**PROCEDURES FOR INVESTIGATING AND REPORTING INCIDENTS OF RESEARCH MISCONDUCT AND NON-COMPLIANCE**

A. **Definitions of Research Misconduct and Non-Compliance**

Reported allegations of research misconduct and non-compliance will be subject to an investigation. These incidents include, but are not limited to, the following:

- Any reported research activity that is being conducted without prior IRB approval
- Any reported significant deviation in activities previously approved by the IRB
- Research misconduct as defined by the Office of Research Integrity (http://ori.dhhs.gov/misconduct/definition_misconduct.shtml):

  Non-compliance is defined as any deviation from academic or regulatory agency rules and regulations regarding human research. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

  - Fabrication is making up data or results and recording or reporting them.
  - Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
  - Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
  - Research misconduct does not include honest error or differences of opinion.

B. **Investigations of Reported Allegations of Research Misconduct or Non-Compliance**

The UT Tyler IRB acknowledges the UT Tyler Handbook of Operating Procedures in that “any inquiry or investigation of allegations of misconduct/fraud in research must proceed promptly and with due regard for the reputation and rights of individuals involved” (Section 3.2.8, p. 2). Any allegation of research misconduct or non-compliance must be reported to the department chair or dean, or, if the allegations involve a chair or dean, then the charges must be reported to the President or designee. In addition, allegations must be reported directly to the IRB Chair and Director of the Office of Research and Technology Transfer before or at the same time the incident is reported to the department Chair/Dean, or if appropriate, the President or designee.

The PI of the research program affected by the allegations will be notified by the department Chair/Dean, or if appropriate, the President or designee. While respecting and regarding the reputation of the involved parties, the departmental
Chair/Dean, or if appropriate, the President or designee shall conduct a thorough investigation of the circumstances and facts. The investigation must be completed within 60 days.

If the research involves human subjects, the IRB Chair will submit all materials relevant to the investigation to the person(s) conducting the investigation. The Chair shall complete the UT Tyler Research Misconduct and Non-Compliance Review Form and brief the IRB at the next convened meeting or at a specially convened meeting, on the details of research misconduct or non-compliance. The IRB will recommend any additional measures to prevent future similar occurrences.

The IRB has the authority to terminate approval of the research, especially that which is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects. The PI will be notified in writing of the requirements or conditions necessary to assure compliance with the restrictions, conditions or decisions of the IRB. Every effort will be taken to insure the confidentiality of all aspects of the investigation and any subsequent IRB actions relating to the incident(s).

Additional procedural responsibilities are delineated in the UT Tyler HOP: http://www2.uttyler.edu/ohr/hop/documents/3.2.8ResearchFraudMisconduct.pdf

C. Reporting of Investigations

Upon completion of the investigative process, the completed IRB Research Misconduct and Non-Compliance Review Form must be submitted to the person(s) conducting the investigation and to the presiding official for the Office of Research and Technology Transfer. If the research project is federally-funded or is associated with an FDA regulated investigational drug or device study, the ORTT presiding official will submit a report to the Office for Human Research Protections (OHRP) and to the FDA.

The reports should indicate how the incident(s) were brought to the attention of the IRB and the specific allegations or observations that were relayed. Reports that are necessary to resolve the incident(s) of misconduct/non-compliance must also include the date(s) the investigation was accomplished, the identity of those involved in the investigation, the results of the investigation in detail, and the restrictions, conditions, or other actions recommended by the departmental Chair, Dean, or if appropriate, President or designee. Finally, the report should also delineate the actions taken by the IRB and/or PI to prevent future occurrences.

D. Record Keeping
All documents relating to the investigation will be retained by the IRB Office in a secure location and will be made available to authorized individuals for further reference. Records are held for at least 10 years.