NIP DIABETES PILOT TRIAL
INFANT SCREENING FORM

Site Number: __ __ __ __ Screening ID: __ __ __ __ __ - __ Participant Letters: __ __ __

Study Coordinator completes this form at the Infant Screening Visit to assess eligibility. In the case of multiple births, complete another NPP04 Infant Screening Form for each infant at this visit.

A. VISIT INFORMATION

1. Date of visit (*e.g. 05/Sep/2006*): __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
2. Was mother participating in this study during pregnancy (Entry A)? Y N
3. Is the mother currently breastfeeding her baby? Y N

   If YES, complete forms related to nursing mothers (NPP09, NPP20M, and NPP22).

B. INFORMED CONSENT

1. Informed consent signed for new child? 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. INFANT DEMOGRAPHIC INFORMATION

1. Date of birth: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
2. Time of birth (*e.g 13:36*): __ __ : __ __ (Hour Min)
3. Sex (*check one*): ☐ 1 Male ☐ 2 Female
4. Ethnicity *(check one):* ☐ 1 Hispanic or Latino ☐ 2 Not Hispanic or Latino
5. Race (*check all that apply*):

☐ 1	a. American Indian or Alaskan Native	☐ 1	f. Other
☐ 1	b. Asian		1) Specify: ______
☐ 1	c. Black or African American		2) Record the 3-digit code for race/ethnicity (*International sites only*): a) ___ ___ ___
☐ 1	d. Native Hawaiian or Other Pacific Islander		b) ___ ___ ___
☐ 1	e. White		c) ___ ___ ___

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.).*

D. PREGNANCY AND INFANT MEDICAL HISTORY

1. Did the mother experience any complications during <u>this</u> pregnancy? Y N
   a. If YES, specify: ______________________________

2. Has the infant had any medical problems <u>since birth</u>? Y N
   a. If YES, specify: ______________________________

E. MOTHER OMEGA-3 FATTY ACID SUPPLEMENTATION

1. Did the mother take vitamins, minerals, dietary supplements or special food products with DHA or omega-3 fatty acids during pregnancy or anytime since delivery? Y N

   If NO, skip to **Section F**.

   a. If the mother is currently breastfeeding her baby, is she willing to discontinue omega-3 fatty acids while nursing and participating in the study? Y N

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

	Brand	a) Dose	b) Unit	c) Frequency	d) Start Date	e) Stop Date	f) Currently taking?
1)	___________	__ __ __	☐ 1 µg ☐ 2 mg	☐ 1 Day ☐ 2 Week	__ __ __ / __ __ __ __ MONTH YEAR	__ __ __ / __ __ __ __ MONTH YEAR	Y N
2)	___________	__ __ __	☐ 1 µg ☐ 2 mg	☐ 1 Day ☐ 2 Week	__ __ __ / __ __ __ __ MONTH YEAR	__ __ __ / __ __ __ __ MONTH YEAR	Y N
3)	___________	__ __ __	☐ 1 µg ☐ 2 mg	☐ 1 Day ☐ 2 Week	__ __ __ / __ __ __ __ MONTH YEAR	__ __ __ / __ __ __ __ MONTH YEAR	Y N

F. MOTHER RECENT EVENTS

1. Did the mother have an immunization within the <u>last 14 days</u>? Y N
2. Has the mother had any febrile infectious illness in the <u>last 14 days</u>? Y N
3. Has the mother had any non-febrile infectious illness in the <u>last 14 days</u>? Y N
4. Did the mother take any antibiotics within the <u>last 14 days</u>? Y N
5. Has the mother taken steroids (oral or inhaled) or other immunosuppressive medications in the <u>last 30 days</u>? Y N
6. Has the mother received any immunoglobulin treatments or blood products since the last visit for those who entered when pregnant (Entry A) or in the last 30 days if screening a new infant (Entry B)? 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.).*

Site: __ __ __ __ Screening ID: __ __ __ __ __ __ - __ Letters: __ __ __ Visit Date: __ __/__ __ __/__ __ __ __

G. MOTHER MEDICATIONS

1. Has the mother taken any medications (prescription and non-prescription NOT including omega-3 fatty acids, DHA, vitamins, or dietary supplements) since giving birth? (*Refer to NWK02 Concomitant Medication Worksheet. Use NPP20M Pregnant Woman/Nursing Mother Vitamin and Dietary Supplement Form to record vitamins and dietary supplements.*) Y N

   If YES, fill in the following table. List all medications taken since giving birth.
   (*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:

Use the Number Codes below to indicate the type of medication used:

Code	Category	Code	Category
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 each Medications Category code.

H. INFANT BIRTH HISTORY

1. Gestational age at birth: __ __ weeks

2. Birth measurements (*if unavailable see below for correct notation*):

   a. Weight: __ . __ kg or __ __ . __ lb

   b. Length: __ __ . __ cm or __ __ . __ in

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: __ __/__ __ __/__ __ __ __

I. INFANT OMEGA-3 FATTY ACID SUPPLEMENTATION

1. Has the parent(s) or legal guardian given the infant vitamins, minerals, dietary supplements or special food products with DHA or omega-3 fatty acids? Y N

   If NO, skip to **J**.

   a. Are the parent(s) willing to discontinue giving omega-3 fatty acids to the infant while participating in the study? Y N

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

	Brand	a) Dose	b) Unit	c) Frequency	d) Start Date	e) Stop Date	f) Currently taking?
1)	___________	__ __ __ __	☐ 1 µg ☐ 2 mg	☐ 1 Day ☐ 2 Week	__ __ __ / __ __ __ __ MONTH YEAR	__ __ __ / __ __ __ __ MONTH YEAR	Y N
2)	___________	__ __ __ __	☐ 1 µg ☐ 2 mg	☐ 1 Day ☐ 2 Week	__ __ __ / __ __ __ __ MONTH YEAR	__ __ __ / __ __ __ __ MONTH YEAR	Y N
3)	___________	__ __ __ __	☐ 1 µg ☐ 2 mg	☐ 1 Day ☐ 2 Week	__ __ __ / __ __ __ __ MONTH YEAR	__ __ __ / __ __ __ __ MONTH YEAR	Y N

J. INFANT RECENT EVENTS

1. Did the infant have an immunization within the last 14 days? Y N
2. Has the infant had any febrile infectious illness in the last 14 days? Y N
3. Has the infant had any non-febrile infectious illness in the last 14 days? Y N
4. Did the infant take any antibiotics within the last 14 days? Y N
5. Has the infant taken steroids (oral or inhaled) or other immunosuppressive medications in the last 30 days? Y N
6. Has the infant received any immunoglobulin treatments or blood products in the last 30 days? 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.).*

Site: __ __ __ __ Screening ID: __ __ __ __ __ - __ Letters: __ __ __ Visit Date: __ __/__ __ __/__ __ __ __

K. INFANT MEDICATIONS

1. Has the parent(s) or legal guardian given their infant any medications (prescription and non-prescription NOT including omega-3 fatty acids, DHA, vitamins, or dietary supplements) since birth? (*Refer to NWK02 Concomitant Medication Worksheet. Use NPP20 Infant Vitamin and Dietary Supplement Form to record vitamins and dietary supplements.*) Y N

   If YES, fill in the following table. List all medications given since birth.
   (*Use the Medication Category Codes 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:

Use the Number Codes below to indicate the type of medication used:

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 each Medications Category code.

L. INFANT PHYSICAL EXAM

1. Heart rate: __ __ __ beats per minute
2. Respiratory rate: __ __ breaths per minute
3. Weight: ___ ___ . ___ kg or ___ ___ . ___ lbs
4. Length: ___ ___ . ___ cm or ___ ___ . ___ in
5. Head circumference: ___ ___ . ___ cm or ___ ___ . ___ in
6. Temperature: ___ ___ . ___ °C or ___ ___ ___ . ___ °F

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L. INFANT PHYSICAL EXAM (CONTINUED)

7. Are the following system(s) normal by history or exam?

System	Normal?	1) If NO, describe abnormality:
a. HEENT	Y N	
b. Neck	Y N	
c. Thyroid	Y N	
d. Lungs	Y N	
e. Chest	Y N	
f. Heart	Y N	
g. Cardiovascular	Y N	
h. Abdomen	Y N	
i. Liver	Y N	
j. Spleen	Y N	
k. Musculoskeletal	Y N	
l. Neurologic	Y N	
m. Urological/Renal	Y N	
n. Skin (including jaundice)	Y N	
o. Nails	Y N	
p. Lymph nodes	Y N	
q. Other:	Y N	

r. Describe any other pertinent findings: ______________________

s. Physical exam conducted by: (*please print clearly*) ______________________ NAME

t. Date physical exam 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.).*

Site: __ __ __ __ Screening ID: __ __ __ __ __ __ - __ Letters: __ __ __ Visit Date: __ __/__ __ __/__ __ __ __

M. MOTHER SPECIMEN COLLECTIONS

	Collected?	a. Comments:
1. Biochemical Autoantibodies	Y N	

N. INFANT SPECIMEN COLLECTIONS

	Collected?	a. If YES, Collection Method (*check all that apply*): Cord Blood	Heel Stick	b. Comments:
1. HLA typing	Y N	☐ 1	☐ 2	
2. Biochemical Autoantibodies	Y N	☐ 1	☐ 2	

Other Cord Blood Collection Specimens:		a. Comments:
3. Vitamin D levels and C-Reactive Protein (CRP)	Y N	
4. Fatty Acids (RBC) and Inflammatory Mediators	Y N	

5. If any cord blood samples were collected, the relationship of the person(s) to the infant who completed the Cord Blood Collection Form and packaged the samples at the delivery hospital (*check all that apply*):

- ☐ 1 Family
- ☐ 1 Study research staff
- ☐ 1 Friend
- ☐ 1 Other
  - 1) Specify: ____________
- ☐ 1 Delivery staff

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.).*