UNANTICIPATED PROBLEMS (UP) POLICY
Nuts & Bolts of What to Report to the IRB

Reportable Categories:

1. On Protocol SAEs† that are unanticipated†† and related or possibly related to the research participation.

2. On Protocol SAEs or AEs that are anticipated and related or possibly related, but are occurring at a significantly higher frequency or severity than expected.

3. On or Off Protocol Unanticipated SAEs or AEs that are related or possibly related, regardless of severity, that may alter the risk to benefit ratio for the subjects and, as a result, warrant changes to the protocol and/or consent process.

4. Other Unanticipated Problems that are On or Off Protocol – Other events that are unanticipated that may place subjects or others at a greater risk of harm or discomfort than was previously known or recognized. Harm to a subject need not occur for an event to be an unanticipated problem.

When determining “unanticipated” status, consider the following:
- Known or foreseeable AEs and risks in the protocol, investigator brochure, current approved consent form, and other relevant study documents.
- Any underlying disease or conditions of the subject who has experienced the AE
- Carefully assess whether the AE is related or possibly related to the subject’s participation
- Any event that is considered rare, even in the absence of drug exposure, is considered unanticipated (e.g. granulocytosis, hepatic necrosis, Stevens-Johnson syndrome, etc.).

† A Serious Adverse Event is defined as any AE that:
- Is fatal
- Is life-threatening
- Is persistent or significantly disabling or incapacitating
- Results in inpatient hospitalization or prolongation of hospitalization
- Results in psychological or emotional harm requiring treatment
- Creates a persistent or significant disability
- Causes a congenital anomaly or birth defect and/or
- Results in a significant medical incident (considered to be a serious study related event because, based upon appropriate medical judgment, it may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition).

†† Unanticipated: Not previously known or expected (including increases in severity or frequency).