

WVU Human Research Protections Program			
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1 PURPOSE

- 1.1 This SOP provides an overview of West Virginia University's human research protections program known as the WVU Office of Human Research Protections (OHRP).

2 OVERVIEW

- 2.1 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 WVU.
- 2.2 In the review and conduct of research, WVU staff's actions are guided by the ethical principles outlined in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, referred to as the *Belmont Report*: respect for persons, beneficence, and justice.
- 2.3 The WVU Office of Human Research Protections is a systemic and comprehensive program designed to afford protections to all human research participants. The actions of WVU staff will conform to the applicable federal, state, and local laws and regulations.
- 2.4 The WVU Human Research Protection Policy Letter delegates responsibility to the Vice President for Research (VPR), who serves as the Institutional Official (IO) to ensure appropriate authority and independence for the program. Through WVU OHRP and IO oversight, the WVU Office of Human Research Protections has sufficient resources to protect the rights and welfare of research participants for the research activities that WVU conducts or oversees.
- 2.5 WVU's transnational research activities are consistent with the ethical principles outlined in the program and meet equivalent levels of participant protection for the research conducted in WVU's principal locations while complying with local laws and considering cultural context.
- 2.6 Research that has been approved by a WVU IRB may be subject to further appropriate review and disapproval by officials of the institution. However, those officials may not approve the research if an IRB has not previously approved it.

3 RESPONSIBILITIES

- 3.1 The Institutional Official and those directly responsible for the human research protections program have the following responsibilities:
- Follow the WVU written policies and procedures (SOPs) that allow the WVU IRBs to function independently of other organizational entities in protecting research participants.

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- Follow the written policies and procedures (SOPs) that specify the ethical standards and practices of the WVU human research protections program.
- Ensure that the SOPs are available to Sponsors, Researchers, Research Staff, research participants, and the WVU IRBs.
- Identify applicable laws in the localities where it conducts human research.
- Ensure that the WVU OHRP staff and the WVU IRB members consider the SOPs, institutional policy, federal/state law in the review and conduct of research and resolve differences between federal or national laws and local laws.
- Provide an educational program that contributes to improving the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.
- Ensure that Federal funds administered by a federal department or agency may not be expended for research involving human subjects unless the requirements of the applicable WVU SOPs have been satisfied.
- Facilitate the operation of the WVU IRBs (membership management, meetings, and record management)
- Provide oversight for all human-subject, research-related activities (systems, SOPs, IRB, education)

4 REFERENCES

WVU Policies:

WVU Human Research Protection Policy Letter dated February 13, 2019
SOP 001 WVU OHRP Overview

Federal Regulations:

45 CFR 46.112
45 CFR 46.122

AAHRPP:

Standard I-1, Element I.1.A, B, C, D, E, G
Standard I-2
Standard I-3