**Chestnut Health Systems Research Adverse Event Report**

All studies are to report unanticipated events to the IRB’s Human Protections Administrator within 2 business days of PI notification. Unanticipated events are events that are not consistent with the foreseeable risk associated with research procedures or are not expected in the natural progression of any underlying condition of the sample. All deaths are considered unanticipated events. Reports should be made to the Human Protections Administrator by sending a copy of a completed Adverse Event Report (Adverse Event report forms for a DSMP may be used or the Adverse Event Form Template located at Y: http://chestnut.org/LI/Institutional-Review-Board).

*To Be Completed by Staff*

**Study:**

**Staff Name of Person Completing This Form:**

**Staff Position:**

**Date This Form Completed:**

**Date That Adverse Event Was Reported to Staff:**

**Date of Adverse Event (indicate if unknown or indicate approximate timeframe):**

**Where Did the Adverse Event Take Place:**

**Who Was Present for the Adverse Event? (Use participant ID instead of name)**

**Describe Adverse Event (Be as specific as possible):**

**Describe Any Actions Taken by Staff in Response to the Adverse Event (Be as specific as possible):**

**Date Supervisor Notified:**

*To Be Completed by Principal Investigator*

**PI name:**

**Relationship to study (Check all that apply):**

 [ ] Probably related to study research or treatment procedures

 [ ] Possibly related to study research or treatment procedures

 [ ] Unlikely to be related to study research or treatment procedures

 [ ] Unrelated to study research or treatment procedures

**Follow-up Actions Taken:**

**Does This Adverse Event Fit the Definition of an Unanticipated Event Above?**

 **If Yes, Date Reported to IRB:**

*For IRB Use*

**Comments:**