Rule 15.99.01.T1 Use of Human Subjects in Research

Approved:	October 3, 2014
Reviewed:	October 9, 2018
Next Scheduled Review:	October 9, 2023

Rule Statement

Tarleton State University (Tarleton) 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. Tarleton assures that all of its research involving human subjects will comply with the terms of its Federalwide Assurance for Protection of Human Subjects. This commitment to the protection of human subjects applies to all research involving human subjects for whom Tarleton 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 provides guidance in complying with federal laws and regulations relating to research involving human 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.

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.

Federalwide 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 (or Participant) 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)), *see also* 21 C.F.R. §§56.102(e) and 812.3(p)).

Human Subjects Protection Program (HSPP) is an office reporting to the Office of Faculty Research in the Office of Sponsored Projects and is responsible for providing support to the Institutional Review Board and implementing a program of compliance oversight.

Institutional Official 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 associate vice president for academic research 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 management of the IRB and HSPP. Day-to-day management of the IRB and HSPP, and administrative/management staff operate under the delegated authority of the Institutional Official.

Institutional Review Board (IRB) is the administrative body appointed by and reporting to the Associate Vice President for Academic Research in accordance with 45 C.F.R. §46.107 and Tarleton Rule 15.01.01.T1 –*Use of Human Subjects in Research* to protect the welfare of human subjects in research activities conducted under the auspices of Tarleton. The chair of the IRB is appointed by the university president.

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.

Protocol Director, also known as the Principal Investigator (PI), is the individual responsible for the conduct of a human subjects research study as described in this rule.

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)) and 21 C.F.R. §50.3(c).

Procedures and Responsibilities

1. GENERAL

1.1 Tarleton 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 performed under the auspices of Tarleton, 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 in accordance with Tarleton's 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 has oversight responsibility and authority for the university's HSPP and appoints the chair and members of the IRB, while the university president appoints the chair. 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 unexpected serious harm to human subjects.

2.2 The IRB **DOES NOT** have authority to grant retroactive approval should research commence without prior IRB approval, and the Institutional Official may not reverse IRB decisions involving disapproval, deferral, suspension or termination of a research study.

2.3 The IRB shall 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 additional information 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.

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, based upon specific conditions of a given protocol.

2.5 The IRB shall notify investigators and the HSPP 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 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 Institutional Official, and appropriate federal agencies.

2.6 The IRB shall conduct continuing reviews of research covered by this rule at intervals appropriate to the degree of risk, 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 the criteria, consistent with applicable state and

federal laws and regulations, for exemption in its policies and procedures and permit HSPP staff to review and approve applications for exemption in accordance with such criteria and as authorized by the IRB.

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 Institutional Official. However, the Institutional Official may not approve the research if it has not been approved by an IRB.

2.9 Information relating to IRB processing times will be made available by the HSPP, and are posted to the Research Compliance website.

3. CRITERIA FOR IRB APPROVAL OF RESEARCH

3.1 To approve research covered by this rule, the IRB shall determine that all of the following requirements are satisfied:

3.1.1 Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

3.1.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3.1.3 Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

3.1.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by state law and federal regulations.

3.1.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by state law and federal regulations including 45 C.F.R. 46.117.

3.1.6 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

3.1.7 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data consistent with the university's obligations under the Texas Public Information Act.

3.1.8 When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

3.1.8(1) University students are vulnerable populations when a decision to participate as subjects is perceived to be required to prevent discrimination either in determination of course grades or in other activities of the academic department. Efforts must be made to avoid coercion.

3.1.8(2) When research takes place involving a foreign culture, the ethical principles and cultural traditions of that society will be respected, including use of the native language when providing information that may lead subjects to agree to participate in the program.

3.1.8(3) By virtue of their dependent positions, laboratory personnel represent a vulnerable population with regard to acting as research subjects. The principal investigator should be sensitive to the need to avoid even subtle coercion and to ensure that all personnel who participate in even minimal risk activities do so entirely voluntarily.

3.2 Compensation of individuals who are members of the university academic staff or regular exempt staff is governed by system policies and regulations.

4. POLICIES AND PROCEDURES

4.1 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.

4.2 New IRB policies and procedures or revisions may be recommended by HSPP staff, faculty, researchers, IRB members, the convened IRB and by any IRB subcommittee.

4.3 Expedited Review

4.3.1 Consistent with federal requirements, the IRB may develop and use an expedited review procedure to review 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.

4.3.2 Under an expedited review procedure, the review may be carried out by the 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 of 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.

4.3.3 If the IRB uses an expedited review procedure, Tarleton has adopted institutional email a method for keeping all members advised of research proposals which have been approved under the procedure.

4.3.4 The Institutional Official may restrict, suspend, terminate, or choose not to authorize an IRB's use of the expedited review procedure.

4.4 Student research projects are reviewed using the same principles and guidelines followed by the IRB for the protection of human subjects in general. 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. This includes graduate theses and dissertation research and honors theses. For all student research projects, a faculty member must be listed in the IRB Application as the Faculty Sponsor and/or PI for the study. The student should be listed in the IRB Application as the research staff. In cases of funded research, the principal investigator identified in the funding instrument should be listed as the Investigator in the IRB Application. For purposes of unfunded research the Faculty Sponsor should be listed as the Investigator.

4.4.1 Individuals serving as Faculty Sponsors/PIs are responsible for:

- overseeing the design and conduct of the study;
- ensuring that the student serving as Protocol Director is appropriately trained and competent to perform the study;
- reviewing the protocol application prior to submission to the IRB;
- providing guidance in the protection of human subjects;
- assuring proper application and reporting to the IRB;

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

4.4.2 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.

4.5 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 obtaining protected health information (PHI) or personally identifiable information (PII), 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.

5. RECORD RETENTION

5.1 HSPP is responsible for maintaining records related to the functions and activities of the IRB in accordance with the system Records Retention Schedule and as prescribed by the university's records retention policy in Tarleton SAP 61.99.01.T0.01 – *Records Management*.

6. TRAINING, OUTREACH AND EDUCATION PLAN

6.1 HSPP is responsible for developing, communicating, implementing and maintaining a Training, Outreach and Education Plan for HSPP. The Plan will be approved by the IRB prior to implementation and will determine the process used to ensure that individuals involved with human research protection have appropriate knowledge and skills.

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 HSPP coordinator, the director of research compliance or the associate vice president for research compliance. The processing of reports or allegations of noncompliance will be conducted according to IRB policies and procedures.

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*

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