**Start Here**

Health Sciences IRBs Unanticipated Problems Reporting Decision Tree, Effective Date 10/9/2017

- Was the event caused by or associated with a device being tested in a clinical trial?
  - No
  - Was the event probably caused by or associated with study participation?
    - No
    - Do not report to the IRB
    - Yes
    - Is the event unexpected (in terms of nature, severity or frequency)?
      - No
      - Do not report to the IRB
      - Yes
      - Is the event a subject death or immediately life-threatening or severely debilitating to the subject or others?
        - No
        - Do not report to the IRB
        - Yes
        - Report to IRB Chair/Director w/in 1 business day

- Yes

- Was the event not previously identified in nature, severity, or frequency in any IRB documents (e.g., consent forms, application materials) OR does the event relate to the rights, safety, or welfare of subjects?
  - No
  - Do not report to the IRB
  - Yes
  - Report to IRB Chair/Director w/in 1 business day

- Does the event suggest 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?*
  - No
  - Do not report to the IRB
  - Yes
  - Will the event, effect, or problem result in a sponsor-initiated (or investigator-initiated in the case of non-industry-sponsored research) change to the IRB application, study protocol, or consent documents or result in the provision of new information to participants or others?
    - No
    - Do not report to the IRB
    - Yes
    - Report w/in 14 business days (5 business days if occurs in local VA subject)

- Do not report to the IRB

* This includes any of the following scenarios per the FDA:
  1) Any adverse experience that, even without detailed analysis, represents a serious unanticipated event that is strongly associated with drug exposure (such as agranulocytosis, hepatic necrosis, Stevens-Johnson Syndrome); OR
  2) A series of adverse events that, on analysis, is both unanticipated and a problem for the study (i.e., the series of events represents a signal that the adverse events were not just isolated occurrences and represent an unanticipated problem); OR
  3) An adverse event that is described or addressed in the investigator’s brochure, protocol, or informed consent documents that occurs at a specificity or severity that is inconsistent with prior observations OR for which the rate of occurrence in the study represents a clinically significant increase in the expected rate of occurrence; OR
  4) A single occurrence (more often a small number of occurrences) of a serious, unexpected event not commonly associated with drug exposure, but uncommon in the study population.

See the reportable event example table for other events that require reporting to the IRB at https://kb.wisc.edu/huirbs/18324 If you are unsure whether to report, contact the IRB Office at 263-2362.