NCI Contract/Grant No._____ DCP Protocol No. _____
IRB Protocol No. _____ PID 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 ◯ in ◯ not available

B. Event Information

◯ Initial Event Report ◯ Follow-up _____	Gender: (choose one) ◯ M ◯ F
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 _____ (Month/Day/Year) Phone No. _____	

NCI Contract/Grant No._____ DCP Protocol No. _____
IRB Protocol No. _____ PID No. _____

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: ◯ Blind ◯ 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? ◯ No ◯ Yes ◯ NA

5. Was Study Drug stopped/interrupted/reduced in response to event? ◯ No ◯ Yes

>> If yes, complete a-e:

a. If stopped, specify date study drug last taken: _____ (Month/Day/Year) ☐ NA

b. If reduced, specify: New dose _____ Date reduced _____ (Month/Day/Year) ☐ NA

c. If interrupted, specify total number of days not given: _____ ☐ NA

d. Did event abate after study drug was stopped or dose reduced? ◯ NA ◯ Yes ◯ No

e. Did event reappear after study drug was reintroduced? ◯ NA ◯ Yes ◯ No

6. Was patient taking any other medications concomitantly at the time of the event? ◯ No ◉ Yes >> If **Yes**, complete below.
(DO NOT LIST DRUGS USED TO TREAT EVENT)

Drug Name	**Dose**		**Route**	**Indication for Use**	**Start Date** (MM/DD/YYYY)	**Stop Date** (MM/DD/YYYY) **or mark (X) if continuing**	
	Units	Frequency					

(continue on a separate sheet if necessary)

E. Adverse Event

1. Relevant Laboratory/Diagnostic Tests No tests performed

Date	Test	Results	
		Actual Value	Normal Range
Month Day Year			
Date	Test	Results	
		Actual Value	Normal Range
Month Day Year			
Date	Test	Results	
		Actual Value	Normal Range
Month Day Year			

(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

Date (if known) Diseases/Surgeries/Treatment

Date (if known) Diseases/Surgeries/Treatment

(continue on a separate sheet if necessary)

3. CTCAE Term: _____ CTCAE version # _____ NA _____

Grade ○1 ○2 ○3 ○4 ○5

4. Why Serious?

☐ Results in death ☐ Is life-threatening ☐ Requires inpatient hospitalization or prolongation of existing hospitalization
☐ Results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
☐ Is a congenital anomaly/birth defect ☐ Important medical event, specify:_____

5. Outcome of Event (at time of report)

○ Resolved - date: _____ (Month/Day/Year) ○ Improved ○ Unchanged ○ Worse ○ Not available
Fatal - date of death: _____ (Month/Day/Year) Autopsy performed? ○Y ○N (choose 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:

○ Unrelated ○ 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

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 expectedness):

Medical Monitor's opinion of seriousness:

☐ Results in death ☐ Is life-threatening ☐ Requires inpatient hospitalization or prolongation of existing hospitalization
☐ Results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
☐ Is a congenital anomaly/birth defect ☐ Important medical event, specify:_____
☐ Not serious, specify _____

Medical Monitor's opinion of expectedness (based on Investigator's Brochure or other information provided to the site):

◯ Expected ◯ Unexpected

Medical Monitor's opinion of the relationship between the event and the study drug. Check applicable box:

◯ Unrelated ◯ Unlikely ◯ Possible ◯ Probable ◯ Definite

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 _____