UPIRSO (Unanticipated Problems Involving Risks to Participants or Others) Checklist
(Is the Report a UPIRSO?) (This form applies to external and local AEs and noncompliance)

Memo Date: _____ Event: _____

Study:_____ **Safety Report #:**_____

Check the appropriate box

☐ **YES**	☐ **NO**	Is the adverse event/noncompliance **Unexpected?**
An unexpected adverse event is defined as any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is **NOT** consistent with either: 1) 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 protocol, investigator brochure, and the current IRB-approved consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or 2) the expected natural progression of any underlying disease, disorder, or condition of the subject experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.		
☐ **YES**	☐ **NO**	Is the adverse event/noncompliance **Related or Possibly Related?**
Adverse events may be caused by one or more of the following: 1) the procedures involved in the research 2) an underlying disease, disorder or condition of the subject; or 3) other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the subject. **Adverse events that are determined to be at least partially caused by (1) would be considered related to participation in the research,** whereas adverse events determined to be **solely** caused by **(2) or (3)** would be considered **unrelated** to participation in the research.		
☐ **YES**	☐ **NO**	Is the adverse event/noncompliance **Serious <u>or</u>** otherwise one that suggests that the research places subjects or others at a **greater risk of physical or psychological harm than was previously known or recognized?**
The first step is to determine if the adverse event is **Serious:** (1) results in death; (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred); (3) results in inpatient hospitalization or prolongation of existing hospitalization; (4) results in persistent or significant disability/incapacity; (5) results in congenital anomaly/birth defect; or (6) based upon appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.		

If all 3 boxes above are marked YES, then submit to the IRB; If one or more of the boxes above are marked NO, then this does not fit the criteria of an Unanticipated Problem Involving Risks to Participants or Others (UPIRSO) and does not need to be submitted to the IRB.

☐ Non-UPIRSO
☐ Insufficient information: Non-UPIRSO
☐ UPIRSO- Submit to IRB

_____
Reviewer's Signature
Comments: