Avera	**Institutional Review Board** **Worksheet: Unanticipated Problems and Protocol Deviations (Non-Compliance)**
	WORKSHEET NUMBER | HRP-321

IRB Number:	
Protocol Number:	
Investigator:	

The event submitted was classified by the PI as a:

☐ Unanticipated Problem
☐ Major Protocol Deviation (non-compliance)

If applicable, did the PI submit a CAPA?

☐ N/A
☐ NO
☐ YES
If Yes, do you find the CAPA plan acceptable?
☐ Yes
☐ No – Explain (below)
☐ Partially, but would like to request changes. (Explain)

I have reviewed this submission and recommend that the IRB take the following action(s):

☐ Acknowledge & accept as submitted, with no further action required.
☐ Request additional information from PI (Explain below).
☐ Require a CAPA (or changes to the submitted CAPA, if applicable).
☐ Require modification(s) to the protocol.
☐ Require changes to the informed consent.
☐ Require current participants to re-consent to participation.
☐ Notify all participants (past or current), if the information might affect their willingness to continue participation.
☐ Request that Research Compliance verify that participant selection is appropriate, and observe an actual informed Consent process with a subject.
☐ Modify the continuing review cycle.
☐ Request additional Investigator and/or staff education.
☐ Request a directed audit of targeted areas of concern by Research Compliance.
☐ Audit to be conducted on study in question (when possible)
☐ Audit to be conducted on staff items related to issue
☐ Audit to be conducted on department where issue occurred
☐ Require a temporary or permanent suspension of enrollment of new participants.
☐ Require suspension or termination of the research.
☐ Other. (Explain below)

Explanation, if needed from above:

_____ _____
(Name) (Date)

IRB Definitions (to assist in making a determination):

Unanticipated Problem:

Any incident, experience or outcome that meets all three 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 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. 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.
3. Increased Risk.
   This suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Major Protocol Deviation: Affect a human subject's rights, safety or well-being or integrity of the data being collected. It may also affect the primary safety or efficacy endpoints of the study.

Non-compliance: Non-compliance is defined as a failure to comply with any of the regulations, Avera IRB policies, or the approved study protocol. Noncompliance may be serious, continuing, neither, or both, or simply minor noncompliance. Noncompliance may result from the action of the human subject, PI, or staff. It may or may not impact the rights and welfare of the human subject or others, or the integrity of the study.

***Minor* Noncompliance:** An occasional instance of noncompliance that is typically administrative in nature and does not affect the rights and welfare of human subject's or put participants at risk of harm. These are not reportable to the IRB, but they are reportable to the sponsor.

***Serious* Noncompliance:** Failure to follow any of the regulations or policies, or failure to follow the determinations of the IRB, and which, in the judgement of the IRB, increases risk to participants, decreases potential benefits, or compromises the integrity of the human research protection program. It also may be an action or omission taken by a researcher that materially increases risk or results in substantial harm to human subjects or others.

***Continuing* Noncompliance:** Non-compliance that occurs repeatedly and suggests a pattern or an underlying problem. It may occur due to a lack of knowledge (unintentional) or due to a deliberate choice to ignore regulations or determinations of the IRB (intentional).