

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

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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 major points set forth in the Belmont Report and adapts the language of that and similar IRB protocols.

I. These three basic principles are 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 usually take the following forms:

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 maintained (if confidentiality a feature of the research);
 - 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 under conditions free of coercion and undue influence.
 - a. Coercion exists when overt threat of harm is intentionally presented.
 - b. 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

- 1. Members of the Institutional Review Board shall determine:
 - a. the validity of the presuppositions of the research;
 - b. the nature, probability and magnitude of risk as well as the clarity with which the risk will be communicated to potential participant;
 - c. 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.);
 - d. the reasonableness of the estimates of probable harm and benefits;
 - e. the appropriateness of involving vulnerable populations.

2. Selection of Subjects

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

Reference: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

COMPOSITION OF THE INSTITUTIONAL REVIEW BOARD

In accordance with the federal Office for Human Research Protections (OHRP), 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 woman, one man, 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). Certification may be through a previous institution via CITI-training (Collaborative Institutional Training Initiative) or the PHRP (Protecting Human Research Participants) program (https://phrptraining.com/).

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:

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

The IRB shall review proposed research at convened meetings, which may take place over technology asynchronously. For exempt, limited, and expedited reviews—at least three members will review the proposed research, including at least one member whose primary concerns are in nonscientific areas. In order for requests for full review be approved, the requests will be sent to the full committee and shall receive the approval of a majority of IRB members. (Procedures based on these OHPR policies: OHPR 46.108 and OHPR 46.110).

THE REVIEW PROCESS

All principal investigators must submit a completed review application to the Board chair and request either *Exempt, Limited, 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. Limited Review: Research that may involve risk to participants (financial standing, employability, educational advancement, or reputation) if confidentiality procedures are not followed. Upon agreement by the chair and two other members of the Board that the researcher/research team is taking adequate provisions to protect privacy and maintain confidentiality, the review application will be approved. The chair and members agreeing to the Limited Review 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.
- III. Expedited Review: Research that involves minimal risk to participants under specified circumstances listed in the Review Category Form. Further, a previously approved Full Review will require a continuing annual review under this category as well previously Limited and Expedited applications if significant changes have been made to their research procedures. Review decisions will be based on the approval of three of the 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.
- IV. 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 even if it is proposed as another category of review. 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.

DEFINITION of RESEARCH and EXCEPTIONS to the Review Process

Research is defined as any systematic investigation done in order "to develop or contribute to generalizable knowledge." Studies conducted solely for educational purposes as class assignments will not fall under this definition unless they are communicated to broader communities outside the classroom. Further, the revised Common Rule has qualified the following activities as not falling under research (2017; see https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf, pp. 7260-7261):

- I. Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
- II. Public health surveillance activities;
- III. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- IV. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

While the above lists activities that fall outside the revised Common Rule's research definition, Cottey's Institution Review Board recommends that those working with human participants still enact an informed consent process that minimizes any risks to participants.

Other exceptions to the review procedure would be "minor" research studies conducted by students as a part of class work. To qualify for exception to the review process, such class assignments must meet specific criteria (See *Appendix A* IRB Guidelines for Minor Studies Conducted by Students as a part of class work).

PROCEDURES FOR OBTAINING IRB APPROVAL

All research investigation involving human subjects/human participants 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 ensure 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. 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 human subjects training certification within the past five years. Students may acquire this certification through Cottey's internal training or through external training such as the Collaborative Institutional Training Initiative (CITI) or the Protecting Human Research Participants training (https://phrptraining.com/). Instructors or faculty advisors should acquire training from an external source.

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. Limited Review: Research that may involve risk to participants (financial standing, employability, educational advancement, or reputation) if confidentiality procedures were not followed.
 - 3 Expedited Review: research that involves no more than minimal risk to participants, but confidentiality may not be obtained.
 - 4. Full Board Review: research that involves more than minimal risk to participants, including research that uses deception of participants.

Exceptions to the review process may be "minor" research studies conducted by students as part of class work (See *Appendix A*) or those activities not defined as research (see pg. 6 above).

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 (see above, pg. 5), as appropriate within five working days of the date the decision is made.

II. The Status of On-going Research after initial IRB approval

- A. Research designated as exempt, limited, or expedited after the initial IRB review may continue from year to year without further review UNLESS those with expedited or limited review designations have made significant changes to their methodologies and/or informed consent process. In this case they will need to undergo an expedited continuing review with these new changes explained.
- B. Research requiring a Full IRB review will require annual continuing reviews under the expedited designation.
- **III. Review** the *IRB Application* and the *IRB Application Guide* and include the following sections
 - A. Brief Project Description
 - B. Description of Risks and Benefits
 - C. Description of Methodology and Personnel
 - D. The Process for Informed Consent

IV. Informed Consent explanation and requirements:

- A. 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.
- B. Basic Elements of Informed Consent
 - 1. A statement that the study involves research and an explanation of the purposes of the research.
 - 2. A statement of the participant parameters, including the expected duration of their participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
 - 3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

- 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- 5. A description of any reasonably foreseeable risks or discomforts to the subject.
- 6. For research involving more than minimal physical 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.
- 7. 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.
- 8. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- 9. A statement regarding the expectation that participants' names will not be attached to their data.
- 10. 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.

See Samples of Informed Consent Forms on the Cottey IRB webpage.

- C. Documentation Requirements: Informed consent shall be documented by the use of a written or oral version of a 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. When research is conducted in person, a copy of the consent form shall be given to the person signing the form.
- D. Waiver of Requirements to Obtain Informed Consent Signature: 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:
 - 1. 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
 - 2. 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.

V. The Use of Deception in Research (based on APA guidelines)

- A. 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*.
- B. 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.
- C. 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.
- D. Post-Participation Debriefing/Feedback: 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, p. 16).
- VI. Exemption from Review: If the principal investigator believes that the research is exempt from the need for the IRB review and approval, they should still submit an IRB application with exempt designated. 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 educational tests, survey or questionnaire procedures, or observations of public behavior (including audio and visual recordings) if information from these data sources cannot be linked to the participant; OR disclosure of this information does not pose any risk (regardless if identifiable or not).
 - 1. 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.
- 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 and demonstration projects supported by a federal agency or department AND designed to study public benefit or service programs.
- E. Research involving taste and food quality evaluation and consumer acceptance studies.

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 <u>only</u> if the investigator does not participate in the activities being observed.
- D. Research falling within category E may <u>not</u> be exempt for minors (anyone under the age of 18) under any circumstances.
- E. Research that is taking place in another country or within an Indigenous community on a Native American reservation.
- VIII. Suspension of Approval: The IRB 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.

APPENDIX A: IRB GUIDELINES FOR MINOR STUDIES CONDUCTED BY STUDENTS AS A PART OF CLASS WORK

In some courses, students collect data individually or in groups as part of course requirements or to facilitate class discussion. The instructor in such a course has the responsibility to discuss the ethics of research with the students who will be engaging in the research and must judge that the potential educational benefits from such research outweigh any risks to the participants. In such courses, the carrying out of the research process makes up a small portion of actual class work.

Research is considered minor only when **all** of the following conditions are met:

- 1. There is no expectation that data from the study, excluding activities not defined as generalizable research (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), will be included in any publication or presentation outside of the classroom.
- 2. There is no expectation that data from the study, excluding activities not defined as generalizable research (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), will be included in any publication or presentation to class guests.
- 3. All participants are age 18 or older.
- 4. Participants are not recruited through any school publication (including the student newspaper), public posting, electronic bulletin board, Cottey listserv, or departmental research participant pool.
- 5. Funding is not sought for research.
- 6. The research does not involve participants from clinically or otherwise sensitive populations.
- 7. Participation in the research takes less than 30 minutes of the participants' time.
- 8. The research does not involve deception.
- 9. No physically invasive procedures are used.
- 10. Contact with participants is well scripted or standardized.
- 11. No potentially self-incriminating, sensitive, or highly personal questions are asked, and participants' identities are kept anonymous.
- 12. Privacy of participants is respected.

If the instructor questions whether the proposed assignment qualifies for the "minor study" exception or should be submitted for Exempt status, he or she should confer with the IRB Chair.

APPENDIX B:

ADDITIONAL INFORMATION REQUIRED FOR FULL REVIEW OF RESEARCH INVOLVING MORE THAN MINIMAL RISK TO PARTICIPANTS

(Based on American Psychological Association Guidelines)

Please provide the requested information for all appropriate categories involved in your research.

RISK

For research in which the possibility of injury is greater than minimal:

- 1. Identify and describe in detail the possible risks, including psychological, physiological, or social injury, to which participants may be exposed.
- 2. Explain why you believe the risks to the participant are so outweighed by the combined benefit to the participant or society at large and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept these risks. Discuss any alternative ways of conducting this research that would present fewer risks to the participant and explain why the method you have chosen is superior.
- 3. Explain fully how the rights and welfare of participants at risk will be protected (e.g., equipment closely monitored, medical exam given prior to procedures, psychological screening of participants, etc.)

EQUIPMENT

For research in which the participants will be in contact with any mechanical, electronic, electrical, or other equipment which might put him/her at risk of accidental harm or injury, should there be a mechanical failure in the equipment:

- 1. Identify and describe in detail the equipment to be utilized and the exact location. Use manufacturer's name and serial numbers and submit copies of manufacturer's literature on the equipment when available.
- 2. Identify and describe in detail how the participant will interact with the equipment.
- 3. Indicate the names and qualifications (with regard to the safe use of the equipment) for all individuals authorized to use the equipment.
- 4. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the equipment.

PSYCHOLOGICAL OR PHYSIOLOGICAL INTERVENTION

For research in which the participants will be exposed to any psychological interventions such as deception, contrived social situations, manipulation of participant's attitudes, opinion or self-esteem, psychotherapeutic procedures, or other psychological influences, or in which the participant will be exposed to any physiological treatments or interventions upon the body by mechanical, electronic, chemical, biological or any other means:

1. Identify and describe in detail the psychological intervention (or manipulation) and the means used to administer the intervention.

- 2. Identify and describe in detail the behavior expected of participant and the behavior of the investigator during the administration of the intervention.
- 3. Describe how the data resulting from this procedure will be gathered or recorded.
- 4. Identify anticipated and possible psychological, physiological, or social consequences of this procedure for the participant.
- 5. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the means used to administer the intervention. For all equipment used, the questions regarding equipment above must be answered.
- 6. For research involving **deception**, explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator.
- 7. For research involving psychological intervention, describe in detail the plan for debriefing participants.

Indicate the investigator's competence and identify his/her qualifications, by training and experience, to conduct this procedure. Give name, title, academic affiliation and program, address, and telephone number of the individual who will supervise this procedure.

DEBRIEFING STATEMENT

(Sample)

This debriefing statement for a study involving deception is from a Spring Hill College IRB proposal.

This experiment was designed to study the ways in which people evaluate themselves and others on the basis of their cognitive abilities. It is a study of social comparison theory, a theory that states everyone wants to evaluate him or herself on important personal qualities. This happens frequently in school, when students compare themselves according to the grades they receive. If we evaluate ourselves favorably compared to our classmates (for example, if we are at the top of the grading curve), then our self-esteem will be boosted. On the other hand, if we are at the bottom of the grading curve, then we will suffer from lowered self-esteem. In the experiment you just completed, we wanted to see how experiencing success or failure affected self-esteem and willingness to compare yourself to others.

It was necessary to withhold the true purpose of this experiment until after you had completed your participation so that you would not second-guess our goals and perhaps change your responses to our questions. Thus, the "Spatial-Verbal Manipulation Test" you took in which you unscrambled letters to make words (an anagram problem) did not measure any kind of cognitive ability. In fact, your score on that test was determined ahead of time. One half of you received a test in which 12 of the 15 word puzzles were solvable and 3 were impossible to solve (they did not form real words). The other half of you received a test which contained only 3 solvable and 12 unsolvable puzzles. It was impossible for you to score any better than you actually did, and everyone in your group scored exactly as you did. Therefore, your score is not related to any ability on your part.

We included this anagram task so that one-half of the participants would be successful and one-half would be unsuccessful on this task. We will analyze your answers to our questionnaires and then study the effect of the test feedback on your responses. We predict that people who feel they have performed poorly will attempt to boost their self-esteem by comparing themselves against a group of people who are worse off.

It is important that you understand that the "Spatial-Verbal Manipulation Test" was created specifically for this study and is not related to your grades or to any cognitive ability. Since most college students think learning is important, we linked our fake test to cognitive abilities so that you would become personally involved in the task and try to do your best. But please be aware that your score on the test was determined by random chance at the start of the study and in no way reflects on your intelligence or abilities.

We ask that you please not discuss this experiment with anyone on campus, since other students may participate during the remainder of the semester. Study results will be made available during (insert Spring/Fall) semester; you may call (insert project director/faculty sponsor name) at (insert phone number) if you would like to know the outcome or would like to talk more about your participation in this study. Do you have any questions about the study that haven't been answered?