

WVU Office of Human Research Protections Overview			
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## 1 PURPOSE

- 1.1 This SOP describes the West Virginia University (WVU) Office of Human Research Protections and provides an overview of the organization's resources, staff, and reporting structure.

## 2 OVERVIEW

- 2.1 WVU has established the Office of Human Research Protections (WVU OHRP) to ensure compliance with policies and procedures to protect human subjects in research. WVU OHRP is a compliance department within the WVU Research Office. The primary responsibility of WVU OHRP is the operation of the human research protection program. (See SOP 002: Human Research Protection Program.)
- 2.2 WVU OHRP provides the written policies and procedures (Standard Operating Procedures, SOPs) for the WVU IRBs to review human subject research and general departmental and research support activities related to human subject protections for the institution. These activities include ensuring that systems and standard operating procedures are in place to support human subject protections while aiding the research community. WVU IRB and OHRP operations follow the criteria within the SOPs unless otherwise stated.
- 2.3 WVU OHRP has instituted standard procedures for determining when the human research protection program oversees activities. WVU OHRP facilitates the review and approval for and provides general support for human subject research for the Research Office and the institution. (See SOP 011: Human Subject Determination.)

## 3 RESOURCES

- 3.1 Through the Institutional Official, WVU OHRP has support for the required resources to perform the human research protection program's functions, including the IRB meetings online and in-person. (Resources include office space, meeting space, storage space, equipment, and electronic systems.) The resources provided include the WVU OHRP electronic submission management system, education program, quality improvement program, and community outreach. Resources are reviewed during the annual budget review process.

## 4 STAFF

- 4.1 The WVU OHRP Director selects employees for WVU OHRP to support the human research protection program, according to WVU Human Resources policies and procedures. Depending on the positions to be filled, qualifications to be considered in the selection of staff may include experience in:
  - IRB Administration
  - Regulatory Compliance

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- 4.2 Staff at the entry or clerical level must demonstrate the desire to learn, and be an active participant in, the regulatory, ethical, and procedural aspects that support a research protection program.
- 4.3 Through informal and formal training, the staff is provided with the opportunity to become knowledgeable about WVU's human research protections program and standard operating procedures.
- 4.4 The staff approved to review protocols are issued a Review Authorization Letter from the Institutional Official detailing the types of reviews they are authorized to complete.
- 4.5 The WVU OHRP Director supervises and evaluates staff on an annual basis, according to WVU Human Resources policies and procedures. The adequacy of personnel and non-personnel resources of the human research protections program is regularly assessed by the WVU OHRP Director and approved by the Institutional Official.

## 5 REPORTING STRUCTURE

- 5.1 WVU OHRP Staff reports to the Director (and, when applicable, the Assistant Director) and perform the tasks required to meet the mission of WVU OHRP and the human subject protection program.
- 5.2 WVU OHRP Assistant Director reports to the Director.
- 5.3 WVU OHRP Director reports to the Associate Vice President for Creative and Scholarly Activities.
- 5.4 WVU Associate Vice President for Creative and Scholarly Activities reports to the Vice President for Research, who serves as the Institutional Official.

## 6 REFERENCES

### WVU Policies:

WVU Human Research Protection Policy Letter dated February 13, 2019

SOP 002 Human Research Protections Program

SOP 011 Human Subject Research Determination (NHSR)

### Federal Regulations:

N/A

### AAHRPP:

Standard I-1, A

Standard I-2