

Form E:	For IRB Use Only:	
ADVERSE EVENTS REPORT	IRB No.	Click here to enter text.
	Date Submitted	Click here to enter text.
	Date Approved	Click here to enter text.

All serious adverse events associated with the study procedures must be reported. All deaths whether or not they are directly related to study procedures, must be reported. However, common sense must play a large role in deciding what to report; not every bruise or rash needs to be reported. If there is a question, investigators are encouraged to err on the side of “over-reporting.”

All forms should be submitted by email to kraig.knudsen@mh.ohio.gov or you may mail them to: Kraig Knudsen, Ph.D., Ohio Department of Mental Health, 30 East Broad Street, 8th Floor, Columbus, Ohio 43214-3430.

TITLE OF RESEARCH:	Click here to enter text.
IRB #:	Click here to enter text.

		DEPT	EMAIL
Principal Investigator	Click here to enter text.	Click here to enter text.	Click here to enter text.
Other Investigator	Click here to enter text.	Click here to enter text.	Click here to enter text.
Other Investigator	Click here to enter text.	Click here to enter text.	Click here to enter text.

DESCRIPTION OF ADVERSE EVENT

EVENT WAS: Unexpected Expected

GRADE OF EVENT (Five choices):

<input type="checkbox"/> Mild	Transient or mild discomfort; no limitation in activity; no medical intervention/therapy
<input type="checkbox"/> Moderate	Mild to moderate limitation in activity, some assistance may be needed; no or minimal medical intervention/therapy required
<input type="checkbox"/> Severe	Marked limitation in activity, some assistance required; medical intervention/therapy required, hospitalization possible
<input type="checkbox"/> Life-Threatening	Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required; hospitalization or hospice care probable
<input type="checkbox"/> Fatal	Subject(s) died

RELATIONSHIP TO DRUG/DEVICE PROCEDURE:

<input type="checkbox"/>	No study drug or device was ever received by the subject	<i>If none, please provide your signature on the last page of this form and return to the IRB.</i>
<input type="checkbox"/>	Not related	No relationship to drug
<input type="checkbox"/>	Probably not related	Relationship is not likely
<input type="checkbox"/>	Possibly related	Relationship may exist
<input type="checkbox"/>	Related	Relationship is likely

Date subject enrolled into the study:	
Concurrent illnesses and medications:	
Date the first investigational drug/device used:	
Dosing schedule (dose/frequency) for each investigational agent/device used:	
Were there any changes or interruptions to the dosing schedule?	<input type="checkbox"/> Yes <input type="checkbox"/> No
What were the reasons for these changes? <i>(Details)</i>	
Was the event anticipated in the protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the risk described in the consent form?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Will there be a revision to the protocol or consent process? <i>(If revisions are required, please provide IRB with a copy of original consent form and a copy of the revised consent form.)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Will revisions require information that will affect all research subjects? <i>(If yes, provide documentation to the IRB that all research subjects have been informed.)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

SIGNATURES:

Principal Investigator or Student	Date
Faculty Advisor <i>(for student apps)</i>	Date

IRB APPROVED:	
Adverse event/injury report reviewed by Full Board on:	
	Date
<input type="checkbox"/> Write to investigator with concerns	
<input type="checkbox"/> Discussed with investigator – No further action required	
<input type="checkbox"/> File with protocol – No further action required	
<input type="checkbox"/> Follow up required.	
<input type="checkbox"/> Additional Comments:	Click here to enter text.
IRB Chair or Designee	Date