

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/
Enrollment | <input type="checkbox"/> 94 Infant Enrollment
/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/
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
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)
Page 2 of 2

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Participant Letters: _____

Date form completed:

____/____/____
DAY MONTH YEAR

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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