15.99.01.W1 Use of Human Subjects in Research

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Rule Summary

West Texas A&M University 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. West Texas A&M University (WTAMU) assures that all its research involving human subjects will comply with the terms of its Federal wide Assurance (FWA) for Protection of Human Subjects. This commitment to the protection of human subjects applies to all research involving human subjects for whom WTAMU is responsible regardless of location of the research and regardless of the source of funding or whether the research is funded or unfunded.

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

Rule

1. GENERAL

1.1 All WTAMU's activities related to human subjects research, regardless of the source of funding, will be guided by 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 WTAMU will obtain an FWA from the U.S. Department of Health and Human Services' (HHS) Office of Human Research Protections (OHRP). All research activities performed under the auspices of WTAMU, 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 an 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 WTAMU's FWA and 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56.

1.2.1 The Office of Research and Compliance is responsible for maintaining an active FWA.

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 single IRB reliance agreements, must be documented in writing and will be utilized as appropriate and are subject to approval by the Institutional Official (IO).

1.4 The IO has oversight responsibility and authority for WTAMU's IRB and appoints the chair and members of the IRB. 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 WTAMU IRB will register with OHRP and comply with 45 C.F.R., Part 46 and any other applicable federal or state, laws, regulations, and policies.

2.2 The WTAMU 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 unexpected serious harm to human subjects, but does not have the authority to retroactively approve research started without prior IRB approval.

2.3 The WTAMU IRB must require that information given to human subjects as part of informed consent is in accordance with applicable federal regulations including 45 C.F.R. §46.116. The IRB may require that information, in addition to 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 subjects and to the ability of those human subjects to give appropriate informed consent.

2.4 The WTAMU IRB must 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 WTAMU IRB must notify investigators and the Academic and Research Environmental Health and Safety Office, 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. 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 appropriate federal agencies and research sponsors.

2.6 The WTAMU IRB must conduct continuing reviews of research covered by this rule at intervals appropriate to the degree of risk as required by federal regulations (see 45 C.F.R. §46.109), but not less than once per year, and must have authority to observe or have a third party observe the consent process and the research.

2.7 The WTAMU IRB has the authority to determine whether an activity falls within the HHS definition of Research that involves Human Subjects and may set the criteria in its policies and procedures, consistent with applicable state and federal laws and regulations, for exemption.

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 an IRB's decision involving disapproval, deferral, suspension, or termination of a research study.

2.9 Information relating to IRB processing times will be made available by the Academic and Research Environmental Health and Safety Office.

3. PROCEDURES

3.1 The WTAMU IRB will maintain procedures reflecting current practices of the IRB in conducting reviews and approvals. The procedures will be consistent with federal requirements, including those specified in 45 C.F.R., Part 46. The procedures will be reviewed at least every 24 months and will include procedures:

3.1.1 for conducting IRB initial approval,

3.1.2 for continuing review of research,

3.1.3 for reporting IRB findings and actions to the investigator and the university,

3.1.4 for determining which projects require review more often than annually,

3.1.5 for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review,

3.1.6 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

3.1.7 for having procedures to ensure 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:

3.1.7.1 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,

3.1.7.2 any suspension or termination of IRB approval.

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

3.3 Exempt and Expedited Review

3.3.1 Consistent with federal requirements, the WTAMU IRB may develop and use procedures for exempt and expedited review 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 Under an expedited review procedure, the review may be carried out by the WTAMU IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB. In reviewing the research, the reviewer(s) may exercise all the authorities of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in the federal regulations.

3.3.3 If the IRB uses an expedited review procedure, it must adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

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

3.4 Student research projects are reviewed using the same principles and guidelines followed by the IRB for the protection of human subjects. Any student-initiated and/or student-conducted human subjects research must be reviewed and approved by the IRB prior to initiation as described above in section 1.2—including graduate theses, dissertation research, and honors theses. For all student research projects, a faculty member must be listed in the IRB Application as the Principal Investigator for the study. The student should be listed in the IRB Application as the co-investigator (with the student researcher designation in the application). In cases of funded research, the Principal Investigator identified in the funding instrument should be listed as the investigator in the IRB Application. If the student is conducting research in a laboratory space, the Principal Investigator of the laboratory space must provide approval of the research process and for research to be conducted in his or her laboratory setting before seeking IRB approval. The faculty advisor and laboratory Principal Investigator may or may not be the same person. The Academic and Research Environmental Health and Safety Office must also approve the use of the laboratory space.

3.4.1 Individuals serving as faculty advisors/Principal Investigator are responsible for:

3.4.1.1 overseeing the design and conduct of the study;

3.4.1.2 ensuring that the student serving as Principal Investigator is appropriately trained and competent to perform the study;

3.4.1.3 reviewing the protocol application prior to submission to the IRB;

3.4.1.4 providing guidance in the protection of human subjects;

3.4.1.5 assuring proper application and reporting to the IRB;

3.4.1.6 working with the student to identify modifications warranted by unanticipated problems or circumstances involving risks to human subjects and others; and,

3.4.1.7 confirming the scientific validity of the study, and confirming, in writing, his or her agreement to fulfill the foregoing responsibilities before a protocol can be approved.

3.4.2 Students are not permitted to serve as the principal investigator for any WTAMU human subjects research proposal.

3.4.3 Except as otherwise provided by law, the responsibilities outlined in this section apply notwithstanding any conflicting responsibilities described in this rule or in IRB procedures.

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 WTAMU IRB will review and approve such research taking into account HIPAA.

5. RECORD RETENTION

5.1 The Academic and Research Environmental Health and Safety Office, in conjunction with the IRB Chair, is responsible for maintaining records related to the functions and activities of the IRB 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/study, as prescribed by the university's records retention policy in Texas A&M University System *61.99.01, Retention of State Records.* For studies regulated by the U.S. Food and Drug Administration (FDA), the retention requirements under FDA regulations must be complied with.

6. TRAINING

6.1 The Academic and Research Environmental Health and Safety Office, in conjunction with the IRB chair, is responsible for developing, communicating, implementing, and maintaining training. Training will be approved by the IRB prior to implementation. Training is necessary to ensure that individuals involved with human research protection have appropriate knowledge and skills. WTAMU requires all individuals conducting or participating in research projects (including faculty, staff, and students) that involve human subjects (or serving on the IRB committee) to complete training for the Protection of Human Subjects. This requirement is met by the successful completion of the online training module(s) from the Collaborative Institutional Training Initiative (CITI). All members of the IRB must also maintain current human subjects protection training for IRB reviews, as required by WTAMU's Human Research Protection Program.

7. REPORTING NON-COMPLIANCE

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 the related procedures, or system related policies and regulations, may be submitted to the IRB chair or the IO. Reports may also be made online via the WTAMU Research Compliance Helpline. 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.

Definitions

Cooperative Research means research conducted under a cooperative agreement approved by the Office of Research 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 OHRP that WTAMU will comply with the U.S. federal regulations for the protection of human subjects in research.

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 obtains (1) data 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 FDA (see 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 Vice President for Research and Compliance is the university's IO for purposes of this rule and is the individual who executes the FWA and is responsible for determining the management of the IRB. Day-to-day management of the IRB, and administrative/management staff operate under the delegated authority of the IO.

Institutional Review Board (IRB) is the administrative body appointed by the Vice President of Research and Compliance. The IRB will report to the Vice President of Research and Compliance in accordance with 45 C.F.R. §46.107 to protect the welfare of human subjects in research activities conducted under the auspices of WTAMU. The chair of the IRB is appointed by the IO.

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 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 not serve as Principal Investigator on any study.

Research for the 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 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. There are different definitions for research under the FDA (see 21 C.F.R. §50.3(c)) and 56.102(c)).

Related Statutes, Policies, or Requirements

45 C.F.R. Part 46
21 C.F.R. Part 50 and Part 56
5 U.S.C. 301
42 U.S.C. 289
The Belmont Report, April 18, 1979
Additional U.S. Food and Drug Administration Regulations
Texas Government Code, Chapter 552
System Regulation 15.99.01 – Use of Human Subjects in Research
WTAMU IRB Manual

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