15.99.01.K1 Use of Human Subjects in Research

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Rule Summary

This rule is required by System Regulation *15.99.01*, *Use of Human Subjects in Research*. Texas A&M University-Kingsville (TAMUK) will comply with applicable laws and regulations relating to human subjects research including the Code of Federal Regulations (C.F.R.), Title 45, Part 46, Protection of Human Subjects (45 C.F.R. Part 46), the ethical principles and guidelines of the Belmont Report, and other laws and regulations as applicable. This commitment to the protection of human subjects applies to all research involving human subjects for whom TAMU-K is responsible regardless of location of the research and regardless of the source of funding or whether the research is funded or unfunded.

Definitions

Federal-wide Assurance (FWA) – The written assurance approved by the Office of Human Research Protections that the university will comply with the requirements for human subjects of research set forth in 45 C.F.R., Part 46 and 21 C.F.R. 56.

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (see 45 C.F.R. §46.102(f)).

Institutional Review Board (IRB) – The administrative body appointed by the vice president for research and innovation in accordance with 45 C.F.R. §46.107 to protect the welfare of human subjects in research activities conducted under the auspices of TAMU-K.

Research – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this rule, whether 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 (see 45 C.F.R. §46.102(d)).

Institutional Official – The Institutional Official (IO) is the individual authorized to act for the university and to assume on behalf of the university the obligations imposed by federal law and regulations. The vice president for research and innovation is the university's IO.

Rule

1. GENERAL

1.1. TAMUK has a responsibility to safeguard the rights and welfare of human subjects in research and other research activities. In compliance with federal regulations and the policy of The Texas A&M University System (System) (System Regulation *15.99.01*, *Use of Human Subjects in Research*), TAMUK requires all research involving human subjects to be approved by the TAMUK Institutional Review Board (IRB).

1.2. The vice president for research and innovation (VPRI) serves as the IO for the IRB, and is responsible for the human research protection program (HRPP) and ensuring compliance with all relevant policies and procedures.

1.3. The Research Compliance unit within the Office of Research and Innovation will submit annual reports of IRB submissions, approvals, amendments, renewals, and Post-Approval Monitoring (PAMs) to the IO. Adverse or unexpected events must be reported immediately to the IO.

1.4. Researchers seeking IRB approval may obtain the appropriate submission materials and information from the Office of Research and Innovation (ORI) or from the ORI Research Compliance IRB webpage.

1.5. TAMU-K maintains an FWA from the Office for Human Research Protections (OHRP). All research activities performed under the auspices of TAMU-K, including cooperative research conducted with one or more public or private entity or entities, in which human subjects are involved must be reviewed and approved by the TAMU-K IRB prior to initiation of the research to ensure that it is conducted in accordance with applicable laws and regulations, university rules and procedures, and ethical guidelines, including TAMU-K's FWA and 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and 28 C.F.R. Part 46

2. SCOPE OF THE IRB

2.1. TAMUK's IRB has jurisdiction over human subject research, subject to TAMUK's Federal-wide Assurance, and is charged with reviewing and approving any research activities involving the use of human subjects, and is responsible for safeguarding the rights and welfare of human subjects in research.

2.2. TAMU-K's IRB reports to the IO.

2.3. Review and Approval of Human Subjects Research

2.3.1. No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research.

2.3.2. It is the responsibility of the TAMU-K IRB to determine what activities constitute "human subjects research."

2.4. Failure to Submit a Project for IRB Review

2.4.1. If research involving human subjects is conducted without prior IRB review and approval, the matter will be referred to the IRB Chair and the IO.

3. MEMBERSHIP OF THE IRB

3.1. TAMUK's IO has oversight responsibility and appoints the chair and members of the IRB Committee. The composition of the IRB will be consistent with the requirements specified in 45 C.F.R. §46.107 as amended and published in the Federal Register. In the case of conflict between regulations of the funding or regulatory agency and the Department of Health and Human Services (DHHS), the more restrictive regulations will prevail.

3.1.1. The membership of the IRB will be subject to the following additional provisions to facilitate the review process:

1. TAMUK IRB must consist, whenever possible, of at least one faculty member from each college within TAMUK. The majority of IRB members must be from tenure/tenure-track faculty members.

2. TAMUK IRB must have on its committee at least one individual who is not otherwise affiliated with the institution or related to a person affiliated with the institution.

3. TAMUK IRB must have on its committee at least one non-scientific member.

3.2. Each faculty member of the committee will be appointed for a term of three years by the IO. Non-faculty members will be appointed for one year renewable terms.

3.3. A single member can serve multiple consecutive terms by mutual agreement between the IO (or the IO's designee) and the individual.

3.4. The IRB Chair must be appointed by the IO from among the tenured/tenure-track faculty at TAMUK. The IRB Chair must be appointed for a term of three years. The IRB Chair may serve multiple consecutive terms by mutual agreement between the IO (or the IO's designee) and the individual.

4. IRB REVIEW OF HUMAN SUBJECTS RESEARCH

4.1. TAMU-K's IRB will register with OHRP and comply with 46 C.F.R, Part 46, Subpart A and any other applicable federal or state, laws, regulations, and policies.

4.2. TAMUK's IRB will review all research on human subjects, regardless of source of funding, to determine whether the research is Exempt Review, Expedited Review, or Convened Review. Faculty conducting human subject research at a location other than

TAMUK must receive approval from TAMUK's IRB or establish a reliance agreement between TAMUK's IRB and the performance site IRB.

4.3. A specific protocol must be developed for each research activity.

4.4. Principal investigators and department heads (or equivalent) are responsible for ensuring that all research involving human subjects (including protocols which may be exempt, as defined by the federal regulations) is submitted to the IRB for review and/or approval.

4.5. Research protocols involving the use of human subjects must provide evidence of the following:

1. Risks are minimized through procedures consistent with sound research design (reasonable risk(s) beyond those incurred in daily life may be outweighed by benefits to the subjects).

2. Selection of subjects is equitable and the setting appropriate.

3. Informed consent is in accordance with state and federal regulations (45 C.F.R., Part 46).

4. Participation of human subjects must be voluntary, and the information provided to gain subject consent must be adequate and appropriate.

5. Consent is documented. Waivers of documentation must be granted in accordance with 45 C.F.R. 46.117.

6. Privacy and confidentiality are maintained consistent with TAMUK's obligation under the Texas Public Information Act.

7. Adequate provisions for monitoring data to ensure safety are made.

8. Appropriate safeguards for vulnerable populations are in place.

4.6. Primary Investigators must be notified via TAMUK email of the IRB's decision. Notification will include resubmittal instructions if required.

5. TRAINING

5.1. All individuals conducting research (including faculty, staff, postdocs, research assistants, students, etc.) that involves human subjects are required to complete training successfully. Researchers may complete the appropriate Collaborative Institutional Training Initiative (CITI) Program course for Social and Behavioral Researchers. One level of training is assigned to undergraduate and graduate level researchers while another more stringent course is assigned to faculty, staff, and Ed.D./Ph.D. candidates. Training is assigned by ORI staff.

5.2. The IRB Chair and/or the IRB Chair's designee, in conjunction with the ORI staff, are responsible for training faculty, students, staff, and new appointees to the IRB regarding additional procedures and requirements for the protection of human subjects.

5.3. The ORI is responsible for monitoring and maintaining records of faculty, staff, and students regarding training requirements for the protection of human subjects.

6. PROTECTED HEALTH INFORMATION

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) 42 U.S.C. §1320d, *et seq.*, contains provisions on the privacy of individually identifiable health information and establishes the conditions under which covered entities might release such information for research purposes. Research projects involving the acquisition of protected health information (PHI), as defined by the Act, from a covered entity are subject to review by the system's HIPAA Compliance Officer or designee, in addition to IRB review, before the IRB's approval is finalized. The study cannot be started prior to receiving both approvals.

7. NON-COMPLIANCE

7.1. Suspension

7.1.1. The IO may suspend any previously approved research for non-compliance with IRB protocol or unexpected serious harm to subjects.

7.1.2. The IRB may suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects as found in 45 C.F.R. §46.113.

7.1.3. Any suspension or termination of approval must include a statement of the reasons for the IRB or IO's action and must be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

7.2. Reporting

Reports of non-compliance must be made to the IO or the IRB Chair or designee via direct reporting, ORI staff, or EthicsPoint hotline/website. Any allegation of noncompliance with federal rules on a project with a federal agency-sponsored grant must also be reported to the A&M System chief research compliance officer.

8. IRB RECORDS AND DOCUMENTS

The ORI will obtain and maintain documentation of IRB activities as defined by Federal regulations. This documentation will include, but is not limited to, copies of all research proposals reviewed, continuing review reports, reports of injuries to subjects, copies of all correspondence between the IRB and the Investigators, minutes of IRB meetings, and the IRB Policy Manual which has the written procedures for the IRB as required by 45 C.F.R. Part 46. These records will be maintained in accordance with state and federal laws and regulations, as well as system policies and regulations.

Related Statutes, Policies, or Requirements

45 C.F.R., Part 46

21 C.F.R., Part 56

34 C.F.R. Part 99 (FERPA)

Public Law 104-191 (HIPPA)

The Belmont Report, April 18, 1979

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

U.S. Department of Health and Human Services Expedited Review

System Regulation *15.99.01, Use of Human Subjects in Research*

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