

MEMORANDUM OF UNDERSTANDING
TEXAS TECH UNIVERSITY INSTITUTIONAL REVIEW BOARD
and
TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER
INSTITUTIONAL REVIEW BOARDS

The mission of both Texas Tech University (TTU) and Texas Tech University Health Sciences Center (TTUHSC) includes conducting research with human subjects in compliance with applicable laws and regulations, such as U.S. Department of Health and Human Services (DHHS) regulations. Both institutions have signed an Assurance with DHHS (TTU Federalwide Assurance # 1568; TTUHSC Federalwide Assurance #6767). Each institution utilizes Institutional Review Boards (IRBs) to assist in protecting the rights and welfare of human subjects participating in research activities conducted at TTU, TTUHSC or their affiliated entities.

Human subjects research must be conducted in accordance with established ethical principles. The research, research staff, the subjects who choose to participate in research, and members of each institution's human research protection programs also share this responsibility.

This Memorandum describes the responsibilities, guidelines and processes which will permit one institution to rely on the other's IRB for initial review and continuing oversight of human subjects research. These can include collaborative efforts between TTU and TTUHSC (a) faculty and/or (b) which use the facilities or (c) study population of one institution by investigators from the other institution. The processes outlined in this Memorandum should serve to eliminate duplicate reviews of the same research project while ensuring that each proposal is reviewed in accordance with federal regulations and applicable institutional policies.

Guidelines for Determining the Appropriate IRB:

1. Collaborating Principal Investigators from TTU and TTUHSC.

For purposes of this Memorandum of Understanding, collaborative research between TTU and TTUHSC will involve at least one investigator from each institution who meets the employing institution's criteria to serve as a Principal Investigator for research involving human subjects (see TTUHSC OP 73.08 and TTU OP 74.09).

Determination of the appropriate IRB review for research involving collaborating investigators from TTU and TTUHSC will be based primarily on the subject population:

- a) Collaborative research conducted using healthy volunteers or persons who are receiving ongoing treatment only at the TTU Burkhardt Center, Counseling Center, Psychology Clinic, Marriage and the Family Clinic, or other places where services are provided at TTU will generally be reviewed by the TTU IRB.
- b) Collaborative research conducted using volunteers with a diagnosed medical condition (requiring the use of medical records of TTUHSC, University Medical Center or another TTTUHSC-affiliated institution to determine eligibility or treatment outcomes) will generally be reviewed by the TTUHSC IRB.

- c) Collaborative research conducted at the Montford Psychiatric Unit will be reviewed by the TTUHSC IRB.
- d) Collaborative research conducted at prison units other than the Montford Unit will be reviewed by the TTUHSC IRB if medical records are necessary for the research. If access to medical records is not required, the project will be reviewed by the TTU IRB.
- e) Collaborative research involving the use of the Texas Tech Neuroimaging Institute (TTNI) equipment or facilities will be reviewed by the TTU IRB.
- f) When necessary research office administrators, with input from the chairs of the TTU and TTUHSC IRBs, will reach a consensus on which IRB is more appropriate for the review of the project and will notify the investigator(s) once the decision has been made.

2. Non-collaborating Principal Investigators using population, facilities, or protected private information of the other institution.

When a Principal Investigator from one institution wishes to conduct research using a subject population, facilities, or private information associated with the other institution (for example, a TTU Psychology faculty member conducting research on diabetic patients seen in a TTUHSC clinic, or a TTUHSC faculty member conducting research on TTU undergraduates' exercise habits) the project will typically be submitted to and reviewed by the IRB of the Principal Investigator's institution.

Exceptions may include the following:

- a) Projects requiring access to medical records belonging to TTUHSC, University Medical Center, or another covered entity affiliated with TTUHSC, will be reviewed by a TTUHSC IRB.
- b) Projects taking place at the Montford Psychiatric Prison Unit will be reviewed by the TTUHSC IRB. Projects taking place at other prison units will be reviewed by the IRB of the Principal Investigator.
- c) Projects taking place at the Texas Tech Neuroimaging Institute and/or utilizing fMRI technology overseen by TTU will be reviewed by the TTU IRB.
- d) The research office administrators, with input from the chairs of the TTU and TTUHSC IRBs, will reach a consensus on which IRB is more appropriate for the review of the project and will notify the investigator(s) once the decision has been made.

Review processes:

- 1. Once the designated IRB for a particular project has been determined, the investigator and study staff will follow training, submission and review processes of that institution's IRB.

2. If there are significant concerns about a particular project, the designated IRB may request that a non-voting representative from the other institution's IRB serve as a consultant during the review process. The reviewing IRB's written procedures regarding consultants will be followed.
3. The designated IRB's decision to approve, require modifications, or disapprove a research proposal will be honored by the other institution's IRB. Investigators may not submit an identical proposal to the other institution's IRB if the proposal was not approved by the IRB to which it was originally submitted. Exceptions may be considered based upon discussion between research office administrators and the chairs of the TTU and TTUHSC IRBs.
4. The designated IRB will be responsible for continuing reviews, amendments, and any required reporting for the duration of the research project.
5. The designated IRB has primary responsibility for compliance monitoring of ongoing projects. However, compliance personnel from either institution will be permitted access to research records in order to confirm that projects are being conducted in accordance with the protocol using applicable policies and regulations.
6. The designated IRB will inform IRB office staff at the other institution's IRB of decisions regarding the collaborative research project. When possible, the non-designated IRB should be informed prior to final decisions regarding suspension or termination of a collaborative research project.

Additional Considerations:

1. Each institution will maintain its Federalwide Assurance during the term of this agreement. If either Assurance is suspended or terminated, the other institution shall be notified within 30 days resulting in immediate termination of this Memorandum of Understanding.
2. This agreement may be modified or amended only if such amendment is made in writing and signed by both parties.

**TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER**

[ON RECORD]

Signature
P. Michael Conn, PhD
Senior Vice President for Research
Associate Provost

Date: March 2015

TEXAS TECH UNIVERSITY

[ON RECORD]

Signature
Robert V. Duncan, PhD
Senior Vice President for Research

Date: March 2015