Alabama College of Osteopathic Medicine

Human Subjects Policy

PURPOSE

The purpose of this policy is to ensure protection of human subjects in research performed under the guidance of ACOM.

DEFINITIONS

1. Human subject – a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
2. Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
3. IRB– Institutional Review Board (for the purposes of this document this is ACOM's IRB)
4. Institutional Official – the key leader authorized to act on the College's behalf, specifically committing the College to compliance with all requirements of the Code of Federal Regulations, 45 CFR 46, and other applicable federal regulations (e.g., FDA 21 CFR 50 and 56).

POLICY

ACOM holds a federal-wide assurance (FWA 00022395, IRB IORG0008298, OMB NO. 0990-0279) from the

Office of Human Research Protection. Under this assurance, ACOM must comply with 45 CFR 46. ACOM chooses not to limit this assurance to federally funded research.

The IRB is the only entity delegated the authority to review all proposed research involving human subjects performed under the auspices of ACOM. All research involving human subjects must be reviewed and approved by the Human Protections Administrator prior to initiation of the research.

ACOM grants the IRB the authority:

1. To follow specific procedures that relate to the operation of the program of human subjects protections.
2. To approve, require modifications to secure approval, and disapprove all research activities involving human subjects overseen and conducted by ACOM.
3. To suspend or terminate IRB approval of research not being conducted in accordance with the IRB's requirements or that had been associated with expected serious harm to participants.

4. To observe, or have a third party observe, the consent process and the conduct of research involving human subjects.

No other College official or committee may approve human subjects research that has not been approved by the IRB. Any attempt to inappropriately influence the IRB will not be tolerated.

All researchers who plan to use human subjects in research must complete a training course on human subjects protections endorsed or sponsored by the Associate Dean of Research. Approval of an IRB application will be withheld until all project personnel have completed the course. A refresher course is required every three years to remain eligible to conduct research using human subjects.

The IRB may conduct for cause and not-for-cause audits to assure compliance. Failure to comply with federal regulations or IRB policies and procedures will result in the initiation of an investigation by the compliance manager. Findings and recommendations will be made by the IRB and may include remedial action including the termination of the project and/or disqualification of the researcher from conducting any further human subjects research. The researcher should communicate directly with the Human subjects administrator to resolve any concerns that may arise regarding a specific IRB decision.

Any individual may file suggestions or concerns regarding ACOM's IRB, research administration or IRB administrative procedures with the IRB Chair, Human Subjects Administrator or other College official as appropriate.