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)*:

☐ -1	Screening	☐ 8	Visit 8	☐ 17	Visit 17	☐ 26	Visit 26
☐ 0	Baseline	☐ 9	Visit 9	☐ 18	Visit 18	☐ 27	Visit 27
☐ 1	Visit 1	☐ 10	Visit 10	☐ 19	Visit 19	☐ 28	Visit 28
☐ 2	Visit 2	☐ 11	Visit 11	☐ 20	Visit 20	☐ 29	Visit 29
☐ 3	Visit 3	☐ 12	Visit 12	☐ 21	Visit 21	☐ 30	Visit 30
☐ 4	Visit 4	☐ 13	Visit 13	☐ 22	Visit 22	☐ 31	Visit 31
☐ 5	Visit 5	☐ 14	Visit 14	☐ 23	Visit 23		
☐ 6	Visit 6	☐ 15	Visit 15	☐ 24	Visit 24		
☐ 7	Visit 7	☐ 16	Visit 16	☐ 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: __ __ __.__ a. Units: ☐1 mg/dl ☐2 mmol/L
(If blood glucose value is unknown for a severe hypoglycemic event, record "*" for this question)

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.

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

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

_____

_____

_____

_____

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).*

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**

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? Y N
   b. Death? Y N
   c. Permanent or severe disability? Y 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? Y N
   b. Cancer? Y N
   c. Life-threatening? Y N
   d. Due to overdose of study medication? Y N
   e. Condition that could have resulted in one of the previous outcomes if left untreated? Y N

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: _____

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: __ __ __ __

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).*