Texas A&M University - Commerce

INSTITUTIONAL REVIEW BOARD

Report of Unanticipated/ Adverse Event/Death

This report must be submitted to the IRB Chair within 24 hours of the event. If serious injury or death is reported as the event, the IRB chair must be notified as soon as the event is noted. Please refer to the A&M-Commerce Policy on Unanticipated and Adverse Events for additional reporting responsibilities.

The following policy comes from:[**http://www.hhs.gov/ohrp/policy/advevntguid.html**](http://www.hhs.gov/ohrp/policy/advevntguid.html)

The Office of Human Research Protection of the USDHHS considers ***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 medical 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.

**Indicate type of event: Unanticipated:** [ ]

 **Adverse:** [ ]

**Title of Protocol:**  Click here to enter text.

**IRB Approval #:**  Click here to enter text.

**Principal Investigator:**  Click here to enter text.

**Subject initials:**  Click here to enter text.

**Participant ID#:**  Click here to enter text.

**Date enrolled in study:**  Click here to enter text.

**Date and time of event:**  Click here to enter text.

**Age or D.O.B at time of event:**  Click here to enter text.

**Describe in detail the event:**  Click here to enter text.

**Follow up action:**  Click here to enter text.

**Referrals made:** Click here to enter text.

**In your opinion was the reported event a result of participation in the research?**

[ ]  **Probably** [ ]  **Possibly** [ ]  **Unlikely** [ ]  **Unknown**

[ ]  **Not Related (Provide Explanation)**

**"SIGNATURE" OF PRINCIPAL INVESTIGATOR**

**PI Name:**  Click here to enter text.

**(Electronic submission of this form by PI indicates signature)**

**Date:**  Click here to enter text.

Upon receipt of this report, the Institutional Review Board (IRB) will decide whether additional information is needed or whether further investigation of the incident is required. In some cases, an investigator may be required to suspend a study pending the outcome of the IRB review.

For IRB response to the above reported adverse event the IRB concludes:

[ ]  **That no further follow-up is required**

[ ]  **Additional materials are requested:**

[ ]  Continue to monitor and provide data when an end point is reached or by Click here to enter text. MM DD YYYY

[ ]  **Other:**

Click here to enter text. Click here to enter text.

**Institutional Review Board Representative Date**