



Adverse Event Expedited Report – Multiple Agents

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 more than 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 <http://ctep.info.nih.gov/AdEERS/default.htm>.

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? <input type="checkbox"/> YES <input type="checkbox"/> NO	IF YES, CHECK AMENDMENT NUMBER: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	INITIAL EXPEDITED REPORT TICKET NUMBER (AMENDMENTS ONLY)
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PROTOCOL TITLE (Continue below, if needed)

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

REPORT DATE ¹	LAST NAME	FIRST NAME	PHONE	<i>Fax</i>	E-MAIL
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)

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(S) – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

AGENT NAME(S) ^{LOV}

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

Comments

Agent Adjustment ^{LOV}

Was administration delayed?

Duration Delay (Enter duration length and check Unit of Measure)

AGENT NAME A ^{LOV}	AGENT NAME B ^{LOV}	AGENT NAME C ^{LOV}	AGENT NAME D ^{LOV}
UNIT OF MEASURE ^{LOV}	UNIT OF MEASURE ^{LOV}	UNIT OF MEASURE ^{LOV}	UNIT OF MEASURE ^{LOV}
<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete Delay Duration below	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete Delay Duration below	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete Delay Duration below	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete Delay Duration below
<input type="checkbox"/> sec <input type="checkbox"/> min <input type="checkbox"/> hrs <input type="checkbox"/> days	<input type="checkbox"/> sec <input type="checkbox"/> min <input type="checkbox"/> hrs <input type="checkbox"/> days	<input type="checkbox"/> sec <input type="checkbox"/> min <input type="checkbox"/> hrs <input type="checkbox"/> days	<input type="checkbox"/> sec <input type="checkbox"/> min <input type="checkbox"/> hrs <input type="checkbox"/> 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:				<input type="checkbox"/> Yes <input type="checkbox"/> No	
AE B:				<input type="checkbox"/> Yes <input type="checkbox"/> No	
AE C:				<input type="checkbox"/> Yes <input type="checkbox"/> 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				
Drug 1	ADVERSE EVENT ^{CTC} (AE A from Section 13)					ADVERSE EVENT ^{CTC} (AE B from Section 13)					ADVERSE EVENT ^{CTC} (AE C from Section 13)				
AGENT NAME ^{LOV} (AGENT NAME A from Section 10)	1	2	③	4	5	1	2	③	4	5	1	②	3	4	5

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} (AGENT NAME A from Section 10)															
AGENT NAME ^{LOV} (AGENT NAME B from Section 10)															
AGENT NAME ^{LOV} (AGENT NAME C from Section 10)															
AGENT NAME ^{LOV} (AGENT NAME D from Section 10)															
DISEASE NAME ^{LOV} (from Section 3)															
Concomitant Medication (A from Section 11)															
Concomitant Medication (B from Section 11)															
Other Contributing Causes (A from Section 12)															
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.

Lab ^{LOV/FT}	Baseline			Nadir/Worst		Recovery/Latest	
	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
- Pathology Report
- Consults
- Progress Notes
- Discharge Summary
- Radiology Reports
- Flow Sheets
- Referral Letters
- Laboratory Reports
- Summary Report Sent to IRB
- Other

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		