



**Natural History Study of the Development of T1D  
CONTROL FOLLOW-UP FORM  
PHASE 3**

**Form NH05C**  
Ver. 1.0  
01SEP2007  
Page 1 of 3

Site Number: \_\_\_\_\_ Participant ID: \_\_\_\_\_ 1<sup>st</sup> three letters of First Name: \_\_\_\_\_

**A. VISIT INFORMATION**

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

2. Follow-up visit month (Use numbers in increments of 12 months; i.e. 12, 24, 36, etc.) \_\_\_\_\_ months

**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 2, he/she is ineligible to participate in the study.**  
**If ineligible:**

- **DO NOT fill out the remainder of this form. Do not send to the Coordinating Center**
- **Complete a Change of Status Form (NH07)**
- **Complete a Diabetes Onset Form (NH08), if the answer to question 1 is YES**

**C. MEDICAL HISTORY**

Has the participant been told by a physician that he/she currently has (or within the last 12 months had) any of the following conditions or diseases?

| Condition/Disease                              | Y | N |
|--|---|---|
| 1. Asthma                                      |   |   |
| 2. High blood pressure                         |   |   |
| 3. High cholesterol                            |   |   |
| 4. Ulcer (stomach or duodenal)                 |   |   |
| 5. Hepatitis/Liver disease                     |   |   |
| 6. Cancer                                      |   |   |
| 7. Celiac Disease                              |   |   |
| 8. Colitis or Colon Problems                   |   |   |
| 9. Addison's Disease                           |   |   |
| 10. Vitiligo                                   |   |   |
| 11. Thyroid disease                            |   |   |
| 12. Congenital heart disease or heart problems |   |   |
| 13. Infectious mononucleosis                   |   |   |
| 14. Epilepsy, convulsions, or seizures         |   |   |
| 15. Pernicious anemia                          |   |   |

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



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**C. MEDICAL HISTORY (cont.)**

Has the participant been told by a physician that he/she currently has (or within the last 12 months had) any of the following conditions or diseases?

| <u>Condition/Disease</u>  |   |   |
|---|---|---|
| 16. Psoriasis   | Y | N |
| 17. Alopecia (hair loss)  | Y | N |
| 18. Rheumatologic disease (e.g. lupus, rheumatoid arthritis, etc.)  | Y | N |
| 19. Allergies   | Y | N |
| a. If YES, specify: _____   |   |   |
| 20. Diseases likely to limit life expectancy or lead to use of immunosuppressive/immunomodulatory therapies | Y | N |

**D. 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: _____                          |   |   |
| 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 |

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



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|              |           |                 |           |   |       |
|--------------|-----------|-----------------|-----------|---|-------|
| Site Number: | _ _ _ _ _ | Participant ID: | _ _ _ _ _ | 1 <sup>st</sup> three letters of<br>First Name: | _ _ _ |
|--------------|-----------|-----------------|-----------|---|-------|

**E. 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 style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; text-align: center;">_ _ _ mm Hg /</td> <td style="width:50%; text-align: center;">_ _ _ mm Hg</td> </tr> <tr> <td style="text-align: center;">Systolic</td> <td style="text-align: center;">Diastolic</td> </tr> </table> | _ _ _ mm Hg / | _ _ _ mm Hg | Systolic | Diastolic |  |
| _ _ _ 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 ( <i>If participant &lt;18 years, use a stadiometer if available</i> ): | _ _ _ . _ cm   | or            |             |          |           |  |
|   |  | _ _ . _ in    |             |          |           |  |

**F. LABORATORY TESTS**

|                               |   |         |       |         |    |    |      |
|-------------------------------|---|---------|-------|---------|----|----|------|
| 1. Date of sample collection: | <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%; text-align: center;">_ _ /</td> <td style="width:33%; text-align: center;">_ _ /</td> <td style="width:33%; text-align: center;">_ _ _ _</td> </tr> <tr> <td style="text-align: center;">MM</td> <td style="text-align: center;">DD</td> <td style="text-align: center;">YYYY</td> </tr> </table> | _ _ /   | _ _ / | _ _ _ _ | MM | DD | YYYY |
| _ _ /                         | _ _ /   | _ _ _ _ |       |         |    |    |      |
| MM                            | DD  | YYYY    |       |         |    |    |      |

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

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

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

|   |   |         |       |         |    |    |      |
|---|---|---------|-------|---------|----|----|------|
| 1. Date of mechanistic sample collection: | <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%; text-align: center;">_ _ /</td> <td style="width:33%; text-align: center;">_ _ /</td> <td style="width:33%; text-align: center;">_ _ _ _</td> </tr> <tr> <td style="text-align: center;">MM</td> <td style="text-align: center;">DD</td> <td style="text-align: center;">YYYY</td> </tr> </table> | _ _ /   | _ _ / | _ _ _ _ | MM | DD | YYYY |
| _ _ /                                     | _ _ /   | _ _ _ _ |       |         |    |    |      |
| MM  | DD  | YYYY    |       |         |    |    |      |

| <u>Sample</u>                             | <u>a. Sample collected?</u> | <u>b. Comments</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                       | _____              |
| If not previously collected,              |                             |                    |
| 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