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

Complete this form 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)*

☐ 3	Week 1	☐ 11	Month 3	☐ 26	Month 15	☐ 30	Month 30	☐ 99	Other
☐ 4	Week 2	☐ 16	Month 6	☐ 27	Month 18	☐ 31	Month 36		
☐ 5	Week 3	☐ 17	Month 9	☐ 28	Month 21	☐ 32	Month 42		
☐ 6	Week 5	☐ 18	Month 12	☐ 29	Month 24	☐ 33	Month 48		

If OTHER,
a. Specify: _____

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**, **STOP** here, DO NOT complete this form, and DO NOT send this form to The Coordinating Center.
Complete a Pregnancy Confirmation Form (**RIT14**). 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 (**RIT13**)

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. SPECIMENS TO BE DRAWN

Mark the specimens that were drawn during this visit. Refer to Visit Checklists Sections "Specimens to be Drawn" and "Mechanistic Specimens to be Drawn", and assigned Schedule of Assessments.

	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 and HACA Levels	__ __/__ __ __/__ __ __ __ 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/CMV PCR	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
9.	☐ 1	EBV/CMV Viral Serology	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
10.	☐ 1	Other Serology	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
	Immunizations (Serology)		
11.	☐ 1	Tetanus Pre-Immunization Serology	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
12.	☐ 1	Hepatitis A Pre-Immunization Serology	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
13.	☐ 1	Hepatitis A Serology	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
14.	☐ 1	PhiX174 Pre-Immunization Serology *(if applicable)*	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
15.	☐ 1	PhiX174 15-Minute Post-Immunization *(if applicable)*	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
	Mechanistic Testing/Storage*		
16.	☐ 1	Flow Cytometry	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
17.	☐ 1	Frozen PBMC/Plasma	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
18.	☐ 1	T cell Proliferation	__ __/__ __ __/__ __ __ __ 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: __ __/__ __ __/__ __ __ __

E. SPECIMENS TO BE DRAWN (CONTINUED)

Mark the specimens that were drawn during this visit. Refer to Visit Checklists Sections "Specimens to be Drawn" and "Mechanistic Specimens to be Drawn", and assigned Schedule of Assessments.

Specimen Collected ***(check all that apply)***		**a. Date Sample Collected** ***(record date below ONLY if different from the visit date above)***
Mechanistic Testing/Storage* (CONTINUED)		
19.	☐ 1 Immunoblot	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
20.	☐ 1 ELISpot	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
21.	☐ 1 Tetramer	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
22.	☐ 1 RNA	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR

*** Depending on age and weight according to assigned Schedule of Assessments**

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).*