

Site Number: _____ Screening ID: _____ - ____ Participant Letters: _____

Study Coordinator completes this form at the Pregnant Woman Screening Visit to assess study eligibility.

A. VISIT INFORMATION

1. Date of visit (e.g. 05/Sep/2006): _____ / _____ / _____
DAY MONTH YEAR

B. INFORMED CONSENT

1. Informed consent signed for pregnant mother and newborn by all required parties? Y N

a. If YES, date of written informed consent obtained: _____ / _____ / _____
DAY MONTH YEAR

2. Permission given to store mother's samples? Y N

a. If YES, permission to store mother's genetic samples? Y N

3. Permission given to store infant's samples? Y N

a. If YES, permission to store infant's genetic samples? Y N

C. PREGNANCY HISTORY

1. Week of pregnancy: _____ weeks

2. When was the pregnancy confirmed? _____ weeks

3. Number of times pregnant, including this pregnancy (e.g. 2 times): _____ times

4. Number of preterm births (< 36 weeks of gestational age): _____ births

5. Number of full term births (≥ 36 weeks of gestational age): _____ births

6. Number of living children: _____ children

7. Has she experienced any of the following complications during previous pregnancies?
(check all that apply)

- | | | | |
|---------------------------------------|-------------------------------|---------------------------------------|--------------------------------------|
| <input type="checkbox"/> ₁ | a. Spontaneous miscarriage | <input type="checkbox"/> ₁ | e. Gestational diabetes |
| <input type="checkbox"/> ₁ | b. Stillbirth | <input type="checkbox"/> ₁ | f. Infants with birth weight < 5 lbs |
| <input type="checkbox"/> ₁ | c. Neonatal death | <input type="checkbox"/> ₁ | g. Infants with birth weight > 9 lbs |
| <input type="checkbox"/> ₁ | d. Eclampsia or pre-eclampsia | <input type="checkbox"/> ₁ | h. Other, 1) Specify _____ |

*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).*

Site: _____ Screening ID: _____ - _____ Letters: _____ Visit Date: ____/____/____

PREGNANCY HISTORY (CONTINUED)

8. During her current pregnancy has she had any illnesses (other than autoimmune diseases)? Y N

a. If YES, specify: _____

9. Does she have diabetes? Y N

If YES, answer the following questions:

a. Specify type of diabetes (*check only one*):

- | | |
|---|--|
| <input type="checkbox"/> ₁ Pre-existing Type 1 diabetes | <input type="checkbox"/> ₄ Gestational diabetes: |
| <input type="checkbox"/> ₂ Pre-existing Type 2 diabetes | 1) Week of pregnancy diagnosed: _____ wks |
| <input type="checkbox"/> ₃ Both pre-existing Type I and Type II diabetes | <input type="checkbox"/> ₅ Do not know type of diabetes |

b. Has she had an HbA1c test result greater than 9% at any time during this pregnancy? Y N

If YES, , sign and date form. Although not eligible, complete the web randomization. Send form(s) to TNCC.

10. Was blood collected for this visit for a local HbA1c test? Y N

If YES,

- 1) Date blood drawn: _____ / _____ / _____
DAY MONTH YEAR
- 2) HbA1c: _____ . _____ %
- 3) Record the normal local lab reference range for HbA1c: _____ . _____ % to _____ . _____ %

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
PREGNANT WOMAN SCREENING FORM**

Form NPP02
22May2007 (v1.2)
Page 3 of 4

Site: _____ Screening ID: _____ - _____ Letters: _____ Visit Date: ____/____/____

D. PREGNANT WOMAN RECENT EVENTS

- | | | |
|---|---|---|
| 1. Has the pregnant mother had an immunization within the <u>last 14 days</u> ? | Y | N |
| 2. Has the pregnant mother had any febrile infectious illness in the <u>last 14 days</u> ? | Y | N |
| 3. Has the pregnant mother had any non-febrile infectious illness in the <u>last 14 days</u> ? | Y | N |
| 4. Has the pregnant mother taken any antibiotics within the <u>last 14 days</u> ? | Y | N |
| 5. Has the pregnant mother taken steroids (oral or inhaled) or other immunosuppressive medications in the <u>last 30 days</u> ? | Y | N |
| 6. Has the pregnant mother received any immunoglobulin treatments or blood products in the <u>last 30 days</u> ? | Y | N |

E. OMEGA- 3 FATTY ACID SUPPLEMENTATION

- | | | |
|--|---|---|
| 1. During this pregnancy has the pregnant mother taken vitamins, minerals, dietary supplements or special food products with DHA or omega-3 fatty acids? | Y | N |
|--|---|---|

If YES,

- | | | |
|--|---|---|
| a. Is she willing to <u>discontinue</u> while participating in the study? STP | Y | N |
|--|---|---|

b. Record all available information on DHA or omega-3 fatty acids taken:

	Brand	a) Dose	b) Unit	c) Frequency	d) Start Date	e) Stop Date	f) Currently taking?
1)	_____	_____	<input type="checkbox"/> 1 µg <input type="checkbox"/> 2 mg	<input type="checkbox"/> 1 Day <input type="checkbox"/> 2 Week	____/____ MONTH YEAR	____/____ MONTH YEAR	Y N
2)	_____	_____	<input type="checkbox"/> 1 µg <input type="checkbox"/> 2 mg	<input type="checkbox"/> 1 Day <input type="checkbox"/> 2 Week	____/____ MONTH YEAR	____/____ MONTH YEAR	Y N
3)	_____	_____	<input type="checkbox"/> 1 µg <input type="checkbox"/> 2 mg	<input type="checkbox"/> 1 Day <input type="checkbox"/> 2 Week	____/____ MONTH YEAR	____/____ MONTH YEAR	Y N
4)	_____	_____	<input type="checkbox"/> 1 µg <input type="checkbox"/> 2 mg	<input type="checkbox"/> 1 Day <input type="checkbox"/> 2 Week	____/____ MONTH YEAR	____/____ MONTH YEAR	Y N
5)	_____	_____	<input type="checkbox"/> 1 µg <input type="checkbox"/> 2 mg	<input type="checkbox"/> 1 Day <input type="checkbox"/> 2 Week	____/____ MONTH YEAR	____/____ MONTH YEAR	Y N

*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
PREGNANT WOMAN SCREENING FORM**

Form NPP02
22May2007 (v1.2)
Page 4 of 4

Site: _____ Screening ID: _____ - _____ Letters: _____ Visit Date: ____/____/____

F. MEDICATIONS TAKEN DURING PREGNANCY

1. During this pregnancy has she taken any medications (consider prescription and non-prescription not including omega-3 fatty acids or DHA)? (Refer to NWK02 Concomitant Medication Worksheet.) Record all vitamins and/or dietary supplements on NPP20M.

Y N

If YES, fill in the following table. List all medications taken during pregnancy. (Use the Medication Category Codes below to complete Category Code):

	Trade Name	1) Category Code	2) Currently taking?
a.	_____	_____	Y N
b.	_____	_____	Y N
c.	_____	_____	Y N
d.	_____	_____	Y N
e.	_____	_____	Y N

Medication Category Codes:			
<i>Use the Number Codes below to indicate the type of medication used:</i>			
001	Antibiotic	006	NSAID
002	Aspirin	007	Steroid Preparation
003	Immunization	008	Thyroid Medication
004	Immunosuppressive	999	Other
005	Non-Insulin Diabetes Medication		

See Manual of Operations for example of medications that fall under the Medications Category code table.

Use the NIP Diabetes Pilot Entry A Web Randomization System to assess the participant's eligibility. Complete the questions on the web eligibility screen for ALL screened participants (eligible and not eligible). If eligible, randomize the participant once baseline data and samples are collected.

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).