

**PRAIRIE VIEW A&M UNIVERSITY  
UNIVERSITY RULE**



**15.99.01.P1 Use of Human Subjects in Research**

Approved August 28, 2014

Revised May 21, 2019

Next Scheduled Review: May 2024

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**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.

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**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](#).

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**Official Procedures and Responsibilities**

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**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 CFR 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.
- 2.2 The Vice President for Research, Innovation and Sponsored Programs 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 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 Office of University Compliance.

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### **Related Statutes, Policies, Regulations and Rules**

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[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](#)

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**Contact Office**

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Office of Research Compliance      936-261-1553

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