DHHS), the board will be composed of a minimum of five members. It will include at minimum one male member, one female member, one member from scientific disciplines, one member from nonscientific disciplines, and one member who is not otherwise affiliated with the institution. Specific to Cottey College, all Board members are expected to have current human subjects training certification (i.e., to be within five years of successful completion throughout their terms) through the Collaborative Institutional Training Initiative program or the National Institutes of Health (prior to September 26, 2018 when this certification program was discontinued.

FUNCTION OF THE BOARD

The IRB has the authority to approve, require modification in order to secure approval, or disapprove all research activities covered by this policy, including:

1. research funded externally by a grant, contract, or similar agreement between the sponsor (public or private) and the College
2. research funded internally by the College by a grant, contract, or similar agreement
3. research conducted upon assignment by the College
4. research actively assisted by the use of College facilities, resources, supplies, equipment, or personnel.

Except when the exempt review procedure is used, the IRB shall review proposed research at convened meetings, which may take place over technology, at which a majority of members are present, including at least one member whose primary concerns are in nonscientific areas. In order for requests for expedited or full review to be approved, the requests shall receive the approval of a majority of those members present at the meeting (OPRR 46.108).

THE REVIEW PROCESS

All principal investigators must submit a completed review application to the Board chair and request either *Exempt, Expedited,* or *Full Review.*

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, e.g., August 28, 2017 would appear as 082817), as appropriate, within five working days of the date the decision is made.

REVIEW CATEGORIES

I. Exempt: Research that involves no risk to participants under specified circumstances listed in the Review Category Form. Upon agreement by the chair and two other members of the Board that the research meets the criteria for the Exempt category, the review application will be approved. The chair and members agreeing to the

Exempt categorization must do so in writing and accompany any comments with their signatures. Email communication sent from a Board member's official email address may be used in place of a hand-written signature.

II. Expedited Review: Research that involves minimal risk to participants under specified circumstances listed in the Review Category Form or involves minor changes in previously approved research during the time for which approval is authorized. It is the decision of the chair to convene the Board for an Expedited Review. Review decisions will be based on the approval of a majority of Board members. Comments and/or recommendations of individual Board members must be made in writing and signed by the members. Email communication sent from a Board member's official email address may be used in place of a hand-written signature.

III. Full Review: Research that involves more than minimal risk to participants, including research that utilizes deception, as listed in the Review Category Form. The chair or any member of the Board may request a Full Review of an application. The full Board will convene, and the decision will be based on the approval of the majority of members. Members' comments and/or recommendations must be submitted in writing and signed by the member. Email communication sent from a Board member's official email address may be used in place of a hand-written signature. Applications in any category may be denied final approval only after a Full Review.

EXCEPTIONS TO THE REVIEW PROCESS

The only exceptions to the review procedure are "minor" research studies conducted by students as part of class work. To qualify for exception to the review process, such class assignments must meet specific criteria. See *Procedures for Obtaining IRB Approval,* Section VI, and especially *Appendix A: IRB Guidelines for Minor Studies.*

PROCEDURES FOR OBTAINING INSTITUTIONAL REVIEW BOARD APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

All research investigation involving human subjects conducted by faculty, staff, or students under the auspices or financial support of Cottey College must be reviewed and approved by the Institutional Review Board (IRB), or be declared exempt from the review by that board. The IRB, operating under the policies and procedures of the College, is established to insure compliance with the National Research Act (Pub. L. 93-348) and the regulations set forth in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46). The purpose of IRB review is to protect the rights and personal privacy of individuals and assure a favorable climate for conducting scientific inquiry.

APPLICATION AND REVIEW

A request for IRB approval of a research project should be prepared in accordance with the instructions in the *Application for Review*. Each *Application for Review,* including all supporting documentation such as recruitment announcements, consent forms, survey and/or interview questions, debriefing forms, and current human subjects training certification (i.e., to be within five years of successful completion, through the Collaborative Institutional Training Initiative program or the National Institutes of Health), is expected to be submitted as an attachment to an email to the Board chair and must bear the signature of the principal investigator. If the project director is an undergraduate, the *Application for Review* must also be signed by the student's faculty advisor or instructor for the research in question. Both the undergraduate and the student's faculty advisor or instructor are required to have acquired human subjects training certification within the past five years. Each *Application for Review,* including all supporting documentation to form one document in total, is also expected to be emailed to the Board chair. *Note: The National Institutes of Health training previously used by Cottey was discontinued on 9/27/18 and the IRB is currently using archived copies of the training. Please contact the Director of Assessment and Institutional Research for this information.*

All research involving human subjects must be reviewed by the IRB. Research is reviewed by an expedited or full board process although some forms of research are exempt from review (see Section VI).

I. New Research

A. The principal investigator may seek review under one of the following categories, outlined in the *Review Category Form*:

1. Exempt Review: research that involves no risk to the participants. Principal investigators should follow the procedures outlined below to apply for an exemption (see section VI).
2. Expedited Review: research that involves no more than minimal risk to participants, or that involves minimal changes to previously approved research during the period of one year or less from the approval date.
3. Full Board Review: research that involves more than minimal risk to participants, including research that uses deception of participants.

The only exceptions to the review process are "minor" research studies conducted by students as part of class work. Criteria for such a designation are contained in *Appendix A: IRB Guidelines for Minor Studies*.

B. Applications are distributed to the Board members for individual review. Applications are considered to be confidential documents and are not to be openly discussed by Board members with others outside the Board.

C. 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, e.g., August 28, 2017 would appear as 082817), as appropriate, within five working days of the date the decision is made.

II. On-going Research

Approval from the IRB will last for one calendar year from the date on the approval form. Research that is not completed in that year must undergo review before the approval expiration date. If there have been no changes to the original research protocol, the principal investigator should submit a new application form and request Exempt Review. However, if changes have been made in the research protocol, the principal investigator must treat the application as a new request.

III. Review of the Guidelines

The principal investigator should review the guidelines and respond to the sections outlined in the *Application for Review*. A request should include:

A. Brief Project Description:
   1. A general description, including the focus and purpose of the proposed research;
   2. previous relevant research; and
   3. the research design, including the type of analysis and justification for the analytical approach; and the resources required to conduct the research.

B. Description of Risks and Benefits:
   1. Description of the risks (e.g., physical, psychological, social) to the subjects and
   2. description of the benefits (e.g., physical, psychological, social) to the subjects and/or the significance of the research.

C. Description of Methodology and Personnel:
   1. Detailed description of the methodology and procedures to be used, especially as they relate to human subjects; and
   2. description of the personnel, including the principal investigator, who will participate in the project and their qualifications for participation.

D. The Process for Informed Consent:

1. General Requirements

   An investigator shall seek the consent of the prospective subject, or the subject's legally authorized representative, only under the circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that also minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative must be in language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language that waives or appear to waive any of the subject's legal rights, or that releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

2. Documentation Requirements

   Informed consent shall be documented by the use of a written consent form approved by the IRB. The consent form may ask a prospective subject to mark "yes" or "no," such as in survey research, or the consent form may ask for a signature by the subject or the subject's representative, such as in interview or experimental research (See the sample *Informed Consent Form*.) When research is conducted in person, a copy of the consent form shall be given to the person signing the form. This consent form may be either of the following:

   a. A written consent document that embodies the elements of informed consent enumerated below.

   b. A "short-form" written consent document stating that the elements of informed consent enumerated below have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. A written summary of what is to be said to the subject or the representative shall be provided to the IRB for review and approval. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short-form. The short-form must be signed by the subject or the representative. The witness must sign both the short-form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary.

   c. The requirements for the investigator to obtain a signed consent form for some or all subjects may be waived by the IRB if it finds either:

      i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with research, and the subject's wishes will govern; or

ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB will require the investigator to provide subjects with a written statement regarding the research.

3. Basic Elements of Informed Consent
   In seeking informed consent, the following information is expected to be provided to each subject:
   a. A statement that the study involves research and an explanation of the purposes of the research.
   b. A description of the participant parameters.
   c. A statement of the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
   d. A description of any benefits to the subject or to others which may reasonably be expected from the research.
   e. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
   f. A description of any reasonably foreseeable risks or discomforts to the subject.
   g. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
   h. A statement that participation is voluntary, refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
   i. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
   j. A statement regarding the expectation that participants' names will not be attached to their data.
   k. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.

4. Waiver of Requirements to Obtain Informed Consent
   The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above if the research could not practically be carried out without the waiver or alteration; and provided the IRB finds and documents that:
   a. The research involves no more than minimal risk to the subjects;
   b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

c. Whenever appropriate, the subject will be provided with additional pertinent information after participation.

IV. The Use of Deception in Research (based on APA guidelines**)**
Research involving deception may not be conducted unless the project director provides adequate rationale that the use of deceptive techniques is justified by the study's prospective educational, scientific, or applied value and that equally effective alternative procedures that do not use deception are not feasible. The principal investigator must complete the form in *Appendix B: Additional Information Required for Full Review of Research Involving More than Minimal Risk to Participants* and submit it with the *Application for Review.*

Researchers may not deceive participants about significant aspects that would affect their willingness to take part in the study, such as physical risks, discomfort, or unpleasant emotional experiences.

Any deception that is an integral feature of the research design or procedure must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research study.

V. Post-Participation Debriefing/Feedback (based on APA guidelines)
When deception has been used, investigators are required to provide a prompt opportunity for participants to obtain appropriate information about the purpose, results, and conclusions of the research study, and to attempt to correct any misconceptions that participants may have about their responses during the study. Debriefing/feedback may also be provided for educational purposes. It is recommended that debriefing/feedback be provided to participants immediately following their participation. In cases where the design of the study prevents immediate debriefing/feedback, delayed debriefing/feedback must be provided as soon as practical, and within six (6) months of completion of the study. If scientific or humane values justify delaying or withholding debriefing/feedback, the researcher must take reasonable measures to reduce the risk of harm to participants. (See the sample *Debriefing Statement* from Spring Hill College.)

VI. Exemption from Review
If the principal investigator believes that the research is exempt from the need for the IRB review and approval, a letter should be sent to the IRB requesting that determination. The letter should include a brief description (no more than two pages) of the project that addresses the items on the *Application for Review* and a designation of the exemption category. The applicant should include a *Review Category Form*, a signed copy of the *Application for Review*, and a sample *Informed Consent Form.* A decision on the request will be confirmed in writing and will normally be made as soon as possible after receipt of the request.

It is the responsibility of the principal investigator to obtain approval or a determination of exempt status before the research activity is initiated. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be given an exempt designation:

A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instruction strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

B. Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement) if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

C. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

D. Research involving the observation (including observation by participants) of public behavior. Such research is <u>not</u> exempt if any of the following conditions exist: (1) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (2) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (3) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

E. Research involving survey or interview procedures. Such research is <u>not</u> exempt if any of the following conditions exist: (1) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (2) the subject's responses, if they become known outside the research, could reasonably place the subject at a risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (3) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

VII. Protection for Special Classes of Subjects

A. Research involving prisoners, pregnant women, fetuses, and human *in vitro* fertilization must receive a full review by the IRB.

B. Research involving minors (anyone under the age of eighteen) may be exempt <u>only</u> as it applies to categories A, B, and C above.

C. Research involving minors (anyone under the age of eighteen) which falls under category D above may be exempt only if the investigator does not participate in the activities being observed.

D. Research falling within category E may not be exempt for minors (anyone under the age of 18) under any circumstances.

VII. Continuing Review and Suspension of Approval

The IRB will conduct review of approved research at intervals appropriate to the degree of risk, but no less than once per year, and has the authority to observe or have a third party observe the consent process and the research. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.