



**Natural History Study of the Development of T1D  
DPT-1 ENTRY FORM  
PHASE 3**

**Form NH10**  
Ver. 1.0  
01NOV2004  
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Site Number: \_\_\_\_\_ Participant ID: \_\_\_\_\_ 1<sup>st</sup> three letters of First Name: \_\_\_\_\_

Complete at the first follow-up visit for participants who were previously enrolled in the Type 1 Diabetes Prevention Trial (DPT-1).

**A. VISIT INFORMATION**

1. Visit Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
MM DD YYYY

**B. ELIGIBILITY**

1. Has the participant been diagnosed with type 1 diabetes (**T1D**)?  Y  N  
2. Is the participant currently pregnant?  Y  N

**If the participant answered YES to question 1 OR question 2, he/she is ineligible to participate in the study. If ineligible, DO NOT fill out the remainder of this form.**

**C. INFORMED CONSENT AND PERMISSIONS**

1. Date the participant signed the Informed Consent Form: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
MM DD YYYY  
2. Did the participant give permission for blood samples to be stored for **future** testing as described in the Phase 3 Informed Consent Form?  Y  N

**D. PARTICIPANT'S PERSONAL INFORMATION**

1. Date of Birth: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
MM DD YYYY  
2. Sex of Participant:  <sub>1</sub>M  <sub>2</sub>F  
3. Ethnicity of participant (*check one*):  
 <sub>1</sub> Hispanic or Latino  <sub>2</sub> Not Hispanic or Latino  <sub>3</sub> Unknown  
4. Race of Participant (*check all that apply*):  
a.  <sub>1</sub> American Indian/Alaskan Native b.  <sub>1</sub> Asian c.  <sub>1</sub> Black/African American  
d.  <sub>1</sub> Native Hawaiian/Other Pacific Islander e.  <sub>1</sub> White f.  <sub>1</sub> Unknown/Not Reported  
g.  <sub>1</sub> Refused

5. Record the DPT-1 participant ID (*if known*): \_\_\_\_\_

Initials of Person Completing this Form: \_\_\_\_\_ Date: \_\_\_\_\_



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**E. FAMILY HISTORY INFORMATION**

1. How many of the participant's blood relatives have **type 1 diabetes** (including deceased relatives)? \_\_\_\_\_

*Provide information for up to 8 of the participant's most closely related blood relatives with type 1 diabetes.*

**Use the letter codes below to indicate the type of relative:**

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

2. Relative with Type 1 Diabetes	3. Sex of Relative	4. Current Age of Relative	5. Age of Diabetes Onset in Relative	6. Age Relative Started Insulin	
<i>See code above</i>	<i>Check One</i>	<i>Age in Years</i>	<i>Age in Years</i>	<i>Age in Years</i>	<i>Comments</i>
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	_____	_____	_____	_____
h. _____	<input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female	_____	_____	_____	_____

**F. MEDICAL HISTORY**

Has the participant been told by a physician that he/she has any of the following conditions?

<u>Condition/Disease</u>	<u>a. Ever been told?</u>		<u>b. Within the last year?</u>	
1. Asthma	Y	N	Y	N
2. High blood pressure	Y	N	Y	N
3. High cholesterol	Y	N	Y	N
4. Ulcer (stomach or duodenal)	Y	N	Y	N
5. Hepatitis/Liver disease	Y	N	Y	N

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**F. MEDICAL HISTORY (cont.)**

Has the participant been told by a physician that he/she has any of the following conditions?

Condition/Disease	a. Ever been told?		b. Within the last year?	
6. Cancer	Y	N	Y	N
7. Celiac Disease	Y	N	Y	N
8. Colitis or Colon Problems	Y	N	Y	N
9. Addison's Disease	Y	N	Y	N
10. Vitiligo	Y	N	Y	N
11. Thyroid disease	Y	N	Y	N
12. Congenital heart disease or heart problems	Y	N	Y	N
13. Infectious mononucleosis	Y	N	Y	N
14. Epilepsy, convulsions, or seizures	Y	N	Y	N
15. Pernicious anemia	Y	N	Y	N
16. Psoriasis	Y	N	Y	N
17. Alopecia (hair loss)	Y	N	Y	N
18. Rheumatologic disease (e.g. lupus, rheumatoid arthritis, etc.)	Y	N	Y	N
19. Allergies	Y	N	Y	N
c. If YES, specify: _____				
20. Diseases likely to limit life expectancy or lead to use of immunosuppressive/immunomodulatory therapies	Y	N	Y	N

**G. CURRENT MEDICATIONS**

Is the participant currently taking any of the following medications?

1. Steroids or glucocorticoids  Y  N  
 a. If YES, specify: \_\_\_\_\_

2. Potassium Depleting Diuretics  Y  N  
 a. If YES, specify: \_\_\_\_\_

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3. Beta Blockers Y N

a. If YES, specify: \_\_\_\_\_

4. Immunosuppressive or immunomodulatory therapies Y N

a. If YES, specify: \_\_\_\_\_

5. Niacin Y N

6. Diphenylhydantoin (Dilantin) Y N

7. Meglitinides Y N

8. Metformin Y N

9. Thiazolidinediones Y N

10. Alpha-glucosidase inhibitors Y N

11. Other glucose lowering agents Y N

**H. HEIGHT, WEIGHT AND VITAL SIGNS**

Collect the following physical assessments:

*Note: The participant should rest for 5 minutes before these assessments are performed*

1. Seated arm blood pressure: \_\_\_\_\_ mm Hg / \_\_\_\_\_ mm Hg  
Systolic Diastolic

2. Seated heart rate: \_\_\_\_\_ Beats/minute

3. Seated respiratory rate: \_\_\_\_\_ Breaths/minute

4. Weight: \_\_\_\_\_ kg or \_\_\_\_\_ lbs

5. Height (If participant <18 years, use a stadiometer if available): \_\_\_\_\_ cm or \_\_\_\_\_ in

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**I. LABORATORY TESTS**

1. Date of sample collection: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
MM DD YYYY

<u>Laboratory Tests</u>	<u>a. Sample collected?</u>	<u>Comment</u>
2. Autoantibodies	Y N	_____
3. HbA1c	Y N	_____
4. OGTT	Y N	_____

**Complete the appropriate Specimen Transmittal Forms and place copies with the Source Documentation.**

**J. COLLECTION OF MECHANISTIC SAMPLES FOR REPOSITING**

*(This section is **ONLY** for use by Regional Clinical Centers)*

1. Date of mechanistic sample collection: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
MM DD YYYY

<u>Samples Collected</u>	<u>a. Sample collected?</u>	<u>Comment</u>
2. Whole Blood for RNA	Y N	_____
3. Whole Blood for Cells	Y N	_____
4. Plasma <i>(from blood for cells)</i>	Y N	_____
5. Serum for Proteomics	Y N	_____
6. Whole Blood for DNA	Y N	_____

**Complete the appropriate Specimen Transmittal Forms and place copies with the Source Documentation.**

Signature of Person Completing this Form \_\_\_\_\_

Date form completed: \_\_\_\_\_  
MM DD YYYY