

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

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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**)

<sub>1</sub> Stage 1     <sub>2</sub> Stage 2     <sub>3</sub> Stage 3 or greater

b. Genitalia (**male**)

<sub>1</sub> Stage 1     <sub>2</sub> Stage 2     <sub>3</sub> Stage 3 or greater

c. Pubic Hair (**both**)

<sub>1</sub> Stage 1     <sub>2</sub> Stage 2     <sub>3</sub> 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 <i>(analysis done at local lab)</i>	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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