

Participant ID:		Date of Registration:	
Local ID:		Letters:	
Status:			
Site:			

OT01 - Initial Visit

* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit: *

▼

[Date](#)

Interviewer User ID: *

B. INFORMED CONSENT

1. Date written informed consent obtained:

▼
2. On the consent form, did the participant give permission to store samples for future testing?
- ☐ YES, permission given to store all samples including genetic samples

☐ YES, permission given to store all samples except genetic samples

☐ NO, permission not given to store any samples

C. FAMILY HISTORY

1. Have any of your first or second degree relatives been diagnosed with T1D since the completion of Natural History Family History Form(NH01F)?

☐ Yes

☐ No

If YES, complete the following table:

Relative with type 1 diabetes	Sex of Relative	Current Age of Relative	Age of T1D Onset in relative	Age relative started insulin	Relative Comments
<div><div></div>▼</div>	<div><div><input type="radio"/> Male</div><div><input type="radio"/> Female</div></div>	<div></div>	<div></div>	<div></div>	<div></div>
<div><div></div>▼</div>	<div><div><input type="radio"/> Male</div><div><input type="radio"/> Female</div></div>	<div></div>	<div></div>	<div></div>	<div></div>
<div><div></div>▼</div>	<div><div><input type="radio"/> Male</div><div><input type="radio"/> Female</div></div>	<div></div>	<div></div>	<div></div>	<div></div>

Add

2. Autoimmune Disease History

Has anyone in your family (first or second degree relatives only) ever been diagnosed with an autoimmune disease(s)?

☐ Yes

☐ No

If YES, complete the following table:

Diagnosis	If other, specify
<div><div></div>▼</div>	<div></div>
<div><div></div>▼</div>	<div></div>

Add

D. MEDICAL HISTORY

1. Have you ever been diagnosed with an autoimmune disease(s)? Yes No

If **YES**, complete the following table:

Diagnosis	If other, specify
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

Add

Ever had asthma or seasonal allergies? Yes No

E. PREGNANCY MONITORING (If participant is male, proceed to section F)

1. If FEMALE, does the participant have reproductive potential? Yes No

2. If FEMALE, is the participant sexually active? Yes No

If **YES** to E1 above, continue. (If not, proceed to **Section F**.)

a. Does she currently use a form of birth control? Yes No

b. Does she plan on becoming pregnant in the next year? Yes No

c. Was a urine pregnancy test completed at this visit? Yes No

1) If YES, was the test result positive? Yes No

F. CONCOMITANT MEDICATIONS (Past or Current Usage)

1. Have you taken in the past, or are you currently taking immunosuppressive or steroid drugs? Yes No

2. Have you taken in the past, or are you currently taking insulin, or other drugs to treat glucose Yes No

3. Have you taken in the past, or are you currently taking growth hormone, anti-convulsants, thiazide or potassium-sparing diuretics, beta-blockers, or niacin Yes No

4. Have you taken in the past, or are you currently taking any non-prescription medications including vitamin or herbal supplements Yes No

G. GENERAL PHYSICAL EXAM

1. Was a physical exam performed at this initial visit? Yes No

a. If NO, date performed:

2. Collect the following physical assessments:

a. Seated arm blood pressure: mmHg mmHg
Systolic Diastolic

b. Weight: kg

c. Height:

cm

in

d. Abdominal circumference:

cm

in

3. Record whether the following systems are reported as normal or abnormal by the participant and normal or abnormal upon examination:

Review of systems	1) Participant reported normal?	2) Normal on exam?	If Either is ABNORMAL, Explain:
a. HEENT	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
b. Neck	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
c. Thyroid	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
d. Lungs	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
e. Chest/Breasts	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
f. Heart/Circulatory	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
g. Abdomen	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
h. Musculoskeletal	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
i. Neurologic	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
j. Genitourinary/Testes	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
k. Skin/Nails	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
l. Lymph nodes	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
m. Other	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
If OTHER, specify:			

4. For subjects less than 18 yrs of age, record the participant's sexual development using the Tanner scale:

a. Breast(female)

☐ Stage 1 ☐ Stage 2 ☐ Stage 3 or greater

b. Genitalia(male)

☐ Stage 1 ☐ Stage 2 ☐ Stage 3 or greater

c. Pubic Hair(both)

☐ Stage 1 ☐ Stage 2 ☐ Stage 3 or greater

H. FORMS COMPLETED

The following forms should be completed during this visit:

1. Volunteer Understanding Assessment

☐ Yes ☐ No

2. Lifestyle Questionnaire

☐ Yes ☐ No

a. Performed on this visit date?

b. If NOT performed at this visit, specify date performed: