UNANTICIPATED PROBLEMS OR ADVERSE EVENT/DEATH

A. Definitions

The UT Tyler IRB and the Office of Human Research Protection consider *unanticipated problems*, in general, to include any incident, experience, or outcome that meets *all* of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The term *adverse event* in general is used very broadly and includes any event meeting the following definition:

Any untoward or unfavorable health-related occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

B. Reporting

Reporting requirements depend on the nature of the adverse event. If the adverse event was an anticipated one within the context of the research study (one that was specified in the informed consent and in the protocol approved by the IRB), the PI reports this to the IRB Chair using the Report Of Unanticipated Problem or Adverse Event/Death within 5 days of the event.
When a subject who is participating in a research study experiences an unanticipated problem, the PI must report the incident within 24 hours of the PI becoming aware of the incident to:

- Chair of the UT Tyler IRB via e-mail and phone voicemail
- Institutional Official (IO): the Director of the Office of Research & Scholarship at UT Tyler
- FDA if the PI holds the Investigational New Drug (IND) or New Device Exemption (IDE)
- Funding agency
- Department chair/administration
- Chair and/or IO report the incident to the Office of Human Research Protections (OHRP) as per Health and Human Services requirements
- (http://www.hhs.gov/ohrp/compliance/reports/index.html)

The PI must complete the Report of Unanticipated Problem or Adverse Event/Death and submit to the IRB Chair within 48 hours of the event.