National Cancer Institute
Division of Cancer Prevention

Serious Adverse Event Form
Instructions for Completion

Version 1.2

DOCUMENT CHANGE RECORD

Version Number	Date	Description
Version 1.0	7/20/10	First version
Version 1.1	10/1/10	Revised first version
Version 1.2	3/28/11	Revised to accommodate IND safety final rule

HEADER INFORMATION

NCI Contract/Grant No.: Enter the assigned NCI contract or grant number (*e.g.,* P50-CA-58186; N01-CN-xxxxx).

DCP Protocol No.: Enter the DCP-assigned protocol number for the trial in which the participant is registered (*e.g.*, MDA03-1-01, N01-CN-xxxxx-Task1).

Note: This number is assigned by DCP, and may be the same as or different from the local protocol number. Enter the DCP Protocol Number, found on the cover page of the protocol, in this field.

IRB Protocol No.: Enter the local IRB-assigned protocol number (*e.g.*, AAAB0407).

REQUIRED FIELDS ON ALL REPORTS:

Today's Date: Enter the date this report was completed using the MM/DD/YYYY format.

Sponsor: This field is prefilled with NCI, DCP as funding sponsor.

Study (Indication): Enter the protocol title as it appears on the protocol document.

Drug(s) Under Investigation: Enter the drug(s) being investigated in the study (*e.g.*, erlotinib).

IND No.: Enter the IND number under which the protocol was submitted. This information is found on the cover page of the protocol.

A. STUDY SUBJECT INFORMATION

Study Participant # or PID #:	Enter the identification code that uniquely identifies the participant to the protocol.
Year of Birth	Enter the study participant's year of birth using the YYYY format.
Weight at Time of Event:	Enter the participant's weight at the time of the event or at the last evaluation visit, using English or metric measurement. If weight was not obtained, mark "not available".
Height at Time of Event:	Provide the participant's height at the time of the event or at the last evaluation visit, using English or metric measurement. If height was not obtained, mark "not available".

B. EVENT INFORMATION

Event Report Type:

Use this section to indicate if this is an initial report or a follow-up to a previously submitted report.

If this is the first time the report is submitted to DCP, mark "Initial Event Report".

If a previous report was submitted to DCP, for the same event and new, updated or corrected information is being provided, indicate "Follow-up" and the consecutive number of the follow-up report. For example, if the report is a follow-up to the initial report, it should be indicated as Follow-up #1. If the report is a follow-up to Follow-up #1, it would be Follow-up #2.

Gender (circle one):

Circle the gender of the participant.

Event Onset Date:

Enter the date the outcome of the event fulfilled one of the serious criteria, using the MM/DD/YYYY format. If the actual date is unknown, enter the month and the year but use "UNK" for DD.

Event Approx. Time:

Enter the time of the event onset, using 12-hour time format. Specify AM or PM. Enter "UNK" if the time is not known.

Event Occurred At Location:

Enter the place where the event occurred. For example, if the event occurred at the participant's home or at another location, enter this information. If the location at which the event occurred is not known, enter "UNK".

Duration of Drug Exposure at Event:

Enter number of days or months the participant had been on study drug at the time of the event.

Primary Event (diagnosis):

List only one event per form. The verbatim term reported by the participant should be used whenever possible or appropriate (*e.g.*, symptom or complaint). It is also appropriate for the investigator to report an accepted medical term in this field (*e.g.*, clinically significant change in laboratory value, condition, diagnosis, disorder, or procedure) as needed, but care should be taken to retain the character and nature of the clinical complaint. Definitions for reporting of selected adverse events for regulatory purposes can be found at http://www.cioms.ch/publications/reporting_adverse_drug.pdf.

Enter a symptom, condition/diagnosis (if available), or procedure as the primary event. If a condition/diagnosis has not been identified, enter the symptom (*e.g.*, chest pain). Update the event to the condition/diagnosis on a follow-up form when available [*e.g.*, coronary artery disease (CAD)].

Treatment of the symptom or condition/diagnosis is only reported in

	the Treatment of Event field, except in specific circumstances: • the event being treated pre-existed at baseline • an elective procedure • a new event occurring on study is treated in a separate hospitalization The even should be characterized as <fill in procedure> for preexisting <fill in condition/diagnosis> (*e.g*., CABG for preexisting CAD) or planned <fill in elective procedure> (*e.g*. left knee replacement) Please note that death is an outcome, not an event. The cause of death should be reported as the event. If the cause is unknown, "death, cause unknown" or "sudden death" can be entered as the event. When identified, the cause of death should be entered as the event on a follow-up form, with supporting documentation if available (*e.g.*, death certificate, autopsy report). Secondary events occurring in the same time frame as the primary event (*e.g*., headache in a participant hospitalized to rule out myocardial infarction) that do not fulfill the serious criteria can be discussed in the Description of Event field. If a second event fulfills the SAE criteria, submit it on a separate SAE form. An example is a participant hospitalized for surgical treatment of prostate cancer (SAE #1) who also experienced post-surgical bleeding that resulted in prolongation of hospitalization (SAE #2)
Primary Treatment Approximate Time:	Enter the time when primary treatment was given to the participant, using 12-hour time format. Specify AM or PM. Enter "UNK" if the time is not known.
Primary Treatment of Event:	Describe interventions specific to the event, including medications administered, procedures the participant has undergone, and any other pertinent information. Utilize sources such as the participant's medical record or hospital progress notes to complete this section.
Attending Physician's Name and Contact Information:	Enter name, phone number, fax number, hospital or clinic's name, and address of the physician who treated the participant.
Describe Event:	The description should support the symptom, procedure, or diagnosis listed as the primary event term, including a brief chronology with dates and additional details of diagnosis and treatment. Medical records and other documentation sent with the SAE Report are supplemental to the description and <u>are not acceptable as a replacement</u> for a clear description. Also, try to avoid use of abbreviations and try not to duplicate information here that is captured elsewhere on the SAE Report. If hospitalized, forward the discharge summary with the report.
Form Completed by:	Print name and title of person completing the form.
Investigator Signature	Form must be signed by the investigator. Enter date the investigator

signed the form and provide the contact phone number for the investigator or site coordinator.

C. SITE INFORMATION

1. Investigator Name Enter the site investigator's name.

2. Address Enter the name and address of the site where the participant enrolled in the study.

D. SUSPECT MEDICATION(S)

Study Design:	Mark the box for "Blind" if the study is blinded; mark the "Open/Unblind" box for an open and/or unblinded study.
Possible Dose:	Indicate the possible doses described in the protocol. Indicate the units of the agent (*e.g.*, mg) as administered for the protocol.
Frequency:	Provide the frequency at which the agent is administered under the protocol.
Route:	Indicate the agent's route of administration (*e.g.*, po).
Study Drug:	Enter the name of the agent the participant is receiving as part of the protocol. If the study is blinded, enter the name of the agent *versus* placebo. (*e.g.*, Atorvastatin *vs*. Placebo) If more than one agent is utilized for the protocol, indicate each agent name.
Formulation:	Indicate the formulation of the study drug, *e.g.*, tablet, solution, *etc.*
Lot No. (if known)	If available, indicate the most recent lot number for the agent administered. Enter "UNK" if the lot number is not available.
Start Date of Study Drug	Enter the date the agent was first administered to the participant on the protocol, using MM/DD/YYYY format.
Was blind broken due to event?	If appropriate, indicate if the blind was broken due to the SAE. If not applicable, mark "NA".

Was Study Drug stopped/interrupted/ reduced in response to event?

Indicate if the study drug was stopped, interrupted, or reduced due to the SAE.

If yes, complete items a through e:

- If stopped, specify date study drug was last taken. Report the date in the MM/DD/YYYY format, or mark "NA" if the drug was not stopped.
- If reduced, specify: New dose—Dose of agent was lowered from the original dose or other dose reductions. Also specify the date that the dose was reduced using the MM/DD/YYYY format.
- If interrupted, specify the total number of days the dose was skipped.
- Did the event abate after study drug was stopped or dose reduced? Mark "NA", "Yes" or "No". This assists the Medical Monitor in assessment of the relationship of the event to study drug.
- Did event reappear after study drug was reintroduced? Mark "NA", "Yes" or "No". This assists the Medical Monitor in assessment of the relationship of the event to study drug.

Was patient taking any other medications concomitantly at the time of the event?

Indicate whether or not participant was taking other concomitant medications at the time of the event by marking "No" or "Yes". If Yes is marked, further information on the concomitant medication is required in the fields below. Do not list drugs used to treat the event.

If the participant was not taking any concomitant medications at the time of the event, proceed to the next section of the report form.

Drug Name:

Provide the name of the concomitant medication. If the brand name drug was taken, record it in this field. If a generic formulation was taken, record the name in this field.

Enter only one medication per line. In the case of combination medications, such as Bactrim, do not record the individual medications on separate lines that make up the combination.

Units (doses):

Record the dose units (*e.g.*, mg) of the medication. For combination medications, record units as tablets, capsules, tablespoons, *etc*.

Frequency:

Provide the frequency at which the agent was last administered (*e.g.*, qd, bid).

Route:

Indicate the route of administration for the agent.

Indication for Use:

Indicate the reason the medication is being taken. (*e.g.*, condition, diagnosis)

Start Date: Indicate the start date the participant began taking the medication in the Month, Day, and Year columns. If the exact date in unknown, indicate at least the year. Enter "UNK" if the month or date is unknown.

Stop Date: Record the date the participant stopped taking the medication in the Month, Day, and Year columns. If the participant is still taking the medication, mark the "(X)" column to indicate this.

E. Adverse Event

Relevant Laboratory/ Diagnostic Tests:

If diagnostic tests, including laboratory tests, relevant to the event were performed, mark Yes and provide the date the test was performed; the name of the test performed; the results; and any comments associated with the test. For laboratory tests, provide the units with the results, as well as the local normal range. Continue on a separate sheet if necessary.

If no diagnostic tests or laboratory tests were performed, mark "No" and continue to the next section of the form.

Relevant Medical History, including preexisting conditions:

Enter information concerning participant's relevant medical conditions and treatments either prior to or during the study (*e.g.*, hypertension, diabetes mellitus, renal hepatic dysfunction), including any significant lifestyle factors and history (*e.g.*, allergies, pregnancy history, smoking, alcohol use, drug abuse, *etc*.). Continue on a separate sheet if necessary.

CTCAE Term and Version:

If a CTCAE term corresponding to the event is available, enter the term and the CTCAE version (designated in the protocol). If a CTCAE term corresponding to the event is not available in the version used, mark "NA" and enter "Other, specify" for the CTCAE term. If the latter is used, NCI, DCP will code the event directly using the appropriate medical dictionary (*e.g.*, MedDRA).

Grade:

Severity is a measure of the intensity of a specific event (*e.g*., grade 4); the event itself may be of minor medical significance (*e.g*., severe headache). Mark the numerical grade related to the CTCAE term that has the description best corresponding to the severity of the event. If an appropriate CTCAE term was not identified, refer to the protocol or CTCAE Other, specify for the general scale and mark the grade with the description corresponding to the severity of the event.

Why Serious?

The criteria for identifying an SAE are based on an outcome or action associated with an event that poses a threat to a participant's life or functioning. Mark the reason the event is considered serious by selecting one of the following criteria:

- Results in death
- Is life-threatening
  [*The participant is, in the view of the Investigator, at immediate risk of death from the reaction as it occurred (i.e., it does not include a reaction that, had it occurred in a more serious form, might have caused death*]
- Requires inpatient hospitalization or prolongation of existing hospitalization
  [*NCI, DCP uses full admission as the definition of hospitalization. It DOES NOT include emergency room visits (even those lasting >24 hr), outpatient procedures, or protocol procedures; however, it does include events resulting from a protocol procedure that fulfill other serious criteria, e.g., prolonged hospitalization or are life-threatening*]
- 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
  [*Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require medical or surgical intervention to prevent one of the outcomes listed above*]
  Indicate the reason for selecting Other, specify.

Outcome of Event (at time of report):

Enter the outcome of the event by selecting from any of the following:

- Resolved—The adverse event ended
  - If resolved please provide the resolution date in Month/Day/Year format.
- Improved—The adverse event has not ended but is improving
- Unchanged—The adverse event is continuing at the same severity
- Worse—The adverse event worsened
- Not Available—Mark if the outcome of the SAE is currently unknown
- Fatal—The adverse event ended with death
  - If fatal, enter the date of death in MM/DD/YYYY format.
  - Cause of Death—Enter the reason for the participant's death.
  - If the cause of death is unknown, enter this information.
- Autopsy performed—Circle "Y" for yes or "N" for no. If

unknown, write "UNK" next to the Y/N.

Investigator's opinion of the relationship between the event and the study drug:

Enter the investigator's assessment of the relationship between the event and the study agent by selecting one of the following elements:

- Unrelated—There is no evidence of any causal relationship.
- Unlikely—There is little evidence to suggest a causal relationship (*e.g.*, the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation for the event (*e.g.*, the patient's clinical condition, other concomitant treatments).
- Possible—There is some evidence to suggest a causal relationship (*e.g.*, the event occurred within a reasonable amount of time after administration of the trial medication). However, the influence of other factors may have contributed to the event (*e.g.*, the patient's clinical condition, other concomitant treatments).
- Probable—There is evidence to suggest a causal relationship, and the influence of other factors is unlikely.
- Definite—There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.

Was this event reported by the Investigator to (check all that apply):

Check the appropriate boxes to indicate all other entities that the SAE was reported to (IRB, manufacturer, other investigators participating in the study). If "Other investigators participating in the study" has been checked, please list the names of the investigators and their study sites.
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If the report was forwarded to other Investigators participating in the study, please, check "Other Investigators…" and list the names and institutions.

F. Comments/Clarifications

This section is for the use of the NCI, DCP Medical Monitor, and should be left blank by the reporting institution.