Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Adverse Event Expedited Report – Single Agent v4.0

INSTRUCTIONS: Use this form to submit an Expedited Report for an Adverse Event (AE) or Death Unrelated to an Adverse Event for NCI clinical trials using one investigational agent sponsored under an NCI IND. Refer to the protocol to determine if NCI IND agents are utilized on the study and how to submit the Expedited Report. **Use this form only when it is impossible to access the Adverse Event Expedited Reporting System (AdEERS) Web application**. The AdEERS Web application can be accessed at https://webapps.ctep.nci.nih.gov/openapps/plsql/gadeers_main$.startup.
This form must be completed using the AdEERS Template Instructions available from the NCI CTEP Help Desk by phone at (301) 840-8202 or by fax at (301) 948-2242. Information components followed by "1," "LOV," "LOV/FT," or "CTC" must be entered using the special instructions below. Please see the AdEERS Template Instructions for a complete description of all components and instructions developed for this template.

1 Date information must be entered in MM/DD/YYYY format except where "MM/YYYY Only" (month and year only) instruction is given.
LOV Information must be entered using standardized values from the AdEERS List of Values (LOV) document available from the AdEERS Web site.
LOV/FT Information must be entered using the AdEERS LOV or, if an appropriate value cannot be found, using Free Text (values other than those listed in the LOV).
CTC Adverse Events are to be reported using the terminology and criteria of the NCI Common Toxicity Criteria (CTC), Version 2.0 (publish date April 30, 1999).

COMPLETING THE REPORT:

1. Complete all MANDATORY COMPONENTS in MANDATORY SECTIONS. Complete all *Requisite Components* in MANDATORY SECTIONS if relevant to the patient.
2. Determine which *Requisite Sections* apply to the patient and complete the MANDATORY COMPONENTS (if any) and *Requisite Components* if relevant to the patient.
3. If additional space is required to complete a report section, copy the page where the section appears, complete your entries, and attach to the final report.
4. Complete the form using black or blue ink and send to the Investigational Drug Branch (IDB), P.O. Box 30012, Bethesda, MD 20824 or fax to 301-230-0159.

1. PROTOCOL INFORMATION – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

NCI PROTOCOL NUMBER

IS THIS AN AMENDMENT TO A PREVIOUSLY SUBMITTED REPORT? ☐YES ☐NO

IF YES, CHECK AMENDMENT NUMBER: ☐1 ☐2 ☐3

INITIAL EXPEDITED REPORT TICKET NUMBER (AMENDMENTS ONLY)

PROTOCOL TITLE (Continue below)

2. REPORTER INFORMATION – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

	LAST NAME	FIRST NAME	PHONE	FAX	E-MAIL
REPORT DATE 1					
REPORTER					
PHYSICIAN INFORMATION (Physician to be consulted for questions)					

Fax is a requisite component for **PHYSICIAN INFORMATION**

3. PATIENT INFORMATION – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

A PATIENT ID is a unique identification code associated with each patient entered in the trial.

PATIENT ID

PATIENT'S INSTITUTION NAME, CITY, AND STATE (OR INSTITUTION CODE – Institution where patient is registered on the protocol or is currently being treated, see http://ctep.cancer.gov/guidelines/codes.html)

BIRTH DATE (MM/YYYY Only) | RACE LOV | GENDER LOV | HEIGHT (cm) | WEIGHT (kg) | *Baseline Performance Status at Initiation of Protocol – ECOG/Zubrod Scale* LOV

DISEASE NAME LOV

Disease Name Not Listed (Enter a specific disease name when "Solid Tumor NOS" or "Hematologic unspecified" is entered in the **DISEASE NAME** *component)*

PRIMARY SITE OF DISEASE LOV

Other Primary Site of Disease (Enter only when an appropriate primary site is not found in the LOV)

IS DATE OF INITIAL DIAGNOSIS KNOWN: ☐YES ☐NO IF YES, ENTER THE DATE OF INITIAL DIAGNOSIS (MM/YYYY Only):

4. COURSE INFORMATION – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

A Treatment Assignment Code (TAC) is a unique identification code associated with each arm or dose level of the protocol.
Example: Drug ###mg / m2 IV over X hr D1-3 / every 3 weeks)

Treatment Assignment Code (TAC)

If the appropriate TAC is unavailable from the LOV or is unknown, items A through D (below) are mandatory for the treatment arm or dose level.

A. Agent Name LOV | *B. Dose* | *C. Administration Route* LOV | *D. Duration and Schedule* LOV

START DATE OF FIRST COURSE 1 | **START DATE OF COURSE ASSOCIATED WITH EXPEDITED REPORT** 1 | **START DATE OF PRIMARY AE** 1

End Date of AE 1 | **COURSE NUMBER ON WHICH AE OCCURRED** | **TOTAL NUMBER OF COURSES TO DATE**

WAS AN INVESTIGATIONAL AGENT(S) ADMINISTERED ON THIS PROTOCOL? ☐YES ☐NO

CROSSOVER STUDIES
The following information is required if this report is associated with a Crossover Study: a) Enter the date the initial Crossover course started in the START DATE OF FIRST COURSE field (Section 4), b) Check YES to WAS AN INVESTIGATIONAL AGENT(S) ADMINISTERED ON THIS PROTOCOL? (Section 4), c) Enter the date the investigational agent was last administered in the DATE LAST ADMINISTERED field (Section 10), and d) Enter the dose administered for the course in the TOTAL DOSE ADMINISTERED THIS COURSE field (Section 10), zero (0) is acceptable if the actual dose is unknown.

5. DESCRIPTION OF EVENT – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

DESCRIPTION AND TREATMENT OF EVENT(S) (Continue below)

HAS PATIENT BEEN RETREATED (TO DATE)? ☐YES ☐NO

PRESENT STATUS LOV **(If you record Fatal/Death or Recovered/Resolved with or without Sequelae as PRESENT STATUS, then** *Date of Recovery or Death* **[see right] is mandatory)** | *Date of Recovery or Death* 1

WAS PATIENT REMOVED FROM PROTOCOL TREATMENT (TO DATE)? ☐YES ☐NO
IF YES, ENTER THE *Date Removed from Protocol Treatment* **(see right)** | *Date Removed from Protocol Treatment* 1

6. DEATH UNRELATED TO ADVERSE EVENT – MANDATORY ONLY IF DEATH IS UNRELATED TO AN AE

Sections 1, 2, 3, 4, 5, 6, 7, and 10 are mandatory when reporting a death caused by suicide, accident, progressive disease, etc.

CAUSE OF DEATH LOV **(If you record Progressive Disease as the CAUSE OF DEATH, then PRIMARY ORGAN SYSTEM FAILURE CAUSING DEATH [see right] is mandatory)** | **PRIMARY ORGAN SYSTEM FAILURE CAUSING DEATH** LOV

7. PRIOR THERAPIES – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

THERAPY LOV **(FOR THE PRIMARY DISEASE)** (If you record any of the following as THERAPY, then PRIOR THERAPY AGENT NAME(S) [in column 6] is mandatory: bone marrow transplant, chemotherapy [NOS], chemotherapy [single or multiple agent systemic], hormonal therapy, or immunotherapy)	**THERAPY START DATE (If known) (MM/YYYY only)**	*Therapy End Date (MM/YYYY only)*	*Comments (Enter additional therapies, prior therapy for diseases other than primary disease, or agents not included in LOV, if needed)*	**PRIOR THERAPY AGENT NAME(S)** LOV **(See note in THERAPY column)**

8. Pre-Existing Condition(s) – This section is required if the patient has Pre-Existing Conditions

Identify any medical condition(s) the patient experienced prior to receiving current protocol therapy.

CONDITION A LOV | **CONDITION B** LOV | *Pre-Existing Condition Not Listed (Enter only when an appropriate condition is not found in the LOV)*

9. Site(s) of Metastatic Disease – This section is required if the patient has Sites of Metastatic Disease

SITE A LOV | **SITE B** LOV | *Sites of Metastatic Disease Not Listed (Enter only when an appropriate site is not found in the LOV)*

10. PROTOCOL AGENT – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

AGENT NAME LOV

DATE LAST ADMINISTERED 1 **(This is mandatory for crossover studies if an investigational agent was administered at any time, see Section 4)**

TOTAL DOSE ADMINISTERED THIS COURSE (Amount of agent given for current dose or cycle, this is not total dose given to date)

UNIT OF MEASURE LOV

Comments

Agent Adjustment LOV *Was administration delayed?* ☐*Yes* ☐*No If yes, complete Duration Delay below*

Duration Delay ☐*sec* ☐ *min* ☐*hrs* ☐*days*

(Enter duration length and check Unit of Measure)

CROSSOVER STUDIES – Instruction is provided in Section 4 regarding required information for reports associated with Crossover Studies.

11. Concomitant Medication(s) – This section is required if any non-protocol medication may have contributed to the event(s)

CONCOMITANT MEDICATION A

CONCOMITANT MEDICATION B

CONCOMITANT MEDICATION C

CONCOMITANT MEDICATION D

12. Other Contributing Cause(s) – This section is required if Other Causes may have contributed to the Adverse Event

OTHER CONTRIBUTING CAUSE A

OTHER CONTRIBUTING CAUSE B

OTHER CONTRIBUTING CAUSE C

OTHER CONTRIBUTING CAUSE D

13. ADVERSE EVENTS (CTC) – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS EXCEPT DEATH UNRELATED TO AE

	CATEGORY CTC	**ADVERSE EVENT** CTC	*If AE is other, Specify: (If an appropriate AE term cannot be identified in the CTC, identify the CTC* **CATEGORY** *and provide AE information in this column)*	**GRADE** CTC **(If you record a GRADE 3 or higher,** *Hospitalization or Prolongation of Hospitalization* **[in column 5] is mandatory)**	*Hospitalization or Prolongation of Hospitalization (See note in* **GRADE** *column)*	*Comments (Enter other relevant information in this column)*
AE A:					☐*Yes* ☐*No*	
AE B:					☐*Yes* ☐*No*	
AE C:					☐*Yes* ☐*No*	

14. ATTRIBUTION FOR ADVERSE EVENT – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS EXCEPT DEATH UNRELATED TO AE

Attribution is the determination whether an AE is related to a medical treatment or procedure. Evaluate each AE the patient experiences to determine what might have caused the event or what interventions or conditions the event might have been attributed to.

IMPORTANT: Every AdEERS report that includes Adverse Events must include for each Adverse Event at least one attribution of Possible, Probable, or Definite to either the Agent, the Disease, Other Causes, or Concomitant Medications. NCI will not accept reports without at least one attribution of Possible, Probable, or Definite to either the Agent, the Disease, Other Causes, or Concomitant Medications for each Adverse Event.

Write the AE term(s) you used in Section 13 in the heading area of columns 2, 3, and 4 (found on page 4). Complete the AGENT NAME, DISEASE, *Concomitant Medication* **and/or** *Other Contributing Causes* **information in column 1 using the same information you provided in Sections 10, 3, 11, and 12. Circle the ATTRIBUTION CODE in each column for each AE based on its relationship to the AGENT NAME, DISEASE,** *Concomitant Medication* **and/or** *Other Contributing Causes* **information provided in column 1. An example is provided below.**

Example	Anorexia					Bilirubin					Pain-Other				
	ADVERSE EVENT CTC **(AE A from Section 13)**					**ADVERSE EVENT** CTC **(AE B from Section 13)**					**ADVERSE EVENT** CTC **(AE C from Section 13)**				
Drug 1	1	2	③	4	5	1	2	③	4	5	1	②	3	4	5
AGENT NAME LOV **(from Section 10)**															

ATTRIBUTION CODES are defined as:

- **1 Unrelated - The Adverse Event is clearly NOT related to the investigational agent, disease, concomitant medication, or other contributing cause.**
- **2 Unlikely - The Adverse Event is doubtfully related to the investigational agent, disease, concomitant medication, or other contributing cause.**
- **3 Possible - The Adverse Event may be related to the investigational agent, disease, concomitant medication, or other contributing cause.**
- **4 Probable - The Adverse Event is likely related to the investigational agent, disease, concomitant medication, or other contributing cause.**
- **5 Definite - The Adverse Event is clearly related to the investigational agent, disease, concomitant medication, or other contributing cause.**

This section continues on page 4.

14. ATTRIBUTION FOR ADVERSE EVENT (Continued)

	ADVERSE EVENT CTC (AE A from Section 13)					ADVERSE EVENT CTC (AE B from Section 13)					ADVERSE EVENT CTC (AE C from Section 13)				
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
AGENT NAME LOV (from Section 10)															
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
DISEASE NAME LOV (from Section 3)															
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Concomitant Medication (A from Section 11)															
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Concomitant Medication (B from Section 11)															
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Concomitant Medication (C from Section 11)															
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Concomitant Medication (D from Section 11)															
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Other Contributing Causes (A from Section 12)															
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Other Contributing Causes (B from Section 12)															

15. Abnormal and Relevant Normal Laboratory Results – This section is required if Laboratory Results are relevant to the report

This section is not required if Microbiology information is provided in Section 16.

	Baseline			*Nadir/Worst*		*Recovery/Latest*	
Lab LOV/FT	*Date 1*	*Value*	*Unit of Measure LOV*	*Date 1*	*Value*	*Date 1*	*Value*
Lab A:							
Lab B:							
Lab C:							

16. Lab: Microbiology – This section is required for reporting infections

Do not complete Section 15 if Microbiology information is provided below.

Infection Type: ☐*Bacterial* ☐*Fungal* ☐*Viral*

Site | *Date 1* | *Infectious Agent*

17. Additional Information Attached – This section is required if relevant to the report

Check those you have attached for submission with this report.

☐*Autopsy Report* ☐*Consults* ☐*Discharge Summary* ☐*Flow Sheets/CRFs* ☐*Laboratory Reports* ☐*Other information, specify:* _____

☐*Pathology Report* ☐*Progress Notes* ☐*Radiology Reports* ☐*Referral Letters* ☐*Summary Report Sent to IRB*

18. Submitter Signature – This section required if submitter is someone other than reporter (from Section 2)

I certify that this Expedited Report has been reviewed and approved by a physician or the medically certified designee responsible for the care of this patient.

LAST NAME | **FIRST NAME** | **PHONE** | *Fax* | **E-MAIL**

SUBMITTER SIGNATURE | **SIGNATURE DATE 1**