

Human Research Protection Policy West Virginia University

West Virginia University (WVU) fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University.

In the review and conduct of research, actions by West Virginia University will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (often referred to as the Belmont Report) and will be performed in accordance with the Department of Health and Human Services (HHS) policy and regulations at 45 CFR 46 (also known as the "Common Rule") as well as the Food and Drug Administration (FDA) policy and regulations at 21 CFR 50 and 21 CFR 56.

The actions of West Virginia University will also conform to all other applicable federal, state, and local laws and regulations.

In order to fulfill this mission, WVU has established a human research protection program (HRPP). The mission of the HRPP is to:

- Safeguard and promote the welfare of human research subjects by ensuring that their rights, safety, and well-being are protected;
- Provide timely and high quality review and monitoring of human subjects research projects; and
- Facilitate excellence in human subjects research.

West Virginia University has designated an Institutional Official who has overall responsibility for the University's human research protection program. The duties of the Institutional Official are as follows:

1. Be responsible for compliance with institutional policies and all applicable regulations for the protection of human subjects.
2. Be the signatory authority for the Federalwide Assurance to the Office of Human Research Protections.
3. Provide support to the human research protections program within the means of the institution.

In the performance of these duties, the Institutional Official has the authority to delegate such activities as may be necessary in order to fulfill these duties.

To conduct its responsibility effectively, West Virginia University maintains multiple Institutional Review Boards (IRBs) to review research protocols involving human subjects. The IRBs are an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University. The IRBs have the following authority:

- a. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the University;
- b. To suspend or terminate approval of research not being conducted in accordance with the IRBs' requirements or that has been associated with unexpected serious harm to participants;
- c. To observe, or have a third party observe, the consent process;
- d. To observe, or have a third party observe, the conduct of the research; and
- e. To determine whether data or information gathered without IRB approval may be published or used for research purposes.

All IRB-approved research studies are subject to ongoing review, which must be conducted in accordance with applicable federal regulations by the designated IRB. If approval by the IRB lapses, all research activity must stop unless the IRB finds that there is an overriding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions.

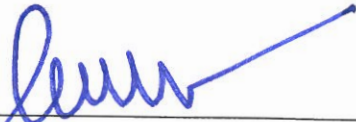
The WVU IRBs have jurisdiction over all human subjects research conducted under the auspices of West Virginia University, regardless of funding source or performance site. Research under the auspices of West Virginia University includes research conducted at WVU, conducted by or under the direction of any employee or agent of WVU (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of WVU using any property or facility of WVU, or involving the use of WVU's non-public information to identify or contact human subjects.

No research involving human subjects may be conducted without IRB approval, and no research may commence until all required Institutional approvals (including IRB) are obtained.

West Virginia University may review any research protocol and has the right to disapprove the implementation of a research protocol that has been approved by WVU IRB. However, no one at WVU shall approve the implementation of any research protocol nor may it override the decision of the IRB concerning a research protocol that has been disapproved by the IRB.

All institutional and non-institutional performance sites for West Virginia University, domestic or foreign, will be obligated by this policy to conform to ethical principles which are at least equivalent to those of WVU or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

The Institutional Official and the IRBs shall adopt operating procedures to implement this policy. These procedures shall serve as the governing procedures for the conduct and review of all human research conducted under the auspices of West Virginia University.



E. Gordon Gee
President, West Virginia University

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