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, please 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. Is the participant currently pregnant**?** Y N

**If the participant answered NO to question 1 <u>OR</u> YES to any of questions 2-6, he/she is <u>ineligible</u> to participate in the study. If ineligible:**

- **DO NOT fill out the remainder of this form. Discard this form**
- **Complete a Change of Status Form (NH07)**
- **Complete a Diabetes Onset Form (NH08) <u>if</u> the answer to question 2 is YES**

## C. INFORMED CONSENT AND PERMISSIONS

1. On the Baseline Risk Assessment (Phase 2) Informed Consent Form, did the participant give permission for:
   a. His/her blood to be tested for HLA genes? Y N
   b. Storage of his/her samples for future testing? Y N
2. Date participant signed the Baseline Risk Assessment (Phase 2) 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? | b. 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 |
| 4. Ulcer (stomach or duodenal) | Y N | Y N |
| 5. Hepatitis/Liver disease | Y N | Y N |

Initials of Person Completing this Form: _____ Date: _____

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

## D. 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 |

a. 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

Initials of Person Completing this Form: _____ Date: _____

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

## 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: ___ ___ ___ mm Hg (Systolic) / ___ ___ ___ mm Hg (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

## G. PRIOR RESEARCH PARTICIPATION

1. Has the participant ever participated in a prevention study for type 1 diabetes? Y N
   a. If Yes, name of study/studies (if known) _____
2. Did the participant participate in DPT-1? Y N
   a. If Yes, record the DPT-1 Participant ID Number (if known) ____ ____ ____ ____ ____ ____ ____

## H. LABORATORY TESTS

1. Date of sample collection: ___ ___ (MM) / ___ ___ (DD) / ___ ___ ___ ___ (YYYY)

| Laboratory Tests | a. Sample collected? | Comment |
|---|---|---|
| 2. Autoantibodies | Y N | _____ |
| 3. HLA | Y N | _____ |
| 4. HbA1c | Y N | _____ |
| 5. OGTT | Y N | _____ |
| 6. IVGTT | Y N | _____ |

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

Initials of Person Completing this Form: _____ Date: _____

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

## I. 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)

| Sample | a. Sample collected? | Comment |
|---|---|---|
| 2. Whole Blood for RNA | Y N | _____ |
| 3. Whole Blood for Cells | Y N | _____ |
| 4. Plasma (*from blood for cells)* | 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)