**Study Title:**

**IRB # Participant ID:**

**Principal Investigator:**

*Note: The use of a note to file is not necessary if this event has been documented on a log or with an assessment form or reported to the IRB.*

1. **Description:**
2. **Corrective & Preventative Action taken (including IRB reporting) if applicable:**
3. **Reportable to (Y/N):**
4. **Sponsor:**
5. **IRB:**
6. **FDA:**
7. **If answered yes, include date of report**
   1. **Sponsor:**
   2. **IRB:**
   3. **FDA:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Person Completing this form**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Person Completing this Form Date**