



TN20 IMMUNE EFFECTS OF ORAL INSULIN TRIAL  
CHANGE IN STUDY DRUG FORM

Form IE05  
10 SEP 2015  
Version 1.0  
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Site Number: \_\_\_\_\_

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

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

Complete this form if the participant is stopping or resuming study drug.

A. VISIT INFORMATION

1. Visit Date:\*

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

B. REPORT INFORMATION

1. Change in Study Drug Status: \*

Discontinuing  
 Re-starting

2. Date change in Study Drug Status Effective: \*

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

3. Reason the study drug was stopped (*check one – complete for discontinuation only*): \*

- Participant refused further treatment
- Adverse event
- Pregnancy
- Lost to Follow Up

- Study discontinuation
- Diabetes Onset
- Withdrawn Consent
- Other

a. IF OTHER, specify:

\_\_\_\_\_  
\_\_\_\_\_

4. Is there a change in study status at this time?

Y  N

If YES, complete the **Change in Status Form**