15.99.01.C1 Use of Human Subjects in Research

Revised: April 25, 2019
Next Scheduled Review: April 25, 2024
Revision History

Rule Summary

Per A&M System (system) Regulation 15.99.01, *Use of Human Subjects in Research*, Texas A&M University-Corpus Christi (TAMU-CC) shall comply with the applicable laws relating to human subjects in research. This rule provides guidance in complying with this system regulation and federal law relating to research on 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.

Rule

1. GENERAL

1.1. This rule and its requirements apply to all TAMU-CC employees and students, visiting researchers, postdoctoral fellows, any person or entity retained by or working for TAMU-CC regardless of location, and/or any person or entity using TAMU-CC employees or students as participants, facilities, property, or other resources for human subjects in research activities regardless of location.

1.2. TAMU-CC applies consistent procedures for safeguarding the rights and welfare of human subjects in research regardless of source of funding or whether the research is funded or unfunded. In the case of conflict between regulations of the funding or regulatory agency and the U.S. Department of Health and Human Services (DHHS), the more restrictive regulations shall prevail. Additional university guidance is set forth in the Human Research Protection Program (HRPP) Standard Operating Procedures (HRPP SOPs).

1.3. The Vice President for Research and Innovation serves as TAMU-CC's Institutional Official (IO), has oversight responsibility for the HRPP and appoints the chair and members of the Institutional Review Board (IRB). Composition of the IRB will be consistent with the requirements specified in 45 C.F.R. §46.107 and 21 C.F.R § 56.107.

1.4. The IRB shall meet the requirements set out in the federal regulations and register with the Office for Human Research Protections (OHRP) of the DHHS.

1.5. TAMU-CC ensures that all of its research involving human participants will comply with the terms of its Federal Wide Assurance (FWA).

1.6. TAMU-CC has developed written IRB procedures in its HRPP SOPs, including procedures relating to the review of human subject research protocols and reporting guidelines.

1.7. TAMU-CC complies with reporting of noncompliance as required at 45 CFR 46.103(b)(5) (for protocols approved prior to January 21, 2019) or45 CFR 46.108(4) (for protocols approved after January 21, 2019); 21 CFR 56.108(b) and 45 CFR 46.113; 21 CFR 56.113.

1.8. TAMU-CC adheres to documentation of IRB activities as required by 45 CFR 46.115; 21 CFR 56.115, including records retention of at least three (3) years.

2. HUMAN SUBJECTS RESEARCH REVIEW AND APPROVAL

2.1. TAMU-CC human subjects research, whether funded or unfunded, and the review and approval process shall be conducted in accordance with the HRPP SOPs. In addition, any approved protocol and the review and approval process will be conducted in accordance with all federal or state laws, system policies and regulations, and TAMU-CC rules and procedures.

2.2. Principal Investigators (PIs) are responsible for ensuring that all non-exempt research involving human subjects are submitted to the IRB for review and approval. Each non-exempt protocol shall be approved by the IRB before the implementation of the protocol.

2.3. PIs are responsible for ensuring that all exempt research involving human subjects are submitted to the Office of Research Compliance (ORC) or its designee for review and determination. Each exempt protocol shall be reviewed and a determination made by the ORC or its designee before the implementation of the protocol.

2.4. For domestic multi-site non-exempt human subjects research studies funded by the National Institutes of Health (NIH) that involve more than one institution, entity, or party engaged in or researching in human subjects in research, all participating sites will use a single IRB (sIRB) to conduct the ethical review required by 45 CFR Part 46.

Related Statutes, Policies or Requirements

Title 45 Code of Federal Regulations, Part 46

The Belmont Report, April 18, 1979
System Regulation *15.99.01, Use of Human Subjects in Research*

This rule supersedes:

- *15.99.01.C1.01, Assurance of Protection of Human Research Subjects*

Appendix

Human Research Protection Program Standard Operating Procedures (HRPP SOPs)

Contact Office

Contact for interpretation and clarification:	Vice President for Research and Innovation (361) 825-2577