Rule Statement

Prairie View A&M University (PVAMU) will comply with applicable laws and regulations relating to human subjects research including 45 C.F.R., Part 46, 21 C.F.R., Part 50 and 21 C.F.R., Part 56. PVAMU ensures that all of its research involving human participants will comply with the terms of its Federal-wide Assurance for Protection of Human Subjects. This commitment to the protection of human subjects applies to all research involving human subjects for which PVAMU is responsible regardless of the location of the research and regardless of the source of funding or whether the research is funded or unfunded.

Reason for Rule

This University Rule is required by System Regulation 15.99.01 Use of Human Subjects in Research to provide guidance in complying with federal laws and regulations relating to research involving human subjects including upholding the ethical principles and guidelines set forth in The Belmont Report, April 18, 1979.

Official Procedures and Responsibilities

1. GENERAL

1.1 Prairie View A&M University (PVAMU) complies with regulations of the Department of Health and Human Services (DHHS) for the protection of human subjects involved in research (45 C.F.R. 46 Protection of Human Subjects as amended and published in the Federal Register). In the case of conflict between regulations of the funding or regulatory agency and DHHS, the more restrictive regulations shall prevail.

1.2 PVAMU recognizes the ethical principles, considerations, and concerns expressed in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (also known as The Belmont Report).

2. INSTITUTIONAL REVIEW BOARD (IRB)

2.1 All research conducted under the auspices of PVAMU, including cooperative research conducted with any public or private entity, in which human subjects
are involved, must be approved by an IRB prior to its initiation. IRBs from both entities will review and approve their respective scope of work for the entity.

2.2 The Vice President for Research and Graduate Studies serves as PVAMU’s Institutional Official and has oversight responsibility and appoints the chair and members of the IRB. Composition of the IRB will be consistent with the requirements specified in 45 C.F.R. §46.107.

3. HUMAN SUBJECT REVIEW AND APPROVAL

3.1 The PVAMU IRB review and approval process shall be conducted in accordance with the PVAMU Office of Research Regulatory Compliance IRB Human Participant Protocol, which governs the involvement of human subjects in research and sponsored programs whether funded or not funded. In addition, the review and approval process will be conducted in accordance with all Federal and State Laws, System Policies and Regulations. No activity involving human subjects may begin before it has been approved by an IRB.

3.1.1 The requirement for an IRB review and approval applies to all PVAMU employees and students, visiting professors/scientists, postdoctoral fellows, and other persons retained by, or working at, or for the University, irrespective of location. This includes cooperative research conducted with one or more private or public entities.

3.1.2 Persons unaffiliated with PVAMU who elect to investigate subjects who are under the protection of PVAMU, such as students, faculty, staff and/or patients are also subject to the IRB review and approval process outlined above.

3.2 Records related to research on human subjects, including any protected health information, will be retained in the Office of Research Regulatory Compliance in accordance with the University’s record’s retention schedule.

3.3 Non-compliance with Federal, State, System or University IRB review and approval procedures will be reported through the Risk, Fraud and Misconduct Hotline or submitted in writing to the University Compliance Office.

Related Statutes, Policies, Regulations and Rules

System Regulation 15.99.01 Use of Human Subjects in Research

45 C.F.R. Part 46

21 C.F.R. Part 50 and Part 56

5 U.S.C. 301

42 U.S.C. 289
The Belmont Report, April 18, 1979

Federal Policy for the Protection of Human Subjects ('Common Rule')

Additional U.S. Food and Drug Administration Regulations

Contact Office

Office of Research Compliance  936-261-1553