

Site Number: \_\_\_\_\_

Screening ID: \_\_\_\_\_ - \_\_\_\_

Participant Letters: \_\_\_\_\_

**For this study, only events Grade 2 and greater will be reported to the Coordinating Center. The Study Coordinator should complete this form to report:**

- A new adverse event, or
- A **change in intensity, frequency, or duration of a previously reported adverse event.**

**If updating a previously reported adverse event, make the necessary changes to the original report and send copies of the updated pages to the Coordinating Center. Include a copy of the first page for updates so that changes can be linked to the original Adverse Event ID Number.**

An *adverse event* is described as any unfavorable or unintended clinical event, sign, symptom, or disease, or any event that has *changed* adversely in nature, intensity, or frequency. Unless this event is a *serious adverse event*, this form should be completed at the next scheduled follow-up visit.

**A. REPORT INFORMATION**

Adverse Event ID Number: ### #

1. Date of report:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DAY MONTH YEAR

2. Last attended study visit (*check one*):

- |                                       |                                      |                                      |                                      |
|---------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> -1 Screening | <input type="checkbox"/> 8 Visit 8   | <input type="checkbox"/> 17 Visit 17 | <input type="checkbox"/> 26 Visit 26 |
| <input type="checkbox"/> 0 Baseline   | <input type="checkbox"/> 9 Visit 9   | <input type="checkbox"/> 18 Visit 18 | <input type="checkbox"/> 27 Visit 27 |
| <input type="checkbox"/> 1 Visit 1    | <input type="checkbox"/> 10 Visit 10 | <input type="checkbox"/> 19 Visit 19 | <input type="checkbox"/> 28 Visit 28 |
| <input type="checkbox"/> 2 Visit 2    | <input type="checkbox"/> 11 Visit 11 | <input type="checkbox"/> 20 Visit 20 | <input type="checkbox"/> 29 Visit 29 |
| <input type="checkbox"/> 3 Visit 3    | <input type="checkbox"/> 12 Visit 12 | <input type="checkbox"/> 21 Visit 21 | <input type="checkbox"/> 30 Visit 30 |
| <input type="checkbox"/> 4 Visit 4    | <input type="checkbox"/> 13 Visit 13 | <input type="checkbox"/> 22 Visit 22 | <input type="checkbox"/> 31 Visit 31 |
| <input type="checkbox"/> 5 Visit 5    | <input type="checkbox"/> 14 Visit 14 | <input type="checkbox"/> 23 Visit 23 |                                      |
| <input type="checkbox"/> 6 Visit 6    | <input type="checkbox"/> 15 Visit 15 | <input type="checkbox"/> 24 Visit 24 |                                      |
| <input type="checkbox"/> 7 Visit 7    | <input type="checkbox"/> 16 Visit 16 | <input type="checkbox"/> 25 Visit 25 |                                      |

3. How many separate adverse events are being reported at this time? \_\_\_\_\_

IF MORE THAN ONE, each adverse event requires the completion of a separate Adverse Event Report Form

**B. GENERAL EVENT INFORMATION**

1. Date of onset of adverse event:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DAY MONTH YEAR

2. Event Type (*check one*):

- 1 Fever
- 2 Cough
- 3 Shortness of Breath
- 4 Hypotension
- 5 Hypertension
- 6 Tachycardia
- 7 Rash
- 8 Pruritus
- 9 Vomiting
- 10 Nausea
- 11 Headache
- 12 Diarrhea
- 13 Abdominal Pain
- 14 Allergic reaction or episode

**Infection**

- 15 Viral infection
- 16 Bacterial infection
- 17 Fungal infection
- 18 Protozoal infection
- 19 Infection of unknown cause

**Laboratory Abnormality**

- 20 Leukopenia
- 21 Neutropenia
- 22 Thrombocytopenia
- 23 Lymphopenia
- 24 Other laboratory abnormality

On all questions write “?” if the desired information is currently unavailable, but is being checked and will be known in future updates.  
Write “\*” if the desired information is permanently unavailable (i.e. will not be known in any future updates).

Site: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_\_ Letters: \_\_\_\_\_ Adverse Event ID Number: \_\_\_\_\_

**B. GENERAL EVENT INFORMATION (Continued)**

2. Event Type (*check one*): (continued)

**Accident**

- 25 Accident requiring medical assistance, but no ER visit or hospital admission
- 26 Accident requiring ER visit, but no hospital admission
- 27 Accident requiring admission to hospital

**Pregnancy**

- 28 Pregnancy (Complete Forms CTL14 and CTL14R)

**Diabetes Related**

- 29 Ketoacidosis with ER visit, but no hospital admission
- 30 Ketoacidosis requiring admission to hospital
- 31 Hypoglycemia with assistance, but without seizure or coma
- 32 Hypoglycemia resulting in seizure and/or coma

**Other**

- 99 Other, a. Specify: \_\_\_\_\_

3. Did the event occur during the infusion of study medication?

Y N

4. If event is severe hypoglycemia, record glucose level during the event:  
(If blood glucose value is unknown for a severe hypoglycemic event,  
record "\*" for this question)

\_\_\_\_\_

a. Units:

- 1 mg/dl
- 2 mmol/L

**C. EVENT DESCRIPTION**

1. Describe the event:

(If an infection, describe  
organism, sensitivity,  
treatment, etc.)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. What was the outcome of the adverse event? (*check one*)

- 1 Recovered, no residual effect
- 2 Residual effect, no treatment
- 3 Residual effect, being treated
- 4 Persistent, no treatment
- 5 Persistent, being treated
- 6 Death

- 99 Other, a. Specify: \_\_\_\_\_

3. Has the adverse event resolved?

Y N

If YES,

a. Date resolved:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

4. Intensity of reported event (*check one*): **NOTE:** Use NCI Common Terminology Criteria for Adverse Events (CTCAE) to grade intensity or TrialNet guidelines

- 2 Grade 2
- 3 Grade 3
- 4 Grade 4
- 5 Grade 5

- Grade 2:** A moderate adverse event. The symptom impairs the participant's usual function, but presents no danger to the participant, or resolves with intervention.
- Grade 3:** A severe adverse event resulting in hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.
- Grade 4:** A life-threatening or disabling adverse event.
- Grade 5:** A fatal adverse event.

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Site: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_\_ Letters: \_\_\_\_\_ Adverse Event ID Number: \_\_\_\_\_

**D. RELATIONSHIP, ACTION TAKEN, AND INTENSITY**

1. Relationship to study medication (*check one*):

- 1 Not related     2 Unlikely     3 Possible     4 Probable     5 Definite

<b>Not related:</b>	No relationship (0% chance) that AE is related to study medication
<b>Unlikely:</b>	Relationship is possible, but not likely (1 – 19% chance) that AE is related to study medication
<b>Possible:</b>	Reasonable likelihood that the study medication caused the adverse event with a chance (20-50%) the AE is related that cannot be excluded
<b>Probable:</b>	Relationship is quite likely (51 – 99% chance) that the AE is related to the study medication
<b>Definite:</b>	Unquestionable relationship (100% chance) that the AE is related to the study medication

2. Was the event related to a study procedure? Y N

If YES,

a. Describe: \_\_\_\_\_

3. Actions taken for the adverse event:

- |                                                 |     |                                          |     |
|-------------------------------------------------|-----|------------------------------------------|-----|
| a. Study infusions interrupted or discontinued? | Y N | e. None?                                 | Y N |
| b. Concomitant medication prescribed?           | Y N | f. Requested testing of viral specimens? | Y N |
| c. Outpatient procedure?                        | Y N | g. Other?                                | Y N |
| d. Non-drug treatment?                          | Y N |                                          |     |

If OTHER,

1) Specify: \_\_\_\_\_

If concomitant medication was prescribed, complete the Concomitant Medications Form (CTL10)

4. Did treatment require any of the following?

- |                                |     |                                           |     |
|--------------------------------|-----|-------------------------------------------|-----|
| a. Visit to study site?        | Y N | d. In-patient rehabilitation?             | Y N |
| b. Visit to emergency room?    | Y N | e. Admission to hospital?                 | Y N |
| c. Out-patient rehabilitation? | Y N | f. Admission to skilled nursing facility? | Y N |

If treatment involved admission to hospital, skilled nursing facility, or in-patient rehabilitation:

g. Record length of stay: \_\_\_\_\_ Days

5. Did treatment of the adverse event require unmasking of the participant's treatment group assignment? Y N

If YES, a. Describe the circumstances:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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Site: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_\_ Letters: \_\_\_\_\_ Adverse Event ID Number: \_\_\_\_\_

**E. CONCLUSION**

1. Include any additional comments (*e.g. note whether or not the participant has experienced this problem before, any follow-up plans, etc.*):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. Was this a serious adverse event? Y N

If YES, complete the following section (Section F)  
If NO, DO NOT complete **Section F**

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Site: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_\_ Letters: \_\_\_\_\_ Adverse Event ID Number: \_\_\_\_\_

**F. SERIOUS EVENT DESCRIPTION (This section only needs to be completed for Serious Adverse Events)**

A **Serious Adverse Event** is defined as occurrence of one or more of the following:

- An event that is of intensity **Grade 3, 4, or 5**
- An overdose
- Any other condition that in the opinion of appropriate medical personnel will result in one of the above outcomes if left untreated
- Death
- Any life threatening condition
- Inpatient hospitalization or prolongation of current hospitalization
- Significant disability or incapacity
- Congenital anomaly/birth defect (*only if the offspring was exposed to the study medication in utero*)

All **Serious Adverse Events** must be reported to the Coordinating Center within **24 hours**.

All **Serious Adverse Events** also require the completion of the **TrialNet MedWatch Form**, which must be faxed to the Coordinating Center at **(866) 804-6058** or **(301) 468-1676** within **24 hours** of clinic notification.

1. Did the adverse event result in any of the following?

- |                                        |                                                       |                                    |                                                       |
|----------------------------------------|-------------------------------------------------------|------------------------------------|-------------------------------------------------------|
| a. Require or prolong hospitalization? | <input type="checkbox"/> Y <input type="checkbox"/> N | c. Permanent or severe disability? | <input type="checkbox"/> Y <input type="checkbox"/> N |
| b. Death?                              | <input type="checkbox"/> Y <input type="checkbox"/> N |                                    |                                                       |

IF ADVERSE EVENT RESULTED IN DEATH:

1) Date of death: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
DAY MONTH YEAR

2) Probable cause of death: \_\_\_\_\_

An adverse event resulting in death requires completion of the Mortality Event Form (CTL13M)

2. Was the serious adverse experience:

- |                        |                                                       |                                                 |                                                       |
|------------------------|-------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------|
| a. Congenital anomaly? | <input type="checkbox"/> Y <input type="checkbox"/> N | d. Due to overdose of study medication?         | <input type="checkbox"/> Y <input type="checkbox"/> N |
| b. Cancer?             | <input type="checkbox"/> Y <input type="checkbox"/> N | e. Condition that could have resulted in one of | <input type="checkbox"/> Y <input type="checkbox"/> N |
| c. Life-threatening?   | <input type="checkbox"/> Y <input type="checkbox"/> N | the previous outcomes if left untreated?        |                                                       |

3. Describe the adverse event in detail (*include information leading up to the event, procedures or tests completed, date stopped study medication, etc.*):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. Was this an "unexpected" adverse event?  Y  N

An **unexpected adverse event** is defined as one for which the specificity or severity of which is **not consistent** with the current Investigator's Brochure. For a complete list of expected adverse events for abatacept see the Manual of Operations.

5. Date the TrialNet MedWatch Form was faxed to the Coordinating Center: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
DAY MONTH YEAR

a. Time the TrialNet MedWatch Form was faxed (24-hour clock): \_\_\_\_\_:\_\_\_\_ (24 hour clock)

**REPORTING OF ADVERSE EVENTS**

Complete this form with as much information as is currently known regarding the adverse event. If information for a question is currently unavailable but will be known, answer with a "?". If information is permanently unknown, and the answer to the question will be unknown in all future updates, answer with an "\*". No questions should be left blank.

Initials (first, middle, last) of person completing this form: \_\_\_\_\_  
F M L

Date form completed: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
DAY MONTH YEAR

Signature of Principal Investigator: \_\_\_\_\_

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**CTLA-4 Ig Study**  
**ADVERSE EVENT REPORT FORM**

**Form CTL13**  
01 JAN 2008  
Version 1.0  
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Site: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_\_ Letters: \_\_\_\_\_ Adverse Event ID Number: \_\_\_\_\_

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**Top Copy** – Send to TrialNet Coordinating Center

**Bottom Copy** – Retain at site