Serious Adverse Event/Adverse Event Process Flow

1. **Adverse Event occurs at Study Site**
   - **Is this adverse event serious?**
     - **YES**: PI is notified as soon as event is known.
     - **NO**: Principal Investigator (or designee) notifies funder, DSMB Chair or Safety Officer within 24 hours of being notified, and also notifies IRB.

2. **DSMB Chair, Safety Officer, or funders may ask for additional information**
   - **Is it an IP?**
     - **YES**: Marketed Drug?
     - **NO**: Is the event fatal, unexpected, or life threatening?
       - **YES**: Report to FDA within 7 days.
       - **NO**: Report other serious and unexpected events within 15 days to FDA.

3. **Must be reported on Adverse Event form**
   - **Is event unexpected, rare, severity or frequency?**
     - **YES**: Is adverse event definitely related, probably related or possibly related to participation in the research?
       - **YES**: Submit with routine DSMB/Safety officer reports.
       - **NO**: Does adverse event suggest that the research places participants or others at a greater risk of physical or psychological harm that was previously known or recognized?
         - **YES**: Report to IRB, OHRP, and funder generally within 2 weeks of event.
         - **NO**: Report to other participating sites for their IRB notification.

4. **Stop**

* Investigational Product