

NCI Contract/Grant No. \_\_\_\_\_

IRB Protocol No. \_\_\_\_\_

## NCI, DIVISION OF CANCER PREVENTION (DCP) SERIOUS ADVERSE EVENT FORM

### REQUIRED FIELDS ON ALL REPORTS

Today's Date:	Sponsor: NCI, DCP	Study (Indication):
Drug(s) under Investigation:	IND No.:	

### A. Study Subject Information

1. Study Participant # or PID #	2. Year of Birth: _____	3. Weight at Time of Event: _____ [ ] kg [ ] lbs. [ ] not available	4. Height at Time of Event: _____ [ ] cm [ ] ft [ ] not available
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### B. Event Information

<input type="checkbox"/> Initial Event Report  <input type="checkbox"/> Follow-up	Gender: (circle one)    M        F	Dose at Event:
Event Onset Date: (Month/Day/Year)	Primary Event (diagnosis):	
Event Approx. Time: (Indicate A.M./P.M.)		
Event Occurred at:		
Duration of Drug Exposure at Event:	Primary Treatment Approx. Time (A.M./P.M.): Primary Treatment of Event:	
Attending Physician (Name): Phone/FAX No.: Hospital/Clinic: Address:		
Describe Event (if applicable, include dates of hospitalization for event):          		
Form Completed by: (Print Name) _____ Title _____		
Investigator Signature _____ Date _____ Phone No. _____ (Month/Day/Year)		

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**ALL FIELDS APPEARING IN THE FOLLOWING PAGES (C-F) MUST BE COMPLETED FOR THE INITIAL REPORT; THEREAFTER, FILL IN ONLY SECTIONS THAT PROVIDE ADDITIONAL/ CORRECTIVE INFORMATION.**

**C. Site information**

1. Investigator Name
2. Address

**D. Suspect Medication(s)**

1. Study Design: <input type="checkbox"/> Blind <input type="checkbox"/> Open/Unblind										
Possible Dose (e.g., 300 mg) _____ Frequency (e.g., qd) _____ Route (e.g., po) _____										
2. Study Drug				Formulation (e.g., tablet, solution)						
Lot No. (If known)										
3. Start Date of Study Drug (Month/Day/Year):										
4. Was blind broken due to event? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA										
5. Was Study Drug stopped/interrupted/reduced in response to event? <input type="checkbox"/> No <input type="checkbox"/> Yes										
>> If yes, complete a-e:										
a. If stopped, specify date study drug last taken: _____ <input type="checkbox"/> NA										
(Month/Day/Year)										
b. If reduced, specify: New dose _____ Date reduced _____ <input type="checkbox"/> NA										
(Month/Day/Year)										
c. If interrupted, specify total number of days not given: _____ <input type="checkbox"/> NA										
d. Did event abate after study drug was stopped or dose reduced? <input type="checkbox"/> NA <input type="checkbox"/> Yes <input type="checkbox"/> No										
e. Did event reappear after study drug was reintroduced? <input type="checkbox"/> NA <input type="checkbox"/> Yes <input type="checkbox"/> No										
6. Was patient taking any other medications concomitantly at the time of the event? <input type="checkbox"/> No <input type="checkbox"/> Yes >> If yes, complete below.										
<b>(DO NOT LIST DRUGS USED TO TREAT EVENT)</b>										
Drug Name				Start Date		Stop Date				
Doses (units, frequency, route, indication for use)				Month	Day	Year	Month	Day	Year	(X)

(continue on a separate sheet if necessary)

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### E. Adverse Event

1. Relevant Laboratory/Diagnostic Tests  No tests performed

Date			Test	Results	
Month	Day	Year		Actual Value	Normal Range

(continue on a separate sheet if necessary)

2. Relevant Medical History, including preexisting conditions (e.g., allergies, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, medical/surgical history, etc.)

Date (if known)	Diseases/Surgeries/Treatment

(continue on a separate sheet if necessary)

3. **NCI Toxicity GRADE of the Event** (use NCI Common Toxicity Criteria):  1  2  3  4  5  
If not gradable by NCI CTC, check one of the following:  Mild  Moderate  Severe  Life-threatening  Fatal

4. Why Serious?  
 Results in death  Is life-threatening  Requires inpatient hospitalization or prolongation of existing hospitalization  
 Results in persistent or significant disability/incapacity  Is a congenital anomaly/birth defect  
 Other, specify: \_\_\_\_\_

5. Outcome of Event (at time of report)  
 Resolved-date: \_\_\_\_\_  Improved  Unchanged  Worse  Not available  
(Month/Day/Year)  
 Fatal-date of death: \_\_\_\_\_ Autopsy performed? Y N  
(Month/Day/Year) (circle one)  
Cause of death: \_\_\_\_\_ (please attach death certificate and autopsy report, if applicable)

6. Investigator's opinion of the relationship between the event and the study drug (If more than one event is being reported, list secondary events and corresponding relationship to study drug in the comments section below.) Check applicable box:  
 Not related  Unlikely  Possible  Probable  Definite

7. Was this event reported by the Investigator to (check all that apply):  IRB  Manufacturer/Distributor  
 Other Investigators participating in this study, if checked, please list names and institutions  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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**F. Comments/Clarifications:**

**FOR NCI USE ONLY**

1. Date NCI notified of event (Month/Day/Year):

2. Medical Monitor Review:

Medical Assessment of Event (including drug relationship and expectancy):

Is this an FDA reportable (7 calendar days) event?  Yes  No

Is this an FDA reportable (15 calendar days) event?  Yes  No

>> If No, specify reason: \_\_\_\_\_

Is more information expected?  Yes  No

>> If Yes, specify: \_\_\_\_\_

Is this event to be communicated to other NCI contractors using this investigational drug?  Yes  No

>> If Yes, how? By telephone (attach a TC Form):  Yes, attached TC Form  No

Other (FAX, mail, e-mail, etc.):  Yes, attached a copy of the correspondence  No

Medical Monitor: Print name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_