15.99.01.K1 Use of Human Subjects in Research

Approved September 17, 2014
Revised September 17, 2014
Revised May 21, 2019
Next Scheduled Review: May 21, 2024

Rule Statement

Texas A&M University-Kingsville (TAMU-K) will comply with applicable laws and regulations relating to human subjects research including the Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45 C.F.R. Part 46) and others as applicable. TAMU-K assures that all of its research involving human subjects 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 rese

5.9.1.1. The review may be carried out by one, two or three faculty members of the IRB. At least one of the reviewers should, if possible, be in the subject area of the research being conducted.

5.9.1.2. The reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove research.

5.9.2. Expedited Review Exclusions

Expedited Review may not be used when identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.

5.10. Full Board Review

5.10.1 All studies that do not qualify for either Exempt Review or Expedited Review shall be subject to Full Board Review by the IRB.

5.10.2. All studies involving vulnerable populations, such as children (individuals under the age of 18 years), prisoners, and pregnant women will be reviewed by the full board.

6. TRAINING

6.1. All individuals conducting research (including faculty, staff, postdocs, research assistants, students, etc.) that involve human subjects are required to complete training successfully. Researchers may complete the appropriate Collaborative Institutional Trailing Initiative (CITI) Program cou F5 12 lk] TJ 2e9 ET BTMtianc3(h)-79n(would R)-25 12haeotl [(in)-uld m [(

Definitions

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