

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

Complete this form for a participant who changes his/her study status.

Change of study status is defined as:

- A participant is ineligible and does not meet all study eligibility criteria.
- An active participant becomes inactive. Inactive status is declared when a participant is:
 - 1) unwilling or unable to continue making future visits or have study tests performed OR,
 - 2) diagnosed with diabetes.
- A participant previously declared “inactive” becomes “active”.

A. REPORT INFORMATION

1. Report Date: _____
MM / DD / YYYY

2. Which was the **last** study visit that the participant attended before changing status? (*check one*)

- | | |
|--|---|
| <input type="checkbox"/> ₁ Initial Screening – Phase 1 | <input type="checkbox"/> ₄ Baseline Risk Assessment – Phase 2 |
| <input type="checkbox"/> ₂ Confirmatory Screening – Phase 1 | <input type="checkbox"/> ₅ Follow Up Risk Assessment – Phase 3 |
| <input type="checkbox"/> ₃ Annual Rescreening – Phase 1 | |

a. Specify the visit number:
(e.g. Use **P1** for Phase 1 visits; Use **P2** for phase 2 visit; Use **00** for the Baseline Phase 3 visit.
Use **06. 12. 18.** etc. for phase 3 visits)

_____ months

B. STATUS CHANGE INFORMATION

1. Date participant changed study status: _____
MM / DD / YYYY

2. Please indicate the change in status that has occurred:

- ₁ Change to active status following period of inactivity
- ₂ Change to inactive status following period of active study participation

a. If participant changed to INACTIVE status indicate reason: (*check one*)

- | | | | |
|--|--|--|---|
| <input type="checkbox"/> ₁ Adverse Event ¹ | <input type="checkbox"/> ₃ Pregnancy ³ | <input type="checkbox"/> ₅ Withdrawn Consent | <input type="checkbox"/> ₇ Entry into a type 1 diabetes prevention study |
| <input type="checkbox"/> ₂ Diagnosis of Diabetes ² | <input type="checkbox"/> ₄ Lost to F/U | <input type="checkbox"/> ₆ Death ¹ | <input type="checkbox"/> ₈ Other |

1. If other specify _____

¹ If adverse event or death, complete the Adverse Event Form (NH06)
² If diagnosis of diabetes, complete the Diabetes Onset Form (NH08)
³ This is a temporary change of status if the woman agrees to continue in the study after delivery

If changing to INACTIVE status due to pregnancy, complete the following questions.

3. Is the participant willing to continue participation after completion of pregnancy? Y N

a. If YES, what is the estimated date of completion of pregnancy? _____
MM / DD / YYYY

Signature of Person Completing this Form _____

Date form completed: _____
MM / DD / YYYY