**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 https://www.chestnut.org/lighthouse-institute/institutional-review-board/).

*To Be Completed by Study Staff*

**Study title:**

**Staff name of person completing this form:**

**Staff position:**

**Date this form completed:**

**Date 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 as described above?**

 **If yes, date reported to IRB:**

*To Be Completed for Studies Involving Clients or Staff of Chestnut Health Systems*

**Does this event need to be reported using Chestnut’s incident report form? (see guidelines below)**

**If yes, date reported:**

Attach a copy of the completed incident report to this form.

**RM 60 INCIDENT REPORTING (see Chestnut Health Systems’ policy handbook for complete information)**

Chestnut Health Systems Incident Report forms are available as paper forms and electronically on the Intranet.

Incident Reports are to be completed in at least the following situations (this list is not exhaustive, merely representative of the types of events that need to be reported):

* 911 calls (police, fire, or EMS)
* Allegations of client abuse / neglect / exploitation
* Building evacuations
* Death
* Door or cabinet found unlocked which would be expected to be locked
* Error by external support services (i.e., lab, pharmacy)
* Exposure to bodily fluids and/or hazardous waste
* Equipment malfunction (medical or mechanical)
* Falls
* Fire
* Injury to client or potential for injury (includes self-injury)
* Injury to staff or potential for injury
* Injury to visitor or potential for injury
* Loss of power
* Medical emergencies
* Medication errors (i.e., incorrect dosage, omission)
* Missing person / elopement
* Physical or verbal aggression
* Physical holds to client (youth residential only)
* Property missing
* Property damage
* Severe weather events causing damage to property or harm to individuals
* Sheltering in place for weather-related events
* Suicide attempt
* Theft risk management
* Threats of violence
* Use of a Chestnut emergency code (Dr. Lock, Dr. Armstrong, CPR Certified staff)
* Vehicle accident

In addition, an Incident Report should be completed whenever a mandated report is made pursuant to CR 15. Unlike other Incident Reports, an Incident Report completed in response to a mandated report should be general and simply state the client identification number and the fact that a mandated report was made to a certain agency, without divulging further details.

Privacy and confidentiality incidents, including instances of a suspected or potential breach of confidentiality, are not reported via incident reports. Please see Chestnut’s policy handbook for instructions.

Client names should not be used in the report; instead client ID numbers should be used.

Incident Reports are to be completed by the staff involved and turned in to a supervisor immediately following the incident and no later than by the end of the staff's working day or shift. If staff is not able to complete the incident report, it is the responsibility of the supervisor to complete the report.

*For IRB Use*

**Comments:**