Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Complete this form for any new adverse event (either reported or observed), whether serious or non-serious, as well as any *changes* in intensity, frequency, or duration of a previously reported adverse event, even if the adverse event is the same. 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. Be sure to always include a copy of the first page for updates so that changes can be linked to the original Adverse Event ID Number.

A. REPORT INFORMATION

Adverse Event ID Number: # # # #

1. Date of report: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. At which visit is this adverse event being reported, or last visit attended if reported in-between visits? *(check one)*

☐ 2	Baseline	☐ 6	Week 4	☐ 14	Month 9	☐ 26	Month 21	☐ 32	Month 36
☐ 3	Week 1	☐ 7	Month 2	☐ 17	Month 12	☐ 29	Month 24	☐ 33	Month 42
☐ 4	Week 2	☐ 8	Month 3	☐ 20	Month 15	☐ 30	Month 27	☐ 34	Month 48
☐ 5	Week 3	☐ 11	Month 6	☐ 23	Month 18	☐ 31	Month 30	☐ 99	Other

3. How many unique adverse events will be reported at this time? __ __

IF MORE THAN 1, each unique adverse event requires the completion of a separate form

B. GENERAL EVENT INFORMATION

1. Date of onset of adverse event: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

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

Study Specific
- ☐ 1 Mono-like symptoms
- ☐ 2 GI Toxicity
- ☐ 3 Leukopenia
- ☐ 4 Neutropenia
- ☐ 5 Allergic reaction or episode
- ☐ 6 Cancer

Infection
- ☐ 7 Viral infection
- ☐ 8 Bacterial infection
- ☐ 9 Fungal infection
- ☐ 10 Protozoal infection
- ☐ 11 Infection of unknown cause

Diabetes Related
- ☐ 12 Ketoacidosis w/ ER visit, but no hospital admission
- ☐ 13 Ketoacidosis requiring admission to hospital
- ☐ 14 Hypoglycemia w/ assistance, but no seizure or coma
- ☐ 15 Hypoglycemia resulting in seizure and/or coma
- ☐ 16 Need for injected glucagon or IV glucose

General Systems
- ☐ 17 Hypertension
- ☐ 18 Hyperlipidemia
- ☐ 19 Renal Insufficiency
- ☐ 20 Psychiatric disease
- ☐ 21 Stroke/Cerebrovascular event
- ☐ 22 Myocardial Infarction/Heart Attack
- ☐ 23 Angina Pectoris
- ☐ 24 Arrhythmia
- ☐ 25 Congestive Heart Failure

Accident
- ☐ 26 Accident requiring medical assistance, but no ER visit or hospital admission
- ☐ 27 Accident requiring ER visit, but not admission to hospital
- ☐ 28 Accident requiring admission to hospital

Pregnancy
- ☐ 29 Pregnancy*
- ☐ 30 Adverse pregnancy outcome

* Complete Pregnancy Confirmation Form (**MMF09**) and Pregnancy Outcome Report Form (**MMF09R**)

☐ 99 Other a. Specify: _____

IF THE EVENT WAS AN INFECTION,
b. Was the infection opportunistic? Y N

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 Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

B. GENERAL EVENT INFORMATION (cont.) *AEID #:* __ __ __ __

3. Briefly describe the event:
(If an infection, describe organism, sensitivity, treatment, etc.)

_____
_____
_____
_____

4. Intensity of reported event *(check one)*:
NOTE: *Use NCI Common Terminology Criteria (CTC) to grade intensity (see MOO)*

☐ 1 Grade 1 ☐ 2 Grade 2 ☐ 3 Grade 3 ☐ 4 Grade 4 ☐ 5 Grade 5

Grade 1:	A mild adverse event. The symptom may be an annoyance, but does not interfere with the participant's function, or requires no intervention.
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.

5. 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/SAE is related to study medication
Unlikely:	Relationship is possible, but not likely (1 – 19% chance) that AE/SAE is related to study medication
Possible	Reasonable likelihood that the study medication caused the adverse event with a chance (20-50%) the AE/SAE is related that cannot be excluded
Probable:	Relationship is quite likely (51 – 99% chance) that the AE/SAE is related to the study medication
Definite:	Unquestionable relationship (100% chance) that the AE/SAE is related to the study medication

6. Type of visit event was first reported at *(check one)*:

☐ 1 Baseline ☐ 3 Routine Follow-up *(planned)*
☐ 2 Interim Follow-up *(unplanned)* ☐ 4 Unattended *(phone-call, etc.)*

7. Was this a serious adverse event? Y N

IF YES, complete **ALL** remaining sections
IF NO, do **NOT** complete **Section C**

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

All serious adverse events **must** be reported to the Coordinating Center within **24 hours** of clinic notification.
Fax this form to the Coordinating Center at **(866) 804-6058** or **(301) 468-1676** (Attn: Seshu Pakalapati)

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 Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

C. SERIOUS EVENT DESCRIPTION

AEID #: __ __ __ __

This section only needs to be completed for **Serious Adverse Events**, otherwise proceed to Section D.
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: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

2. Probable cause of death: _____

An adverse event resulting in death requires completion of a Mortality Event Form (**MMF07M**)

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. Indicate the duration of the serious adverse event *(check one)*:

☐ 1 Less than one day

☐ 2 Greater than one day, but not more than one week

☐ 3 Greater than one week

5. 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 Mycophenolate mofetil (MMF) and Daclizumab (DZB) see the Manual of Operations

6. Date the TrialNet MedWatch Form was faxed to the Coordinating Center: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

a. Time the TrialNet MedWatch Form was faxed (24-hour clock): __ __: __ __ (HH:MM)

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 Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

D. ACTIONS TAKEN

AEID #: __ __ __ __

1. Was the study medication suspended *(either temporarily or permanently)*? Y N
   IF YES,
   a. Was the adverse experience reversed when the study medication was stopped? Y N
   b. Was the study medication restarted? Y N
      IF YES,
      1. How long was the participant off the study medication? __ __ __ Days
      2. Did the adverse event recur when the study medication was restarted? Y N

2. What actions were taken for the adverse event?

a. Dose change in study medication?	Y	N	d. Non-drug treatment?	Y	N
b. Concomitant medication prescribed?	Y	N	e. Other?	Y	N
c. Outpatient procedure	Y	N			

   IF OTHER,
   1. Specify _____

3. 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. Indicate length of stay: __ __ __ Days

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

5. Was insulin therapy changed significantly during the adverse event? Y N

E. OUTCOME

1. Has the adverse event resolved? Y N
   IF YES:
   a. Date resolved: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

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

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

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

F. CONCLUSION *AEID #:* __ __ __ __

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

_____
_____
_____
_____
_____

G. DEFINITIONS AND REPORTING OF ADVERSE EVENTS

An *adverse event* is defined 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. If this is a **serious adverse event**, the initial version of this form should be completed with as much information as is known at the time, then faxed to the Coordinating Center within **24 hours** of notification of the adverse event. In addition, if this is a **serious adverse event**, the **TrialNet MedWatch Form** must be completed and faxed to the Coordinating Center at **(866) 804-6058** or **(301) 468-1676** within **24 hours** of clinic notification.

A *serious adverse event* is defined as occurrence of one or more of the following:

- 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)*
- An overdose
- Any other condition that in the opinion of appropriate medical personnel will result in one of the above outcomes if left untreated

An *unexpected* adverse event is defined as one for which the specificity or severity is not consistent with the current Investigator's Brochure. For a complete list of expected adverse events for Mycophenolate mofetil (MMF) and Daclizumab (DZB) see the Manual of Operations.

This form should be completed with as much information as is currently known regarding the adverse event. A question should be answered with a "?" if the desired information is currently unavailable, but will be known in future updates. A question should be answered with "*" if information is permanently unknown, and the question will be unknown in all future updates. No questions should be left blank.

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

Date form completed: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

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).*