

**Frankford Hospital
Institutional Review Board (IRB)**

Red Lion & Knights Road
Mansion House, Third Floor
Philadelphia, PA 19114



On-Site Adverse Event Reporting Form

Guidelines for Submissions

Investigators must report all unexpected adverse events, serious adverse events, and expected adverse events of moderate or greater severity associated with the research study. If the event occurred at the local site, it must be reported to the IRB within 5 working days. If the event occurred at another location, it must be reported within 30 days of receipt by the investigator.

- An adverse event is considered serious if it is fatal or life-threatening; requires hospitalization; produces a disability; or produces a congenital anomaly/birth defect.
- An adverse reaction is considered to be of moderate or great severity if it requires medical evaluation (such as additional lab testing) and/or medical treatment; or it is a serious adverse reaction.
- An adverse reaction is considered to be unexpected if it is not identified in nature, severity, or frequency in the current IRB-approved research protocol or informed consent document.
- An adverse reaction is considered to be associated with the research intervention if there is a reasonable possibility that the reaction may have been caused by the research treatment.

Date of Report:		IRB Control #	
Title of Study:			
Principal Investigator:		Phone:	
Study Coordinator:		Phone:	
Address:			
Sponsor:		Date PI Notified:	
<input type="checkbox"/> Initial Report		<input type="checkbox"/> Follow-up Report	
Type of Report:			
<input type="checkbox"/> Unexpected		<input type="checkbox"/> Serious Adverse Event	
<input type="checkbox"/> Expected (Moderate/Greater Severity)			
Onset Date:		End Date:	
Subject Initials:		Subject #:	
Event caused the following (check all that apply):			
<input type="checkbox"/> Permanent Disability		<input type="checkbox"/> Hospitalization or Prolonged Hospitalization	
<input type="checkbox"/> Intervention to Prevent Disability		<input type="checkbox"/> Death	
<input type="checkbox"/> Life-threatening Complications		<input type="checkbox"/> Other	
Description of Event:			
Action Taken Regarding Study Drugs and/or Participation (check all that apply):			
<input type="checkbox"/> No Action (continued on study)		<input type="checkbox"/> Study Drug interrupted	
<input type="checkbox"/> Study Drug/Participation Stopped		<input type="checkbox"/> Discontinued From Study on:	
<input type="checkbox"/> Study Drug Dosage Changed			

Event Outcome (if not stated above):

- Resolved
- Stabilized
- Ongoing Monitoring (please provide follow-up information until resolved)
- Other:

Was the event:

- Study Related
- Possibly Related
- Not Related
- Probably Related
- Unable to Determine to be Related

Current Status of Study:

- Open to Accrual
- Closed to Accrual, but Monitoring Participants
- Temporarily Suspended
- Closed

Does this event require a change to (please provide copies to the IRB):

- Protocol
- Consent Form
- No Changes Required

If changes were required to the consent form, will additional information be provided to participants that have already been enrolled?

- Yes
- No

Report prepared by:

Date:

Signature:

Principal Investigator:

Signature:

Date: