

INSTITUTIONAL POLICY: R-05

CATEGORY: Research

SUBJECT: Human Subject Research

EFFECTIVE DATE: August 20, 2010

LAST REVISION DATE: N/A

APPLICABILITY Faculty, Students, Staff, and all others involved in human subject research

R 05-1. Authority

1.1 WV Code §18B-1-6

1.2 WV CSR §133-4

R 05-2. Assurance

The West Virginia School of Osteopathic Medicine hereby gives notice that it will comply with the U.S. Department of Health and Human Services Public Welfare policy on Protection of Human Subjects (45 CFR 46) and the Food and Drug Administration (FDA) Policy on Protection of Human Subjects (21 CFR 50) and FDA policy on IRBs (21 CFR 56) in a manner set forth within the WVSOM Federal Wide Assurance (FWA) (# 00007632). This assurance is applicable to all research, training, and biological testing activities involving human subjects research conducted at this institution or at another institution as a consequence of the subgranting or subcontracting of an activity by this institution.

R 05-3. Definitions

3.1 Clinical investigation. Defined as in FDA regulation 21 CFR 50: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research, or marketing permit.

3.2 Human subject.

3.2.1 Defined as in the common rule (45 CFR 46): A living individual about whom an investigator (whether professional or student) conducting research obtains

3.2.1.1 Data through intervention or interaction with the individual, or

3.2.1.2 Identifiable private information.

- 3.2.2 Defined as in FDA regulation 21 CFR 50: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.
- 3.3 Research. Defined as in the common rule (45 CFR 46): A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

R 05-4. Policy

The West Virginia School of Osteopathic Medicine:

- 4.1 Will comply with all applicable provisions of the Common Rule (45 CFR 46) and the FDA (21 CFR 50 and 56) regarding human subjects research.
- 4.2 Is guided by the U.S. Government Principles described in the Belmont Code, which includes Respect for persons, Beneficence, and Justice.
- 4.3 Acknowledges and accepts responsibility for ethical treatment of human subjects involved in activities covered by the FWA assurance. This institution will make a reasonable effort to ensure that all individuals involved in the use of human subjects in research understand their individual and collective responsibilities for compliance with the assurance as well as all other applicable laws and regulations pertaining to human subjects research (including but not limited to HIPAA, FERPA and WV state laws). This institution has established written procedures for maintaining the FWA and updating it in a timely manner. Any changes to the FWA must be approved by the Assurance Signatory Official prior to the changes being made.
- 4.4 Has an Institutional Review Board (IRB) established in compliance 45 CFR 46 and 21 CFR 56. This IRB reviews and determines if activities are “research” as defined by 45 CFR 46 or “clinical investigation” as defined by 45 CFR 50 and whether they involve “human subjects.” The principle investigator (PI) must have a discussion with the IRB chair or designee prior to initiating ANY project involving humans. This IRB has written procedures in compliance with 45 CFR 46 and 21 CFR 50, and 56 that all IRB members and all investigators must follow. Any changes to these procedures must be approved by the IRB chair, the Associate Vice-President for Grants and Research, the Associate Dean for Assessment and Professional Development, and the Assurance Signatory Official prior to implementation.
- 4.5 Has a budget that allows for education of the IRB members, investigators, and other involved WVSOM employees.
- 4.6 Has written procedures that allow for the designation of other institutional review boards on our FWA as well as written procedures that allow for designation of the WVSOM IRB to other institutional FWAs. These latter procedures also indicate how WVSOM enters into cooperative agreements with other institutions for the purposes of FWA-IRB designation.