

THE CITADEL

Procedures for Review of Research Involving Human Subjects

The Citadel conforms to the regulations specified in Title 45 Part 46 (Department of Health and Human Services) and Title 34 Part 97 (Department of Education) of the Code of Federal Regulations (45 CFR 46, 34 CFR 97) as amended June, 1991, concerning the protection of human subjects involved in research. In order to conform to the federal regulations The Citadel has established an Institutional Review Board (IRB) and Departmental Review Boards (DRBs) whose primary responsibility is to ensure compliance with College policy as well as with applicable state and federal regulations which are currently in force or which may be introduced in the future. The role of DRBs is to examine research proposals and determine whether further review by the IRB is necessary and to make recommendations for changes to reviewed research proposals that will bring such proposals into compliance with applicable regulations.

Who must Submit Proposals for Review?

All research conducted by faculty or students that involves human subjects must be submitted for review. This includes both Honor's and Master's theses research that involves human subjects. Even research that is approved by another IRB (such as another institution) must be reviewed through the College's system. **No research project which involves human subjects may begin prior to receiving approval.**

What Types of Research Must Be Reviewed?

All research involving human subjects must be reviewed. Human subjects research will fall into one of three general categories. These categories are Exempt Research, Minimal Risk Research, and Greater Than Minimal Risk Research. ***The DRB/IRB Committee(s), not the researcher, determines whether a particular research project is exempt, minimal risk, or greater than minimal risk.*** Research involving minimal risk may move through the review process under expedited procedures providing sufficient safeguards have been taken to reduce risk to subjects and to obtain proper informed consent. All research that involves greater than minimal risk must be fully reviewed by both the DRB and IRB .

Minimal risk is defined as "...the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" [45 CFR 46.102 (I)]. Greater than minimal risk research must convincingly demonstrate that the risks to the subjects "...are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result [45 CFR 46.111 (a)(2)].

What Are the Elements of Informed Consent?

An essential provision of federal regulations is informed consent. Informed consent is defined as "...the legally effective informed consent of the subject or the subject's legally authorized representative [45 CFR 46.116]. Particular attention to informed consent must be exercised with vulnerable populations, such as children, prisoners, pregnant women, mentally disabled subjects, or subjects that are economically or educationally disadvantaged [45 CFR 46.111(b)]. Informed consent must contain certain information at a minimum as follows:

- 1-a statement that the participant is part of a research project;
- 2-an explanation of the purpose(s) of the research;
- 3-the expected duration of the subject's participation
- 4-descriptions of reasonably foreseeable risks/discomforts that may occur as a result of participation;
- 5-an explanation of any compensations or treatments available if injury occurs, what that compensation/treatment consists of, and information on where it may be obtained;
- 6-the name of the individual to contact for pertinent questions about the research, the research subject's rights, or for help in the event of a research-related injury;
- 7-a statement that indicates that participation is voluntary, that refusal to participate will not result in penalty, and that the subject may discontinue participation at any time without prejudice or penalty;
- 8-a statement describing the extent, if any, to which confidentiality of records that identify the subject will be maintained;
- 9-a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, and;
- 10-a description of benefits to the subject and/or others that may reasonably be expected from the research [adapted from 45 CFR 46, pp. 28016-28017].

Both the DRB or IRB may require that additional information be presented to participants as part of the informed consent procedure if the information would meaningfully add to the protection, rights, and welfare of the subjects [45 CFR 46.109(b)]. In the case of participants who have not reached legal age, both parental or guardian permission and the child's assent are required. Both parental/guardian permission and the child's assent must be affirmative; mere failure to object is not sufficient to construe permission or consent. In all instances where consent is documented in writing, a copy of the consent document must be given to the participant to read.

In some research, it may be necessary, for the success of the research, to not fully inform individuals because disclosing information will affect the results of the study. In these instances it is necessary to clearly explain in the research proposal why the information will not be provided and how individuals will be debriefed at the conclusion of the research. All research involving deception or lack of full disclosure must be reviewed at DRB **and** IRB levels.

Criteria for Evaluating Research Proposals

The DRB and IRB will ensure that all research proposals meet the technical requirements

of the law. In addition, DRB/IRB committees will use the following criteria to evaluate research proposals:

- 1-The risk to subjects are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk.
- 2-The risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result from the research.
- 3-The selecting of subjects is equitable.
- 4-Informed consent will be obtained from each prospective subject and, if necessary, from the subject's legally authorized representative.
- 5-Informed consent will be appropriately documented.
- 6-The research plan makes adequate provisions for monitoring the data collected to insure the safety of subjects.
- 7-Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data about or from these subjects.
- 8-For vulnerable subjects, additional safeguards have been implemented to protect against undue influence or coercion.

Additional Responsibilities of DRB/IRB Committees

DRB/IRB Committees have authority, under Federal guidelines, to approve, disapprove, or require modifications of a research project [45 CFR 46.109(a)], including evaluation of the design and procedures being proposed the DRB/IRB has authority to suspend or terminate approved research that is not being conducted consistent with the approved procedures or the law [45 CFR 46.113]. Research studies from students must be sponsored by a faculty member or faculty committee, with sponsor name(s) and signature(s), before the research proposal will be reviewed.

Notification of Research Proposal Review

Individuals submitting research proposals will be notified in writing or e-mail of DRB/IRB action to include any specific suggestions regarding consent forms, confidentiality, minimization of risk, subject selection, or adequacy of the design and/or statistics.

Proposal for Research Involving Human Subjects

Name: _____

Department: _____
Status (student, faculty, etc.): _____
If student, faculty advisor/sponsor: _____

I. In a 2 to 3 page summary, provide a general description of the research project making sure that this description covers the following areas:

- A. The research question(s)
- B. A clear statement of research methodology, including the number of subjects to be used and the statistical analysis(es) planned.
- C. The scientific or educational benefits of the research.
- D. The potential risk to subjects, IF ANY. Describe fully.
- E. Describe intended participants, procedures that will be used to recruit those participants, any payments or compensations planned, whether results will be made available to participants and how.
- F. Description of any deception, necessity of the deception, and plans for debriefing subjects at the conclusion of participation.
- G. Estimates of the following:
 - 1-average amount of time required for participation (indicate hours, minutes)
 - 2-total number of items on questionnaires or tests

II. Provide copies of the following:

- A. All standardized test protocols and any questionnaires to be used.
- B. Description of any self-developed measures; any existing data on such measures.
- C. Any interview questions to be asked. (If the interview will be unstructured, then indicate the general topics to be covered.)
- D. The form to be used to obtain informed consent. If written consent will not be obtained, attach a statement of how consent will be obtained or an explanation of how subjects will be debriefed and protected.

III. Will the participants be (check one):

- a. fully informed partially informed deceived
- b. told that they may terminate participation at any time?..... yes no
- c. informed that, without penalty, they may refuse to respond to particular questions?..... yes no
- d. informed that, without penalty, they may stop participation at any time.... yes no
- e. given a copy of the consent document to read..... yes no

IV. Will the research involve:

- a. physical stress or tissue damage?..... yes no
- b. the likelihood of psychological stress?..... yes no

- c. deception about purposes or research (but not about risks involved)?..... yes no
- d. invasion of privacy from potentially sensitive or personal questions?..... yes no
- e. biomedical procedures?..... yes no
- f. procedures designed to modify the knowledge, thinking, attitudes, feelings, or other aspects of the behavior of subjects?..... yes no
- g. the giving of false or misleading information to subjects?..... yes no
- h. the withholding of information such that “informed consent” is in question?..... yes no
- I. procedures will cause any degree of discomfort, harassment, invasion of privacy, or threat to the dignity of subjects?..... yes no

If you responded “yes” to a through I under Section IV above, be sure you have fully addressed issues of risk/deception under Section I, D or F, in the summary. If you are a student, be sure to explain in Section I, D or F, how your faculty advisor/sponsor will supervise the project.

V. Is this project specifically designed to involve subjects who:

- a. are minors (less than 18 years of age)?..... yes no
If yes, will consent of parents/guardian be obtained?..... yes no
- b. are prisoners?..... yes no
- c. are institutionalized?..... yes no
- d. are college students?..... yes no
- e. are K-12 students?..... yes no
If yes, has permission of the school been obtained?..... yes no
If yes, will consent of parent/guardian be obtained?..... yes no
- f. have disabilities?..... yes no

VI. Which of the following best describes your research project (mark all that apply)?

- | | |
|---|---------------------------------------|
| <input type="checkbox"/> historical | <input type="checkbox"/> descriptive |
| <input type="checkbox"/> causal-inferential | <input type="checkbox"/> archival |
| <input type="checkbox"/> correlational | <input type="checkbox"/> experimental |

VII. Which of the following best describes your data collection method?

- | | |
|--|--|
| <input type="checkbox"/> observation | <input type="checkbox"/> interview |
| <input type="checkbox"/> survey | <input type="checkbox"/> educational tests |
| <input type="checkbox"/> psychological tests | <input type="checkbox"/> physiological markers |

**DRB/IRB Action
(Attach to Research Proposal)**

The research proposal met the requirements for exempt research as follows (assure that

proper procedures for confidentiality and informed consent are evident: check all that apply):

- ___/ research involving normal educational practices, in established or commonly accepted educational settings, such as research on or comparisons among instructional strategies, curricula, or classroom management methods [45 CFR 46 101 (b)(1)]
- ___/ research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if the data are recorded so that subjects cannot be identified either by names or special code identifiers and where disclosure of information will not place subjects in criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation [45 CFR 46 101 (b)(2)(I)]
- ___/ research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publically 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 subjects [45 CFR 46 101 (4)]
- ___/ research involving surveys or interviews of respondents who are elected or appointed public officials or candidates for office [45 CFR 46 101 (3) (I)]
- ___/ research or demonstration projects designed to study, evaluate, or otherwise examine public benefit or service programs [45 CFR 46 101 (5)(I)]
- ___/ consumer acceptance studies [45 CFR 46 (6)]

Review Completed (date) ___/___/___

DRB Signatures _____

The research contained minimal risk and meet the requirements for expedited review .

Review Completed (date) ___/___/___

DRB Signatures _____

IRB Chair Signature _____

The research contained greater than minimal risk potential and received full committee review.

Review Completed (date) ___/___/___

IRB Chair Signature _____

Review Recommendations:

- Accept the proposal without revision.
- Send the proposal back for the needed revisions; let Chair determine adequacy of revisions.

- Send the proposal back for the needed revisions; let Committee review revisions.
- Have a meeting of either the DRB or IRB, as indicated, to discuss the proposal.
- Reject the proposal.

Basis of Rejection

Signature of DRB or IRB Chair, as required

Date ___/___/___

CONSENT FORMS

General Guidelines:

Regular Form: The regular form should be used for complicated studies or studies where the researcher may have no direct contact with subjects. The form should address all

aspects of conformed consent as detailed on page 2, 1-10.

Short Form/Oral Presentation: The short form or oral presentation are appropriate when procedures are rather simple or when the researcher will have direct contact with subjects. Both forms of consent should still address all aspects of conformed consent. A signature is not required for oral presentations but must include the date that it was read to each subject. Survey research via mail does not require return of an informed consent form since return of the survey is implied consent.

SAMPLE CONSENT: REGULAR FORM

THE CITADEL

Consent to Act as a Human Subject

Subject's name: _____

Date of Consent: ____/____/____

Project Title: A re-investigation of the Crissman Moral Behavior Scale: 2003

Description and Explanation of Procedures:

You will be asked to respond to the 50-item Crissman Moral Behavior Scale as part of a large study involving undergraduates at The Citadel and the College of Charleston. Responding to the Crissman Scale will require about 20 minutes of your time and will be scored utilizing a Likert Scale. You will also be asked to provide some additional information such as age, gender, race/ethnicity, college class standing (freshman, sophomore, junior, senior) and college major. The study will compare responses of the subject group to responses of past subject groups from 1929, 1939, 1949, 1959, and 1969 looking for changes in moral perceptions.

You will not be required to place your name on any of the data collection sheets, thereby ensuring that your responses will not be identified separately from group data. All data will be analyzed as group data, will be considered confidential, and will be securely stored (or destroyed) once entered for data analysis(es).

Your participation is completely voluntary. Should you decide not to participate, or should you decide to discontinue participation at any point in time, you may do so without penalty or prejudice.

Risks and Discomforts:

The Crissman Moral Behavior Scale asks questions about moral behavior in general, not as applied to your behavior. Therefore, there should be no risk or discomfort through sensitive disclosures related to your behavior specifically.

Potential Benefits:

The Crissman Moral Behavior Scale has been administered five times over the last 74 years. This administration will allow comparison of college students' perceptions to those of past generations. The data should provide indications of changes in moral perceptions, if any, that will be of interest to researchers.

Compensation and Treatment for Injury:

Your course instructor has agreed to provide extra credit for your participation in this study. You should check with your course instructor for more information about that extra credit.

While the Crissman Moral Behavior Scale is not expected to cause any discomfort, should you nevertheless feel uneasy about questions asked, you may contact Dr. Michael Politano, Department of Psychology, 953-5321 (politano@citadel.edu) who will direct you to

appropriate resources.

Consent:

I have been satisfactorily informed about the procedures described above and the possible risk and benefits of the project, and I agree to participate in this project. Any questions that I have about the procedures have been answered. I understand that this project and this consent form have been approved by the Departmental Review Board or Institutional Review Board, as appropriate, which ensures that research projects involving human subjects follow federal regulations. If I have any further questions about this project, I will call the Department of Psychology at (843) 953-5320.

I understand that I am free to withdraw my consent to participate in the project at any time without penalty or prejudice. In addition, I will not be identified by name as a participant in this project.

Any new information that might develop during the project will be provided to me if that information might affect my willingness to participate in the project.

Subject's Signature

Witness to Signature

If subject is a minor or for some reason unable to sign, complete the following:

Subject is _____ years olds or unable to sign because _____

Parent(s)/Guardian Signature