

The Citadel's Institutional Review Board Research Proposal

The Citadel's Institutional Review Board (IRB) is comprised of one representative from each school, the chair, and a nonaffiliated Citadel member.

Mary Watson	School of Engineering
Dena Garner	School of Science and Mathematics
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Table of Contents

	Page
Who is required to submit a proposal for review?	2
What types of research must be reviewed?	2
What are the elements of informed consent?	4
What criteria are used to evaluate IRB Research Proposals?	5
How do I submit an IRB Research Proposal?	6
When will I be notified of the IRB Committee's decision?	6
Citadel's IRB Research Proposal	7
Sample Informed Consent Form	11

The review process takes approximately 2-3 weeks.

To submit an IRB Research Proposal and attachments:

- Save documents in Word or PDF format.
- Email documents to renee.jefferson@citadel.edu.

The Citadel's Institutional Review Board Policies, Procedures, and Proposal 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.

(1) Who must submit IRB Research 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.

(2) 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.

Exempt Research requires that the only involvement of human subjects will be in one or more of the following categories and that proper procedures for confidentiality and informed consent are evident.

- a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **[45 CFR 46.101 (b) (1)]**
- b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at

risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **[45 CFR 46.101 (b) (2)]**

- c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (ii) of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **[45 CFR 46.101 (b) (3)]**
- d. Research involves 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 (b) (4)]**
- e. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. **[45 CFR 46.101 (b) (5)]**
- f. Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. **[45 CFR 46.101 (b) (6)]**

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)]**. 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.

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)]**. All research that involves greater than minimal risk must be fully reviewed by both the DRB and IRB.

The DRB/IRB Committee(s), not the researcher, determines whether a particular research project is exempt, minimal risk, or greater than minimal risk.

(3) What are the elements of Informed Consent? *(A sample form is located on pages 10 and 11.)*

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]. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject, or the representative, shall be in language understandable to the subject or the representative.

- a. 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. [45 CFR 46.116]
- b. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. [45 CFR 46.116]
- c. 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)]
- d. Both the DRB and/or the 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 seeking informed consent, the following basic elements shall be provided to each subject [45 CFR 46.116 (a)]:

- a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- b. A description of any reasonably foreseeable risks or discomforts to the subject;
- c. A description of any benefits to the subject or to others which may reasonably be expected from the research;

- d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f. 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;
- g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- h. A statement that participation is voluntary, refusal to participate will involve 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.

(4) What criteria are used to evaluate IRB Research Proposals?

The DRB and IRB will ensure that all research proposals meet the technical requirements of the law. In order to approve research covered by this policy the DRB/IRB shall determine that all of the following requirements are satisfied.

- a. The risk to subjects are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk. **[45 CFR 46.111 (a) (1)]**
- b. 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. **[45 CFR 46.111 (a) (2)]**
- c. The selecting of subjects is equitable. **[45 CFR 46.111 (a) (3)]**
- d. Informed consent will be obtained from each prospective subject and, if necessary, from the subject's legally authorized representative. **[45 CFR 46.111 (a) (4)]**
- e. Informed consent will be appropriately documented. **[45 CFR 46.111 (a) (5)]**
- f. The research plan makes adequate provisions for monitoring the data collected to insure the safety of subjects. **[45 CFR 46.111 (a) (6)]**
- g. Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data about or from these subjects. **[45 CFR 46.111 (a) (7)]**

- h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. **[45 CFR 46.111 (b)]**

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.

(5) How do I submit the IRB Research Proposal?

- a. The Citadel's IRB Research Proposal is located on pages 7 through 9.
- b. Copy these pages into a Word or another word-processing document.
- c. Some parts of the proposal require information to be placed in a separate document. This information may be placed into Word or another word-processing document.
- d. Complete forms and documents may be submitted in Word or PDF.
- e. Email the completed IRB Research Proposal and documents to renee.jefferson@citadel.edu.
- f. You will receive an email message confirming receipt of the proposal within 48 hours.

(6) When will I be notified of the IRB Committee's Decision?

You will be notified of the IRB Committee's decision approximately 2-3 weeks after submitting the proposal.

The Citadel's IRB Research Proposal for Research Involving Human Subjects

Name(s):

Status (e.g., student or faculty):

If student, faculty advisor/sponsor:

Department:

Research Study Title:

You will be asked to place some responses into a separate document. Please include the section number and/or corresponding letter for these responses.

I. Research Project Description

In an attached document, provide a general description of the research project making sure that this description covers the following areas. Use the following as the section heading: **I. Research Project Description**.

- A. The research question(s), objective(s), and/or hypothesis(es)
- B. A clear statement of research methodology, including the number of subjects to be used and the statistical analysis or analyses 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. Estimate of the average amount of time required for participation (indicate hours, minutes).
- H. Estimate the total number of interview questions, or items on survey, questionnaire, or test.

II. Data Collection Information

- A. Will a standardized test protocol and a questionnaire be used? Yes No

If yes, submit it in an attached document. Use the following as the section heading: II.A.

- B. Will a standardized test be used? Yes No

If yes, submit it in an attached document.

- C. Will self-developed measures be used (e.g., survey or interview questions, observation checklist items)? Yes No

If yes, submit it in an attached document and include any existing data you may have on these measures. Use the following as the section heading: II.C.

If the measures have not been developed, then provide a detailed description of the topics to be covered. Use the following as the section heading: II.C.

III. Informed Consent (*Sample form is located on pages 10 and 11.*)

- A. Will the participants be fully informed, partially informed, or deceived? *Select one response.*
 fully informed partially informed deceived

- B. Will the participants be told that they may terminate participation at any time? Yes
 No

- C. Will the participants be informed that, without penalty, they may refuse to respond to particular questions? Yes No

- D. Will the participants be informed that, without penalty, they may stop participation at any time? Yes No

- E. Will participants and/or their parents or guardians be given a written informed consent to sign? Yes No

If yes, submit the form in an attached document.

If no, then in an attached document describe how consent will be obtained or explain how the participants will be debriefed and protected. Use the following as the section heading: III.E.

IV. Will the research involve any of the following? (Select all that apply.)

- Physical stress or tissue damage
- Likelihood of psychological stress
- Deception about purposes or research (but not about risks involved)
- Invasion of privacy from potentially sensitive or personal questions
- Biomedical procedures
- Procedures designed to modify the knowledge, thinking, attitudes, feelings, or other aspects of the behavior of subjects
- Giving of false or misleading information to subjects
- Withholding of information such that "informed consent" is in question
- Procedures will cause any degree of discomfort, harassment, invasion of privacy, or threat to the dignity of subjects.

Attention: If you selected any of the options in this section, be sure you have fully addressed issues of risk and deception under Section I (Item D or F) in the summary.

V. Participants of the Research Study (Select all that apply.)

- Minors (less than 18 years of age)
Will consent of parents/guardian be obtained? Yes No
- P-12 students
Will permission of the school be obtained? Yes No
Will consent of parent/guardian be obtained? Yes No
- College students
- Have disabilities
- Prisoners
- Institutionalized
- Other, please list:

VI. Which of the following best describes your research project? *Select all that apply.*

- Archival
- Causal-inferential
- Correlational
- Descriptive
- Experimental
- Historical
- Other, please list:

**VII. Which of the following best describes your data collection method?
(*Select all that apply.*)**

- Educational tests
- Interview
- Observation
- Psychological tests
- Physiological markers
- Survey
- Other, please list:

- End of Proposal –

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, (843) 953-5321 (politanom@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 old or unable to sign because

Parent(s)/Guardian Signature