Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

Complete this form at Baseline and for all regularly scheduled follow-up visits.

A. VISIT INFORMATION

1. Visit Date: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

2. For which visit is this form being completed? *(check one)*

☐ 0	Baseline	☐ 8	Visit 8	☐ 16	Visit 16	☐ 24	Visit 24
☐ 1	Visit 1	☐ 9	Visit 9	☐ 17	Visit 17	☐ 25	Visit 25
☐ 2	Visit 2	☐ 10	Visit 10	☐ 18	Visit 18	☐ 26	Visit 26
☐ 3	Visit 3	☐ 11	Visit 11	☐ 19	Visit 19	☐ 27	Visit 27
☐ 4	Visit 4	☐ 12	Visit 12	☐ 20	Visit 20	☐ 28	Visit 28
☐ 5	Visit 5	☐ 13	Visit 13	☐ 21	Visit 21	☐ 29	Visit 29
☐ 6	Visit 6	☐ 14	Visit 14	☐ 22	Visit 22	☐ 30	Visit 30
☐ 7	Visit 7	☐ 15	Visit 15	☐ 23	Visit 23	☐ 31	Visit 31

3. Did visit occur at a site other than the primary study site? Y N
   If YES,
   a. Record Site Number for reimbursement: __ __ __ __

***NOTE**: Site Number **must** correspond to a TrialNet Clinical Center, Affiliate, or Participating Physician*

B. VACCINATIONS

1. Since the last scheduled visit, have you had any vaccinations other than those administered as part of the study? Y N
   If YES,
   a. Specify: _____

C. PREGNANCY MONITORING

1. If FEMALE, does the participant have reproductive or childbearing potential? Y N
   If YES, continue (otherwise, proceed to **Section D**)
   a. Do you currently use a form of birth control? *(Females of reproductive age are expected to use a form of birth control, or practice abstinence)* Y N
   b. Do you plan on becoming pregnant before the study end? Y N
   c. Are you currently taking birth control medication? Y N
   d. Was a urine pregnancy test completed at this visit? Y N
      If YES,
      1) Was the test result positive? Y N

If the **pregnancy test** result was **positive**, complete a Pregnancy Confirmation Form (**CTL14**). The Coordinating Center must be notified within 24 hours of clinic notification of an active pregnancy in a study participant.

D. ADVERSE EVENT ASSESSMENT

1. During the interval since the last scheduled clinic visit, have you had any symptoms, injuries, infections, illnesses or side effects, or worsening of pre-existing conditions? Y N

If YES, complete an Adverse Event Report Form (**CTL13**) if ≥ Grade 2 severity.
If the adverse event is Grade 1 record on source document.

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: __ __ __ Visit Date: __ __ / __ __ __ / __ __ __ __

E. PHYSICAL EXAM

1 Collect the following physical assessments:

a. Weight: __ __ __.__ kg or __ __ __. __ __ lbs

b. Height: __ __ __.__ cm or __ __. __ __ in

c. Seated blood pressure:
Note: *Have the participant rest for 5 minutes before assessment.*

__ __ __ mmHg / __ __ __ mmHg
Systolic Diastolic

2. Were there any abnormalities on the physical exam? Y N

If YES,

a. Specify: _____

If YES, complete an Adverse Event Report Form (**CTL13**) if ≥ Grade 2 severity.
If the adverse event is Grade 1 record on source document.

F. SPECIMENS

Refer to Visit Checklists and Schedule of Assessments to determine which of the specimens below are required at this visit. Then, mark the specimens that were actually obtained.

	Specimen Collected ***(check all that apply)***		**a. Date Sample Collected** ***(record date below ONLY if different from the visit date above)***
	Chemistries and Autoantibodies		
1.	☐ 1	CBC with Differential *(analysis done at local lab)*	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
2.	☐ 1	Chemistries	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
3.	☐ 1	Serum for Autoantibodies	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
4.	☐ 1	PK Analysis	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
	Metabolic Testing		
5.	☐ 1	HbA1c	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
6.	☐ 1	4-hour MMTT	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
7.	☐ 1	2-hour MMTT	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
	Viral Testing		
8.	☐ 1	EBV PCR (for EBV seronegative only as routine; others for clinical indication only)	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
9.	☐ 1	EBV/CMV Viral Serology	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
10.	☐ 1	Other Serology	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR

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: __ __ __ Visit Date: __ __ / __ __ __ / __ __ __ __

F. SPECIMENS (Continued)

Specimen Collected ***(check all that apply)***

a. Date Sample Collected ***(record date below ONLY if different from the visit date above)***

Immunizations (Serology)

11.	☐ 1	Tetanus Post-Immunization Serology (Visit 27 only)	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
12.	☐ 1	Flu Post-Immunization Serology	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR

Mechanistic Testing/Storage*

13.	☐ 1	Frozen PBMC/Plasma	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
14.	☐ 1	RNA	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
15.	☐ 1	Flow cytometry	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
16.	☐ 1	HLA	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
17.	☐ 1	Serum	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR

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

Date form completed: __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR

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).*