

Site Number: _____	Participant ID: _____	Participant Letters: _____
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**A. VISIT INFORMATION**

1. Date Initial Visit completed (e.g. 10/Sep/2015): \*

____/____/____ DAY MONTH YEAR
----------------------------------

**B. INFORMED CONSENT**

1. Date written informed consent/assent obtained: \*

____/____/____ Day Month Year
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2. On the consent form, did the participant/participant's legal guardian consent to continued storage of residual blood samples in the NIDDK Repository after TrialNet has ended? \*

Yes  
 No

3. Was the Volunteer Understanding Assessment Completed?\*

Yes  
 No

**C. MEDICAL HISTORY**

1. Autoimmune Disease History

a. Has the participant ever been diagnosed with an autoimmune disease(s)? \*

Yes    No    Unknown

If YES,

Addison's Disease (Adrenal Insufficiency)

Yes    No

Date of diagnosis

____/____/____ DAY MONTH YEAR
----------------------------------

Alopecia

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Celiac Disease (Gluten Allergy or Celiac Sprue)

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Grave's Disease (Hyperthyroidism)

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Hypogonadism or Premature Menopause

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Hypoparathyroidism

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Autoimmune Thyroid Disease (Hypothyroidism or Hashimoto's Disease)

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Inflammatory Bowel Disease

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Lupus

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Multiple Sclerosis

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Pernicious Anemia

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Psoriasis

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Rheumatologic Disease

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Vitiligo

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------

Other, specify: \_\_\_\_\_

Yes    No

____/____/____ DAY MONTH YEAR
----------------------------------



**TN20 IMMUNE EFFECTS OF ORAL INSULIN TRIAL  
INITIAL (-1) VISIT FORM**

**Form IE01**

15JAN16

Version 2.0

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

**2. Antibiotic Use**

Has the participant used antibiotics in the past 3 months\*

Yes  No  Unknown

**D. FAMILY HISTORY**

1. Have any of the participant's first or second degree relatives been diagnosed with Type 1 Diabetes (T1D) since the completion of the **Natural History Family History Form (NH01F)?\***

Y N

2. Relative with Type 1 Diabetes

3. Sex of Relative

4. Current Age of Relative

5. Age of T1D Onset in Relative

6. Age Relative Started Insulin

Comments

Select One	CHECK ONE	Age in Years	Age in Years	Age in Years	Comments
a. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____
b. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____
c. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____
d. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____
e. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____
f. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____
g. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____

<b>P</b> =Parent	<b>IT</b> =Identical Twin	<b>FS</b> =Brother/Sister	<b>AU</b> =Aunt/Uncle	<b>C</b> =Cousin
<b>GP</b> =Grandparent	<b>NT</b> =Non-identical Twin	<b>HS</b> =Half Brother/Sister	<b>N</b> =Niece/Nephew	<b>CH</b> =Child

**7. Autoimmune Disease History**

Has anyone in the participant's family (first or second degree relatives only) ever been diagnosed with an autoimmune disease(s)? \*

Yes  No  Unknown

If YES,  
Addison's Disease (Adrenal Insufficiency)

Yes  No

Date of diagnosis

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

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

Alopecia	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Celiac Disease (Gluten Allergy or Celiac Sprue)	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Grave's Disease (Hyperthyroidism)	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Hypogonadism or Premature Menopause	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Hypoparathyroidism	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Autoimmune Thyroid Disease (Hypothyroidism or Hashimoto's Disease)	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Inflammatory Bowel Disease	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Lupus	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Multiple Sclerosis	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Pernicious Anemia	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Psoriasis	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Rheumatologic Disease	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Vitiligo	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR
Other, specify: _____	<input type="radio"/> Yes <input type="radio"/> No	____/____/____ DAY MONTH YEAR

**E. PREGNANCY MONITORING**

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

If YES,

a. Was a urine pregnancy test completed at this visit? \*  Y  N

If YES,

1) Was the test result positive? \*  Y  N

**F. 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? \*  Yes  No

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

	Findings	If ABNORMAL, explain:
a. HEENT*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
b. Neck/Thyroid*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
c. Heart*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
d. Lungs*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
e. Pulses*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
f. Musculoskeletal*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
g. Genitalia*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
h. Abdomen*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
i. Lymphatics*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
j. Skin*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
k. Neurologic*	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____
l. Other*	<input type="radio"/> Abnormal <input type="radio"/> Not Assessed	_____

**G. TEST RESULTS**

1. Random fingerstick glucose (per clinic meter): \* \_\_\_\_\_ mg/dl  not done