Human Subjects in Research Policy

RP-10

About This Policy

Effective Dates:
08/01/2023
Last Updated:
08/01/2023
Responsible University Administrator(s):
Assistant Provost for Research
Approving Body:
Office of the Provost
Policy Contact:
Office of the Provost, The Citadel

Policy Statement (Purpose and Scope)

The purpose of this policy is to support current and future faculty who wish to use human subjects in research. Regulation of human subject use for research is outlined by the United States Department of Health and Human Services (HHS) in Title 45 Part 46 of the Code of Federal Regulations (CFR), also known as the "Common Rule" and replicated throughout the CFR for various agencies. The College expects all of its human research facilities and programs to maintain high ethical standards for the rights and welfare of human subjects, and to be operated in accordance with applicable legal requirements. This policy outlines the principles that govern the ethical conduct of human subject research activities, ensures legal compliance, and establishes roles and responsibilities of those individuals who are involved in the care and use of human subjects in research.

Policy

It is the policy of the Office of Research and Grants that use of human subjects in research shall conform to all applicable laws, rules, and regulations of the United States Government and the State of South Carolina. Furthermore, all such research and instruction must be performed in compliance with the highest standards of ethics, practice, and conduct of each of the fields or disciplines involved in each of the specific research projects.

To ensure compliance with regulations regarding the protection of human subjects in research, the Assistant Provost for Research, as the appointee of the Provost shall appoint the Institutional Research Board (IRB), which meets regulatory requirements and is charged with the responsibility of ensuring the rights and welfare of human research subjects at the College. The IRB is a committee that shall consist of no fewer than 5 voting members and shall include at least:

1. One individual concerned with scientific areas

2. One individual concerned with nonscientific areas (i.e. ethicist)

3. One individual not affiliated with the College

One individual may fulfill more than 1 requirement above but the committee cannot consist of fewer than 5 members.

The Assistant Provost for Research and IRB Chair will take additional steps so that IRB membership reflects College diversity with respect to gender, ethnicity, and professional discipline.

Non-voting, or ex officio, members may be appointed at the discretion of the IRB Chair.

The IRB shall have the responsibility to review and the authority to approve, require modifications to secure approval, or withhold approval of, all research involving human subjects conducted by the College or anyone using College facilities, in accordance with policies and procedures established for this purpose.

The IRB will apply the definitions of "human subject" and "research" as outlined in Title 45 Part 46 of the Code of Federal Regulations (CFR), also known as the "Common Rule". Educational and institutional improvement activities that fail to meet either or both definitions do not require IRB approval, however, the IRB Chair is responsible for evaluating if both definitions are met.

The IRB, or its staff acting on behalf of the IRB, has the authority to inspect research facilities and obtain records and other relevant information relating to projects it has approved. The IRB may suspend or terminate approval of projects it has approved and take actions that it deems necessary to ensure compliance with applicable legal requirements and College policies or which have been associated with unexpected serious harm to subjects.

The IRB Chair will issue a formal letter for approved research to the research investigator. This approval is valid for one (1) year, at which time research investigators must apply for an extension or file a protocol close-out letter.

No individual or College committee may approve and/or commence a project involving the use of human subjects for research, teaching or testing that has not been reviewed and approved by the IRB. Activities that do not meet the definitions of both "human subjects" and "research" do not require IRB review. Individuals and College committees should direct questions regarding specific activities to the IRB Chair.

Determination of "exempt" or "expedited review" research, as outlined in the Common Rule, is made by the IRB and not by an individual or college committee.

Human subject research must meet or exceed the minimum standards set forth in the Common Rule pertaining to informed consent collection and documentation from subjects or guardians.

Research investigators are responsible for reporting changes in research protocols during the period of investigation to the IRB. Documentation will be stored by IRB and significant changes, as judged by the IRB Chair or representative, may require for formal amendment submission with additional IRB review.

All adverse events in human subject research must be reported to the IRB Chair in a timely manner. Serious and protocol-related adverse effects, whether expected or unexpected, will be reviewed by the IRB to determine if a change in procedures or consent documentation is warranted.

Any College faculty or staff member may serve as the principle investigator on a research protocol. Cadets and students may be research investigators but must be sponsored by a faculty or staff member. Investigators not affiliated with the College must be sponsored by a College faculty or staff member to conduct human subject research at the College.

Research investigators conducting cooperative research involving multiple US institutions are generally only required to have a single institution conduct a full IRB review. If this is the College, documentation of the

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 that department. As of the 2018 revised Common Rule, 19 agencies (including HHS) adhere to the regulation and thus the Common Rule may be found in various agency locations in the CFR. These include the Departments of Homeland Security, Agriculture, Energy, Commerce, Housing and Urban Development, Justice, Labor, Defense, Education, Veterans Affairs, and Transportation. Additionally, the National Aeronautics and Space Administration, Social Security Administration, Agency for International Development, Environmental Protection Agency, National Science Foundation, Office of the Director or National Intelligence, Central Intelligence Agency, and Consumer Product Safety Commission. Research conducted or funded by any of these agencies is subject to adherence to the Common Rule. The Federal Register citation is 82 FR 7149.
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> While part of HHS, the Food and Drug Administration (FDA) maintains a separate policy governing human subject research, Code of Federal Regulations Title 21 Part 50, and IRBs, Part 56. Research related to or funded by the charge of the FDA will be reviewed applying these standards.
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> As an educational institution, research involving students must also be evaluated for accordance with the Family Educational Rights and Privacy Act (FERPA) to ensure that education records retain privacy

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 professional or student) conducting research obtains, uses, studies, or analyzes information or biospecimens
2. Research – Research is a systematic investigation designed to develop or contribute to generalizable knowledge. This includes research development, testing, and evaluation.
3. CFR – Code of Federal Regulations
4. Common Rule – text found in 45 CFR 46
5. The College- The Citadel, The Military College of South Carolina
6. IRB – Institutional Review Board
7. Exempt Research – Research that falls into specific categories as listed in 45 CFR 46.104
8. Expedited Review – Review of a submitted Protocol by two (2) IRB members, or a member and the Chair, rather than full panel review. Applicable to research posing minimal risk and in specific categories listed in 63 FR 60364-60367
9. HHS- US Department of Health and Human Services
10. OHRP- Office for Human Research Protections, within HHS
11. FDA- Food and Drug Administration, within HHS
12. FERPA – Family Educational Rights and Privacy Act

Additional Information

1. Code of Federal Regulations Title 45 Part 46 (Common Rule): https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#part-46
2. Code of Federal Regulations Title 21 Part 50: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1
3. Code of Federal Regulations Title 21 Part 56: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56&showFR=1
4. The Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
5. The Nuremberg Code: https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation
6. Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/