Department of Health & Human Services

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

Adverse Event Expedited Report – Single Agent

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.

REPORT SECTIONS: The template includes 18 report sections that are categorized as either MANDATORY or *requisite*. MANDATORY SECTION titles (see a through c, below) appear in CAPITAL LETTERS and must be completed for proper assessment of the report. *Requisite Section* titles (see d, below) appear in *italic letters* and must be completed if relevant to the patient for whom the report is being filed. Each section title is followed by a description of when they are MANDATORY and/or *requisite*:

a. MANDATORY when submitting all Expedited Reports (SECTIONS 1, 2, 3, 4, 5, 7, AND 10)
b. MANDATORY when submitting all Expedited Reports except for a Death Unrelated to an AE (SECTIONS 13 AND 14)
c. MANDATORY when submitting an Expedited Report for a Death Unrelated to an AE (SECTION 6)
d. *Requisite* if the report section is relevant to the patient for whom the report is being filed (*sections 8, 9, 11, 12, 15 or 16, 17, and 18*)

INFORMATION COMPONENTS: Within each report section is a set of information components that are also categorized as MANDATORY or *requisite*. The same formatting is used to identify MANDATORY COMPONENTS and *Requisite Components*. Note: *Requisite Sections* (type d, above) often include MANDATORY COMPONENTS that must be completed if relevant to the patient. Information components followed by "1," "LOV," "LOV/FT," or "CTC" must be entered using the special instructions below:

1 Date information must be entered in MM/DD/YYYY format except where "Month/Year Only" instruction is given.
LOV Information must be entered using standardized values from the AdEERS List of Values (LOV) document available at http://ctep.info.nih.gov/InfoForms/default.htm.
LOV/FT Information must be entered using the AdEERS LOV or, if an appropriate value cannot be found, entered using Free Text (a value other than those listed in the AdEERS LOV). Only five components allow Free Text entry, all others must be entered using values from the LOVs.
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). The List of Values for CATEGORY and ADVERSE EVENT are the same values as listed in the CTC. The most comprehensive approach to identify the appropriate CTC CATEGORY and ADVERSE EVENT term is to use the Index Search in the Interactive CTC Application available at http://ctep.info.nih.gov/CTC3/default.htm.

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, Maryland 20824 or fax to 301-230-0159.

Other References available from the AdEERS main page (http://ctep.info.nih.gov/AdEERS/default.htm) or the NCI CTEP Help Desk: NCI Guidelines: Expedited Adverse Event Reporting Requirements for NCI Investigational Agents (both the September 17, 1999 and the Effective Date: January 01, 2001 versions), AdEERS Templates Instructions, AdEERS Templates List of Values, AdEERS Application v3.0, AdEERS Application v3.0 Training Reference, and AdEERS Computer Based Training (CBT) v2.0.

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, if needed)

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

	LAST NAME	FIRST NAME	PHONE	*Fax*	E-MAIL
REPORT DATE 1					
REPORTER					
OTHER PHYSICIAN (Complete when a physician other than the PI is to be consulted for questions)					

PATIENT'S INSTITUTION NAME, CITY, AND STATE (OR INSTITUTION CODE – see http://ctep.info.nih.gov/CtepInformatics/Instcode.htm) (Institution where patient is registered on protocol or currently being treated)

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 | **BIRTH DATE (Month/Year Only)** | **RACE** LOV

GENDER LOV | **HEIGHT (cm)** | **WEIGHT (kg)**

Baseline Performance Status at Initiation of Protocol – ECOG/Zubrod Scale LOV

DISEASE NAME LOV | **PRIMARY SITE OF DISEASE** LOV/FT

IS DATE OF INITIAL DIAGNOSIS KNOWN: ☐YES ☐NO **IF YES, ENTER THE DATE OF INITIAL DIAGNOSIS (Month/Year Only):**

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

Treatment Assignment Code

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

If the Treatment Assignment Code is unknown, items A through D (below) are mandatory

A. Agent Name LOV | *B. Dose* | *C. Administration Route* LOV | *D. Schedule and Treatment Arm or Dose Level* 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**

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

DESCRIPTION OF REACTION AND TEMPORAL RELATIONSHIP TO INVESTIGATIONAL AGENT ADMINISTRATION (Continue below, if needed)

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/FT **(FOR THE PRIMARY DISEASE)** (If you record any of the following as THERAPY, then PRIOR THERAPY AGENT NAME [in column 4] is mandatory: bone marrow transplant, chemotherapy [NOS], chemotherapy [single or multiple agent systemic], hormonal therapy, or immunotherapy)	**THERAPY START DATE (If known)** (Month/Year only)	*Therapy End Date (Month/Year 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/FT:

CONDITION B LOV/FT:

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

SITE A LOV/FT:

SITE B LOV/FT:

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

AGENT NAME LOV

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 Delay Duration below*

Duration Delay
(Enter duration length and check Unit of Measure) ☐*sec* ☐ *min* ☐*hrs* ☐*days*

11. Concomitant Medication(s) – This section is required if the patient received Concomitant Medication

CONCOMITANT MEDICATION A:

CONCOMITANT MEDICATION B:

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:

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.

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)															

This section continues on page 4.

14. ATTRIBUTION FOR ADVERSE EVENT (Continued)

ATTRIBUTION CODES are defined as:

1 Unrelated - The Adverse Event is clearly NOT related to the investigational agent.
2 Unlikely - The Adverse Event is doubtfully related to the investigational agent.
3 Possible - The Adverse Event may be related to the investigational agent.
4 Probable - The Adverse Event is likely related to the investigational agent.
5 Definite - The Adverse Event is clearly related to the investigational agent.

	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**
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* ☐*Laboratory Reports* ☐*Other*

☐*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**