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

A. VISIT INFORMATION

1. Visit Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
2. Follow-up visit month (Use numbers in increments of 6 months; i.e. **06**, **12**, **18**, etc.) ___ ___ months
   Note: If Baseline Phase 3 visit, please indicate month "0".

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 <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 1 is YES**

C. INFORMED CONSENT AND PERMISSIONS *(complete only at <u>first</u> Phase 3 visit)*

1. On the Follow-up Risk Assessment (Phase 3) Informed Consent Form, did the participant give permission for blood samples to be stored for future testing? Y N
2. Date the participant signed the Follow-up Risk Assessment (Phase 3) Informed Consent Form: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

D. MEDICAL HISTORY

Has the participant been told by a physician that he/she currently (or within the last 6 months) has any of the following conditions/diseases?

Condition/Disease		
1. Asthma	Y	N
2. High blood pressure	Y	N
3. High cholesterol	Y	N
4. Ulcer (stomach or duodenal)	Y	N
5. Hepatitis/Liver disease	Y	N
6. Cancer	Y	N
7. Celiac Disease	Y	N
8. Colitis or Colon Problems	Y	N
9. Addison's Disease	Y	N
10. Vitiligo	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 currently (or within the last 6 months) has any of the following conditions/diseases?

Condition/Disease	
11. Thyroid disease	Y N
12. Congenital heart disease or heart problems	Y N
13. Infectious mononucleosis	Y N
14. Epilepsy, convulsions, or seizures -Within the last year	Y N
15. Pernicious anemia	Y N
16. Psoriasis	Y N
17. Alopecia (hair loss)	Y N
18. Rheumatologic disease - Within the last year (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

E. 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: _____

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. LABORATORY TESTS

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

Laboratory Tests	**a. Sample collected?**	**Comment**
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.

H. 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)