decision can be provided to other institutions' IRB for their records upon request. If another institution conducts the IRB review, the investigator at the College is responsible for providing documentation to the College IRB.

Research investigators who conduct human subject research without appropriate IRB approval or continue a protocol without renewal may place the College out of compliance with Federal requirements. This could result in Federal actions preventing researchers, departments, or the College from human research or related funding. If the IRB becomes aware of non-approved research, the Chair will issue a letter to the investigator, the department head, and Assistant Provost for Research, instructing the research to cease. At the next convened IRB meeting, IRB members will discuss possible sanctions. Sanctions will be based on the level of risks to human subjects and will be subject to approval from the Provost.

All IRB members and research investigators are responsible for completing training modules on the CITI Program website or other training as authorized by the Assistant Provost for Research. Failure to complete training may result in member removal from IRB or postponement of approval on research protocols.

The IRB shall maintain records relating to all review and decisions for research protocols for no less than three (3) years after the conclusion of the research, in line with guidelines in the Common Rule.

The Office of Research and Grants of The Citadel and the IRB recognize the following principles and regulatory authorities for the protection of human research subjects:

> The Belmont Report outlines three basic ethical principles which are employed by the IRB to assess proposals and should be considered by research investigators when planning new research: (1) Respect for Persons, treatment of individuals as an autonomous agent and protection of those with diminished capacity; (2) Beneficence, an obligation to minimize possible harms; and (3) Justice, determination of the balance of those receiving benefit or burden from research.
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> The Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS) is responsible for policy development and regulatory oversight of biomedical and behavioral research conducted or supported by HHS. This office enables the registration of IRBs and the acquisition of Federalwide Assurances (FWA).
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> The Common Rule, Code of Federal Regulations Title 45 Part 46, was created by HHS as the regulation

for human subjects.

When human subject research is related to health information, the HIPAA Privacy Rule (Code of Federal Regulations Title 45 Parts 160 and 164) applies in addition to the Common Rule protections. As such, the standards of the Privacy Rule will be applied during IRB review.

Definitions

1. Human subject - A human subject is a living individual about whom an investigator (whether