



Institutional Review Board
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**ADVERSE EVENT REPORTING FORM FOR HOLY CROSS HOSPITAL
 SUBJECTS ONLY**

Complete this entire form. Do not leave any blanks. If something does not apply to your study enter "N/A."

Section 1.	
IRB Protocol Number:	
Protocol Title:	
Principal Investigator:	
Report prepared by:	

SECTION 2. Attach a copy of all relevant information		
Date of Adverse Event:	Subject's Initials _____ IND Safety Report Number: _____ MedWatch Number: _____	Type of Report: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____
Research involves a : <input type="checkbox"/> Drug <input type="checkbox"/> Device <input type="checkbox"/> Procedure Name of Drug, Device, Procedure:	Adverse Event appears to be (check one): <input type="checkbox"/> Related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related <input type="checkbox"/> Unknown Expectedness: <input type="checkbox"/> Expected <input type="checkbox"/> Not expected Severity of Adverse Event: <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Fatal	
Is the drug/device investigational (not FDA approved): <input type="checkbox"/> Yes <input type="checkbox"/> No Has the Adverse Event been reported to: <input type="checkbox"/> Sponsor, Date of report: _____ <input type="checkbox"/> FDA, Date of report: _____ <input type="checkbox"/> OHRP, Date of report: _____	Type of Adverse Event (check all that apply): <input type="checkbox"/> Death <input type="checkbox"/> Life threatening <input type="checkbox"/> Disability <input type="checkbox"/> New cancer <input type="checkbox"/> Hospitalization <input type="checkbox"/> Extended hospitalization <input type="checkbox"/> Congenital abnormality <input type="checkbox"/> Required intervention to prevent permanent damage <input type="checkbox"/> Significant overdose or protocol error <input type="checkbox"/> Other, explain: _____ Outcome (check all that apply): <input type="checkbox"/> Treatment on hold <input type="checkbox"/> Event resolved <input type="checkbox"/> Discontinued from study <input type="checkbox"/> Patient expired <input type="checkbox"/> Treatment continued <input type="checkbox"/> Unknown <input type="checkbox"/> Other, explain: _____ Recovery of Subject: <input type="checkbox"/> Complete <input type="checkbox"/> Moderate <input type="checkbox"/> Minimal <input type="checkbox"/> None <input type="checkbox"/> Not yet resolved <input type="checkbox"/> Unknown	

Brief description of the adverse event (including diagnosis):

SECTION 3.

Was this Adverse Event addressed in the protocol and consent form?

Yes No

Was this Adverse Event addressed in the Investigator's Brochure?

N/A

Will changes be needed to the protocol or to the informed consent?

Yes No

N/A

Yes No

N/A

SECTION 4.

Individual reporting event: _____
Print/Type Name

Date: _____

Signature