1. PURPOSE

This procedure describes the review of non-reportable events.

2. PROCEDURE

The Avera Institutional Review Board (IRB) does not require the reporting of adverse events unless the event is an Unanticipated Problem (i.e. unexpected, related or possibly related, and increased risk to subjects to the research). Principal Investigators (PIs) are not required to report other events. However, the IRB office will accept reports of these events if sponsors require PIs to report such events to the IRB, or when the PI is unsure whether the event should be reported.

Refer to this SOP in help determining which events are reportable: SOP 410 Reportable New Information: Adverse Events, Serious Adverse Events & Unanticipated Problems

3. DEFINITIONS

Unanticipated Problem: Any incident, experience or outcome that meets all of the following criteria:

1. **Unexpected**
   An event is unexpected if it occurs in one or more human subjects or others participating in a research protocol, and the event's nature, severity or frequency is not consistent with either:
   - the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable PI brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
   - the expected natural progression of any underlying disease, disorder, or condition of the human subject(s) experiencing the adverse event and the human subject's predisposing risk factor profile for the adverse event.
2. **Related or possibly related**
   Events that related or possibly related to participation in the research may be caused by one or more of the following:
   - The procedures involved in the research;
   - An underlying disease, disorder or condition of the subject;
   - Other circumstances unrelated to the research or any underlying disease, disorder or condition of the subject.

   In general, events that are determined to be at least partially caused by the procedures in a study would be considered related to participation in the research, whereas events determined to be solely caused by the subject's condition or state of illness or other circumstances clearly outside of the study would be considered unrelated to participation in the research.
3. **Increased Risk (either serious or not serious)**
   AEs that are unexpected, related or possibly related to participation in research, and serious are the most important subset of adverse events representing UPs, because such events always suggest that the research places human subjects or others at a greater risk of physical or psychological harm than was previously known or recognized. These events warrant consideration of substantive changes in the research protocol or informed consent

process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects.

Other AEs that are unexpected and related, or possibly related, to participation in the research, but not serious, would also be UPs if they suggest that the research places human subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

4. SPECIFIC PROCEDURES

4.1 Non-reportable events do not need to be submitted to the IRB. However if they are submitted due to a requirement from a sponsor, then all submitted non-reportable events will be reviewed by the IRB, and they may ask for additional information.

4.2 The principal investigator should follow the internal clinical research processes.

5. RESPONSIBILITY

The IRB staff will review all reported events, and triage them to the IRB Chair or designee if appropriate for full board discussion.

6. APPLICABLE REGULATIONS AND GUIDELINES

Guidance of Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

REVISION HISTORY

Revision Number	Version Date	Approved By, Date Approved
02	1/28/2019	Avera Institutional Official, 3/19/2019
• Defined again which events are reportable (UPs), and how to define the three required elements that gets an AE to the level of an UP. • If events that don't have to be reported to the IRB are required to be submitted by the sponsor, they will be reviewed by the IRB, and the IRB may ask for additional information. • Removed section titled Procedures Employed to Implement This Policy with individual tasks and who is responsible for each item.		
01	August 2016	Director HSRP / August 2016