Reportable Event Reviewer Checklist

Reviewer: _____ Submission ID: _____

Principal Investigator: _____ Protocol #: _____

A. EVENT ASSESSMENT

1. Does the report bring light to any new information (e.g., new risks, new procedures, etc.) that the local PI needs to incorporate into their study documents?

   ☐ Yes (elaborate in comments) ☐ No

2. If so, has an accompanying amendment been submitted for review?

   ☐ Yes ☐ No ☐ N/A

3. If the report describes a new risk, does the full committee need to conduct a new risk assessment?

   ☐ Yes (defer to Full Committee) ☐ No ☐ N/A

4. If the report includes a corrective action plan, is the corrective action plan adequate?

   ☐ Yes ☐ No (elaborate in comments) ☐ N/A

5. Do subjects need to be notified about the event?

   ☐ Yes: ☐ Notification or ☐ Reconsent
   ☐ No (elaborate in comments)
   ☐ N/A

6. Did the reported event occur at an unaffiliated site under the purview of another IRB?

   ☐ Yes (skip Sections B and C) ☐ No

7. Is this a follow-up report regarding an event that was previously reported and evaluated by the IRB?

   ☐ Yes (skip Sections B and C) ☐ No

B. SERIOUS AND/OR CONTINUING NON-COMPLIANCE

1. Did the reported event involve a failure to comply with the terms of the IRB's approval, federal regulations, state or local laws, or University policy?

   ☐ Yes (do not complete Section C) ☐ No (skip to Section C)

2. Does the reported event represent serious non-compliance?

   ☐ Yes (defer to Full Committee and/or Compliance Board) ☐ No

Serious non-compliance is defined as failure to follow any of the regulations and policies or failure to follow the determinations of COMIRB such that risks to subjects are increased, potential benefits to subjects are decreased, and the integrity of the human research protection program is compromised.

Example: *Research conducted without IRB approval is generally considered serious non-compliance.*

3. Does the reported event represent continuing non-compliance?

   ☐ Yes (defer to Full Committee and/or Compliance Board) ☐ No

Continuing non-compliance is defined as a pattern of non-compliance reports that, in the judgement of the panel Chair(s) or convened panel, suggests a likelihood that instances of noncompliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance within 30 days.

Comments about Serious or Continuing Non-compliance (if any):

C. UNANTICIPATED PROBLEM

1. Did the reported event represent an unanticipated problem involving risks to subjects or others?
   NOTE: Each of the following criteria must be met in order for the event to meet the definition of an unanticipated problem.

   ☐ The problem was unexpected (not adequately identified in any study-related documents, e.g., the protocol, consent form, investigator's brochure, package inserts, literature, etc.).

   ☐ The problem was related to the study.

   ☐ Participants or others were harmed or placed at increased risk of harm.

   ☐ Yes (defer to Full Committee) ☐ No

*An unanticipated problem is defined as any event or information that was **unforeseen** and indicates that the research procedures **approved by the IRB and carried out as expected**, caused harm (including physical, psychological, economic, or social harm) to participants or others, or indicates that participants or others are at increased risk of harm than was previously known or recognized.*

Comments about Unanticipated Problem (if any):

D. REVIEWER RECOMMENDATION

☐ Noted

☐ Minor Modifications

☐ Defer to Full Board

☐ Defer to Compliance Board

Event Assessment Comments (if any):

Reviewer Signature _____ Date _____