Rule 15.99.01.K1 Use of Human Subjects in Research

Approved Sept. 17, 2014
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Next Scheduled Review: Sept. 17, 2019

Rule Statement

Texas A&M University-Kingsville 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. Texas A&M University-Kingsville 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 research involving human subjects for whom Texas A&M University-Kingsville is responsible regardless of location of the research and regardless of the source of funding or whether the research is funded or unfunded.

Reason for Rule

This rule is required by System Regulation *15.99.01, Use of Human Subjects in Research*.

Procedures and Responsibilities

1. GENERAL

1.1 Texas A&M University-Kingsville (TAMU-K) 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 Regulation 15.99.01, *Use of Human Subjects in Research*), the University requires all research involving human subjects to be approved by the TAMU-K Institutional Review Board (IRB).

1.2 Researchers seeking approval for projects may obtain the appropriate forms from the Office of Research and Sponsored Programs (ORSP) at telephone number 361-593-3344 or from the IRB webpage at http://www.tamuk.edu/osr/.

1.3 Quarterly, in January, April, July, and October, ORSP shall submit a report to the IRB and the Associate Vice President for Research and Graduate Studies (AVPR) listing all protocols reviewed during the previous quarter by the IRB, including a

summary of any adverse events and the IRB's response to those events. The AVPR also serves as the Institutional Official.

2. SCOPE OF THE IRB

TAMU-K's IRB has jurisdiction over human subject research, subject to TAMU-K's Federal-wide Assurance.

2.1 Review and Approval of Human Subjects Research

2.1.1 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.

2.1.2 It is the responsibility of the IRB Chair, his/her designee, or the full IRB to determine what activities constitute "human subjects research."

2.2 Failure to Submit a Project for IRB Review

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

3. MEMBERSHIP OF THE IRB

3.1 TAMU-K's IRB membership is defined by Federal regulations in *45 CFR §46.107*. The IRB will be sufficiently qualified through the experience and expertise of its members and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Currently, TAMU-K has two IRBs.

3.1.1 IRB #1 is the primary committee utilized by TAMU-K during the Fall and Spring academic semesters. The membership of IRB #1 will be subject to the following additional provisions to facilitate the review process:

3.1.1.1 TAMU-K IRB #1 shall consist, whenever possible, of at least one faculty member from each College within TAMU-K. The majority of IRB members shall be from the tenure/tenure-track faculty members.

3.1.1.2 TAMU-K IRB#1 shall have on its committee at least one individual who is not otherwise affiliated with the institution.

3.1.1.3 TAMU-K IRB#1 shall have at least one non-scientific member.

3.1.2 IRB #2 is the primary committee utilized by TAMU-K during the summer semesters. The membership of IRB #2 overlaps the membership of IRB #1. The membership of IRB #2 will be subject to the following additional provisions to facilitate the review process:

3.1.2.1 TAMU-K IRB #2 shall consist of at least three tenure/tenure-track faculty members.

3.1.2.2 TAMU-K IRB #2 shall have on its committee at least one individual who is not otherwise affiliated with the institution.

3.1.2.3 TAMU-K IRB #2 shall have at least one non-scientific member.

3.2 Each member of the committees will be appointed for a term of three years by the Chief Executive Officer (CEO) or the CEO's designee. The designee at TAMU-K is the AVPR.

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

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

4. MEETINGS OF THE IRB

The IRBs will convene meetings as needed to conduct Full Board Reviews, or at least twice a year, whichever is greater. Research will be reviewed at convened meetings at which the majority of the IRB members are present. Quorum for the meeting is defined as a simple majority, including at least one member whose primary concerns are in non-scientific areas. IRB#1 may establish its own operating procedures within these prescribed guidelines. IRB#2 will abide by the operating procedures established by IRB#1.

5. IRB REVIEW OF HUMAN SUBJECTS RESEARCH

TAMU-K's IRBs will review human subjects research activities to determine whether the research is Exempt Review, Expedited Review, or Full Board Review. Faculty conducting human subject research at a location other than TAMU-K must receive approval from TAMU-K's IRB or establish a reliance agreement between TAMU-K's IRB and the performance site IRB.

A specific protocol shall be developed for each research activity.

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 approval.

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

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

5.1.2 Selection of subjects is equitable and the setting appropriate.

5.1.3 Informed consent is in accordance with state and federal regulations.

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

5.1.5 Consent is documented. Waivers of documentation shall on be granted in accordance with *45 CFR 46.117*.

5.1.6 Privacy and confidentiality are maintained consistent with TAMU-K's obligation under Texas Public Information Act.

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

5.1.8 Appropriate safeguards for vulnerable populations are in place.

5.2 Primary Investigators shall be notified via university email of the IRB's decision. Notification will include resubmittal instructions if required.

5.3 All documentation associated with IRB reviews is maintained by the ORSP. ORSP provides staff support to the IRB in all phases of its work, including tracking and monitoring submissions, and maintaining records related to all research involving human participants. The department of Graduate Studies is responsible for determining that projects involving human participants for thesis and dissertation research have received approval by the IRB before data collection begins.

5.4 Continuing review of research protocols is conducted at intervals appropriate to the degree of risk, but not less than once per academic year. The IRB can approve a protocol for 12 months and a continuation/renewal for an additional 12 months. If the investigator, during the course of conducting the research, revises the protocol (e.g., makes changes to the informed consent form, survey instruments used or number and nature of participants), he/she must submit immediately an addendum to the approved protocol for review by the IRB.

5.5 Exempt Review

5.5.1 Eligibility for Exempt Review

The IRB Chair (or the Chair's designee) may determine a research activity to be exempt only when the involvement of human subjects will be in one or more of the exemption categories, found in *45 C.F.R. 46.*

5.6 Expedited Review

5.6.1 Eligibility for Expedited Review

The IRB may permit the use of Expedited Review procedures for eligible human subject research activities, as defined by Federal regulations. The IRB may use an Expedited Review procedure to review either or both of the following:

5.6.1.1 Research that involves no more than minimal risk or which appears on the list of Expedited Review categories as defined by Office of Human Research Protections.

5.6.1.2 Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

5.6.1.3 Continuing review of previously approved expedited studies.

5.6.1.4 Continuing review of previously approved full board studies that have gone through at least one renewal cycle at the full board level and approved by the full board for continuing review under the expedited category.

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b. where no subjects have been enrolled and no additional risks have been identified; or

c. where the remaining research activities are limited to data analysis.

5.6.2 Expedited Review Procedure

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.

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

5.6.3 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.

5.7 Full Board Review

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

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 involves human subjects are required to complete training successfully. Researchers may complete the CITI *Students conducting no more than minimal risk research* course or *the NIH Protecting Human Research Participants Training* course. Training is assigned by ORSP staff.

6.2 The Chair and/or others the Chair's designee, in conjunction with the ORSP 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.

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

7. 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.

8. NON-COMPLIANCE

8.1 Suspension

8.1.1 The AVPR as Chief Research Compliance Officer may suspend any previously approved research for non-compliance with IRB protocol or unexpected serious harm to subjects.

8.1.2 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.*

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

8.2 Reporting

Reports of non-compliance shall be made to the Chief Research Compliance Officer or the IRB via direct reporting, ORSP staff, or EthicsPoint hotline/website.

9. IRB RECORDS AND DOCUMENTS

The Office of Research and Sponsored Programs (ORSP) 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.*

Related Statutes, Policies, or Requirements

45 C.F.R., Part 46 (The Common Rule)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

The Belmont Report, April 18, 1979
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

34 C.F.R. Part 99 (FERPA)
http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=11975031b82001bed902b3e73f33e604&rgn=div5&view=text&node=34:1.1.1.1.33&idno=34

Public Law 104-191 (HIPPA)

http://www.gpo.gov/fdsys/pkg/PLAW-104publ191/html/PLAW-104publ191.htm

System Regulation 15.99.01 – *Use of Human Subjects in Research*
http://www.tamus.edu/offices/policy/policies/

TAMU-K IRB Procedures Manual
http://www.TAMU-K.edu/osr/forms.html

Definitions

Federal-wide Assurance (FWA) is 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.*

Human Subject means 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) is the administrative body appointed by the Vice President for Research and Graduate Studies in accordance with *45 C.F.R. §46.107* to protect the welfare of human subjects in research activities conducted under the auspices of Texas A&M University-Kingsville.

Research means 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 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 (*see 45 C.F.R. §46.102(d)).*

Contact Office

The Office of Research and Sponsored Programs
(361) 593-3344