INSTITUTIONAL POLICY: R-05

Category:	Research
Subject:	Human Subjects Research
Effective Date:	August 20, 2010
Last Revision Date:	November 13, 2015 (updated January 7, 2019)
Applicability:	Faculty, Students, Staff, and all others involved in human subjects research

R 05-1. Authority

W. Va. Code § 18B-1-6

R 05-2. Purpose

The purpose of this policy is to provide a Human Research Protection Program ("HRPP") for the West Virginia School of Osteopathic Medicine ("WVSOM") in order to ensure that all research involving human participants safeguards and promotes health and welfare, protects human rights, ensures the safety and wellbeing of participants, and complies with all applicable federal, state, and local laws and regulations. WVSOM is committed to conducting research with the highest regard for the welfare of human subjects.

R 05-3. Definitions

3.1 "Human Subject" means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

3.2 "Human Subjects Research" means any activity that meets the definition of "research" and involves "human subjects" as defined by the Common Rule (45 C.F.R. 46).

3.3 "Institutional Official" or "IO" means the individual responsible for ensuring that the HRPP and IRB at WVSOM have the resources and support to comply with all federal regulations that govern human subjects research. The IO represents WVSOM as the signatory official and assumes the obligations of the institution's assurances.

3.4 "Institutional Review Board" or "IRB" means the board designated by WVSOM to oversee and approve or disapprove research involving human subjects to protect their rights and welfare.

3.5 "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

R 05-4. Human Research Protection Program

4.1 WVSOM maintains an HRPP that is responsible for ensuring that the institution carries out the purpose of this policy. The HRPP shall:

4.1.1 Safeguard and promote the health and welfare of human subjects by ensuring that their rights, safety, and wellbeing are protected;

4.1.2 Provide timely review and monitoring of human subjects research projects;

4.1.3 Facilitate excellence in human subjects research;

4.1.4 Educate investigators and research staff about their ethical responsibility to protect research participants; and

4.1.5 Intervene to respond directly to the concerns of research participants when appropriate.

4.2 All actions of the HRPP will be guided by the principles of justice, beneficence, and respect for persons as set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report) and performed in accordance with applicable provisions of the U.S. Department of Health and Human Services ("DHHS") policy and regulations at 45 C.F.R. 46 (also known as the "Common Rule").

4.3 The HRPP consists of individuals and committees that include the IO, the IRB, and other committees or subcommittees that address human subjects research (e.g., Biosafety Committee, Conflict of Interest in Research Committee, Research Committee), investigators, IRB staff, and research staff.

R 05-5. Institutional Official

The Institutional Official shall:

5.1 Be responsible for overseeing the activities of WVSOM's HRPP and IRB.

5.2 Be responsible for ensuring that WVSOM's HRPP and IRB have the resources and support to comply with all federal regulations that govern human subjects research.

5.3 Represent WVSOM as the signatory official for WVSOM's Federalwide Assurance to the DHHS Office of Human Research Protections and assume the obligations of WVSOM's assurances.

R 05-6. Institutional Review Board

6.1 WVSOM operates under the authority of its Federalwide Assurance (FWA00007632) with one IRB to review all human subjects research protocols. WVSOM's IRB is an autonomous administrative body responsible for ensuring that the rights and welfare of human subjects are protected. The IRB ensures that the research meets regulatory requirements for initial and continuing review and any modifications of approved research.

6.2 The IRB has the authority to:

6.2.1 Approve, require modification of, defer, or disapprove research activities conducted under the auspices of WVSOM's IRB, including any proposed changes to ongoing human subjects research;

6.2.2 Suspend or terminate approval of ongoing approved research that is not being conducted in accordance with regulatory or IRB requirements or that has been associated with unexpected, serious harm to subjects;

6.2.3 Require progress reports from investigators and oversee the conduct of each research project;

6.2.4 Place restrictions on a research project; and

6.2.5 Observe, or have a third party observe, the consent process and the conduct of the research.

6.3 The IRB serves as the Privacy Board for matters involving identifiable information in research.

R 05-7. Office of Research and Sponsored Programs

The Office of Research and Sponsored Programs ("ORSP") shall oversee the administration of the HRPP and ensure that communication is maintained among the IRB, WVSOM officials, federal regulatory agencies, and other applicable individuals or entities concerning human subjects research. The ORSP shall be equipped with the necessary resources to perform the administrative functions of the HRPP.

R 05-8. Review and Approval of Human Subjects Research

8.1 All human subjects research conducted under the auspices of WVSOM's IRB must meet the criteria for one of the following methods for review:

8.1.1 Exempt

8.1.2 Expedited Review

8.1.3 Full Committee Review

8.2 No research involving human subjects may be conducted until all required institutional approvals, including the IRB, are obtained.

8.3 Research that has been approved by the IRB may be subject to review, modification, deferment, disapproval, suspension, or termination by the Institutional Official (President), Vice-Presidents, or Dean. Such actions may be made in WVSOM's best interest, provided that the aggrieved investigator is afforded all the appeal rights set forth in the HRPP Standard Operating Procedures. The WVSOM officials may strengthen requirements and/or conditions or add other modifications to secure WVSOM approval. Previously approved research proposals and/or consent forms must be reviewed and approved by the IRB before any such changes or modifications are initiated.

R 05-9. Appeal of IRB Decisions

An investigator may appeal an IRB decision to disapprove, defer, suspend, or terminate a research study. Detailed information concerning the appeals process is set forth in the HRPP Standard Operating Procedures.

R 05-10. IRB Records

WVSOM shall maintain, retain, and safeguard IRB records, study files, minutes, membership rosters, and other IRB documentation as required by federal and state law.

R 05-11. Procedures

WVSOM's IRB shall maintain operating procedures to implement this policy and serve as the HRPP Standard Operating Procedures for the conduct and review of all human research conducted under the auspices of WVSOM. Such operating procedures must be approved by the IRB Chair and follow the requirements set forth in WVSOM's Procedure for the Adoption, Amendment, or Repeal of Institutional Operating Procedures.

R 05-12. Implementation of Policy

This policy will be implemented using applicable WVSOM policies and procedures, including the HRPP Standard Operating Procedures.

R 05-13. References

13.1 Common Rule - Protection of Human Subjects, 45 C.F.R. 46.

13.2 Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report)

13.3 WVSOM HRPP Standard Operating Procedures.

13.4 WVSOM Institutional Policy R-04: Conflict of Interest in Research and Procedure for Institutional Policy R-04: Conflict of Interest in Research.