

Site Number: _____

Screening ID: _____ - ____

Participant Letters: _____

Complete this form during the Screening Visit.

A. VISIT INFORMATION

1. Date Screening Visit Completed (e.g. 05/Sep/2005):

____/____/____
DAY MONTH YEAR

2. 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. INFORMED CONSENT

1. Date written informed consent obtained:

____/____/____
DAY MONTH YEAR

2. On the consent form, was permission given for samples of the participant's blood to be stored for DNA testing?

Y N

3. On the consent form, was permission given for samples of the participant's blood to be stored for other tests?

Y N

4. On the consent form, did the participant agree to receive the PhiX immunization course? (if unknown at screening, write "?" and complete later)

Y N

C. DEMOGRAPHIC INFORMATION

1. Date of birth:

____/____/____
DAY MONTH YEAR

2. Age (years):

3. Date of diagnosis of type 1 diabetes:

____/____/____
DAY MONTH YEAR

4. Sex:

₁ Male ₂ Female

5. Ethnicity (check one):

₁ Hispanic or Latino ₂ Not Hispanic or Latino

6. Race (check all that apply):

- | | |
|--|--|
| a. <input type="checkbox"/> ₁ American Indian or Alaskan Native | d. <input type="checkbox"/> ₁ Native Hawaiian or Other Pacific Islander |
| b. <input type="checkbox"/> ₁ Asian | e. <input type="checkbox"/> ₁ White |
| c. <input type="checkbox"/> ₁ Black or African American | f. <input type="checkbox"/> ₁ Other |

If OTHER, 1) Specify: _____

2) Record the 3-digit code for race/ethnicity (International sites only):

a) _____
b) _____
c) _____

7. How did the participant first hear about this study (check one)?

- | | | | |
|--|---|--|--|
| <input type="checkbox"/> ₁ Health Care Provider | <input type="checkbox"/> ₃ Family/Friend | <input type="checkbox"/> ₅ Radio/TV | <input type="checkbox"/> ₇ Magazine |
| <input type="checkbox"/> ₂ Meeting/Presentation | <input type="checkbox"/> ₄ Poster | <input type="checkbox"/> ₆ Internet | <input type="checkbox"/> ₈ Other |

If OTHER, a. Specify: _____

D. CONCOMITANT MEDICATIONS

1. Are you currently taking steroids? (Steroid use is an exclusion criterion for this study)

Y N

a. If YES, specify: _____

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).*

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2. Are you currently taking anti-infection (*antibiotics and anti-fungals*) medications? Y N

a. If YES, for what? _____

3. Are you currently taking anti-hypertensive medications? Y N

a. If YES, specify: _____

4. Are you currently taking any other prescription medication(s), non-prescription medication(s), or supplements other than insulin? Y N

If YES, list medications/supplements:

- a. _____
- b. _____
- c. _____
- d. _____
- e. _____
- f. _____
- g. _____
- h. _____
- i. _____
- j. _____

E. SPECIMENS TO BE DRAWN

The following specimens should be drawn during this visit:

	Collected on this visit date?	a. If NO, date sample collected
1. CBC with Differential <i>(analysis done at local lab)</i>	Y N	____/____/____ DAY MONTH YEAR
2. Chemistries	Y N	____/____/____ DAY MONTH YEAR
3. HIV, Hep B and C	Y N	____/____/____ DAY MONTH YEAR
4. Serum for Autoantibodies	Y N	____/____/____ DAY MONTH YEAR
5. HbA1c	Y N	____/____/____ DAY MONTH YEAR
6. 4-hour MMTT	Y N	____/____/____ DAY MONTH YEAR
7. HLA/DNA	Y N	____/____/____ 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).*