

Site Number: _____	Participant ID: _____	Participant Letters: _____	
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Complete this form for each protocol deviation that occurs. A protocol deviation is defined as any action taken that is counter to the specific instructions given in the protocol.

A. PROTOCOL DEVIATION INFORMATION

1. Date protocol deviation occurred *

____/____/____ DAY MONTH YEAR

2. Visit protocol deviation occurred (*check one*):*

- | | | |
|---|--|---|
| <input type="checkbox"/> Visit -1
<input type="checkbox"/> Visit 0
<input type="checkbox"/> Visit 1 (Month 1)
<input type="checkbox"/> Visit 2 (Month 2) | <input type="checkbox"/> Visit 3 (Month 3)
<input type="checkbox"/> Visit 4 (Month 6)
<input type="checkbox"/> Visit 5 (Month 7)
<input type="checkbox"/> Visit 6 (Month 8) | <input type="checkbox"/> Visit 7 (Month 9)
<input type="checkbox"/> Visit 8 (Month 12)
<input type="checkbox"/> PRN Visit |
|---|--|---|

3. Protocol deviation (*check one*):*

- | | | | |
|---|--|---|-------------------------------|
| <input type="checkbox"/> Code of Federal Regulations not followed (<i>check one</i>): * | | | |
| <input type="checkbox"/> Informed consent not obtained prior to study procedure
<input type="checkbox"/> Personnel performed study visit procedures not assigned on Site Delegation Log | <input type="checkbox"/> Participant signed expired consent
<input type="checkbox"/> Other (<i>describe details of deviation in section 4</i>). | | |
| <input type="checkbox"/> Randomization of ineligible subject (<i>check one</i>): * | | | |
| <input type="checkbox"/> Randomization exceeded 52 day window for OGTT
<input type="checkbox"/> Randomization exceeded 210 day window for mIAA and other autoantibody confirmation | <input type="checkbox"/> Participant not eligible due to other eligibility criteria not met (<i>describe details of deviation in section 4</i>). | | |
| <input type="checkbox"/> Entire study visit completed outside visit window
<input type="checkbox"/> Study visit missed
<input type="checkbox"/> Sample(s) collected outside visit window (<i>check all that apply</i>): * | | | |
| <input type="checkbox"/> OGTT
<input type="checkbox"/> DNA | <input type="checkbox"/> HbA1c
<input type="checkbox"/> RNA | <input type="checkbox"/> Autoantibodies
<input type="checkbox"/> Mechanistic Serum | <input type="checkbox"/> PBMC |

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Required DNA sample(s) collected and/or processed incorrectly (*check all that apply*): *

- | | | |
|--|--|--|
| <input type="checkbox"/> Glucola consumed in longer than 5 minutes

<input type="checkbox"/> Incorrect dose of Glucola given to participant

<input type="checkbox"/> OGTT performed on participant with fasting BG \geq 250 mg/dL | <input type="checkbox"/> Exceeded Glucola volume limit for participant

<input type="checkbox"/> Participant did not fast prior to OGTT

<input type="checkbox"/> Other (<i>describe details of deviation in section 4</i>). | <input type="checkbox"/> OGTT started after 10AM

<input type="checkbox"/> Total amount of Glucola required to perform OGTT not consumed |
|--|--|--|

Sample(s) collected and/or processed incorrectly (*check all that apply*): *

- | | | | |
|---|--|---|-------------------------------|
| <input type="checkbox"/> OGTT

<input type="checkbox"/> DNA | <input type="checkbox"/> HbA1c

<input type="checkbox"/> RNA | <input type="checkbox"/> Autoantibodies

<input type="checkbox"/> Mechanistic Serum | <input type="checkbox"/> PBMC |
|---|--|---|-------------------------------|

Required study visit procedure (s) not completed (*check all that apply*): *

- | | | |
|---|--|---|
| <input type="checkbox"/> AEs not assessed

<input type="checkbox"/> Study drug not dispensed

<input type="checkbox"/> Study drug compliance not assessed | <input type="checkbox"/> Physical exam not performed

<input type="checkbox"/> Medical history not reviewed

<input type="checkbox"/> Other (<i>describe details of deviation in section 4</i>). | <input type="checkbox"/> Vital signs not performed

<input type="checkbox"/> Pregnancy test not performed |
|---|--|---|

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Required sample(s) not collected (*check all that apply*): *

- | | | | |
|-------------------------------|--------------------------------|--|-------------------------------|
| <input type="checkbox"/> OGTT | <input type="checkbox"/> HbA1c | <input type="checkbox"/> Autoantibodies | <input type="checkbox"/> PBMC |
| <input type="checkbox"/> DNA | <input type="checkbox"/> RNA | <input type="checkbox"/> Mechanistic Serum | |

Sample(s) collected in error or that do not follow protocol (*check all that apply*): *

- | | | | |
|-------------------------------|--------------------------------|--|-------------------------------|
| <input type="checkbox"/> OGTT | <input type="checkbox"/> HbA1c | <input type="checkbox"/> Autoantibodies | <input type="checkbox"/> PBMC |
| <input type="checkbox"/> DNA | <input type="checkbox"/> RNA | <input type="checkbox"/> Mechanistic Serum | |

Sample(s) lost (*check all that apply*): *

- | | | | |
|-------------------------------|--------------------------------|--|-------------------------------|
| <input type="checkbox"/> OGTT | <input type="checkbox"/> HbA1c | <input type="checkbox"/> Autoantibodies | <input type="checkbox"/> PBMC |
| <input type="checkbox"/> DNA | <input type="checkbox"/> RNA | <input type="checkbox"/> Mechanistic Serum | |

Study medication/pharmacy error (*check one*): *

- | | |
|---|---|
| <input type="checkbox"/> Study drug was not dispensed at visit when dispensation was required | <input type="checkbox"/> Other (<i>describe details of deviation in section 4</i>). |
| <input type="checkbox"/> Study drug was not returned | |

Other¹

If OTHER,

a. Specify deviation: * _____

4. Describe deviation and circumstances: * _____

5. Corrective action taken _____



**TN20 IMMUNE EFFECTS OF ORAL INSULIN TRIAL
PROTOCOL DEVIATION FORM**

Form IE10
10SEP15
Version 1.0
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Site Number: _____

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Was PI Notified? *

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