TEXAS STATE UNIVERSITY
SAN MARCOS
The rising STAR of Texas

Institutional Review Board

Unanticipated Problem/Adverse Event Report

Date of this Report:	
IRB Protocol #:	**Department:**

Project Title

_____

_____

Principal Investigator Information

Name		Relationship to Texas State: Faculty □ Staff □ Student □
Home Mailing Address (for students) City/State/Zip:		
Office Phone:	Home Phone (for students):	Email:

Sponsor:
Has the sponsor been notified? Yes □ No □
Date of Notification:

Unanticipated Event/Adverse Event/Unanticipated Adverse Device Effect Information

Submit 1 Adverse Event Report for each subject. You may use additional sheets to describe the nature of the adverse event. If a separate notification is required for sponsored studies and/or regulatory agencies, please include a copy of that notification.

Participant #	Date of Adverse Event	Description of Unanticipated Problem/Adverse Event	Was the Problem or Event Unexpected? Yes □ No □

Was the Problem or Event Serious? Yes □ No □	Study Related Probem or Event? Yes □ No □	Does the problem or event suggest that the research places subjects or others at a greater risk of harm? Yes □ No □
Should the protocol and/or consent forms be revised Yes □ No □ Does the event have implications for the conduct of the study? Yes □ No □		Will additional information be given to enrolled subjects? Yes □ No □
If Yes, please submit a copy of the corrected amendment forms with **bold** changes and a clean copy incorporating the changes.		

Principal Investigator's Signature: _____ Date: _____

DEFINITIONS:

1. *Unanticipated problem* (non FDA research) include any incident, experience, or outcome that meets *all* of the following criteria:

    - *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;

    - *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

    - 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. For example, breach of confidentiality is considered to place subjects at risk, but is only unanticipated if it was not described as a risk in the consent form

2. For FDA governed research, please note that the criteria of an unanticipated problem is slightly different.

    - Unexpected

    - Serious

    - Would have implications for the conduct of the study (e.g., requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator's brochure).

3. An adverse event is any untoward or unfavorable occurrence in a human subject, temporally associated with the subject's participation in the research. Adverse events encompass both physical and psychological harms.

    Attribution: Adverse event attribution will fall into one of the following categories:

    - *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);

    - unrelated events are those that could in no way be attributed to study participation. These events are not reportable.

    Severity: Adverse event severity will fall into one of the following categories:

- *Mild**:*** Event results in transient discomfort; does not influence performance or functioning; does not require intervention or treatment; does not limit or interfere with daily activities; expected to resolve quickly with no physical, psychological, social, or economic consequences.

- *Moderate:* Of sufficient severity to make the patient uncomfortable; may include worsening of conditions present at the onset of the study; treatment of symptom(s) may be needed; expected to resolve but short term physical, psychological, social, or economic consequences are possible.

  Severe: Event results in significant symptoms that prevents normal daily activities; may require hospitalization or invasive intervention. Long term physical, psychological, social, or economic consequences are possible.

4. Devices may have an Unanticipated Adverse Device Effect Information (UADE) to participants or others. The investigation device exemption (IDE) regulations define an UADE as “any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects”.

UADEs must be reported by the primary investigator to the sponsor and the IRB.