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Attachment V

Adverse Event Reporting Chart: Summary of Investigator's Reporting Obligations to the National Cancer Institute, Division of Cancer Prevention and Control, Chemoprevention Branch of Adverse Events Phase I-III Clinical Trials

Reaction	***Reporting Obligation***
a. ALL SERIOUS ADVERSE EVENTS (Fatal, all life-threatening events (Grade 4)[2], any serious adverse event that results in hospitalization, cancer, a congenital anomaly, drug overdose, or a permanently disabling event.)	REPORT BY PHONE TO CB WITHIN 24 HOURS[1] (written report to follow within 48 hrs[3]).
b. ALL ADVERSE EVENTS (SERIOUS, NON-SERIOUS)[4]	REPORTED in the CRF and Progress Reports.

[1]Telephone number available 24 hours daily: 301-496-8563 (Recorder after hours); FAX: 301-402-0553, include date, time, your name, phone number, affiliation, reason for calling/FAXing, NCI contract and protocol number

[2]Use designated DCT/NCI Common Toxicity Criteria.

[3]Report to: **Medical Monitor (as specified in the contract)**
Chemoprevention Branch
DCPC/National Cancer Institute/NIH
Executive Plaza North, Suite 201
<u>For Express (*e.g.*, Federal Express , DHL, Airborne) or Hand Delivery</u>
6130 Executive Blvd.
Rockville, MD 20852

[4]A list of all known toxicities can be found in the Investigator's Brochure or package insert.

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NCI, DCPC, CHEMOPREVENTION BRANCH
SERIOUS ADVERSE EVENT FORM

REQUIRED FIELDS ON ALL REPORTS

Today's Date:	Drug under Investigation:	Study (Indication)
Sponsor: NCI, DCPC, Chemoprevention Branch		
IND No.	IRB Protocol No.	

[ ] Initial [ ] Follow-up	Patient No.	Dose:.
	Sex:	
	Age:	
Event onset date: (Month/Day/Year)	Primary Event (diagnosis)	
Duration of Exposure:		

Describe Event (if applicable, include dates of hospitalization for event)

Form completed by: PI (Print Name) _____ Title _____

PI Signature _____ Date _____ Phone No. _____
(Month/Day/Year)

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ALL FIELDS APPEARING IN THE FOLLOWING PAGES (A-E) MUST BE COMPLETED FOR THE INITIAL REPORT; THEREAFTER, ONLY COMPLETE TO PROVIDE ADDITIONAL/CORRECTIVE INFORMATION.

A. Site information

1. Investigator Name
2. Address

B. Patient Information

1. Patient Initials	2. Date of Birth: _____ (Month/Day/Year)	3. Weight at time of event: _____ [ ] kg [ ] lbs [ ] not available

C. Suspect Medication(s)

1. Study Design: [ ] Blind [ ] Open/Unblind
   >> If open, specify: Dose (*e.g.,* 300 mg) _____ Frequency (*e.g.,* qd) _____ Route

2. Study Drug	Formulation (e.g., tablet, solution)
	Lot No. (if known)

3. Start Date of Study Drug (Month/Day/Year):

4. 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: _____ [ ] NA (Month/Day/Year)

b. If reduced, specify: new dose _____ Date reduced _____ [ ] NA (Month/Day/Year)

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

5. 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 Doses (units, frequency)	Start Date			Stop Date or mark (X) if continuing			
	Month	Day	Year	Month	Day	Year	(X)

(continue on a separate sheet if necessary)

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D. Adverse Event

1. Relevant Laboratory/Diagnostic Tests [ ] No tests performed

Date			Test	Results
Month	Day	Year		

(continue on a separate sheet if necessary)

2. Relevant Medical History, including preexisting conditions (*e.g.,* allergies, race, 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):

4. Why Serious?
[ ] fatal [ ] congenital anomaly [ ] new/prolonged hospitalization
[ ] life-threatening [ ] cancer [ ] required intervention to prevent permanent impairment/damage
[ ] significant disability [ ] overdose [ ] other, specify: _____

5. Treatment of Event

6. Outcome of Event (at time of report)
[ ] resolved [ ] improved [ ] unchanged [ ] worse [ ] not available
[ ] fatal >>> date of death (Month/Day/Year): _____
cause of death: _____

7. Investigator's opinion of the relationship between the event and the study drug (If more than one event being reported, list secondary events and corresponding relationship to study drug in the comments section below.)
[ ] Present (circle one - possible, probable, definite) [ ] Absent (none, unlikely)
[ ] unknown

8. 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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E. Comments/Clarifications:

FOR NCI USE ONLY

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

2. Medical Monitor Review:

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

Is this an FDA reportable (3-day) event? [ ] Yes [ ] No Date reported:_____

Is this an FDA reportable (10-day) event? [ ] Yes [ ] No Date reported:_____

>> If No, specify reason:_____

Is more information expected? [ ] Yes [ ] No

>> If Yes, specify:_____

Was this event 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 _____

Distribution: (circle one, after copying)

NCI Files CCSA Files Monitor/Manager Files