Adverse Event Reporting Form

ADVERSE EVENT: Any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure, that is not listed as a risk on the consent form, regardless of whether it is considered related to the treatment or procedure; also an "unanticipated problem" of any nature (e.g., psychological or social harm)

Research Protocol Title: ______
IRB Number: ______
Patient Number: ______

Principal Investigator: ______
Address: ______
Phone: ______  Email: ______

Research Coordinator: ______
Address: ______
Phone: ______  Email: ______

Date of Adverse Event: ____________   Date PI Became Aware: ______________   Date IRB Notified: _______

1. Adverse Event: _______________

2. The site where research was preformed:
   - [ ] SLH - Allentown
   - [ ] SLH – Miners
   - [ ] SLW - Warren
   - [ ] SLH – Bethlehem
   - [ ] Private Office (Specify location(s): _____
   - [ ] SLH - Quakertown
   - [ ] Other (Specify): ______

3. The research involves:
   - [ ] Drug(s) Name of drug(s): ______
   - [ ] Device(s) Name of device(s): ______
   - [ ] Research-related procedures Name or description of procedures: ______

4. The adverse event... (check all that apply)
   - [ ] Was fatal (resulted in death)
   - [ ] Was life threatening (immediate risk of death), but not fatal
   - [ ] Resulted in a disability (temporary or permanent)
   - [ ] Resulted in hospitalization or prolonged hospitalization
   - [ ] Resulted in congenital anomaly or birth defect

5. The Adverse Event was: [ ] Expected    [ ] Unexpected

6. The relationship of the adverse event to the study is...
   - [ ] Definitely related (The event has a timely relationship to the administration of the investigational drug/study procedure and follows a known pattern of response for which no alternative cause is present)
   - [ ] Probably related (The event has a timely relationship to the administration of the investigational drug/study procedure and follows a known pattern of response, but a potential alternative cause may be present)
   - [ ] Possibly related (The event has a timely relationship to the administration of the investigational drug/study procedure, follows no known pattern of response, but for which a potential alternative cause does not exist)
Unrelated  *(There is evidence that the event is definitely related to a cause other than the investigational drug/study procedure; in general, no timely relationship to the administration of the drug/procedure exists, or if so, the event does not follow a pattern of response and an alternative cause is present)*  
Unknown

7. Please provide the Grade of the Adverse Event (Oncology Only): _____

8. Please provide the Severity of the event by checking the appropriate box below:
   - [ ] Mild
   - [ ] Moderate
   - [ ] Severe
   - [ ] Other: _____

9. Brief Description of the Adverse Event:

10. Briefly describe the action taken:

11. Will the protocol be changed as a result of the adverse event?
   - [ ] Yes (Please include necessary documents and amendment form)
   - [ ] No

12. Will the currently or previously enrolled subjects be notified of the adverse event?
   - [ ] Yes (Please include copies of the information to be conveyed to subjects)
   - [ ] No  Rationale: _____

Principal or Co-Investigator's Signature: ____________________________________________

Date: __________________________

Person Completing Form  Signature: ____________________________________________

Date: __________________________