15.99.01.D1 Use of Human Subjects in Research

Approved: July 28, 2014
Revised: August 5, 2019
March 28, 2025
Next Scheduled Review: March 28, 2030

Rule Summary

Texas A&M University-Central Texas (A&M-Central Texas) will comply with applicable laws and regulations relating to human subjects research including 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56. A&M-Central Texas assures that all its research involving human participants will comply with the terms of its Federalwide Assurance (FWA) for Protection of Human Subjects. This commitment to comply with the Common Rule (46 C.F.R, Part 46, Subpart A) will apply to all non-exempt human subjects research that A&M-Central Texas is engaged in regardless of funding source.

This rule is required by System Regulation 15.99.01, *Use of Human Subjects in Research*, and is developed to ensure compliance with federal and state laws and regulations, and university procedures applicable to the protection of human research subjects, including the ethical principles and guidelines set forth in The Belmont Report, April 18, 1979, for the protection of human subjects of research, and in the Declaration of Helsinki.

Definitions

Federalwide Assurance (FWA) is the written assurance approved by the U.S. Department of Health and Human Services' (HHS) Office of Human Research Protections (OHRP) that the university will comply with the U.S. federal regulations for the protection human subjects in research.

Human Research Protection Program (HRPP), in cooperation with the IRB and Institutional Biosafety Committee (IBC), is responsible for the protection of the rights and welfare of human subjects who participate in research conducted under the auspices of A&M-Central Texas and by A&M-Central Texas faculty, staff and students. The head of the HRPP, who reports to the IO, is the Deputy Chief Research Officer.

Human Subject for the purposes of this rule is defined by HHS and means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (*see* 45 C.F.R. §46.102(e)). There are different definitions for human subjects under the U.S. Food and Drug Administration (FDA) (*see* 21 C.F.R. §§56.102has and 812.3(p)).

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. (*See* 45 C.F.R. §46.103(c)). The Chief Research Officer (CRO) is the IO and is the individual who executes the FWA and is responsible for determining the overall management of the IRB and IBC. Day-to-day management of the IRB and IBC and administrative/management staff operate under the delegated authority of the IO.

The Institutional Biosafety Committee (IBC) is the administrative body appointed by and reporting to the CRO, in accordance with the National Institute of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines). The chair of the IBC is selected by the CRO in collaboration with the IBC membership.

Institutional Review Board (IRB) is the administrative body appointed by and reporting to the CRO in accordance with 45 C.F.R. §46.107. The chair of the IRB is selected by the CRO in collaboration with the IRB membership.

Principal Investigator/PI means an individual under whose immediate direction research is conducted or, in the event of research conducted by a team of individuals, is the leader of that team. A student may only serve as a Co-Principal Investigator/Co-PI on a faculty-sponsored study.

Research for purposes of this rule is defined by HHS and means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (*see* 45 C.F.R. §46.102(l)). Activities that meet this definition constitute research for purposes of this rule, whether they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. There are different definitions for research under the FDA (*see* 21 C.F.R. §50.3(c) and 56.102(c)).

Rule

1. GENERAL

    1.1 All A&M-Central Texas's activities related to human subjects research, regardless of the source of funding, will be guided by the ethical principles and guidelines set forth in The Belmont Report, published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and in the Declaration of Helsinki.

    1.2 A&M-Central Texas will obtain an FWA from OHRP. All research activities involving human subjects that are performed under the auspices of A&M-Central Texas, including cooperative research conducted with one or more public or private entity or entities, must be reviewed and approved by the A&M-Central Texas 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 A&M-Central Texas's FWA and 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56. Some research activities may involve human subjects in biosafety research; these research activities must be reviewed by the IBC as well as the IRB.

1.3 In the conduct of cooperative research projects involving more than one institution, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable laws and regulations. Joint review arrangements, where the university seeks to rely on the review of another qualified IRB, or similar arrangements, must be documented in writing and are subject to approval by the IO.

1.4 The IO has oversight responsibility for the A&M-Central Texas IRB, which reports to the IO. Composition of the A&M-Central Texas IRB will be consistent with the requirements specified in 45 C.F.R. §46.107.

2. IRB REVIEW OF RESEARCH

2.1 The A&M-Central Texas IRB will register with OHRP and comply with the Common Rule and any other applicable federal or state laws, regulations, and policies.

2.2 The A&M-Central Texas IRB has authority to review, approve, disapprove or require changes in research or related activities involving human subjects in accordance with applicable federal regulations, including 45 C.F.R. §46.109. The IRB also has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unanticipated serious harm to human subjects but does not have the authority to retroactively approve research started without prior IRB approval. Reviews of research protocols will be conducted at meetings of the full board of the IRB, which must occur at least once every long semester, or by other appropriate mechanisms determined by the IRB. Minutes will be recorded and written up for each full board meeting and must be approved by the IRB at a later meeting.

2.3 The A&M-Central Texas IRB will establish specific criteria for approval of research protocols in accordance with relevant federal, state, system, and university guidelines.

2.4 The A&M-Central Texas IRB will require that information given to human subjects as part of an informed consent process is in accordance with applicable federal regulations, including 45 C.F.R. §46.116. The IRB may require that additional information, beyond that specifically mentioned in the regulations, be given to the human subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of human subjects and to the ability of those human subjects to give appropriate informed consent.

2.5 The A&M-Central Texas IRB will require documentation of informed consent or may waive documentation in accordance with applicable federal regulations, including 45 C.F.R. §46.117.

2.6 The A&M-Central Texas IRB will notify investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. No research activity may be started prior to the receipt by the PI of final approval from the IRB Chair (or his or her designee). If the IRB decides to disapprove a research activity, it must include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Any suspension or termination of IRB approval will be reported promptly to the investigator, appropriate university officials (including the IO), and relevant federal agencies and research sponsors.

2.7 The A&M-Central Texas IRB will conduct continuing reviews of research covered by this rule at intervals appropriate to the degree of risk as required by federal regulations (e.g., 45 C.F.R. §46.109), but not less than once per year, and will have authority to observe or have a third party observe the consent process and the research.

2.8 The A&M-Central Texas IRB has the authority to determine whether an activity falls within the HHS definition of Research that involves Human Subjects and may set criteria in its policies and procedures, consistent with applicable state and federal laws and regulations, for research that does not need IRB approval.

2.9 Research covered by this rule that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by the IO. However, the IO may not reverse IRB decisions involving disapproval, deferral, suspension, or termination of a research study.

3. POLICIES AND PROCEDURES

3.1 The IRB will maintain policies and procedures reflecting current practices of the IRB in conducting reviews and approvals. The policies and procedures will be consistent with federal requirements, including those specified in 45 C.F.R., Part 46. All IRB policies and procedures are fully documented in the A&M-Central Texas IRB Standard Operating Procedures (SOPs), which must be reviewed by all PIs prior to completing a protocol form for submission to the IRB to make sure the PI is aware of all relevant information regarding submission of a research protocol. The policies and procedures will be reviewed at least every 36 months and will include procedures for:

3.1.1 Conducting IRB initial and continuing review (not less than once per year) of research and for reporting IRB findings and actions to the investigator and the university;

3.1.2 (ii) Determining which projects require review more often than annually, and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;

3.1.3 Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject; and

3.1.4 Ensuring prompt reporting to the IRB, appropriate university officials, the head of any U.S. federal department or agency conducting or supporting the research (or designee), OHRP, and other external entities, as required, of (a) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB; and (b) any suspension or termination of IRB approval.

3.2 New IRB policies and procedures or revisions may be recommended by faculty, staff, researchers, IRB members, the convened full board of the IRB, and by any IRB subcommittee.

3.3 Exempt and Expedited Review

3.3.1 Consistent with federal requirements, the IRB may develop and use procedures for exempt and expedited reviews of research involving no more than minimal risk, and/or minor changes in previously approved research during the period (of one year or less) for which approval is authorized, if those protocols meet the federal guidelines for those categories as determined by the IRB.

3.3.2 If the IRB uses an exempt or expedited review procedure, it will adopt a method for keeping all members advised of research proposals that have been approved under that procedure.

3.3.3 The IO may restrict, suspend, terminate or choose not to authorize an IRB's use of an exempt or expedited review procedure, provided, however, that the IO cannot reverse IRB decisions involving disapproval, deferral, suspension, or termination of a research study.

4. PROTECTED HEALTH INFORMATION

4.1 The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the regulations promulgated thereunder contain provisions to protect patients from inappropriate disclosures of their protected health information (PHI), as defined under HIPAA. HIPAA establishes the conditions under which covered entities are allowed to disclose PHI to researchers to access and use such PHI for research purposes. When human subjects research involves the disclosure of PHI from a covered entity, The A&M-Central Texas IRB will review and approve such research taking into account HIPAA.

5. RECORD RETENTION

5.1 The IRB Chair and/or the Office of Research will obtain and maintain all appropriate records including, but not limited to, copies of all protocols reviewed, continuing review reports, documentation of informed consent procedures, reports of any adverse events in research studies, meeting minutes, and records of all correspondence to/from principal investigators of official actions, for a minimum of three years from the completion of a research project. Official records will be maintained in the Office of Research. For FDA-regulated studies, the retention requirements under FDA regulations will need to be complied with.

6. TRAINING, OUTREACH AND EDUCATION PLAN

6.1 The Faculty Scholarship Research Committee (FSRC) is responsible for finalizing, communicating, implementing and maintaining a Training, Outreach and Education Plan (Plan) for research. The Plan will be developed by the IRB prior to submission to the FSRC and will determine the process used to ensure that individuals involved with human research protection have appropriate knowledge and skills. The Plan may be included in the IRB SOPs. All researchers testing human subjects must undergo human subjects

protection training prior to starting their projects. The certificate that verifies the training, which is submitted with the research protocol, must be valid throughout the entire time the protocol is active. All members of the IRB must also maintain current human subjects protection training for IRB reviews, as required by the HRPP.

7. REPORTING NONCOMPLIANCE

7.1 Reports or allegations of noncompliance by researchers, or individuals other than researchers, such as research staff, IRB staff, IRB members, with federal and state laws and regulations, IRB requirements, this university rule or related procedures, or system related policies and regulations, may be submitted to the IRB chair, the Research Compliance Officer, and the Chief Research Officer. The processing of reports or allegations of noncompliance will be conducted according to IRB policies and procedures. 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.

Related Statutes, Policies, or Requirements

42 U.S.C. §1320d, *et seq.*

45 C.F.R., Part 46

21 C.F.R., Parts 50 (312 and 812) and 56

Belmont Report

NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

Texas Government Code, Chapter 552

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

System Regulation *15.99.05, Research Compliance*

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