Institutional Review Board (IRB) Guidelines
(Approved February 8, 2010)

Immediate Purpose of this Document
This document represents a critical early step in the process by way of which The Citadel will establish a fully-functioning IRB with a true institution-wide foundation. It is intended to be a "working" document in that it will provide basic, general guidance for the IRB, thus allowing it to be fully functional as more thorough and detailed documentation of policy and procedures is being developed.

Purpose of the IRB
The Citadel's IRB is responsible for the oversight of all research involving human participants that is conducted either at The Citadel or under the auspices of the institution. Its basic goal is to insure that all such research complies with federal regulations. Mandated by the United States Department of Health and Human Services, IRBs serve to protect human research participants by applying the guidelines provided by Title 45, Part 46, of the Code of Federal Regulations. Consequently, this IRB has the authority to approve or disapprove any such research activities if they involve human participants; furthermore, the IRB also has the authority to suggest or require changes in research procedures before granting permission for that research to proceed.

Composition of the IRB
1. The IRB will consist of six regular voting members, five of whom will be Citadel faculty -- one each from the School of Business Administration, the School of Education, the School of Engineering, the School of Humanities and Social Sciences, and the School of Science and Mathematics. As prescribed by the Code of Federal Regulations (46.107), the sixth voting member of the IRB will be an individual who is not affiliated with The Citadel (and who is not part of the immediate family of someone associated with the institution).

2. The Dean of The Citadel Graduate College (or a designee of that individual) will serve as the IRB Chair and will sit as an ex-officio member of the IRB who votes only if necessary to break a tie. However, this individual may serve as one of the two initial reviewers for a project that may ultimately be determined not to require full-board review; if such a case should be determined to require full-board review, this individual would still not cast a vote as part of that process (except in the event of a tie, as noted).

3. The initial composition of this IRB is as follows:

   Ed Timmerman  School of Business Administration
   Renee Jefferson  School of Education
   Jeff Davis  School of Engineering
   Al Finch  School of Humanities and Social Sciences
   Dena Garner  School of Science and Mathematics
   Richard Aust  Non-Citadel Representative (MUSC)
The length of the term of service as well as the procedures for replacing board members will be determined at a later time, and the initial composition of the IRB will remain as stated here until that time.

4. All members of the IRB will have completed IRB training through the online course available at the National Institutes of Health website. (Comparable training provided by other agencies is an acceptable alternative.) Certification of the completion of such training will be provided by the IRB member and will be kept on file in the office of the Dean of The Citadel Graduate College.

**IRB Procedures**

1. The form to be used in submitting a proposal to the IRB can be found on The Citadel's website at the Research Committee page, accessible through the "Faculty Committees" page. The link titled "Human Subjects Guidelines" provides access to the form.

2. Two hard copies of the completed form are to be submitted to the Dean of The Citadel Graduate College, whose office serves as the contact point for all IRB-related matters.

3. The Dean retains one copy of the submission and forwards the other to the IRB member representing the School of the faculty member who has submitted the proposal. (Proposals from students must be submitted by a supervising faculty member.) The IRB member ordinarily provides the initial review of the proposal and then forwards it to a second reviewer. The second reviewer may or may not be a member of the IRB but should have completed appropriate IRB training (as described in the foregoing). If there are extenuating circumstances that make it difficult for the IRB member to complete an initial review in a timely manner, the IRB member may designate another trained individual (who may or may not be a member of the IRB) to provide the initial review. If an IRB member submits a proposal, the Dean will follow a parallel course of action.

4. The process as described thus far serves: (a) to provide confirmation of a judgment from the first reviewer that the proposed research qualifies as "exempt" and thus does not require further review; or (b) to provide an "expedited review" if such is the judgment of the first reviewer. If there is uncertainty as to whether a proposal should be given "exempt" or "expedited" status, the reviewer may refer the proposal back to the Dean for final determination. As appropriate, reviewers may request clarification and/or additional materials from the faculty member who has submitted the proposal.

5. In the case of an "exempt" or "expedited" judgment, the completed review, bearing the signatures of the reviewers and indicating their assessment of the proposal, is returned to the Dean. The Dean communicates the decision to the faculty member who has submitted the proposal and informs the individual that he or she may proceed with the research.

6. If the initial review determines that a full-board review is required, a meeting of the IRB will take place within 30 days after that decision is communicated to the Dean of The Citadel Graduate College. As necessary, the IRB may request clarification and/or additional materials from the faculty member who has submitted the proposal. The Dean communicates the IRB's final decision to the faculty member who has submitted the proposal and informs the individual that he or she may (or may not) proceed with the research.
7. Until the structure of the IRB as presented in this document is modified, all six members (and the Chair or his designee) must be present and must vote in a full-board review. (A member who cannot be present for such a meeting is required to send a designee, subject to the approval of the Dean.) The final decision will be determined by rule of the simple majority. In the event of a tie, the IRB Chair will cast the deciding vote.

8. IRB approval is considered to be in effect for one year from the date of approval. In the case of a project that extends beyond one year from this date, the faculty member who submitted the original proposal is required to provide in writing to the Dean of The Citadel Graduate College a brief update on the status of the project, including a statement that specifically provides assurance that there have been no procedural changes in the research protocol that could compromise the original decision of the IRB. If, during the course of the research, any such changes should be deemed necessary by the researcher, the faculty member must notify the IRB Chair. The IRB Chair will determine whether those changes are of such significance that the original review process and decision would be compromised as a consequence of implementing those changes. If such is determined to be the case, a new review of the project will be required, and a new IRB proposal must be submitted. That new proposal is subject to the complete set of review procedures described in the present document.

(Updated April 8, 2010)