

Site Number: \_\_\_\_\_

Participant ID: \_\_\_\_\_

Participant Letters: \_\_\_\_\_

**Complete this form for two circumstances:**

- (1) An active participant withdraws or**
- (2) A participant who was withdrawn decides to become reactivated in the study**

**Withdrawn status is declared when a participant is unwilling, or unable, to continue making future follow-up visits. Complete this form for every change of status that occurs. For example, if a participant becomes withdrawn and then reactivates at a later date, two separate forms should be completed.**

1. Date Form Completed:\*

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

2. Date of Change in Status:\*

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

**A. STATUS CHANGE INFORMATION**

1. Change in status that has occurred (*check one*): \*

- A An active participant withdraws (proceed to **Section B**)
- B A participant who was withdrawn decides to become reactivated in the study (proceed to **Section C**)

**B. PARTICIPANT WITHDRAWING FROM THE STUDY**

1. Date of withdrawal: \*

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

2. Record the primary reason for withdrawal (*select one*): \*

- |                                     |  |   |                             |
|-------------------------------------|--|---|-----------------------------|
| <input type="radio"/> Death         | <input type="radio"/> Pregnancy  | <input type="radio"/> Lost to follow-up       | <input type="radio"/> Other |
| <input type="radio"/> Adverse event | <input type="radio"/> Withdrew consent   | <input type="radio"/> Ineligible to Screen    |                             |
|                                     | <input type="radio"/> Maximum Follow-up Reached [Visit 8 (Month 12) completed] | <input type="radio"/> Ineligible to Randomize |                             |

a. If OTHER, specify: \*

a. If withdrew consent selected, record the reason why: \*

- Moved to a farther location and unwilling to travel
- Participant's physician has asked them to withdraw from the study
- The participant is unwilling to have additional Specimen collections
- Participant is unhappy about the frequency of the follow-up visits
- Participant has a new job or a new situation has occurred which makes participation burdensome
- The participant has an illness or hospitalization of self or family
- Fear of Study Drug Risks
- Does not want to be blinded to individual test results during the study
- Other

a. If OTHER, specify: \*

3. Is the participant still willing to be contacted? \*

- Yes  No  Unknown



**TN20 IMMUNE EFFECTS OF ORAL INSULIN TRIAL  
CHANGE OF STATUS FORM**

**Form IE07**

Version 1.0

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Site Number: \_\_\_\_\_

Participant  
ID: \_\_\_\_\_

Participant  
Letters: \_\_\_\_\_

**C. REACTIVATION OF PREVIOUSLY WITHDRAWN PARTICIPANT**

1. Date of reactivation: \*

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DAY MONTH YEAR