

## **AE REPORTING DEFINITIONS & REGULATIONS**

**Serious Adverse Event** are any adverse experience(s) that result in any of the following outcomes: death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Adverse events encompass both physical and psychological harms. Important medical events that may not result in death, be life-threatening or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical, surgical intervention or psychological counseling to prevent one of the outcomes listed in this definition.

**Unexpected Adverse Event** is any adverse experience associated with the study article or study participation for which the specificity or severity is not consistent with the current investigator brochure, or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. "Unexpected" refers to an adverse experience that has not been previously observed.

**Associated with the Study Article** or study Participation means that there is a reasonable possibility that the experience may have been caused by the study article or study participation.

### **Unanticipated problems involving risks to subjects or others**

45 CFR 46.103(b)(5)(i)

Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB

21 CFR 56.108(b)

- (1) Any unanticipated problems involving risks to human subjects or others;
- (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or
- (3) any suspension or termination of IRB approval.

### **Unanticipated adverse device effects**

21 CFR 812.150(b)(1)

A sponsor who conducts an evaluation of an unanticipated adverse device effect under 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests.

### **All adverse drug reactions that are both serious and unexpected**

GCP – 3.3.8(c)

(c) all adverse drug reactions (ADRs) that are both serious and unexpected

## **IRB REPORTING REQUIREMENTS**

Reports of adverse events at internal or external sites should be submitted only if they are determined by the UMKC site PI/Sub-I to be: **unanticipated; serious; and possibly, probably or clearly related** to the study drug / study article/ study device/study participation (rather than unrelated unlikely related or unable to assess relation to study participation).

1. External adverse events (such as “IND Safety Reports” provided by the sponsor of the research) must be reported to the IRB within 25 working days of their receipt.
2. Internal adverse events, other than deaths, must be reported to the IRB within 10 working days of their occurrence.
3. Internal adverse device events, other than deaths, must be reported to the IRB within 10 working days of their occurrence.
4. Internal deaths that are unanticipated and are possibly, probably, or clearly related to the study drug / study article/ study participation must be reported to the IRB within 24 hours of their occurrence.
5. Internal adverse device events resulting in death that are unanticipated and are possibly, probably, or clearly related to the study device must be reported to the IRB within 24 hours of their occurrence.
6. Internal unanticipated problems other than adverse events must be reported to the within 10 working days of their occurrence.

**If the adverse event(s) meet the above referenced criteria, please complete the Adverse Event Report Form below**

**If the study sponsor requires IRB submission of all IND safety reports, you may submit these reports with a cover letter, which includes reference number(s) that link the AE to a safety report, the type of report(s) being submitted, a statement that these events are not considered reportable by the above UMKC IRB definitions and signed by the site PI/Sub-I. Receipt of such reports will be acknowledged by the IRB but will not be reviewed.**

**DO NOT SUBMIT**

**PAGE 1 and 2 ARE FOR INFORMATION PURPOSES ONLY**

**DO NOT SUBMIT**

**UMKC IRB  
ADVERSE EVENT REPORT FORM**

<b>IRB #</b>			
<b>Project Title:</b>			
<b>Principal Investigator:</b>			
<b>Campus contact information:</b>			
<b>Coordinator:</b>			
<b>Campus contact information :</b>			
Please type all submission answers and provide appropriate information. Incomplete or handwritten forms will be returned to the investigator			
<b>Date of Event:</b>		<b>Date of Report:</b>	
<b>Is this an internal or external adverse event?</b> <input type="checkbox"/> Internal <input type="checkbox"/> External			
<b>Subject/Event Number:</b>			
<b>What type of report is this?</b> <input type="checkbox"/> Initial <input type="checkbox"/> Follow up			
<b>EVENT REPRESENTS AN UNANTICIPATED PROBLEM INVOLVING RISKS TO PARTICIPANTS OR OTHERS?</b> (IF ALL ARE CHECKED YES, IT IS AN UNANTICIPATED PROBLEM AND ADDITIONAL ACTIONS MUST BE DETERMINED IF NO, THE REPORT MAY BE RETURNED WITH NO FURTHER DETERMINATION)	<b>No</b>	<b>YES</b>	<b>N/A OR COMMENTS</b>
<b>IS THE DESCRIBED PROBLEM UNFORESEEN?</b> (UNFORESEEN IS DEFINED AS NOT LISTED IN CONSENT AND/OR PROTOCOL INCREASE IN SEVERITY FROM EXPECTED INCREASE IN FREQUENCY FROM EXPECTED)			
<b>IS THE DESCRIBED EVENT RELATED TO THE RESEARCH?</b> (If adequate data to assess this aspect is NOT available to investigator the answer is no).			
<b>DOES THE DESCRIBED EVENT AFFECT THE SAFETY AND WELFARE OF CURRENT OR FUTURE PARTICIPANTS?</b>			

<b>Summary description of the adverse event in site PI own words:</b>	
<b>Are subjects still being recruited?</b> Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Are subjects still being followed?</b> Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Is a protocol change recommended?</b> Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Is a consent form change recommended?</b> Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Will currently enrolled subjects be notified of this event?</b> Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, describe method of notification:	
<b>If a change is recommended, please provide an amendment form with appropriate documentation as required by the UMKC IRB.</b>	

_____ <b>Signature of Site Investigator</b>	_____ <b>Date</b>
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\*\*\*\*\*FOR IRB USE ONLY\*\*\*\*\*

**Further Action Required:** Yes  No

<b>Full IRB Review</b> <input type="checkbox"/>	<b>Notify Subjects of Risk</b> <input type="checkbox"/>	<b>Amend Protocol:</b> <input type="checkbox"/>
<b>Letter to Investigator Accepting AE with no further questions</b> <input type="checkbox"/>	<b>Revise Consent Form</b> <input type="checkbox"/>	<b>Other:</b>

**Review by Chair and/or**

**Designee:** \_\_\_\_\_ **Date:** \_\_\_\_\_

- \*One copy of each should be provided to the IRB for review:
- 1 SAE REPORT FORM SIGNED BY THE PI / Sub-I
  - 1 copy of each subjects SAE documentation
  - 1 copy of the current stamped consent form