



**Natural History Study of the Development of T1D
CONTROL ENTRY FORM**

Form NH12

Ver. 1.0

01SEP2007

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Site Number: _____ Participant ID: _____ 1st three letters of First Name: _____

A. VISIT INFORMATION

1. Visit Date: _____ / _____ / _____
MM DD YYYY

B. ELIGIBILITY

1. Does the participant have at least one blood relative (living or deceased) with type 1 diabetes (T1D)?	Y	N
2. Has the participant been diagnosed with type 1 diabetes (T1D)?	Y	N
3. Has the participant ever used insulin (current or previous) or any oral hypoglycemic drugs such as sulfonylureas, metformin, thiazolidinediones, alpha-glucosidase inhibitors or other glucose lowering drugs?	Y	N
a. If YES, specify: _____		
4. Is the participant currently using immunosuppressive or immunomodulatory therapies, or systemic glucocorticoids?	Y	N
5. Does the participant have known severe active diseases, and/or diseases which are likely to limit life expectancy or lead to use of immunosuppressive or immunomodulatory therapies during the course of the study?	Y	N
6. Has the participant ever tested positive for pancreas or diabetes autoantibodies?	Y	N
7. Is the participant currently pregnant?	Y	N

If the participant answered NO to question 1 OR YES to any of questions 2-7, he/she is ineligible to participate in the study. If ineligible:

- **DO NOT complete the remainder of this form. Do not send to the Coordinating Center.**
- **Complete a Diabetes Onset Form (NH08) if the answer to question 2 is YES**

C. INFORMED CONSENT AND PERMISSIONS

1. Date participant signed the Informed Consent Form: _____ / _____ / _____
MM DD YYYY

D. MEDICAL HISTORY

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

Condition/Disease	a. Ever been told?	If YES	1. Within the last year?
1. Asthma	Y N		Y N
2. High blood pressure	Y N		Y N
3. High cholesterol	Y N		Y N

Initials of Person Completing this Form: _____ Date: _____



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4. Ulcer (stomach or duodenal)	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
5. Hepatitis/Liver disease	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
6. Cancer	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
7. Celiac Disease	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
8. Colitis or Colon Problems	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
9. Addison's Disease	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
10. Vitiligo	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
11. Thyroid disease	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
12. Congenital heart disease or heart problems	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
13. Infectious mononucleosis	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
14. Epilepsy, convulsions, or seizures	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
15. Pernicious anemia	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
16. Psoriasis	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
17. Alopecia (hair loss)	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
18. Rheumatologic disease (e.g. lupus, rheumatoid arthritis, etc.)	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
19. Allergies	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N

b. If YES, specify: _____

E. CURRENT MEDICATIONS

Is the participant currently taking any of the following medications?

1. Steroids Y N
a. If YES, specify: _____
2. Potassium Depleting Diuretics Y N
a. If YES, specify: _____
3. Beta Blockers Y N
a. If YES, specify: _____
4. Immunosuppressives or immunomodulatory therapies Y N
a. If YES, specify: _____
5. Niacin Y N
6. Diphenylhydantoin (Dilantin) Y N

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F. 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:	<table border="1" style="margin: auto;"> <tr> <td style="text-align: center;">____ mm Hg / ____ mm Hg</td> </tr> <tr> <td style="text-align: center;">Systolic Diastolic</td> </tr> </table>	____ mm Hg / ____ mm Hg	Systolic Diastolic		
____ mm Hg / ____ mm Hg					
Systolic Diastolic					
2. Seated heart rate:	<table border="1" style="margin: auto;"> <tr> <td style="text-align: center;">____ Beats/minute</td> </tr> </table>	____ Beats/minute			
____ Beats/minute					
3. Seated respiratory rate:	<table border="1" style="margin: auto;"> <tr> <td style="text-align: center;">____ Breaths/minute</td> </tr> </table>	____ Breaths/minute			
____ Breaths/minute					
4. Weight:	<table border="1" style="margin: auto;"> <tr> <td style="text-align: center;">____ . ____ kg</td> <td style="text-align: center;">or</td> <td style="text-align: center;">____ . ____ lbs</td> </tr> </table>	____ . ____ kg	or	____ . ____ lbs	
____ . ____ kg	or	____ . ____ lbs			
5. Height (If participant <18 years use a stadiometer if available):	<table border="1" style="margin: auto;"> <tr> <td style="text-align: center;">____ . ____ cm</td> <td style="text-align: center;">or</td> <td style="text-align: center;">____ . ____ in</td> </tr> </table>	____ . ____ cm	or	____ . ____ in	
____ . ____ cm	or	____ . ____ in			

H. 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. HLA	Y N	_____
4. HbA1c	Y N	_____
5. OGTT	Y N	_____

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

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I. COLLECTION OF MECHANISTIC SAMPLES FOR REPOSITING

1. Date of mechanistic sample collection: _____

MM / DD / YYYY

<u>Sample</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 file copies with the Source Documentation.

Signature of Person Completing this Form

Date form completed:

MM / DD / YYYY