

15.99.01.D1 Use of Human Subjects in Research

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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 of its research involving human participants will comply with the terms of its Federalwide Assurance (FWA). This commitment to the protection of human subjects applies to all research involving human subjects for which A&M-Central Texas is responsible regardless of location of the research and regardless of the source of funding or whether the research is funded or unfunded.

Definitions

Cooperative Research means research conducted under a cooperative agreement approved by the Office of Human Research Protection in which multiple institutions agree to participate in a research project while relying on one primary Institutional Review Board's review and approval to avoid duplication of effort.

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 (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)), *see also* 21 C.F.R. §§56.102(e) 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 is the university's Institutional Official for purposes of this rule and is the individual who executes the FWA and is responsible for determining the overall management of the IRB. Day-to-day management of the IRB and HSPP, and administrative/management staff operate under the delegated authority of the Institutional Official (IO); the IO is the Chief Research Officer/Human Subjects Administrator (CRO/HRA).

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

Non-compliance for purposes of this rule means the failure to comply with state and federal regulations, system policies or regulations, university rules or procedures, IRB procedures or the requirements or determinations of the IRB in the conduct of human subjects research.

Principal Investigator/PI means the individual responsible for the conduct of a human subjects research study as described in this rule. A student may only serve as a Co-Principal Investigator/Co-PI on a faculty-sponsored study.

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(l)) and 21 C.F.R. §50.3(c).

Rule

1. GENERAL

1.1 A&M-Central Texas 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* (The Belmont Report).

1.2 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 Institutional Review Board (IRB) prior to initiation of the research in accordance with A&M-Central Texas's FWA and 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56.

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, are subject to approval by the Institutional Official.

1.4 The Institutional Official (IO) has oversight responsibility for the IRB, which reports to the IO. Composition of the IRB will be consistent with the requirements specified in 45 C.F.R. §46.107.

2. IRB REVIEW OF RESEARCH

2.1 The 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 each 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.

2.2 The IRB shall establish specific criteria for approval of research protocols in accordance with relevant federal, state, system, and university guidelines.

2.3 The IRB shall require that information given to human subjects as part of an informed consent process is in accordance with applicable federal regulations. 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.

2.4 The IRB shall require documentation of informed consent or may waive documentation in accordance with applicable federal regulations, including 45 C.F.R. §46.117.

2.5 The IRB shall 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 shall 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 approval will be reported promptly to the investigator, appropriate university officials (including the IO), and relevant federal agencies and research sponsors.

2.6 The IRB shall conduct continuing reviews of research covered by this rule at intervals appropriate to the degree of risk as required by federal regulations (e.g., the Common Rule), but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

2.7 The IRB has the authority to determine whether or not an activity falls within the definition of Human Subjects Research and may set criteria in its policies and procedures, consistent with applicable state and federal laws and regulations, for research which does not need IRB approval.

2.8 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. The policies and

procedures will be reviewed at least every 36 months and will include procedures (i) for conducting IRB initial and continuing review of research and for reporting IRB findings and actions to the investigator and the university; (ii) for 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; and (iii) for 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 procedures to ensure prompt reporting to the IRB, appropriate university officials, and external entities 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. All IRB policies and procedures are fully documented in the A&M-Central Texas IRB Handbook, 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.

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, as long as 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 shall adopt a method for keeping all members advised of research proposals which have been approved under that procedure.

The IO may restrict, suspend, terminate, or choose not to authorize an IRB's use of an exempt or expedited review procedure.

4. PROTECTED HEALTH INFORMATION

4.1 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 obtaining protected health information (PHI), as defined by the Act, from a covered entity are subject to review by the A&M System 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.

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.

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 Handbook. 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.

7. REPORTING NONCOMPLIANCE

7.1 Reports or allegations of noncompliance with federal regulations, IRB requirements, this rule or related system regulation 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 Research Compliance Office.

Related Statutes, Policies, or Requirements

42 U.S.C. §1230d, *et seq.*

[45 C.F.R., Part 46](#)

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

[Belmont Report](#)

56 Fed. Reg. 28012, 28022, June 18, 1991, as amended at 70 Fed. Reg. 36328, June 23, 2005

[Texas Government Code, Chapter 552](#)

System Regulation [15.99.01, Use of Human Subjects in Research](#)

Contact Office

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