ADVERSE EVENT EXPEDITED REPORT

Template Instructions

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ADVERSE EVENT EXPEDITED REPORT INSTRUCTIONS

General Information

The *Adverse Event Expedited Report – Single Agent* and *Multiple Agents* templates were created to provide Reporters with the ability to submit an Expedited Report for an Adverse Event or for a Death Unrelated to an Adverse Event in the rare situation when it is impossible to access the Adverse Event Electronic Reporting System (AdEERS) Web application.

To facilitate CTEP conversion from paper reports to the electronic system, all data on paper must be completed using the standard language provided in the AdEERS application. The goal of AdEERS is to increase the efficiency, completeness and accuracy of safety monitoring and reporting to the FDA. Therefore, the *Adverse Event Expedited Report – Single Agent* and *Multiple Agents* templates must be completed using the accompanying List of Values (LOV) and the report sections identified as mandatory must be complete before CTEP will accept and process the report.

The following instructions should be reviewed before completing the Expedited Report.

Reporting Requirements

The revised expedited Adverse Event reporting requirements become effective January 1, 2001. All active NCI clinical trials using investigational agents sponsored under an NCI Investigational New Drug Application (IND) are required to include Adverse Event reporting requirements in the protocol document or to amend existing protocol documents by January 1, 2002.

An Expedited Report is required when:

- The protocol utilizes an investigational agent supplied under an Investigational New Drug Application (IND) sponsored by DCTD, NCI. NCI requires that Expedited Reports for these protocols must be submitted via the AdEERS Web application or the *Adverse Event Expedited Report – Single Agent* and *Multiple Agents* templates.

- An event occurs on an arm of a trial using both a Commercial Agent and an investigational agent sponsored under an NCI IND. The combination is considered investigational.

An Expedited Report is NOT required when:

- The protocol does not utilize an investigational agent sponsored under an NCI IND. The sponsor defines requirements for Expedited Reports for investigational agents sponsored under a pharmaceutical company IND and therefore the protocol document must be consulted to determine expedited reporting requirements.

- An event occurs on an arm of a trial using a Commercial Agent only. The report is to be sent directly to the FDA using the MedWatch form and a copy of the MedWatch form is sent to the NCI.

- An event occurs on a Commercial Agent-only arm of an NCI trial that utilizes an investigational agent on another arm.

- The protocol utilizes Commercial Agents only.

Refer to the protocol document to determine if an NCI IND agent is utilized on the study and how to submit the Expedited Report.

To learn more about Adverse Event reporting requirements, review the *NCI Guidelines: Expedited Adverse Event Reporting Requirements for NCI Investigational Agents.* Copies of this document are available through the NCI CTEP Help Desk by phone at (301) 840-8202 or by fax at (301) 948-2242 or from the CTEP Web site at http://ctep.cancer.gov/reporting/adeers.html.

Single Agent vs. Multiple Agents Template

The *Adverse Event Expedited Report – Single Agent* template is used to submit Expedited Reports for an Adverse Event or for a Death Unrelated to an Adverse Event. This form is utilized for trials with only one investigational agent sponsored under an NCI IND.

The *Adverse Event Expedited Report – Multiple Agents* template is identical to the *Single Agent* template except that it provides additional space to record up to four agents associated with the trial.

Note: This document uses the *Multiple Agents* template to provide examples of the form when specifying instruction.

Report Sections and Information Components

MANDATORY */ Requisite Sections*

Both the *Adverse Event Expedited Report – Single Agent* and *Multiple Agents* templates include 18 report sections that are categorized as either **MANDATORY** or *requisite*. **MANDATORY SECTION** titles appear in **CAPITAL LETTERS** and *requisite section* titles appear in *italic letters*. There are seven **MANDATORY SECTIONS** (see a, below) that must be completed for proper assessment of the report. These are completed regardless of whether an Adverse Event or a Death Unrelated to an Adverse Event is being reported. The remaining sections may be **MANDATORY** or *requisite* depending on the report type or if information relevant to the patient is available. The report sections are categorized as follows:

a. **MANDATORY** when submitting all Expedited Reports. Sections 1, 2, 3, 4, 5, 7, and 10 must be completed to report an Adverse Event or a Death Unrelated to an Adverse Event.

b. **MANDATORY** when submitting all Expedited Reports except for a Death Unrelated to an Adverse Event. In addition to the sections listed in type a (above), sections 13 and 14 must also be completed when submitting a report for an Adverse Event.

c. **MANDATORY** when submitting a Death Unrelated to an Adverse Event (when the death is caused by suicide, accident, progressive disease, etc.). In addition to the sections listed in type a (above), Section 6 must also be completed when submitting a report for a Death Unrelated to an Adverse Event.

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 are *requisite* (required) if information relevant to the patient is available. For example, the Pre-Existing Condition(s) Section (Section 8) must be completed if the patient had a medical condition prior to receiving current protocol therapy.

The following table illustrates the **MANDATORY** and *requisite* report sections.

Section Number and Title	MANDATORY SECTIONS		Requisite Sections
	Mandatory when reporting an Adverse Event(s)	Mandatory when reporting a Death Unrelated to an Adverse Event	Required if relevant information is available
1 **PROTOCOL INFORMATION**	●	●	
2 **REPORTER INFORMATION**	●	●	
3 **PATIENT INFORMATION**	●	●	
4 **COURSE INFORMATION**	●	●	
5 **DESCRIPTION OF EVENT**	●	●	
6 **DEATH UNRELATED TO ADVERSE EVENT**		●	
7 **PRIOR THERAPIES**	●	●	
8 *Pre-Existing Condition(s)*			●
9 *Site(s) of Metastatic Disease*			●
10 **PROTOCOL AGENT**	●	●	
11 *Concomitant Medication(s)*			●
12 *Other Contributing Cause(s)*			●
13 **ADVERSE EVENT (CTC)**	●		
14 **ATTRIBUTION FOR ADVERSE EVENT**	●		
15 *Abnormal and Normal Laboratory Results*			either Section 15 **or** 16 is required
16 *Lab: Microbiology*			
17 *Additional Information Attached*			●
18 *Submitter Signature*			●

Information Components

Each component of a **MANDATORY** or *requisite* section is information necessary for thorough assessment of the patient's Adverse Event or death. There are many components, however, that either may not be relevant to the patient or may need to be completed according to special instruction. These components are formatted differently or are followed by superscript codes to indicate the requirement. The descriptions below provide the manner in which the components are treated and their requirement.

MANDATORY COMPONENTS

MANDATORY COMPONENTS are identified by the use of **CAPITAL LETTERS**. These elements must be completed for report submission.

MANDATORY COMPONENTS within *Requisite Sections* indicate that the component must be completed if the section is relevant to the patient. For example, in Section 8, if a pre-existing condition is relevant to the patient's Adverse Event, then the **CONDITION** component is **MANDATORY**.

Requisite (non-mandatory) *Components* within a **MANDATORY** or *Requisite* Section

These components appear in *italic letters* to differentiate them from the **MANDATORY COMPONENTS** in the section. Completion of these elements is required only if the information is relevant to the patient. For

example, in Section 3, the *Baseline Performance Status at Initiation of Protocol* component is completed when the status is available for the patient and is relevant to the report.

In some cases, a *requisite component* may become **MANDATORY** depending on how a subsequent question was answered. In these cases, special instruction is written adjacent to the component. For example, in Section 5, the *Date of Recovery or Death* component must be provided if one of the following values was recorded in the **PRESENT STATUS** component: "Fatal/Death," "Resolved with Sequelae," or "Resolved without Sequelae."

Date Components (¹)

All date information requires a four-digit year entry. The majority of the date components are followed by "¹" and are entered using the MM/DD/YYYY date format. Other date components include "MM/YYYY" instruction to indicate that only the Month and Year are required.

List of Values (LOV)

Lists of Values (LOV) are used throughout the templates to standardize the data entered into the AdEERS application. Components followed with "LOV" must be completed using standardized values obtained from the *Adverse Event Expedited Report List of Values* document available at http://ctep.cancer.gov/reporting/adeers.html, from the NCI CTEP Help Desk by phone at (301) 840-8202 or by fax at (301) 948-2242, or within AdEERS.

List of Values or Free Text (LOV/FT)

Components followed by "LOV/FT" are completed using standardized values obtained from the LOVs as above. However, if an appropriate value cannot be found from the LOVs, the component is completed with Free Text (values other than those available from the LOVs). There is one component that provides this option, all other components must be entered using the LOVs or by using alternative components.

Common Toxicity Criteria (CTC)

Adverse Events are to be reported using the terminology and criteria of the *NCI Common Toxicity Criteria (CTC), Version 2.0*. Components followed by "CTC" use the List of Values presented 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 Web Application available at http://ctep.cancer.gov/reporting/ctc.html. The *NCI Common Toxicity Criteria (CTC), Version 2.0 (publish date April 30, 1999)* is available from the same site, or from the NCI CTEP Help Desk.

References

References and products available from the AdEERS main page (http://ctep.cancer.gov/reporting/adeers.html), or from the NCI CTEP Help Desk..

NCI Guidelines:
  Expedited Adverse Event Reporting Requirements for NCI Investigational Agents (September 17, 1999)
  Expedited Adverse Event Reporting Requirements for NCI Investigational Agents (Effective Date: January 01, 2001)

AdEERS Templates:
    Single Agent Template
    Multiple Agents Template
    AdEERS Template Instructions
    AdEERS Template List of Values

AdEERS Application v3.0

AdEERS Application v3.0 Training Reference

AdEERS Computer Based Training (CBT) v2.0

Section-Specific Instruction

The following instructions explain the requirements of each component within each report section of the templates.

It is requested that the templates be completed using black or blue ink and mailed or faxed to the Investigational Drug Branch (IDB) using the address or fax number located on the first page of the template.

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

Instruction:

1   Enter the unique NCI-assigned protocol number for the trial the patient is registered.

NOTE: Often, a protocol will have more than one local protocol number depending on the organizations participating on the trial. However, protocols are assigned only one NCI protocol number. Only enter the NCI-assigned protocol number in the **NCI PROTOCOL NUMBER** component.

2   Place an "X" in the **YES** or **NO** checkbox.

3   If **YES** was chosen for the previous component, place an "X" in the **1**, **2**, or **3** checkbox to indicate the amendment you are submitting.

4   Enter the report ticket number of the initial Expedited Report you are amending.

NOTE: The **INITIAL EXPEDITED REPORT TICKET NUMBER (AMENDMENTS ONLY)** component is mandatory only when amending the initial Expedited Report.

The Reporter (and Submitter, if different than the Reporter) will receive an Expedited Report Ticket Number for each report submitted. The Reporter (and Submitter) should document the ticket number on their copy of the initial template and other related records, if needed. The ticket number is a seven-digit number sent from CTEP via email or fax. The **NCI PROTOCOL NUMBER**, **EXPEDITED REPORT TICKET NUMBER**, and **PATIENT ID** (located in Section 3) are required to retrieve existing report records in the AdEERS Web application to generate reports or modify records in the event of an amendment.

5   Enter the **PROTOCOL TITLE** as it is written on the protocol document.

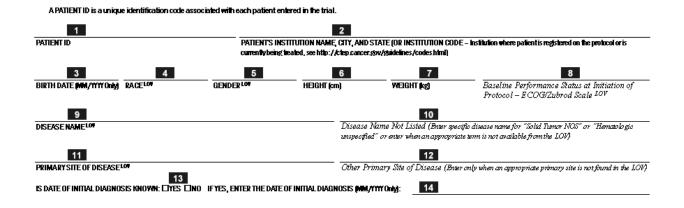## 2. REPORTER INFORMATION - THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

	LAST NAME	FIRST NAME	PHONE	FAX	E-MAIL
REPORT DATE [1]					
REPORTER [2]					
PHYSICIAN INFORMATION (Physician to be consulted for questions) [3]				[4]	

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

Instruction:

[1]   Enter the date the report is being submitted using the MM/DD/YYYY date format.

[2]   Enter the Reporter's **LAST NAME**, **FIRST NAME**, **PHONE**, **FAX** and **E-MAIL** information.

[3]   Complete this component when a Physician other than the Principle Investigator is to be consulted for questions. Enter the other Physician's **LAST NAME**, **FIRST NAME**, **PHONE**, and **E-MAIL** information.

[4]   Enter the Physician's *fax* number if the Physician has access to a fax machine.

NOTE: Accurate e-mail addresses are critical. E-mail messages are sent to the Reporter (and Submitter) to document the NCI Protocol Number, Expedited Report Ticket Number, and Patient ID assigned to the Expedited Report. These three elements are required for future retrieval of Expedited Reports in AdEERS. For more information, see the **INITIAL EXPEDITED REPORT TICKET NUMBER (AMENDMENTS ONLY)** component description in the **PROTOCOL INFORMATION** Section (page 5).

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.

[1]	[2]
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)

[3]	[4]	[5]	[6]	[7]	[8]
BIRTH DATE (MM/YYYY Only)	**RACE** LOV	**GENDER** LOV	**HEIGHT (cm)**	**WEIGHT (kg)**	*Baseline Performance Status at Initiation of Protocol – ECOG/Zubrod Scale* LOV

[9]	[10]
DISEASE NAME LOV	*Disease Name Not Listed (Enter specific disease name for "Solid Tumor NOS" or "Hematologic unspecified" or enter when an appropriate term is not available from the LOV)*

[11]	[12]
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   [13]   IF YES, ENTER THE DATE OF INITIAL DIAGNOSIS (MM/YYYY Only): [14]

Instruction:

[1]   Enter the identification code that uniquely identifies the patient to the protocol. The Reporter has the discretion to assign the **PATIENT ID** code using up to 20 alphanumeric characters.

NOTE: See the **INITIAL EXPEDITED REPORT TICKET NUMBER (AMENDMENTS ONLY)** component description in the **PROTOCOL INFORMATION** Section (page 5) for more information on the **PATIENT ID** and its use in amending Expedited Reports.

2   Enter the name, city, and state of the **PATIENT'S INSTITUTION** or the **INSTITUTION CODE** where the patient is being treated or was initially registered for the protocol. This may differ from the institution where the Reporter is located.

NOTE: Institution Codes are alphanumeric values assigned by CTEP to each institution participating on NCI clinical trials and can be used in place of the institution name, city, and state information. The complete list of CTEP Institution Codes is available from the CTEP Web site at http://ctep.cancer.gov/guidelines/codes.html or through the NCI CTEP Help Desk by phone at (301) 840-8202 or by fax at (301) 948-2242.

3   Enter the month and year the patient was born in MM/YYYY format.

4   Enter the patient's race using the standardized values from the **RACE** LOV.

5   Enter the patient's **GENDER** using the standardized values from the **GENDER** LOV.

6   Enter the patient's **HEIGHT** in centimeters. Calculate the patient's height using the following formula: Height in inches x 2.5 = Height in centimeters

7   Enter the patient's weight in kilograms. Calculate the patient's weight using the following formula: Weight in pounds/2.2 = Weight in kilograms

NOTE: The Body Surface Area (BSA) will be calculated during the AdEERS data entry process using the provided height and weight information.

8   Enter the patient's baseline performance status using the standardized values from the *Baseline Performance Status at Initiation of Protocol-ECOG/Zubrod Scale* LOV. Karnofsky and Lansky equivalents are available in Appendix A.

NOTE: Protocols using the Karnofsky or Lansky scale must map the performance status to the appropriate ECOG scale found in Appendix A.

9   Enter the patient's disease using the standardized values from the **DISEASE NAME** LOV. If an appropriate disease name is not available, enter either "Solid Tumor NOS" or "Hematologic unspecified" in the **DISEASE NAME** component, then enter the specific disease name in the *Disease Name Not Listed* component.

10   The *Disease Name Not Listed* component is used to enter a specific disease name when either "Solid Tumor NOS" or "Hematologic unspecified" is entered in the **DISEASE NAME** component.

11   Enter the site of the patient's primary disease using the standardized values from the **PRIMARY SITE OF DISEASE** LOV.

12   Enter an appropriate site only if one is not available from the **PRIMARY SITE OF DISEASE** LOV.

13   Place an "X" in the **YES** or **NO** checkbox.

14   If **YES** was chosen for the **IS DATE OF INITIAL DIAGNOSIS KNOWN** component, enter the month and year of the patient's initial diagnosis.

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

1 Treatment Assignment Code (TAC)

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 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(s) *LOV*	B. Dose	C. Administration Route *LOV*	D. Duration and Schedule *LOV*
2	**3**	**4**	**5**

6 START DATE OF FIRST COURSE [1]	**7** START DATE OF COURSE ASSOCIATED WITH EXPEDITED REPORT [1]	**8** START DATE OF PRIMARY AE [1]
9 End Date of AE [1]	**10** COURSE NUMBER ON WHICH AE OCCURRED	**11** TOTAL NUMBER OF COURSES TO DATE

WAS AN INVESTIGATIONAL AGENT(S) ADMINISTERED ON THIS PROTOCOL? ☐YES ☐NO **12**

CROSSOVER STUDIES **13**

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

Instruction:

1 Enter the Treatment Assignment Code that the patient is allocated to on the trial. If the Treatment Assignment Code is unknown, information describing the treatment arm or dose level must be completed in the *Agent Name(s)*, *Dose*, *Administration Route*, and *Duration and Schedule* components (items **2** – **5**, below).

NOTE: A Treatment Assignment Code (TAC) is a short description of a treatment arm or dose level. TACs define agent name(s), dose as defined in the protocol (per m^2; per kg, etc.), route, and schedule. TACs are available for all protocols approved at CTEP since March 5, 1998.

2 If the Treatment Assignment Code is unknown, enter the name of the agent (or agents for the *Multiple Agents* template, as shown) the patient received from those listed in the protocol document.

NOTE: Each agent included on a treatment arm or dose level (TAC) in the *Multiple Agents* template must be addressed one at a time in the *Agent Name(s)*, *Dose*, *Administration Route*, and *Duration and Schedule* components (items A – D). It is recommended that all agent-related information requested within each agent row is completed before completing the next agent row.

The *Agent Name(s)* component is presented differently depending on whether you are using the *Single Agent* or *Multiple Agents* template. The *Single Agent* template provides space to record only one agent, while *Multiple Agents* template provides four spaces for agent names.

If more than four agents are to be described, make a copy of Section 4, add the agent and dose information, and attach it to the final report.

Use the agent name(s) listed in the protocol document to complete the *Agent Name(s)* component.

3 Enter the amount of agent administered to the patient.

4 Enter the route the agent was administered using the standardized values from the *Administration Route* LOV.

5 Enter the duration and schedule of the administration. The schedule information entered must utilize a standardized value from the *Schedule* LOV.

NOTE: To enter the *Agent Name(s), Dose, Administration Route,* and *Duration and Schedule* components, use the following format and extent: Agent names(s), dose as defined in the protocol (i.e., amount per kg, m^2, etc.), route, schedule, and duration and schedule. Example:

A. Agent Name(s)	B. Dose	C. Administration Route	D. Duration and Schedule
Drug 1	2.5 mg/kg	IV	Over 24 hours on days 1, 3, 5 every 28 days
Drug 2	1.5 Million IU/m^2	SQ	Days 8 to 10 every 28 days

Some protocols do not have defined courses or cycles such as those with daily administration of an agent. For these protocols:

- The **START DATE OF COURSE ASSOCIATED WITH EXPEDITED REPORT** component is entered with the date the patient last received the agent prior to experiencing the Adverse Event or death

- The **COURSE NUMBER ON WHICH AE OCCURRED** component is entered as 1 (one)

- The **TOTAL NUMBER OF COURSES TO DATE** component is entered as 1 (one)

6 Enter the first administration date of the first agent (for the TAC assigned to the patient). Use the MM/DD/YYYY date format.

7 Enter the date the course (or cycle) began that is associated with the Adverse Event(s) or death for this report. Use the MM/DD/YYYY date format.

8 Enter the date of the most serious Adverse Event included on this report. Use the MM/DD/YYYY date format.

9 Enter the date the Adverse Event ended using the MM/DD/YYYY date format. Because end dates are not always known, this information is not mandatory.

10 Enter the course (or cycle) that is associated with the Adverse Event(s) or death for this report.

11 Enter the total number of courses (or cycles) that the patient has competed or begun.

12 Place an "X" in the **YES** or **NO** checkbox.

NOTE: If **NO** was checked, please refer to the Reporting Requirements section on page 1 to determine whether an Expedited Report is required.

13 The following information is required if this report is associated with a Crossover Study:
   a. In Section 4, enter the date the initial Crossover course started in the **START DATE OF FIRST COURSE** component,
   b. In Section 4, place an "X" in the **YES** checkbox to answer **WAS AN INVESTIGATIONAL AGENT(S) ADMINISTERED ON THIS PROTOCOL?**,
   c. In Section 10, enter the date the investigational agent was last administered in the **DATE LAST ADMINISTERED** component, and
   d. In Section 10, enter the dose administered for the course in the **TOTAL DOSE ADMINISTERED THIS COURSE** component. Zero (0) is acceptable if the actual dose is unknown.

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

Section 5 provides several spaces to describe the event. If additional space is needed, make a copy of Section 5, complete the description, and attach it to the final report.

1
DESCRIPTION AND TREATMENT OF EVENT(S) (Continue below)

2
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)

3
Date of Recovery or Death [1]

4
HAS PATIENT BEEN RETREATED (TO DATE)? ☐YES ☐NO

WAS PATIENT REMOVED FROM PROTOCOL TREATMENT (TO DATE)? ☐YES ☐NO **5**
IF YES, ENTER THE *Date Removed from Protocol Treatment* (see right)

6
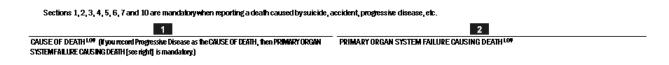*Date Removed from Protocol Treatment* [1]

Instruction:

1 Enter the description of the Adverse Event. Additional information including supporting documentation for the Adverse Event must be included with the report and indicated in the *Additional Information Attached* section (Section 17) of the template.

NOTE: This is one of the most critical sections of the report. Detailed information must be provided to evaluate the Adverse Events and/or the death reported. Enter a description of the presentation of the event, clinical findings, treatment of the events, and timing of events related to agent administration or investigational intervention. Provide physical assessment findings, results of diagnostic tests, and all other pertinent information. Document procedures performed such as surgery, thoracentesis, colonoscopy, autopsy, etc.

2 Enter the value that best describes the patient's present status using the standardized values from the **PRESENT STATUS** LOV. If any of the following values are recorded in this component, then the **DATE OF RECOVERY OR DEATH** component is mandatory: "Fatal/Death," "Recovered/Resolved with Sequelae," "Recovered/Resolved without Sequelae."

3 Enter the date of the patient's recovery or death using the MM/DD/YYYY date format. This component is mandatory when "Fatal/Death," "Recovered/Resolved with Sequelae," or "Recovered/Resolved without Sequelae" is entered in the **PRESENT STATUS** component.

4 Place an "X" in the **YES** or **NO** checkbox.

NOTE: **TO DATE** refers to the date of the report. Answer **YES** if agent was administered to the patient after the Adverse Event occurred, as of the date of the report.

5 Place an "X" in the **YES** or **NO** checkbox. If **YES** is entered, then the **DATE REMOVED FROM PROTOCOL TREATMENT** component is mandatory.

NOTE: **TO DATE** refers to the date of the report. Answer **YES** if the patient was removed from protocol treatment after the Adverse Event occurred, as of the date of the report.

6 Enter the date the patient was removed from protocol treatment using the MM/DD/YYYY date format. This component is mandatory if **YES** was chosen in the **WAS PATIENT REMOVED FROM PROTOCOL TREATMENT (TO DATE)?** component.

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

Section 6 is mandatory when reporting a death that is clearly not related to an Adverse Event listed in the CTC (see the **ADVERSE EVENTS [CTC]** Section on page 16 for more information). Complete this section when a death occurred because of accident, homicide, progressive disease, sudden death, suicide, or unknown reasons.

Reporting a Death Unrelated to an Adverse Event requires an abbreviated report where only Sections 1, 2, 3, 4, 5, 6, 7, and 10 are completed. However, if information is available for any other section of the report and could provide valuable information to assess the death, completion of those sections is required.

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

1	**2**
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

Instruction:

1   Enter the cause of death using the standardized values from the **CAUSE OF DEATH** LOV. If "Progressive Disease" is recorded in this component, then the **PRIMARY ORGAN SYSTEM FAILURE CAUSING DEATH** component is mandatory.

2   Enter the primary organ system that failed resulting in the patient's death. Select standardized values from the **PRIMARY ORGAN SYSTEM FAILURE CAUSING DEATH** LOV. This component is mandatory when "Progressive Disease" is entered in the **CAUSE OF DEATH** component.

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)
1	**2**	**3**	**4**	**5**

Instruction:

1   Enter any prior therapy previously administered to the patient for the current primary disease using the standardized values from the **THERAPY** (MedDRA terms) LOV. If the following Prior Therapies are recorded in the **THERAPY** component, then the **PRIOR THERAPY AGENT NAME(S)** component is mandatory:

- Bone Marrow Transplant
- Chemotherapy NOS
- Chemotherapy Multiple Agents Systemic
- Chemotherapy Single Agent Systemic
- Hormonal Therapy
- Immunotherapy

NOTE: The **THERAPY** LOV includes a "No Prior Therapy" value for those patients who have never received previous therapy.

2   Enter the month and year the patient initially received the prior therapy, if known.

3   Enter the month and year the prior therapy ended.

4   Enter any additional information regarding the therapy selected, any therapy not listed, agents not listed in the **PRIOR THERAPY AGENT NAME(S)** LOV, or prior therapy for diseases other than the current primary disease.

NOTE: Prior therapies for a disease other than the protocol's (current) primary disease (for example, radiation for thyroid cancer in 1955) are to be reported if relevant to the report and are described in the *Comments* component.

     When reporting a prior therapy for a disease other than the primary disease, include therapy, disease, and date (year).

5   Enter the name of the agent administered to the patient for a prior Bone Marrow Transplant, Chemotherapy NOS, Chemotherapy Multiple Agents Systemic, Chemotherapy Single Agent Systemic, Hormonal Therapy, or Immunotherapy using the standardized values from the **PRIOR THERAPY AGENT NAME(S)** LOV. If the name of the agent does not appear in the **PRIOR THERAPY AGENT NAME(S)** LOV, then enter the name in the *Comments* component.

NOTE: Identification of specific agents included in a prior therapy is mandatory when it is relevant to the assessment of an Adverse Event. Some examples include:

- Cumulative anthracycline dose for cardiac toxicity
- Other neurotoxic agents for neurotoxicity
- Prior cisplatin for renal toxicity
- All prior chemotherapy for secondary solid tumors
- Prior alkylating agents and nitrosoureas when prolonged myelosuppression is reported

     If the agent cannot be found in the **PRIOR THERAPY AGENT NAME(S)** LOV, enter the agent name in the *Comments* component.

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

Section 8 is an optional report section and should be completed if the patient had conditions prior to the Adverse Event.

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

1	**2**	**3**
CONDITION A LOV	**CONDITION B** LOV	Pre-Existing Condition Not Listed (Enter only when an appropriate condition is not found in the LOV)

Instruction:

1   Enter the patient's pre-existing condition using the standardized values from the P*re-Existing Condition(s)* LOV.

2   Enter a second pre-existing condition, if needed.

3   Enter a term in the *Pre-Existing Condition Not Listed* component only when an appropriate value cannot be found in the *Pre-Existing Condition(s)* LOV.

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

Section 9 is an optional report section and should be completed 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)*

Instruction:

1   Enter the patient's site of metastatic disease using the standardized values from the *Site(s) of Metastatic Disease* LOV.

2   Enter a second site of metastatic disease, if needed.

3   Enter a term in the *Sites of Metastatic Disease Not Listed* component only when an appropriate value cannot be found in the *Sites of Metastatic Disease* LOV.

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

Instruction:

1   Depending on the number of agents involved, enter the name of the agent(s) the patient received in the **AGENT NAME(S)** component (or in the column headings marked **AGENT NAME A**, **AGENT NAME B**, **AGENT NAME C**, and **AGENT NAME D** for the *Multiple Agents* template, as shown) from those listed in the protocol document. If the agent given was not administered as defined in the TAC, then enter the adjustment in the *Agent Adjustment*, *Was administration delayed?*, and *Delay Duration* components. If additional explanation is required, enter a description in the *Comments* component.

NOTE: The **AGENT NAME(S)** component is presented differently depending on whether you are using the *Single Agent* or *Multiple Agents* template. The *Single Agent* template provides space to record only one agent, while *Multiple Agents* template provides four spaces for agent names.

If more than four agents are to be described, make a copy of Section 10, add the agent information, and attach it to the final report.

Each agent included on a treatment arm or dose level (TAC) in the *Multiple Agents* template, must be addressed one at a time in this section of the report. It is recommended that all agent-related

information requested within each agent column is completed before completing the next agent column. See the **COURSE INFORMATION** Section (page 8) for more information about TACs.

Use the agent name(s) listed in the protocol document to complete the **AGENT NAME(S)** component.

2 Enter the date that the agent(s) were last administered using the MM/DD/YYYY date format. This information is mandatory if **YES** was checked for the component **WAS AN INVESTIGATIONAL AGENT(S) ADMINISTERED ON THIS PROTOCOL?** in Section 4.

3 Enter the total amount of agent administered to the patient for the current course (or cycle). This is the dose calculated based on the TAC that defines amount per m2, amount per kg, etc. Only numbers are entered in this component with a limit of six digits after a decimal. Do NOT enter the following:

- Data including "per m2," "per kg," etc.
- The total dose given to date

4 Enter the **UNIT OF MEASURE** component with the amount of agent administered using standard values from the **TOTAL DOSE ADMINISTERED THIS COURSE UNIT OF MEASURE** LOV.

5 Enter any additional information regarding each agent, or additional explanation regarding a TAC adjustment, if relevant to the report.

6 Enter the adjustment using the standardized values from the *Agent Adjustment* LOV. Enter this information only when the agent was not given exactly as described in the TAC. Provide additional explanation in the *Comments* component, if needed.

7 Place an "X" in the *Yes* or *No* checkbox. If *Yes* was chosen, then the *Delay Duration* component is mandatory.

8 Enter the duration of the delay and place an "X" in the *sec*, *min*, *hrs*, or *days* checkboxes to indicate the duration *Unit of Measure*.

NOTE: The following provides more information regarding the use of the *Agent Adjustment, Was administration delayed?*, and *Delay Duration* components during the entry of a TAC deviation.

A TAC describes the agent, route, duration, and schedule.

Example TAC: Name of Agent 2 mg/m^2 IV over 2 hours days 1, 3, 5 every 30 days.

The correct calculation if the Example TAC is administered exactly as the TAC is described would be:

Patient BSA = 2.0 m^2
Daily dose = 4.0 mg
Daily dose 4.0 mg administered on days 1, 3, 5 = 4.0 mg x 3 =12 mg
TOTAL DOSE ADMINISTERED THIS COURSE = 12 mg

Using the Example TAC (above), provide information regarding any deviation from the TAC as follows.

<u>TAC Dose Deviation</u>

On day 5 the 4.0 mg daily dose was decreased by ½ in response to patient complaints of myalgia and the patient's request to decrease the dose.
TOTAL DOSE ADMINISTERED THIS COURSE = 10 mg
Comments = Dose decreased by ½ on day 5 related to patient complaints of myalgia and patient request to decrease dose.
Agent Adjustment = Dose reduced (from the *Agent Adjustment* LOV)

<u>TAC Route Deviation</u>

Describe in *Comments* component.

<u>TAC Duration Deviation</u>

The day 5 administration was adjusted to over 4 hours.

> *Comments* = Day 5 dose extended to 4 hours related to patient complaints of patient anxiety and dyspnea.
>
> *Delay Duration* = 2 *hrs*

> TAC Schedule Deviation

> The day 5 administration was administered on day 7.

>> *Comments* = Dose scheduled for day 5 was held until day 7 at request of patient for out of town travel.

9 Enter crossover study information, if applicable. See the instructions in Section 4 for additional details.

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

Section 11 is an optional report section and is completed if the patient received any non-protocol medication.

CONCOMITANT MEDICATION A	CONCOMITANT MEDICATION B
CONCOMITANT MEDICATION C	CONCOMITANT MEDICATION D

Instruction:

> Enter as many as four non-protocol medications that the patient received that may have contributed to the Adverse Event.

NOTE: Document concomitant medications and dates of their administration temporally related to the investigational intervention and the event. Consider and report any non-protocol medications that may have contributed to an event such as abnormal liver function tests. The relationship of each medication to each Adverse Event is addressed in the **ATTRIBUTION FOR ADVERSE EVENT** Section (Section 14).

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

Section 12 is an optional report section and should be completed to describe other circumstances that may be related to the patient's Adverse Event. Examples include flu, Central Line Placement, IV hydration, etc.

OTHER CONTRIBUTING CAUSE A	OTHER CONTRIBUTING CAUSE B
OTHER CONTRIBUTING CAUSE C	OTHER CONTRIBUTING CAUSE D

Instruction:

> Enter the descriptions of causes that may have contributed to the Adverse Event.

13. ADVERSE EVENT (CTC) – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

Section 13 is mandatory for all Adverse Event Expedited Reports. This section is not required if reporting a Death Unrelated to an Adverse Event.

Section 13 is designed to hold information related to up to three Adverse Events. If additional events are to be described, make a copy of Section 13, add the event information, and attach it to the final report.

Each Adverse Event must be addressed one at a time in **AE A**, **AE B**, and **AE C** components. It is recommended that all Adverse Event-related information requested within each row is completed before completing the next row.

Adverse Events must 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 the **CATEGORY** and **ADVERSE EVENT** components 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.

	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:	1	2	3	4	☐Yes ☐No	6
AE B:					☐Yes ☐No	
AE C:					☐Yes ☐No	

Instruction:

1 Enter the CTC Category name appropriate for the Adverse Event in the **CATEGORY** column in the rows labeled **AE A**, **AE B**, or **AE** C.

2 Enter the **ADVERSE EVENT** appropriate for the selected CTC Category.

3 Enter the name of Adverse Event in the *If AE is other, Specify* component only if it is not listed in CTC v2.0.

NOTE: Each of the 24 CTC Categories include the Adverse Event "Other, specify." This is used to capture events not yet included in CTC v2.0. The *If AE is other, Specify* component is entered when:
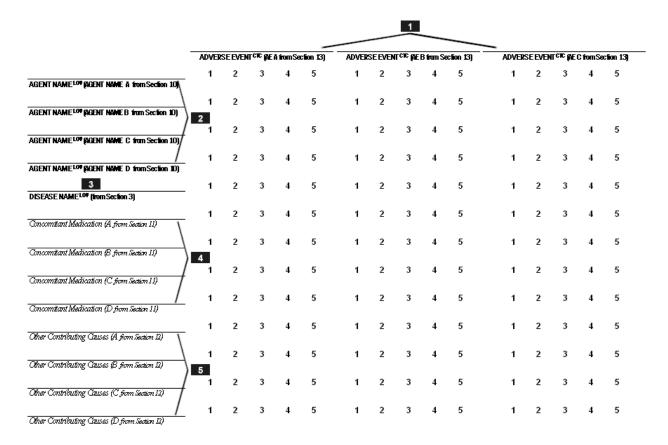
- A suitable Adverse Event cannot be found under the appropriate Category in the CTC v2.0, or
- The NCI Agent-Specific Expected Adverse Event List for agents on the protocol may include unique events not listed in the CTC v2.0

4 Enter the grade appropriate for each Adverse Event. If grade 3, 4, or 5 is entered, then the *Hospitalization or Prolongation of Hospitalization* component is mandatory.

5 Place and "X" in the *Yes* or *No* checkbox if grade 3, 4, or 5 is entered in the **GRADE** component.

NOTE: Any medical event equivalent to CTC grade 3, 4, or 5 that precipitated hospitalization (or prolongation of existing hospitalization) must be reported regardless of requirements for Phase of trial, expected or unexpected, or attribution.

6 Enter additional information relevant to the Adverse Event, if needed.

14. ATTRIBUTION FOR ADVERSE EVENTS – THIS SECTION IS MANDATORY FOR ALL EXPEDITED REPORTS

Section 14 is mandatory for all Adverse Event Expedited Reports. This section is not required if reporting a Death Unrelated to an Adverse Event.

Attribution is the determination whether an Adverse Event is related to a medical treatment or procedure. Evaluate each Adverse Event the patient experiences to determine what might have caused the event or what interventions or conditions the event might have been associated. Evaluation of an Adverse Event involves assessing the relationship of the event to:

- Investigational Agents
- Disease
- Concomitant Medications
- Other Contributing Causes

Instruction:

1 Copy the Adverse Event(s) you previously entered in the **AE A**, **AE B**, or **AE C** components from Section 13 into the heading area of columns 2, 3, and 4.

2 Copy the agent name(s) you previously entered in the **AGENT NAME(S)** component (or the **AGENT NAME A**, **AGENT NAME B**, **AGENT NAME C**, or **AGENT NAME D** components for the *Multiple Agents* template) from Section 10.

NOTE: The **AGENT NAME(S)** component is presented differently depending on whether you are using the *Single Agent* or *Multiple Agents* template. The *Single Agent* template provides space to record only one agent, while *Multiple Agents* template provides four spaces for agent names.

Use the agent name(s) listed in the protocol document to complete the **AGENT NAME(S)** component.

If more than four agents are to be described, make a copy of Section 14, complete the attribution, and attach it to the final report.

3   Copy the **DISEASE NAME** you previously entered in Section 3.

4   Copy the concomitant medications you previously entered in the **CONCOMITANT MEDICATIONS A**, **B**, **C**, and **D** components from Section 11.

5   Copy the other contributing causes you previously entered in the **OTHER CONTRIBUTING CAUSE A**, **B**, **C**, and **D** components from Section 12.

Completing Section 14

Each Adverse Event included must be addressed one at a time in this section of the report. It is recommended that all Adverse Event-related information requested within each column is completed before completing the next column.

One attribution code (number 1 through 5) under each Adverse Event column is circled to indicate the attribution. Attribution codes are listed on the template. Circle the code to answer:

- Was (the first event) related to the Agent(s)? Repeat this question for each Agent on the *Multiple Agents* template.
- Was (the first event) related to the Disease?
- Was (the first event) related to the Concomitant Medication(s)? Repeat this question for each Concomitant Medication entered on the report.
- Was (the first event) related to Other Contributing Causes? Repeat this question for each Contributing Cause entered on the report.

For each question, circle the code that best describes the attribution: Unrelated, Unlikely, Possible, etc.

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

Section 15 is required if the patient has abnormal lab results or normal lab results that are relevant to the report.

If the following Microbiology labs are being recorded, enter the information in Section 16 (do NOT enter in Section 15):

- Bacterial Infection NOS
- Fungal Infection NOS
- Viral Infection NOS

Each lab should be addressed one at a time in this section of the report. It is recommended that all lab-related information requested within each lab row be completed before completing the next lab row.

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:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Lab B:								
Lab C:								

Instruction:

1 Enter the lab name(s) in the *Lab A*, *Lab B*, and *Lab C* components using the standardized values in the *Lab* LOV. Free text (values other than those available from the LOV) can be entered in this component only if an appropriate value cannot be found from the LOV.

2 Enter the date the baseline lab was taken using the MM/DD/YYYY format.

3 Enter the value for the *Baseline* lab.

4 Enter the value's *Unit of Measure* using the standardized values in the *Laboratory Results Unit of Measure* LOV. The unit of measure entered will be applied to the *Nadir/Worst* and *Recovery/Latest* lab values.

5 Enter the date the nadir (or worst) lab was taken using the MM/DD/YYYY format.

6 Enter the value for the nadir (or worst) lab.

7 Enter the date the recovery (or latest) lab was taken using the MM/DD/YYYY format.

8 Enter the value for the recovery (or latest) lab.

NOTE: The *Baseline, Nadir/Worst,* and *Recovery/Latest* components are mandatory for all labs (except Microbiology). Occasionally the baseline, nadir/worst, and recovery/latest labs may be the same. For example, baseline values might not be available for an abnormal lab that occurred during treatment. The baseline and date values entered should reflect the first lab value obtained.

Summary of acceptable lab date combinations:

- *Baseline* date can be equal to or less than *Nadir/Worst* and/or *Recovery/Latest* dates
- *Nadir/Worst* date can be equal to or greater than *Baseline* date; can be equal to or less than *Recovery/Latest* date
- *Recovery/Latest* date can be equal to or greater than *Baseline* and/or *Nadir/Worst* dates

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

Section 16 is required if the patient has Microbiology labs that are relevant to the report. Do NOT complete this section if Section 15 was completed.

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

Infection Type: ☐*Bacterial* ☐*Fungal* ☐*Viral* **1** _____ **2** _____ **3** _____ **4** _____
    Site   Date ^{1} Infectious Agent

Instruction:

1 Place an "X" in the *Bacterial*, *Fungal*, or *Viral* checkbox to indicate the type of Microbiology lab the patient had.

2 Enter the site of infection or the source of culture specimen.

3 Enter the date of infection using the MM/DD/YYYY format.

4 Enter the infectious agent.

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

Section 17 is required if any of the listed items will be attached to the submitted 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*

Instruction:

Place an "X" in the checkboxes for those items you have attached for submission with the report.

NOTE: It is essential to provide documentation to assess events that occur on clinical trials. Some examples of important information to include for:

Death Due to Progressive Disease
- Objective confirmation of disease (i.e., CT, MRI, x-ray, autopsy)
- In the unusual event where objective confirmation cannot be obtained, provide a copy of the attending physician's notes
- Report the organ system involved in the immediate cause of death

Abnormal Liver Function
- Concomitant medications and dates of their administration temporally related to the investigational intervention and the event(s)
- Blood transfusions and dates of administration
- Hepatitis screening
- CT scan/ultrasound (if there is suspicion of increased liver metastases or dilated hepatic ducts)
- Prior history of hepatic problems such as hepatitis
- Baseline and recovery laboratory values

Cardiac Event
- History of cardiac problems
- History of a similar event
- Risk factors (e.g., family history, smoking, hypertension, cholesterol/lipid abnormalities, obesity)

Thrombotic Event
- Prior history
- Known risk factors
- History of decreased activity due to Adverse Events related to treatment or due to tumor

Abnormal Blood Laboratory Values
- Provide baseline and recovery values and dates

Infection
- Laboratory values including CBC with differential
- Culture results (blood, urine, stool, CNS, etc)
- Submit Expedited Report

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

Section 18 is required if the person submitting the report is different than the Reporter entered in 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.

1	**2**	**3**	**4**	**5**
LAST NAME	FIRST NAME	PHONE	*Fax*	E-MAIL

6	**7**
SUBMITTER SIGNATURE	SIGNATURE DATE [1]

Instruction:

1   Enter the submitter's **LAST NAME**.

2   Enter the submitter's **FIRST NAME**.

3   Enter the submitter's **PHONE** number.

4   Enter the submitter's *fax* number, if available.

5   Enter the submitter's **E-MAIL** address.

6   Sign the completed form.

7   Enter the date the report was signed.

NOTE: By signing this form, the submitter is certifying that:

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

Appendix A: ECOG/Zubrod Scale with Karnofsky and Lansky Equivalents

PERFORMANCE STATUS CRITERIA

Karnofsky and Lansky performance scores are intended to be multiples of 10.

ECOG (Zubrod)		Karnofsky		Lansky*	
Score	Description	Score	Description	Score	Description
0	Fully active, able to carry on all pre-disease performance without restriction.	100	Normal, no complaints, no evidence of disease.	100	Fully active, normal.
		90	Able to carry on normal activity; minor signs or symptoms of disease.	90	Minor restrictions in physically strenuous activity.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	80	Normal activity with effort; some signs or symptoms of disease.	80	Active, but tires more quickly
		70	Cares for self, unable to carry on normal activity or do active work.	70	Both greater restriction of and less time spent in play activity.
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours.	60	Requires occasional assistance, but is able to care for most of his/her needs.	60	Up and around, but minimal active play; keeps busy with quieter activities.
		50	Requires considerable assistance and frequent medical care.	50	Gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities.
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours.	40	Disabled, requires special care and assistance.	40	Mostly in bed; participates in quiet activities.
		30	Severely disabled, hospitalization indicated. Death not imminent.	30	In bed; needs assistance even for quiet play.
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair.	20	Very sick, hospitalization indicated. Death not imminent.	20	Often sleeping; play entirely limited to very passive activities.
		10	Moribund, fatal processes progressing rapidly.	10	No play; does not get out of bed.

*The conversion of the Lansky to ECOG scales is intended for NCI reporting purposes only.