



NIP DIABETES PILOT TRIAL
NURSING MOTHER VISIT FORM

Form NPP09

06Dec2006 (v1.3)

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Site Number: _____

Screening ID: _____ - ____

Participant Letters: _____

The Study Coordinator completes this form for NURSING MOTHERS ONLY at the Infant Screening Visit, Infant Enrollment Visit, and 3, 6, 9, and 12 Months Old Visits. There are no specimen collections at the Infant Screening Visit.

A. VISIT INFORMATION

1. Date of visit (e.g. 05/Sep/2006):

Form for date entry: ___/___/___ with labels DAY, MONTH, YEAR

2. Visit (check one):

- Checkboxes for visit types: 1 Infant Screening, 2 Infant Enrollment, 3 3 Months Old, 6 6 Months Old, 9 9 Months Old, 12 12 Months Old, 93 Infant Enrollment combined with 3 Months Old, 94 Infant Enrollment combined with 6 Months Old

B. NURSING MOTHER MEDICAL HISTORY

1. Has the nursing mother had any of the following conditions since the last visit or if first visit, since giving birth?

Table with 2 main columns: Conditions/ Disease and 1) If YES, number of times? (Circle number or enter # of times). Rows include Breast inflammation/mastitis, Sore throat or tonsillitis, Chronic earache, Cold or influenza, Bronchitis, Sinus infection, Prolonged diarrhea, History of celiac disease.

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).



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C. NURSING MOTHER RECENT EVENTS

1. Is this an Infant Screening Visit? Y N

If YES, STOP HERE, SIGN AND DATE THE FORM, and SEND to TNCC.

2. Has the nursing mother had an immunization within the last 14 days? Y N

3. Has the nursing mother had any febrile infectious illness in the last 14 days? Y N

4. Has the nursing mother had any non-febrile infectious illness(es) in the last 14 days? Y N

5. Has the nursing mother taken any antibiotics within the last 14 days? Y N

6. Has the nursing mother taken steroids (oral or inhaled) or other immunosuppressive medications in the last 30 days? Y N

7. Has the nursing mother received any immunoglobulin treatments or blood products since the last visit? Y N

D. NURSING MOTHER MEDICATIONS

1. Is this an Infant Screening Visit? Y N

If YES, STOP HERE, SIGN AND DATE THE FORM, and SEND to TNCC.

2. Has the nursing mother taken any medications (prescription and non-prescription NOT including omega-3 fatty acids, DHA, vitamins, or dietary supplements) since infant's birth or last 3 month Follow-up Visit? Y N

If YES, fill in the following table. List all medications taken since last follow-up visit. (Use the Medication Category Codes on the next page to complete Category Code):

Table with 4 columns: Trade Name, 1) Category Code, 2) Currently taking? (Y/N), and a. through e. rows for medication entries.

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Table with Medication Category Codes. Includes instructions: 'Use the Number Codes below to indicate the type of medication used:'. Rows include: 001 Antibiotic, 002 Aspirin, 003 Immunization, 004 Immunosuppressive, 005 Non-Insulin Diabetes Medication, 006 NSAID, 007 Steroid Preparation, 008 Thyroid Medication, 999 Other.

E. NURSING MOTHER SPECIMEN COLLECTIONS

Note: There are no specimen collections at the Infant Screening Visit.

1. Is this an Infant Enrollment Visit? Y N

If YES, collect specimens for each item below.

Table for specimen collection items: a. Fatty Acids (RBC) and Inflammatory Mediators, b. Vitamin D levels and C-Reactive Protein (CRP), c. Fatty Acids (Breast Milk). Columns: Collected? (Y N), 1) Comments:

2. Is this a 3, 6, 9 or 12 Months Old Follow-up Visit? Y N

If YES, collect the following specimen only.

Table for specimen collection item: a. Fatty Acids (Breast Milk). Columns: Collected? (Y N), 1) Comments:

Initials (first, middle, last) of person completing this form: F M L

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).