TN20 IMMUNE EFFECTS OF ORAL INSULIN TRIAL
STUDY VISIT FORM

Form IE02
10SEP15
Version 1.0
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Type 1
Diabetes
TrialNet

Site Number: ＿＿ ＿＿ ＿＿ ＿＿　　Participant ID: ＿＿ ＿＿ ＿＿ ＿＿ ＿＿ ＿＿　　Participant Letters: ＿＿ ＿＿ ＿＿

A. VISIT INFORMATION

1. Date Visit Completed (*e.g. 10/Sep/2015*): *　　＿＿ ＿＿ / ＿＿ ＿＿ / ＿＿ ＿＿ ＿＿ ＿＿
   　　DAY　　MONTH　　YEAR

B. MEDICAL HISTORY

1. Have there been any changes in health since the last scheduled visit?*　　Y　N

2. Have there been any changes in concomitant medications since the last scheduled visit?*　　Y　N

C. PREGNANCY MONITORING

1. Does the participant have reproductive or childbearing potential? *　　O Y　　O N

If YES,
   a. Was a urine pregnancy test completed at this visit? *　　O Y　　O N
   If YES,
      1) Was the test result positive? *　　O Y　　O N

D. GENERAL PHYSICAL EXAM

1. Seated arm blood pressure: *　　＿＿ ＿＿ ＿＿ / ＿＿ ＿＿ ＿＿　　□ not done
   mmHg (Systolic)　　mmHg (Diastolic)

2. Weight: *　　＿ ＿ ＿.＿ kg　　□ not done

3. Height: *　　＿ ＿ ＿.＿ cm　　□ not done

   a. Was a physical exam performed at this visit? *　　O Yes　　O No

	Findings	If ABNORMAL, explain:
a. HEENT*	O Normal O Abnormal O Not Assessed	_____
b. Neck/Thyroid*	O Normal O Abnormal O Not Assessed	_____
c. Heart*	O Normal O Abnormal O Not Assessed	_____

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Participant Letters: ___ ___ ___

d. Lungs*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

e. Pulses*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

f. Musculoskeletal*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

g. Genitalia*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

h. Abdomen*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

i. Lymphatics*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

j. Skin*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

k. Neurologic*
- ○ Normal
- ○ Abnormal
- ○ Not Assessed

_____

l. Other*
- ○ Abnormal
- ○ Not Assessed

_____

E. COMPLIANCE (The Study Coordinator should assess the participant's study drug compliance and record on Source Document)

1. Was the participant contacted at a minimum of every other week between visits?*   Y   N

2. Is the participant currently taking study drug?*   Y   N