DEFINITIONS FOR UNANTICIPATED PROBLEM TO SUBJECTS OR OTHERS (UPR) REPORTING

Unanticipated Problem: 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 (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. (Note: the IRB makes this determination. The PI must report unexpected + related/possibly related events regardless of perceived risk)

Both risks to subjects and risks to other individuals (e.g., research personnel, subjects’ family members) are included in the concept of UPRs. Risks may reflect any type of potential harm (e.g., physical, psychological, social, legal, economic).

Examples of unanticipated problems include but are not limited to:

- An adverse event to a local subject that was unexpected and related to the protocol, regardless of the severity of the event.
- More frequent or severe side effects than were anticipated as described in the protocol and consent form
- Experiences or side effects of one or more subjects that were not described in the protocol or consent form;
- Any unapproved change or modification to an IRB approved protocol (deviation), intentional or unintentional, that places one or more subjects at risk or affects the integrity of study data;
- Changes to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a subject;
- Complaints that indicates unexpected risks, or complaint that cannot be resolved by the principal investigator;
- Malfunctioning of research equipment that results or could result in risk to subjects or others;
- Suspension of enrollment (by the investigator, sponsor) due to issues identified with the study that may involve risk to subjects;
- Events that requires prompt reporting to the sponsor (i.e. pregnancy);
- Interim findings (data analysis and/or safety reports) and/or data safety monitoring reports that indicate an unexpected change to the risks or potential benefits of the research, in terms of severity or frequency;
- Publications in the literature that indicating new risks;
- Changes in product labeling indicating new risks;
- Breach of confidentiality (e.g. laptop containing identifiable private information is stolen or lost even if data files remain intact);
- Violations of applicable institutional (e.g. UF, VA) information security requirements;
- Loss of research data (e.g. paper records lost or destroyed; electronic records lost if hard drive crashes and data not backed up);
- Incorrect labeling, dosing, or dispensing of study medication or test article even if there is no indication of harm (e.g. randomization error);
- Unexpected disclosure of an event (e.g. child abuse) that requires reporting under state law; and/or
- Any unanticipated event that influences the risk-benefit of the research.