RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

The Principal Investigator (PI) acknowledges and accepts responsibility for protecting the rights and welfare of human research subjects, for the scientific and ethical conduct of the research study, and for complying with all applicable Federal, State, local, and institutional regulations and guidelines.

The PI intending to involve human research subjects will not make the final determination of exemption from coverage under 45 CFR 46.101. This is the responsibility of the UT Tyler IRB after reviewing the exempt study application.

PIs must have an approved, current, signed Conflict of Interest Form on file with the Office of Research and Technology Transfer before a proposal can be processed.

In addition, the PI shall:

• Ensure the PI, co-investigators, research assistants are properly trained in all aspects of the protocol, including any investigational product(s), and are knowledgeable concerning protection of the rights and welfare of human research subjects and for complying with all applicable UT Tyler, state and federal guidelines. See policy regarding education under "Submission of Proposals” section, Required Education, of this Handbook.

• Prepare a protocol/proposal giving a complete description of the proposed research. As per recommendations of the Office of Human Research Protection, written proposals must be submitted with the appropriate IRB application. The proposal may be brief but include details on the protocol itself. In addition, the protocol must reflect provisions for the adequate protection of the rights and welfare of prospective research subjects and insure that pertinent laws and regulations are observed. This requirement is applicable even in cases where the research is exempt under 45 CFR 46.101.

• Be responsible for complying with all UT Tyler IRB decisions, conditions, and requirements.

• Be responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement, and for insuring that no human subject will be involved in the research prior to the obtaining of the consent. All signed consent documents are to be retained in a manner approved by the UT Tyler IRB.

• Promptly report proposed changes in previously approved human subject research activities to the UT Tyler IRB using the Modification Form. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
• Be responsible for reporting progress of approved research to UT Tyler IRB, as often as and in the manner prescribed by the UT Tyler IRB, but no less than once per year, using the Continuing Review form or the Discontinuance Form, whichever is appropriate one year post approval.

• Be responsible for notifying the UT Tyler IRB if the project is terminated or discontinued prior to one year, by using the Discontinuance Form. (additional information is available on the Submission and Review policies and procedures). If the study is terminated per request of a sponsor or other entity, the PI must notify the UT Tyler IRB immediately.

• Promptly report to the UT Tyler IRB any injuries to human subjects, or other unanticipated problems involving risks to subjects and others, using the Unanticipated-Adverse Event Form, within timelines established in the Reporting of Unanticipated-Adverse Events policy and procedure.

• Forward a copy of all reports of audits performed by funding agencies, sponsor monitors, regulatory agencies, or any other external or internal entity to the IRB promptly upon receipt of the report from the auditing entity.

• Retain all study records for a minimum of three years following completion of the study.