



POLICY ON THE INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Policy Number: 3.0.5

Version Number: 002

Classification: Research Compliance

Effective Date: February 5, 2019

Responsible University Office: Office of Research Compliance

1.0 Purpose

This policy has been developed to ensure compliance with the Common Rule (45 CFR 46) and other federal regulations that outline the oversight of research projects involving the use of human subjects. To meet these requirements and assure adherence to federal regulations, Clemson University (CU) has established an Institutional Review Board for the Protection of Human Subjects in Research (IRB) to review all activities that meet the definition of human subjects research in the federal regulations. This policy describes the responsibilities and authority of this oversight committee/board.

2.0 Applicability

This policy applies to all human subjects research conducted or supported by the faculty, students, staff, or other representatives of CU, regardless of where the research is conducted. The CU IRB may choose to accept the review and approval of another duly constituted IRB with a federal wide assurance (FWA) for research conducted at other sites.

The IRB shall review and approve all human subjects research before it can be conducted by anyone on the premises of CU property or within CU facilities.

The Vice President for Research will serve as the Institutional Official.

3.0 Government Rules and Regulations

Applicable regulations include 45 CFR 46 (Common Rule - DHHS), CFR 21 (various regulations – FDA), 34 CFR Part 98 & 99 (PPRA & FERPA – DoEd) and Health Insurance Portability and Accountability Act (HIPAA).

4.0 Definitions

Institutional Review Board (IRB). An IRB is a board designated by CU to review, to approve the initiation of, and to conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The IRB may be assigned other review functions as deemed appropriate by the organization.

Federalwide Assurance (FWA). The FWA is an agreement with the Department of Health and Human Services Office of Human Research Protection (OHRP) declaring that all institutional components listed under the CU's FWA will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.

Institutional Official (IO). The IO is responsible for ensuring that the IRB at CU has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all assurances, and assumes the obligations of the institution's assurance.

Human Subjects Research. Human subjects research for the purposes of this policy is defined as an activity that meets the definitions of "research" and involves "human subjects" as defined at 45 CFR part 46.

5.0 Policy

- A. The IRB, which is housed administratively within the Office of Research Compliance (ORC), shall exercise its authority in full accordance with Health and Human Services regulations at 45 CFR part 46 and CU policies and procedures. This authority includes review and approval of exempt research under 45 CFR part 46.101 (b); research, which qualifies for expedited review under 45 CFR part 46.110; and research, which requires review by the full IRB. The IRB has the empowerment, flexibility and discretion to raise the standards of protection above those afforded to research subjects in 45 CFR part 46 as it deems appropriate and necessary in particular cases although it may not lower the protections below those afforded by 45 CFR part 46.

- B. IRB members are to report any attempts to unduly influence their decisions to the ORC. The ORC will investigate the allegations, and if true, will take any needed corrective action.
- C. Per Health and Human Services regulations at 45 CFR part 46.112, the institution acknowledges that research, which has been approved by the IRB may be subject to further appropriate review by the IO, or his/her designee. However, no official may approve research if it has not been approved by the IRB. In addition, any attempt to unduly influence the IRB from both within and outside the Institution is strictly prohibited and must be reported to the IO or ORC who will take appropriate action.
- D. Approval of research by the IRB can be overturned by the IO or his/her designee.

6.0 Responsibilities

The Institution will apply 45 CFR part 46, including Subpart A, B, C, and D, to all human subjects research regardless of funding.

Human subjects research that would fall under the purview of FDA may be referred to the Greenville Health System IRB as per prearranged agreement.

7.0 Sanctions for Non-Compliance

The ORC will be notified in situations of possible non-compliance, which consists of the failure to comply with any Health and Human Services regulations, and/or IRB requirements; Noncompliance is assessed as non-serious, serious, or continuing. A complete review of the IRB study record will be performed by the ORC staff to determine what further action should be taken.

IRB approval may be suspended or terminated if research is not being conducted in accordance with IRB or regulatory requirements.

8.0 Approval Signatures

This policy has been approved by:



Tanju Karanfil
Vice President for Research

1.28.2021

Date

REVISION HISTORY		
EFFECTIVE DATE	REVISION NUMBER	MODIFICATION
February 5, 2019	01	Incorporated into VPR Policy Template
January 28, 2021	02	Policy number changed from 3.0.6 to 3.0.5