

Site Number: _____ Screening ID: _____ - _____

Participant Letters: _____

Complete this form during the Screening Visit.

A. VISIT INFORMATION

1. Date Screening Visit Completed (e.g. 05/Feb/2008):

____/____/____
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 for *screening* obtained:

____/____/____
DAY MONTH YEAR

2. On the *screening* consent form, was permission given for DNA samples to be stored?

Y N

3. On the *screening* consent form, was permission given for *non*-DNA samples to be stored?

Y N

C. DEMOGRAPHIC INFORMATION

1. Date of birth:

____/____/____
DAY MONTH YEAR

2. Age (years): _____

3. Sex:

☐ ₁ Male

☐ ₂ Female

4. Ethnicity (*check one*):

☐ ₁ Hispanic or Latino

☐ ₂ Not Hispanic or Latino

5. Race (*check all that apply*):

a. ☐ ₁ American Indian or Alaskan Native

d. ☐ ₁ Native Hawaiian or Other Pacific Islander

b. ☐ ₁ Asian

e. ☐ ₁ White

c. ☐ ₁ Black or African American

f. ☐ ₁ Other

If OTHER, 1) Specify: _____

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

a) _____

b) _____

c) _____

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

☐ ₁ Health Care Provider

☐ ₃ Family/Friend

☐ ₅ Radio/TV

☐ ₇ Magazine

☐ ₂ Meeting/Presentation

☐ ₄ Poster

☐ ₆ Internet

☐ ₈ Other

If OTHER, a. Specify: _____

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D. MEDICATIONS OTHER THAN INSULIN

1. 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. _____

2. Are any of these medications steroids? (*Steroid use is an exclusion criterion for this study*)

Y N

a. If YES, specify: _____

E. REVIEW OF SYSTEMS

1. Record whether there are any abnormalities in the following systems review

	1) Normal?	If ABNORMAL, a) Explain:
a. HEENT	Y N	_____
b. Pulmonary	Y N	_____
c. Cardiovascular	Y N	_____
d. Endocrine (other than T1D)	Y N	_____
e. Gastrointestinal	Y N	_____
f. Reproductive	Y N	_____
g. Musculoskeletal	Y N	_____
h. Neurological	Y N	_____
i. Integument	Y N	_____

2. Are there any additional abnormalities not already indicated above?

Y N

a. If YES, describe: _____

F. PHYSICAL EXAM

1. Collect the following physical assessments:

- a. Weight: _____ kg or _____ lbs
- b. Height: _____ cm or _____ in

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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F. PHYSICAL EXAM (Continued)

c. Seated arm blood pressure:

Note: Have the participant rest for 5 minutes before assessment.

_____ mmHg / _____ mmHg
Systolic Diastolic

2. Indicate the participant's sexual development using the Tanner Scale:

(Complete question for participants 17 years of age or younger)

Tanner Stage

Check One

a. Breast (**female**)

☐ ₁ Stage 1 ☐ ₂ Stage 2 ☐ ₃ Stage 3 or greater

b. Genitalia (**male**)

☐ ₁ Stage 1 ☐ ₂ Stage 2 ☐ ₃ Stage 3 or greater

c. Pubic Hair (**both**)

☐ ₁ Stage 1 ☐ ₂ Stage 2 ☐ ₃ Stage 3 or greater

3. Were there any abnormalities on the physical exam?

Y N

If YES,

a. Specify: _____

4. Was a urine pregnancy test completed at this visit?

Y N

If YES,

a. Was the test result positive?

Y N

If the **pregnancy test** result was **positive**, **STOP HERE**, DO NOT perform the MMTT, DO NOT complete this form, and DO NOT send this form to The Coordinating Center.

G. SPECIMENS

The following specimens should be drawn during this visit:

	Collected on this visit date?	a. If NO, date sample collected
1. CBC with Differential (analysis done at local lab)	Y N	____/____/____ DAY MONTH YEAR
2. Chemistries	Y N	____/____/____ DAY MONTH YEAR
3. EBV/CMV Serology	Y N	____/____/____ DAY MONTH YEAR
4. HIV, Hep B and C	Y N	____/____/____ DAY MONTH YEAR
5. Serum for Autoantibodies	Y N	____/____/____ DAY MONTH YEAR
6. 4-hour MMTT	Y N	____/____/____ DAY MONTH YEAR
7. PPD Test	Y N	____/____/____ DAY MONTH YEAR
8. EBV PCR	Y N	____/____/____ DAY MONTH YEAR
9. PBMC/plasma	Y N	____/____/____ DAY MONTH YEAR

Initials (first, middle, last) of person completing this form:

____ F M L

Date form completed:

____/____/____
DAY MONTH YEAR

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**CTLA-4 Ig Study
SCREENING FORM**

Form CTL01

01 JAN 2008

Version 1.0

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