

7.3 ADVERSE EVENT REPORTING

When a subject who is participating in a research study experiences an unanticipated or serious adverse event, the PI must **promptly report** the incident to the IRB. A summary of the adverse event must be submitted to the IRB using IRB Form #7A or 7B (found at <http://research.utmb.edu/irb/forms.shtm>). For adverse events or reactions that occur at UTMB, the following apply (hospitalization for any reason must be reported):

- (1) If the adverse event or reaction was anticipated in the protocol and the subject was informed about the possibility of the event in the consent form, there is no need to inform the IRB unless the adverse event was unexpectedly serious, life threatening, or fatal.
- (2) If the adverse event or reaction was unanticipated, unexpectedly serious, life threatening, resulted in hospitalization or prolongation of hospitalization or death, or there are suspicions that exposure to and investigational drug/device prior to conception or during pregnancy resulted in an adverse outcome to a child, the adverse event must be reported to the IRB office within 24 hours. If the adverse event occurs after hours or on a week-end, notification should be left on the IRB Voice Mail at extension 6-9475.
- (3) If the research study is being supported by an industry sponsor, the PI is also responsible for notifying the sponsor. The sponsor must then notify the FDA within 24 hours.
- (4) If the PI holds the Investigational New Drug (IND) or Investigational New Device Exemption (IDE) in his/her name, he/she is required to notify the FDA of the adverse event or reaction within 24 hours, in addition to notifying the IRB.
- (5) Notifying the IRB does not relieve the PI from his/her responsibility to notify the sponsor, FDA, and Hospital Risk Management. If the research is federally funded, the IRB is required to notify the Office of Human Research Protections.
- (6) Within 10 working days, the PI must submit a written report of the adverse event or reaction to the IRB using IRB Form #7B (found at <http://research.utmb.edu/irb/forms.shtm>).

For industry sponsored research trials of drugs or devices, sponsors are required to inform investigators of adverse events or reactions that occur at other sites. When PIs are informed of the adverse events in sponsor safety memos, safety monitoring reports and other correspondence, the PI must review the adverse event/safety monitoring report and then notify the IRB using IRB Form #7A (found at <http://research.utmb.edu/irb/forms.shtm>). This should be done as promptly as possible after receipt of the report from the sponsor. All adverse events are reported to the IRB and if there appears to be ongoing increased risk to subjects, enrollment of new subjects could be suspended pending further IRB investigation of subject risk.

NOTE: to access the complete UTMB Institutional Review Board Policies and Procedures Manual [click here](#)