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

Study Coordinator completes this form when the Infant's HLA results are known and the Infant is determined eligible.

A. VISIT INFORMATION

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

2. Visit (*check one*):
   - ☐ 2 Infant Enrollment
   - ☐ 94 Infant Enrollment combined with 6 Months old
   - ☐ 93 Infant Enrollment combined with 3 Months old
   - ☐ 95 Entry A Infant Screening combined with Infant Enrollment

3. Infant's date of birth: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

4. Is there more than one eligible infant from the same immediate family? Y N

> If YES, fill out a separate NPP06 Infant Enrollment Medical History Form for each child.

B. INFANT MEDICAL HISTORY

1. Did the infant have any of the conditions listed below at birth and in the first week of life?

Condition		1) If YES, describe:
HEENT		
a. Eye discharge/pinkeye (not blocked tear ducts)	Y N	
b. Mouth sores (includes ulcers, thrush, cold sores)	Y N	
Respiratory		
c. Respiration (breathing) problems	Y N	
d. Cold or runny nose	Y N	
e. Aspiration (Meconium or other)	Y N	
f. Periods of no breathing (apnea)	Y N	
g. Pneumonia/ RSV	Y N	

B. INFANT MEDICAL HISTORY (CONTINUED)

1. Did the infant have any of the conditions listed below at birth and in the first week of life?

Condition		1) If YES, describe:
Gastrointestinal		
h. Diarrhea	Y N	
i. Yellow skin (jaundice)	Y N	
1) If YES, Light therapy (phototherapy)	Y N	
j. Bloody stool	Y N	
Neurologic		
k. Seizures	Y N	
l. Meningitis	Y N	
Infections		
m. Rash (not diaper rash)	Y N	
n. Fever (over 100°F or 37.7°C)	Y N	
o. Other infection	Y N	
Hematologic		
p. Blood group incompatibility (Rh or ABO)	Y N	
q. Blood transfusion	Y N	
r. Blood poisoning (sepsis)	Y N	
s. Low blood sugar/hypoglycemia (< 40 mg/dL within first 24 hours and/or < 60 mg/dL thereafter)	Y N	
t. Excessive bleeding	Y N	
u. Anemia	Y N	

B. INFANT MEDICAL HISTORY (CONTINUED)

1. Did the infant have any of the conditions listed below at birth and in the first week of life?

Condition		1) If YES, describe:
Other Conditions		
v. Birth defect (congenital abnormality)	Y N	
w. Birth trauma	Y N	
x. Edema or swelling	Y N	
y. Surgery	Y N	
z. Other	Y N	

2. Has the infant had any of the below illness(es) after the first week of life?

Illness		1) If YES, number of times? (*Circle number or enter # of times*)
HEENT		
a. Eye discharge/pinkeye (not blocked tear ducts)	Y N	1 2 3 4 5 __
b. Mouth sores (includes ulcers, cold sores, thrush)	Y N	1 2 3 4 5 __
c. Ear infection	Y N	1 2 3 4 5 __
Respiratory		
d. Respiration (breathing) problems	Y N	1 2 3 4 5 __
e. Cold or runny nose	Y N	1 2 3 4 5 __
f. Croup (*e.g. barking cough*)	Y N	1 2 3 4 5 __
g. Bronchitis/Bronchiolitis	Y N	1 2 3 4 5 __
h. Pneumonia/ RSV	Y N	1 2 3 4 5 __
i. Cough (not related to Croup, Bronchitis /Bronchiolitis, Pneumonia/RSV)	Y N	1 2 3 4 5 __

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

B. INFANT MEDICAL HISTORY (CONTINUED)

2. Has the infant had any of the below illness(es) after the first week of life?

Illness		1) If YES, number of times? (Circle number or enter # of times)
Gastrointestinal		
j. Colic	Y N	1 2 3 4 5 __
k. Vomiting (≥ 3 times in 24 hours)	Y N	1 2 3 4 5 __
l. Diarrhea (≥ 3 times in 24 hours)	Y N	1 2 3 4 5 __
m. Gastrointestinal infection	Y N	1 2 3 4 5 __
n. Intestinal parasite	Y N	1 2 3 4 5 __
o. Yellow skin (jaundice)	Y N	1 2 3 4 5 __
p. Bloody stool	Y N	1 2 3 4 5 __
Neurologic		
q. Seizures	Y N	1 2 3 4 5 __
r. Meningitis	Y N	1 2 3 4 5 __
Infections		
s. Fever (over 100˚ F or 37.7˚ C)	Y N	1 2 3 4 5 __
t. Strep infection	Y N	1 2 3 4 5 __
Infections		
u. German measles (rubella)	Y N	1 2 3 4 5 __
v. Measles	Y N	1 2 3 4 5 __
w. Chicken pox	Y N	1 2 3 4 5 __
x. Mumps	Y N	1 2 3 4 5 __
y. Rash (not diaper rash)	Y N	1 2 3 4 5 __
Hematologic		
z. Excessive bleeding	Y N	1 2 3 4 5 __

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).*

B. INFANT MEDICAL HISTORY (CONTINUED)

2. Has the infant had any of the below illness(es) after the first week of life?

Illness		1) If YES, number of times? (*Circle number or enter # of times*)
Other Conditions		
aa. Surgery	Y N	1 2 3 4 5 __
2) If YES, specify what surgery:		
ab. Other 1:		1 2 3 4 5 __
ac. Other 2:		1 2 3 4 5 __
ad. Other 3:		1 2 3 4 5 __

C. INFANT RECENT EVENTS

1. Is this an Entry A Infant Screening combined with Infant Enrollment Visit? If YES, Skip to **Section D** Infant Medications.	Y N
2. Did the infant have an immunization within the last 14 days?	Y N
3. Has the infant had any febrile infectious illness in the last 14 days?	Y N
4. Has the infant had any non-febrile infectious illness in the last 14 days?	Y N
5. Did the infant take any antibiotics within the last 14 days?	Y N
6. Has the infant taken steroids (oral or inhaled) or other immunosuppressive medications in the last 30 days?	Y N
7. Has the infant received any immunoglobulin treatments or blood products since the last visit?	Y N

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D. INFANT MEDICATIONS

1. Is this an Entry A Infant Screening combined with Infant Enrollment Visit? Y N

   If YES, Skip to **Section E** Infant Immunization History.

2. 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 the Infant Screening Visit? (*Refer to NWK02 Concomitant Medication Worksheet. Use NPP20E All Mothers Infant Enrollment 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 the Infant Screening Visit. (*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:

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.

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

E. INFANT IMMUNIZATION HISTORY

1. Has the infant had any vaccinations since birth? (*check all that apply*) Y N

	Vaccination		If YES, date vaccination given:
☐ 1	Hepatitis B (HepB) vaccine	1)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		2)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		3)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		4)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
☐ 1	Rotavirus vaccine	1)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		2)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		3)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
☐ 1	DTaP/DTP vaccine	1)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		2)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		3)	__ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
		4)	__ __/ __ __ __/ __ __ __ __ 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).*

E. INFANT IMMUNIZATION HISTORY (CONTINUED)

1. Has the infant had any vaccinations since birth? (*check all that apply*)

	Vaccination		If YES, date vaccination given:
☐ 1	Haemophilus influenzae type b (Hib) vaccine	1)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
		2)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
		3)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
☐ 1	Inactive polio (IPV) vaccine	1)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
		2)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
		3)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
☐ 1	Pneumococcal (PCV) vaccine	1)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
		2)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
		3)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
☐ 1	Influenza (LAIV) vaccine (live attenuated)	1)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
☐ 1	Influenza (TIV) vaccine (trivalent inactivated)	1)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
☐ 1	Tetanus and diphtheria toxoids (Td)	1)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
☐ 1	Hepatitis A vaccine	1)	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR

E. INFANT IMMUNIZATION HISTORY (CONTINUED)

1. Has the infant had any vaccinations since birth? (*check all that apply*)

Vaccination		If YES, date vaccination given:
☐ 1 Other		
1) Other 1:		a) __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
		b) __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
2) Other 2:		a) __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
		b) __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
3) Other 3:		a) __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR
		b) __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR

F. NEXT STEPS

1. Is this an Infant Enrollment combined with 6 Months Old study visit? Y N

If YES, complete the Infant Physical Exam Section in the NPP11 Infant 6, 12, 18 and Every 6 Months Old Visit Form and the NPP12 6, 18, 30, And Every 6 Months Infant Specimen Collection Form.

2. Was mother enrolled during pregnancy? Y N

If YES, complete NPP15 Study Substance Dispensation and Return Form and NPP08 Entry A Non-Nursing Mother Visit Form.

a. If NO, is mother currently nursing infant? Y N

If YES, complete NPP09 Nursing Mother Visit Form.

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

Date form completed: __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR

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