

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

Screening ID: \_\_\_\_\_ - \_\_\_\_

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

**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. Complete a separate form for mother and infant.**

**A. REPORT INFORMATION**

Deviation ID Number:  ## ## #

1. Date of report:

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

2. Last attended study visit *before* the protocol deviation occurred?

- |   |   |   |   |
|---|---|---|---|
| <input type="checkbox"/> 91 Pregnant Screening/<br>Enrollment   | <input type="checkbox"/> 94 Infant Enrollment<br>/6 month Visit     | <input type="checkbox"/> 15 15 Months old | <input type="checkbox"/> 36 36 Months old |
| <input type="checkbox"/> 1 Infant Screening                     | <input type="checkbox"/> 95 Entry A Screening/<br>Infant Enrollment | <input type="checkbox"/> 18 18 Months old | <input type="checkbox"/> 42 42 Months old |
| <input type="checkbox"/> 2 Infant Enrollment                    | <input type="checkbox"/> 6 6 Months old                             | <input type="checkbox"/> 21 21 Months old | <input type="checkbox"/> 48 48 Months old |
| <input type="checkbox"/> 3 3 Months old                         | <input type="checkbox"/> 9 9 Months old                             | <input type="checkbox"/> 24 24 Months old | <input type="checkbox"/> 99 Other         |
| <input type="checkbox"/> 93 Infant Enrollment/ 3<br>month visit | <input type="checkbox"/> 12 12 Months old                           | <input type="checkbox"/> 24 24 Months old |   |
|   |   | <input type="checkbox"/> 30 30 Months old |   |

a. If OTHER, specify date of visit:

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

**B. PROTOCOL DEVIATION INFORMATION**

1. Date protocol deviation occurred

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

2. Protocol deviation reported for (*check one*):

1 Mother

2 Infant

3. Protocol deviation (*check one*):

1 Randomization of ineligible subject

a. If checked, approved by Eligibility Committee?  Y  N

2 Entry A Infant screening conducted outside of visit window (>28 days after birth)

3 Baseline procedure/blood collection required by protocol not completed

4 Study substance error (e.g. incorrect dose or randomization color given to subject)

Other

99

If OTHER,

b. Specify deviation:

4. Describe deviation and circumstances:

5. Corrective action taken depending on circumstances:

**Signature of PI:** \_\_\_\_\_

**Signed?**  Y  N

**Date signed:**

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

**Initials (first, middle, last) of person completing this form:**

\_\_\_\_  
F M L

*On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates.  
Write "\*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*



**NIP DIABETES PILOT TRIAL  
PROTOCOL DEVIATION FORM**

**Form NPP19**  
15Nov2007(v1.1)  
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Site Number: \_\_\_\_\_

Screening ID: \_\_\_\_\_ - \_\_\_\_

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

**Date form completed:**

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

*On all questions write “?” if the desired information is currently unavailable, but is being checked and will be known in future updates.  
Write “\*” if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

**White Copy** – Send to TrialNet Coordinating Center

**Yellow Copy** – Retain at site