COMPLIANCE AND MONITORING OF PROTOCOLS

The UT Tyler IRB is responsible for conducting the safety and monitoring process for all approved protocols. The researcher and team’s obligation to protect human research participants does not end with initial approval of the study or an informed consent (written or otherwise). In any research, the commitment to participants is to safeguard their interests throughout the study.

Data and safety monitoring plays an essential role in protecting the safety of participants and ensuring integrity of the research study.

The objectives of data and safety monitoring are to:
- Ensure that risks associated with research participation are minimized to the extent practical and possible.
- Avoid exposure of participants to excessive risk.
- Ensure data integrity.
- Stop a study: (1) if safety concerns arise; or (2) as soon as the study objectives have been met.

Monitoring should be commensurate with risks and with the size and complexity of the research.

IRB committee members protect the safety of participants by being familiar with the study and ensuring the integrity of the study by reviewing data on such aspects as participant enrollment, site visits, study procedures, forms completion, data quality, losses to follow-up, and other measures of adherence to protocol. In addition, monitoring of adverse events, discussion of concerns in this regard, and making of recommendations regarding appropriate study and operational changes are conducted.

The UT Tyler IRB reserves the right to conduct monitoring at any time without prior notification of visits.

During the process of compliance and monitoring and continuing reviews of a research project, material provided to the Institutional Review Board and the ORTT shall be considered privileged information and the Board shall assure the confidentiality of the data contained within any submitted documents that contains subject/participant identifying information.

All federally funded human subject clinical research protocols must have a data and safety monitoring plan. The plans must include a description of the reporting mechanism should an adverse event occur. All data and safety monitoring plans must include, at a

UT Tyler IRB Handbook
minimum, a description of the reporting mechanism of adverse events to the IRB (see the UT Tyler Policy On Unanticipated Problems Or Adverse Event/Death). In addition, the study sponsor, the FDA (if the researcher sponsors the IND or IDE for the agent or device), and the NIH must be notified according to their policies and procedures. For NIH-supported multi-center clinical trials, see http://grants.nih.gov/grants/guide/notice-files/not99-107.html.

NIH policy and guidance for data and safety monitoring can be found at: http://grants.nih.gov/grants/guide/notice-files/not98-084.html

Researchers must ensure that the NIH is informed of any actions taken by the IRB as a result of safety monitoring reviews.