COLLABORATIVE AND NON-COLLABORATIVE RESEARCH INVOLVING TTUHSC AND TTU FACULTY MEMBERS

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).

Determining 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 Burkhart Center, Counseling Center, Psychology Clinic, Marriage and the Family Clinic, TTU Equestrian Center, or other places where services are provided at TTU will generally be reviewed by the TTU IRB.

b) Collaborative research conducted using volunteers whose participation requires the use of medical records of TTUHSC, University Medical Center, or another TTUHSC-affiliated institution in order to determine eligibility or treatment outcomes will generally be reviewed by the TTUHSC IRB.

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.

<u>Exceptions may include the following</u>:

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) 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.