

ELIGIBILITY SCREENING I

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ID
2. Current Clinic: SITE
3. Patient's Letter Code: INITS
4. Visit: M - SEQNO
VISIT sequence #
5. Visit Date: - - VIS_DT
Month Day Year

PART II: INCLUSION CRITERIA

- | | Yes | No |
|---|--------|-------------------------------|
| 1. Diagnosis of Hb-SS or Hb S-beta-0-thal? | (1) | (2) |
| | | (INEL) |
| | | DIAGHBSS |
| 2. A. Date of Birth: <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | |
| | | BIRTH_DT |
| | | <small>Month Day Year</small> |
| B. Is the child between 9 and 17 months of age inclusive? | (1) | (2) |
| | | (HOLD) |
| | | AGEINCL4 |
| <div style="border: 1px solid black; padding: 2px; display: inline-block;">If NO, answer Item 2C.</div> | | |
| C. Will the child be between 9 and 17 months of age inclusive, during the study recruitment period? | (1) | (2) |
| | (HOLD) | (INEL) |
| | | WILL1217 |
| 3. Has informed consent been obtained? | (1) | (2) |
| | | (HOLD) |
| | | CONSNT04 |
| 4. Has HIPAA authorization form been obtained? | (1) | (2) |
| | | (HOLD) |
| | | HIPAA04 |
| 5. Does the family have telephone service for contact as required? | (1) | (2) |
| | | (HOLD) |
| | | PHONE04 |

PART III: EXCLUSION CRITERIA

- | | | Yes | No |
|-------|---|---------------|-----------------|
| 1. A. | Splenectomy?SPLENCBL | (1)
(INEL) | (2) |
| B. | Chronic transfusion program? CHRTRFBL | (1)
(INEL) | (2) |
| C. | Transfusion within last 2 months? TRN2MO04 | (1)
(HOLD) | (2) |
| 1. | If yes, Date <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | TRN04_DT |
| | Month Day Year | | |
| D. | Known hereditary persistence of Hb-F? HERPHFBL | (1)
(INEL) | (2) |
| E. | Stroke or Grade III/IV intracranial STROKEBL | (1)
(INEL) | (2) |
| F. | Malignancy? MALIGBL | (1)
(INEL) | (2) |
| G. | Cerebral palsy and/or mental retardation? ... PALSYBL | (1)
(INEL) | (2) |
| H. | Other condition or severe chronic illness? OTHCHRBL | (1)
(INEL) | (2) |
| I. | S-beta+ thalassemia? SBTHALBL | (1)
(INEL) | (2) |
| J. | Previous or current hydroxyurea therapy? ... PRVHUBL | (1)
(INEL) | (2) |
| K. | Other antisickling agent, previous or current? ANTISKBL | (1)
(INEL) | (2) |
| L. | Current participation in other intervention TRIALSBL | (1)
(INEL) | (2) |

PART IV: SIBLING INFORMATION

- | | | | |
|----|---|-------------|-----------|
| 1. | Does the child have a sibling either enrolled or in screening in BABY HUG? SIB_ENR | Yes
(1)* | No
(2) |
|----|---|-------------|-----------|

*A. If yes, what is the sibling's Patient ID? **SIBLING**

PART V: COORDINATION

1. Checked for completeness and accuracy:

- | | | |
|----|---|-----------------|
| A. | Certification number: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> | CERT_NO |
| B. | Signature: _____ | CERT_SIG |
| C. | General Comments: | GEN_CMNT |

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	- <input type="text"/> <input type="text"/>

ELIGIBILITY SCREENING II

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: **ID** 2. Current Clinic: **SITE**
3. Patient's Letter Code: **INITS** 4. Visit: **VISIT** - **sequence #**
5. Visit Start Date: - - **VIS_DT**
- Month Day Year

PART II: EXCLUSIONS REVIEW

1. A. Is the child between 9 and 17 months of age? **AGEINCL5** YE (1) NO (2)
(HOLD)
- B. Transfusion within last 2 months? **TRN2MO05** (1) (2)
(HOL)
1. IF YES, Date? - -
Month Day Year **TRN05_DT**
2. A. Has informed consent been obtained? **CONSNT05** (1) (2)
(INEL)
- B. Has HIPAA authorization form been obtained? **HIPAA05** (1) (2)
(INEL)
- C. Family has telephone service for contact as required? **PHONE05** (1) (2)
(INEL)
- D. Concurrence that participation appropriate by Clinical Center Director? **PAPRVCCD** (1) (2)
(INEL)
- E. Concurrence that participation appropriate by Patient-Family Advocate? **PAPRVPFA** (1) (2)
(INEL)

If Item 2A, 2B, 2C, 2D or 2E. is **NO**, Skip to PART V.

PART III: SPECIMENS COLLECTION

1. Were any blood specimens collected? **BLOODCOL** YES (1) NO (2)

If **NO**, answer Item 1.A. If **YES**, Skip to Item 1.B.

- A. Reason(s) specimen not collected
1. No access **NOVENACS** (1) (2)
(INEL)
2. Patient declined or blood draw not possible today **PTNTDCLN** (1) (2)
(HOLD)
3. Parent refused **PRNTREFS** (1) (2)
(INEL)

IF 1 or 3 (INELIGIBLE), Skip to PART V.
IF 2 (no blood drawn), Skip to PART IV.

B. Specimen collected:

- | | | | | | | | |
|---|-----------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| 1. Hematology (0.5 ml EDTA lavender-top) | SCHEMAT | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 2. Biochemistry specimen collected just prior to urine osmolality specimen (2.0 ml red-top) | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | SCBIOCH | | | | | |
| 3. Pitted cell count specimen collected and prepared within 1 hour of collection (0.1 ml EDTA lavender top) | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | SCPITCEL | | | | | |
| 4. Cytogenetics (4.0 ml Na Heparin green top) | SCCYTOG | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 5. DNA (3.0 ml EDTA lavender top) | SCDNA | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 6. Immunology (record labels on Form 42) | SCIMMUN | Yes
(1) | No
(2) | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 7. Penicillin compliance specimen | SCPENCIL | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 8. Consent for specimens to be used in other research, teaching or new product development by this university medical center and its staff. | SCCONS1 | Yes
(1) | No
(2) | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 9. Consent for other doctors to use stored specimens to study an illness not related to sickle cell anemia. | SCCONS2 | Yes
(1) | No
(2) | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

PART IV: SPECIAL TESTS AND PROCEDURES

1. Please record the dates that the following special tests or procedures were performed:

- | | | Month | Day | Year | |
|--------------------------------|-----------------|----------------------|----------------------|----------------------|----------------------|
| A. Urinalysis | URNLS_DT | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| B. Urine concentrating ability | URNCA_DT | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| C. Liver-spleen scan | LIVSP_DT | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| D. Abdominal ultrasound | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 1. How many hours NPO? | | <input type="text"/> | <input type="text"/> | | ABD_NPO |
| E. Neurological Evaluation | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| F. Bayley's | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| G. Vineland | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

ID Number	Visit	Seq
<input type="text"/>	<input type="text"/>	<input type="text"/>
	-	<input type="text"/>

		TRNDP_DT		TRNDP_ND	
H.	Transcranial doppler	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	(1) N/D
	1. If not attempted, reason:				TRNDNP
	Patient not available		(1)		
	Parent/guardian refusal		(2)		
	Other		(3)		
	a. Specify: _____				TRNDNPSP
2.	Urinalysis				
	A. Red cells				REDCELLS
	Normal dipstick, normal chemistry or less than 3/high-power field				(1)
	3-20/high-power field				(2)
	more 20/high-power field				(3)
	B. White cells				WHTCELLS
	Normal dipstick, normal chemistry or less than 3/high-power field				(1)
	3-20/high-power field				(2)
	more 20/high-power field				(3)
	C. pH	<input type="text"/>	.	<input type="text"/>	
	D. Protein				URINPR
	(1) Negative (2) Trace (3) Small (4) Moderate (5) Large				
	E. Hemoglobin				URINHB
	(1) Negative (2) Trace (3) Small (4) Moderate (5) Large				
	F. Specific gravity - urine	<input type="text"/>	.	<input type="text"/> <input type="text"/> <input type="text"/>	URINSG
3.	Urine concentrating ability				
	A. How many hours NPO?		<input type="text"/> <input type="text"/>		URN_NPO
	B. Urine osmolality specimen collected just after biochemistry specimen	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			URINOS
4.	A. O ₂ saturation (pulse oxymetry)	<input type="text"/> <input type="text"/> <input type="text"/>	%		O2SAT
	B. Second measurement	<input type="text"/> <input type="text"/> <input type="text"/>	%		O2SATSM

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	- <input type="text"/> <input type="text"/>

5. Child's recumbent length
- A. Measurement #1 . cm **AVERAGE HEIGHT = HEIGHT HEIGHT1**
- B. Measurement #2 . cm **HEIGHT2**
- C. Measurement #3 . cm **HEIGHT3**
 (If #1 and #2 differ by more than 0.5 cm)
- D. Rate hair style interference on child's length **HAIRHGT**
 None (1)
 Some (2)
 Not noted (3)

6. Child's weight
- A. Measurement #1 . kg **AVERAGE WEIGHT = WEIGHT WEIGHT1**
- B. Measurement #2 . kg **WEIGHT2**
- C. Measurement #3 . kg **WEIGHT3**
 (If #1 and #2 differ by more than 0.2 kg)

7. Child's head circumference
- A. Measurement #1 . cm **AVERAGE HEAD CIRCUMFERENCE = HEADC HEADC1**
- B. Measurement #2 . cm **HEADC2**
- C. Measurement #3 . cm **HEADC3**
 (If #1 and #2 differ by more than 0.4 cm)
- D. Rate hair style interference on child's head circumference? **HAIR**
 None (1)
 Some (2)
 Not noted (3)

8. Anthropometry measurement date **MSRMT_DT**
 - -
 Month Day Year

PART V: COORDINATION

1. Checked for completeness and accuracy:
- A. Certification number: - **CERT_NO**
- B. Signature: _____ **CERT_SIG**
- C. General Comments: **GEN_CMNT**

ID Number Visit - Seq

PEDIATRIC HYDROXYUREA CLINICAL TRIAL
HISTORY AND PHYSICAL EXAMINATION AT ENTRY

BABY HUG Form 06
 Rev 1 02/19/04
 Page 1 of 3

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ID 2. Current Clinic: SITE
3. Patient's Letter Code: INITS 4. Visit: M - sequence #
 VISIT SEQNO
5. Form Completed Date: - - VIS_DT
 Month Day Year

PART II: MEDICAL HISTORY

1. Sickle cell diagnosis SCDIAG
- | | | | | |
|---------------|--|-----|--|--|
| SS | | (1) | | |
| S-beta-0 Thal | | (2) | | |
-
2. Gestational age at birth GEST_AGE weeks (1) N/A GESTAGNA
-
3. Please indicate the number of episodes the child has had since birth
- | | | | | |
|----|---|---|------------|---|
| A. | Hospitalization(s) HOSPBL | <input type="text"/> <input type="text"/> | | |
| | 1. For fever FEVERBL | <input type="text"/> <input type="text"/> | (1) | N/A FEVER_NA |
| B. | Dactylitis DACTBL | <input type="text"/> <input type="text"/> | (1) | N/A DACTBLNA |
| | 1. Age of first dactylitis AGEDACT | <input type="text"/> <input type="text"/> | months (1) | N/A AGEDACNA |
| C. | Pain PAINBL | <input type="text"/> <input type="text"/> | (1) | N/A PAINBLNA |
| D. | Acute chest syndrome ASCBL | <input type="text"/> <input type="text"/> | (1) | N/A ASCBL_NA |
| E. | Priapism PRIAPBL | <input type="text"/> <input type="text"/> | (1) | N/A PRIAPNA |
| F. | Splenic sequestration SPLSEQBL | <input type="text"/> <input type="text"/> | (1) | N/A SPLSEQNA |
| G. | Transfusion TRNSFBL | <input type="text"/> <input type="text"/> | (1) | N/A TRNS_NA |
| H. | Bacteremia/sepsis other than meningitis SEPSISBL | <input type="text"/> <input type="text"/> | (1) | N/A SEPSISNA |
| I. | Meningitis MENINBL | <input type="text"/> <input type="text"/> | (1) | N/A MENIN_NA |
| J. | Aplastic crisis APLCRBL | <input type="text"/> <input type="text"/> | (1) | N/A APLCR_NA |
| K. | Transient ischemic attack TIABL | <input type="text"/> <input type="text"/> | (1) | N/A TIABL_NA |
| L. | Seizures (non-febrile) SEIZNFBL | <input type="text"/> <input type="text"/> | (1) | N/A SEIZNFNA |
| M. | Seizures (febrile) SEIZFBBL | <input type="text"/> <input type="text"/> | (1) | N/A SEIZFBNA |
| N. | Osteomyelitis OSTEOMBL | <input type="text"/> <input type="text"/> | (1) | N/A OSTEOMNA |

PART III: MEDICAL EXAMINATION

1. Spleen (00 if not palpable):
- A. Midclavicular line cm **SPLNMDCL**
- B. Anterior axillary line cm **SPLNINTC**
2. Liver (00 if not palpable): cm **LIVRCMBL**
3. Child's recumbent length:
- A. Measurement #1 . cm **HEIGHT1**
- B. Measurement #2 . cm **HEIGHT2**
- C. Measurement #3 . cm **HEIGHT3**
 (If #1 and #2 differ by more than 0.5 cm)
Average height = HEIGHT
- D. Rate hair style interference on child's length **HAIRHGHT**
- None (1)
- Some (2)
- Not noted (3)
4. Child's weight:
- A. Measurement #1 . kg **WEIGHT1**
- B. Measurement #2 . kg **WEIGHT2**
- C. Measurement #3 . kg **WEIGHT3**
 (If #1 and #2 differ by more than 0.2 kg)
Average weight = WEIGHT
5. Child's head circumference:
- A. Measurement #1 . cm **HEADC1**
- B. Measurement #2 . cm **HEADC2**
- C. Measurement #3 . cm **HEADC3**
 (If #1 and #2 differ by more than 0.4 cm)
Average head circumference = HEADC
- D. Rate hair style interference on child's head circumference? **HAIR**
- None (1)
- Some (2)
- Not noted (3)
6. Anthropometry measurement date: - - **MSRMT_DT**
- Month Day Year
- ID Number Visit Seq
-

PART IV. COORDINATION:

1. Checked for completeness and accuracy:

A. Certification number:

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CERT_NO

B. Signature: _____

CERT_SIG

C. General Comments: _____

GEN_CMNT

ID Number

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Visit Seq

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DEMOGRAPHIC AND HOUSEHOLD INFORMATION

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: **ID** 2. Current Clinic: **SITE**
3. Patient's Letter Code: **INITS** 4. Visit: **VISIT** - **sequence #** **SEQNO**
5. Form Completed Date: - - **VIS_DT**
Month Day Year

PART II: DEMOGRAPHICS

1. Participant's racial category(ies). **NOTE:** More than one racial category may be answered 1-Yes.
- | | | | |
|---|-----|-----|-----------------|
| | Yes | No | |
| A. American Indian/Alaska Native | (1) | (2) | AMINDALN |
| B. Asian | (1) | (2) | ASIAN |
| C. Native Hawaiian/Other Pacific Islander | (1) | (2) | NHWNOPIS |
| D. Black or African-American | (1) | (2) | BLACK |
| E. White or Caucasian | (1) | (2) | WHITE |
| F. Unknown/Not Reported | (1) | (2) | ETHUNKN |
| G. Other | (1) | (2) | ETHOTHER |
2. Hispanic/Latino (1) (2) (3) **HISPANIC**
3. Caribbean (1) (2) (3) **CARIBBN**
4. Gender Male (1) **GENDER**
 Female (2)
5. How many rooms are in the patient's residence?
 (Not counting kitchen, bathrooms, halls, or foyers.) **ROOMS** N/A (1) **ROOMS_NA**
6. How many people live in the patient's household
 not counting the patient?
- | | | | |
|---------------------------------|--------------|---|-------------------------|
| A. Number of people under 18 | CHLDN | <input type="text"/> <input type="text"/> | N/A (1) CHLDN_NA |
| B. Number of people 18 and over | ADULT | <input type="text"/> <input type="text"/> | (1) ADULT_NA |

7. Who is the patient's PRIMARY caretaker (the one who takes care of him/her most of the time)?

PRCARTKR

- Mother (1)
- Stepmother (2)
- Father (3)
- Stepfather (4)
- Adoptive mother (5)
- Adoptive father (6)
- Foster mother (7)
- Foster father (8)
- Sister(s)/Stepsister(s) (9)
- Brother(s)/Stepbrother(s) (10)
- Aunt(s)/Uncle(s) (11)
- Grandparent(s) (12)
- Other female relative(s) (13)
- Other male relative(s) (14)
- Other unrelated female(s) (15)
- Other unrelated male(s) (16)
- N/A (17)

8. What is the highest level of school that the patient's PRIMARY caretaker completed?

PCSCHOOL

- None (1)
- 4th Grade or Less (2)
- 5th, 6th, 7th or 8th Grade (3)
- 9th, 10th, or 11th Grade (4)
- High School Diploma or Equivalent (5)
- Some College, But No Degree (6)
- Associate Degree in College (7)
- Bachelor's Degree (BA, AB, BS) (8)
- Master's Degree (MA, MS, MEng, MBA, MEd.) etc.) (9)
- Professional School Degree (MD, DDS, etc.) (10)
- Doctorate Degree (Ph.D., Ed.D.,etc.) (11)
- N/A (12)

ID Number

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Visit Seq

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9.	What is the employment status of the patient's PRIMARY caretaker?		Yes	No	N/A
A.	Full-time work (35 hours week or more)	PCFTWORK	(1)	(2)	(3)
B.	Part-time work (Less than 35 hours/week)	PCPTWORK	(1)	(2)	(3)
C.	Laid off, unemployed or currently looking for work	PCUNEMPL	(1)	(2)	(3)
D.	Disabled	PCDISABL	(1)	(2)	(3)
E.	Retired	PCRETIRE	(1)	(2)	(3)
F.	Keeping house	PCKHOUSE	(1)	(2)	(3)
G.	Attending school 35 hours a week or more	PCAS35HM	(1)	(2)	(3)
H.	Attending school less than 35 hours a week	PCAS35HL	(1)	(2)	(3)
I.	Doing volunteer work	PCVRWORK	(1)	(2)	(3)
J.	Other	PCOTWORK	(1)	(2)	(3)
K.	Employed in the last 5 years?	PCEMP5YR	(1)	(2)	(3)

If not employed in last 5 years, Skip to Item 10.

L.	What is/was the PRIMARY caretaker's main occupation? (What kind of work does she/he usually do?)	
	<u>Professional or technical</u> , for example: teacher, clergyperson, scientist, librarian, engineer or writer.	(1) PCRTOCPN
	<u>Manager or administrator (except farm)</u> , for example: school administrator, office manager, treasurer, inspector, sales manager, bank officer.	(2)
	<u>Sales worker</u> , for example: advertizing agent, sales person, sales demonstrator.	(3)
	<u>Clerical worker</u> , for example: cashier, dispatcher, file clerk, messenger, secretary.	(4)
	<u>Operative</u> , for example: assembler, dressmaker, gas station attendant, butcher, painter, bus or truck driver.	(5)
	<u>Laborer (except farm)</u> , for example: construction worker, gardener, fisherman, garbage collector.	(6)
	<u>Farm owner, tenant or manager</u>	(7)
	<u>Farm foreman or laborer</u>	(8)
	<u>Service worker</u> , for example: chambermaid, janitor, waiter, practical nurse, child care giver, hairdresser, airline attendant, firefighter, police officer.	(9)
	Other	(10)
	N/A	(11)

ID Number

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Visit Seq

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10. Who is the patient's OTHER caretaker (who also takes care of him/her)? **OTHCRTKR**

- Mother (1)
- Stepmother (2)
- Father (3)
- Stepfather (4)
- Adoptive mother (5)
- Adoptive father (6)
- Foster mother (7)
- Foster father (8)
- Sister(s)/Stepsister(s) (9)
- Brother(s)/Stepbrother(s) (10)
- Aunt(s)/Uncle(s) (11)
- Grandparent(s) (12)
- Other female relative(s) (13)
- Other male relative(s) (14)
- Other unrelated female(s) (15)
- Other unrelated male(s) (16)
- No other caretaker (17)
- N/A (18)

If there is NO father or other caretaker, skip to item 13.

11. What is the highest level of school that the patient's father or OTHER caretaker completed?

OC SCHOOL

- None (1)
- 4th Grade or Less (2)
- 5th, 6th, 7th or 8th Grade (3)
- 9th, 10th, or 11th Grade (4)
- High School Diploma or Equivalent (5)
- Some College, But No Degree (6)
- Associate Degree in College (7)
- Bachelor's Degree (BA, AB, BS) (8)
- Master's Degree (MA, MS, MEng, MBA, MEd., etc.) (9)
- Professional School Degree (MD, DDS, DVM, LLB, etc.) (10)
- Doctorate Degree (Ph.D., Ed.D., etc.) (11)
- N/A (12)

ID Number

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Visit Seq

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12.	What is the employment status of the patient's father or OTHER caretaker?	Yes	No	N/A	
A.	Full-time employment (35 hours week or more)	(1)	(2)	(3)	OCFTWORK
B.	Part-time employment (Less than 35 hours/week)	(1)	(2)	(3)	OCPTWORK
C.	Laid off, unemployed or currently looking for work	(1)	(2)	(3)	OCUNEMPL
D.	Disabled	(1)	(2)	(3)	OCDISABL
E.	Retired	(1)	(2)	(3)	OCRETIRE
F.	Keeping house	(1)	(2)	(3)	OCKHOUSE
G.	Attending school 35 hours a week or more	(1)	(2)	(3)	OCAS35HM
H.	Attending school less than 35 hours a week	(1)	(2)	(3)	OCAS35HL
I.	Doing volunteer work	(1)	(2)	(3)	OCVRWORK
J.	Other	(1)	(2)	(3)	OCOTWORK
K.	Employed in last 5 years?	(1)	(2)	(3)	OCEMP5YR

If not employed in last 5 years, Skip to Item 13.

L.	What is/was the OTHER caretaker's main occupation? (What kind of work does she/he usually do?)				
	Professional or technical, for example: teacher, clergyperson, scientist, librarian, engineer or writer.			(1)	OCRTOCPN
	Manager or administrator (except farm), for example: school administrator, office manager, treasurer, inspector, sales manager,			(2)	
	Sales worker, for example: advertizing agent, sales person, sales demonstrator.			(3)	
	Clerical worker, for example: cashier, dispatcher, file clerk, messenger, secretary.			(4)	
	Operative, for example: assembler, dressmaker, gas station attendant, butcher, painter, bus or truck driver.			(5)	
	Laborer (except farm), for example: construction worker, gardener, fisherman, garbage collector.			(6)	
	Farm owner, tenant or manager			(7)	
	Farm foreman or laborer			(8)	
	Service worker, for example: chambermaid, janitor, waiter, practical nurse, child care giver, hairdresser, airline attendant, firefighter, police			(9)	
	Other			(10)	
	N/A			(11)	

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> -	<input type="text"/> <input type="text"/>

13. Counting ALL sources of income, such as salary, wages, tips, Social Security, SSI, pensions, interest, dividends, and contributions from others, which category (ask for the number response) includes your HOUSEHOLD'S total annual income before taxes LAST YEAR (Answer only one (1) response)

- | | | |
|------------------------|------|-----------------|
| Less than \$10, 000 | (1) | FAMINCOM |
| \$10,000 to \$19,999 | (2) | |
| \$20,000 to \$29,999 | (3) | |
| \$30,000 to \$39,999 | (4) | |
| \$40,000 to \$49,999 | (5) | |
| \$50,000 to \$59,999 | (6) | |
| \$60,000 to \$69,999 | (7) | |
| \$70,000 to \$79,999 | (8) | |
| \$80,000 to \$89,999 | (9) | |
| \$90,000 to \$99,999 | (10) | |
| \$100,000 to \$124,999 | (11) | |
| \$125,000 to \$149,999 | (12) | |
| \$150,000 or More | (13) | |
| N/A | (14) | |

14. What type of medical insurance does the patient have? (Answer each item)

- | | Yes | No | N/A | |
|----------------------|-----|-----|-----|-----------------|
| A. Private Insurance | (1) | (2) | (3) | PRIVTINS |
| B. Medicare | (1) | (2) | (3) | MEDICARE |
| C. Medicaid | (1) | (2) | (3) | MEDICAID |
| D. State Program | (1) | (2) | (3) | STATEPRG |
| E. No Insurance | (1) | (2) | (3) | NOINSRNC |
| F. Any managed care? | (1) | (2) | (3) | AMNGCARE |

PART III: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: - **CERT_NO**

B. Signature: _____ **CERT_SIG**

C. General Comments: **GEN_CMNT**

ID Number

Visit Seq
 -

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ID 2. Current Clinic: SITE

3. Patient's Letter Code: INITS 4. Visit: VISIT sequence # M - SEQNO

5. Date Form Completed: - - VIS_DT
 Month Day Year

PART II: GROWTH HISTORY FROM BIRTH

1. Gestational age at birth weeks GESTAGW

2. Neonatal anthropometry (1-2 days of birth)

A. Length **NEWB_HT** . cm (1) N/A **NWBHT_ND**

B. Weight **NEWB_WT** g (1) N/A **NWBWT_ND**

C. Head circumference **NEWB_HC** . cm (1) N/A **NWBHC_ND**

3. 2-4 months of age

A. Date of measurement **A3MO_DT** - - (1) N/A **A3MO_NA**
 Month Day Year

B. Length **A3MO_HT** . cm (1) N/A **A3MOHTND**

C. Weight **A3MO_WT** . kg (1) N/A **A3MOWTND**

D. Head circumference **A3MO_HC** . cm (1) N/A **A3MOHCND**

ID Number Visit Seq

 -

4. 5-7 months of age

A6MO_DT

A. Date of measurement - - (1) N/A **A6MO_NA**
 Month Day Year

B. Length **A6MO_HT** . cm (1) N/A **A6MOHTND**

C. Weight **A6MO_WT** . kg (1) N/A **A6MOWTND**

D. Head circumference **A6MO_HC** . cm (1) N/A **A6MOHCND**

5. 8-10 months of age

A9MO_DT

A. Date of measurement - - (1) N/A **A9MO_NA**
 Month Day Year

B. Length **A9MO_HT** . cm (1) N/A **A9MOHTND**

C. Weight **A9MO_WT** . kg (1) N/A **A9MOWTND**

D. Head circumference **A9MO_HC** . cm (1) N/A **A9MOHCND**

6. 11-13 months of age

A12MO_DT

A. Date of measurement - - (1) N/A **A12MO_NA**
 Month Day Year

B. Length **A12MO_HT** . cm (1) N/A **A12MHTND**

C. Weight **A12MO_WT** . kg (1) N/A **A12MWTND**

D. Head circumference **A12MO_HC** . cm (1) N/A **A12MHCND**

ID Number Visit - Seq

PART III. COORDINATION:

1. Checked for completeness and accuracy:

A. Certification number:

		-		
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CERT_NO

B. Signature:

CERT_SIG

C. General Comments:

GEN_CMNT

ID Number

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Visit

Seq

			-		
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TREATMENT INITIATION VISIT

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ID
2. Current Clinic: SITE
3. Patient's Letter Code: INITS
4. Visit: 000 VISIT - 00 sequence # SEQNO
5. Visit Start Date: - - VISIT_DT
 Month Day Year

PART II: FINAL REVIEW

1. Has patient been transfused since randomization? . . . TRNRND21 Yes (1) No (2)
 If YES, complete Event Form 50.
2. Routine study visit blood collection
- A. Hematology/HbF (required) (0.5 ml EDTA lavender-top) HBF21
- B. Biochemistry (required) (1.0 ml red-top) BIOCHEM

PART III: DISPENSED TREATMENT

1. A. Record bottle # of study treatment dispensed to patient today.
 TXBOTNO
- B. Daily dose
1. . mg TXDOSEMG
2. . ml TXDOSEML

PART IV: CHILD'S MEASUREMENTS

1. Child's recumbent length
- A. Measurement #1 . cm AVERAGE HEIGHT = HEIGHT HEIGHT1
- B. Measurement #2 . cm HEIGHT2
- C. Measurement #3 . cm HEIGHT3
 (If #1 and #2 differ by more than 0.5 cm)
- D. Rate hair style interference on child's length HAIRHGT
 None (1)
 Some (2)
 Not noted (3)

2. Child's weight

- AVERAGE WEIGHT = WEIGHT**
- A. Measurement #1 . kg **WEIGHT1**
- B. Measurement #2 . kg **WEIGHT2**
- C. Measurement #3 . kg **WEIGHT3**
- (If #1 and #2 differ by more than 0.2 kg)

3. Child's head circumference

- AVERAGE HEAD CIRCUMFERENCE = HEADC**
- A. Measurement #1 . cm **HEADC1**
- B. Measurement #2 . cm **HEADC2**
- C. Measurement #3 . cm **HEADC3**
- (If #1 and #2 differ by more than 0.4 cm)
- D. Rate hair style interference on child's head circumference? **HAIR**
- None (1)
- Some (2)
- Not noted (3)

PART V: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number: - **CERT_NO**
- B. Signature: _____ **CERT_SIG**
- C. General Comments: **GEN_CMNT**

ID Number

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Visit Seq

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4. Room (water) background:

A. First count:

--	--	--	--	--	--

cpm **ROOMFRST**

B. Second count:

--	--	--	--	--	--

cpm **ROOMSEC** (1) N/D **ROOMSCND**

5. Standard:

A. First count:

--	--	--	--	--	--

cpm **STNDFRST**

B. Second count:

--	--	--	--	--	--

cpm **STNDSEC** (1) N/D **STNDSCND**

6. A. One-hour time (24-hr clock):

			:		
--	--	--	---	--	--

ONEHR **ONEMN**

B. DTPA measurement:

--	--	--	--	--	--

cpm **ONEDTPA** (1) N/D **ONE_ND**

C. Second DTPA measurement:

--	--	--	--	--	--

cpm **ONEDTPA2** (1) N/D **ONE_ND2**

D. Tube label (3 ml in EDTA):

--	--	--	--	--	--

ONEHULBL

7. A. Two-hour time (24-hr clock):

			:		
--	--	--	---	--	--

TWOHR **TWOMN**

B. DTPA measurement:

--	--	--	--	--	--

cpm **TWODTPA** (1) N/D **TWO_ND**

C. Second DTPA measurement:

--	--	--	--	--	--

TWODTPA2 (1) N/D **TWO_ND2**

D. Tube label (3 ml in EDTA):

--	--	--	--	--	--

TWOHULBL

8. A. Four-hour time (24-hr clock):

			:		
--	--	--	---	--	--

FORHR **FORMN**

B. DTPA measurement:

--	--	--	--	--	--

cpm **FORDTPA** (1) N/D **FOR_ND**

C. Second DTPA measurement:

--	--	--	--	--	--

cpm **FORDTPA2** (1) N/D **FOR_ND2**

D. Tube label (3 ml in EDTA):

--	--	--	--	--	--

FORHULBL

ID Number

--	--	--	--	--

Visit

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Seq

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9. GFR from DTPA

- A.

--	--	--

 ml/min **GFRDTP_A**
- B.

--	--	--

 ml/min/m² **GFRDTP_B**
- C.

--	--	--

 ml/min/1.73m² **GFRDTP_C**

PART III: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number:

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CERT_NO
- B. Signature: _____ **CERT_SIG**
- C. General Comments: **GEN_CMNT**

ID Number

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Visit

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 -

Seq

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STUDY VISIT

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: ID
- 2. Current Clinic: SITE
- 3. Patient's Letter Code: INITS
- 4. Visit: VISIT - sequence # **SEQNO**
- 5. Visit Start Date: - - **VIS_DT**
Month Day Year

PART II: PHYSICAL EXAMINATION AND MEDICAL REVIEW

- 1. Spleen (00 if not palpable):
 - A. Midclavicular line cm **SPLNMDCL** (1) N/D **SPLNMCND**
 - B. Anterior axillary line cm **SPLNINTC** (1) N/D **SPLNICND**
- 2. A. Temperature **TEMP** . **TEMPMEAS** degrees F (1) (1) N/D **TEMPND**
degrees C (2)
- B. Pulse **PULSE** /min (1) N/D **PULSEND**
- C. Respiration **RESP** /min (1) N/D **RESPND**
- 3. Child's recumbent length
 - A. Measurement #1 . cm **HEIGHT1** (1) N/D **HEIGHTND**
 - B. Measurement #2 . cm **HEIGHT2**
 - C. Measurement #3 . cm **HEIGHT3**
(If #1 and #2 differ by more than 0.5 cm)
- Average height = HEIGHT**
- D. Rate hair style interference on child's length **HAIRHGHT**
 - None (1)
 - Some (2)
 - Not noted (3)

4. Child's weight

A. Measurement #1

WEIGHT1

. kg

(1) N/D WEIGHTND

B. Measurement #2

WEIGHT2

. kg

C. Measurement #3

WEIGHT3

. kg

(If #1 and #2 differ by more than 0.2 kg)

Average weight = WEIGHT

5. Child's head circumference

A. Measurement #1

HEADC1

. cm

(1) N/D HEADCND

B. Measurement #2

HEADC2

. cm

C. Measurement #3

HEADC3

. cm

(If #1 and #2 differ by more than 0.4 cm)

Average head circumference = HEADC

D. Rate hair style interference on child's head circumference

None

(1)

HAIR

Some

(2)

Not noted

(3)

6. Number of reportable events and/or hospitalizations since last completed study visit?

N_EVTS

(1) N/A V_EVTSNA

If any, complete Form 50, Reportable Event and/or Hospitalization.

7. Since last visit?

Yes

No

N/A

A. Fever more than 101.5 degrees F. (38.4 degrees C.)

(1)

(2)

(3)

FEVER31

B. Any vaccinations since last visit?

(1)

(2)

(3)

VACCINE

If yes, update Vaccination Record and Immunology Specimen Collection - Form 42.

ID Number

Visit

Seq

-

8. Routine treatments since last visit? Yes No N/A
- A. Did the child take their night-time dose of twice daily prophylactic penicillin last night? (1) (2)* (3) **PENCILN**
- *1. If no, did the child take another antibiotic? (1)[†] (2) **ANANTBTC**
- †a. Specify: _____ **ANANT_SP**
- B. How many doses of twice daily prophylactic penicillin or similar antibiotic were missed in the last week? **PENDOSE** (1) **PENNA**
9. For 3-month, 9-month, 15-month or 21-month visit, has Form 33 been completed? Yes No N/A **WHCHVIS**
- (1) (2) (3)

PART III: STUDY TREATMENT REVIEW AND BLOOD SPECIMEN COLLECTION

1. Retrieve study treatment from last visit
- A. Record Rx # **RECORDRX** Not Returned (1) Lost (2) **RXNORET**
- B. Approximately how much volume **VOLLFT** cc N/A (1) **VOLNA**
- C. Any irregular treatment administration since last visit? Yes No (1) (2) **IRRTRT**

If **YES**, complete Form 66 (Study Treatment Dosing Irregularity)

2. Were blood specimens collected for this visit? (1) (2) **BLOODCOL**

If **NO**, answer 2A.
 If **YES**, Skip to 2B.

- A. Reason blood specimens not collected today.
1. Difficulty with blood drawing (1) (2) **DIFBLDDW**
2. Patient/Family refusal (1) (2) **PATRFUSL**
3. Other (1)* (2) **OTHNOBLD**

OTHBLDSP

*a. Specify: _____

Skip to PART IV.

ID Number Visit - Seq

2. B. Routine study visit blood collection

1. Hematology (required)

(0.5 ml EDTA lavender-top)

HBF31

--	--	--	--	--

HBF31ND
(1) N/D (2) NA

2. Biochemistry (check child's schedule)

(1.0 ml red top)

BIOCHEM

--	--	--	--	--

BIOCHND
(1) N/D (2) N/A

3. A. Is there any reason you would **NOT** recommend study treatment to this child today?

(1) Tx OK (2) Not OK

TXOK

B. 1. If **Tx OK**, dispense study treatment and record bottle number

--	--	--	--	--	--	--	--

TXBOTNO

2. Daily dose

a.

			.		mg
--	--	--	---	--	----

TXDDOSMG

b.

	.		ml
--	---	--	----

TXDDOSML

3. Volume dispensed

			cc
--	--	--	----

VOLDISP

C. If **NOT OK**, or treatment not dispensed for other reason, check here to confirm that study treatment was not dispensed

(1)

TXNOTOK

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

		-		
--	--	---	--	--

CERT_NO

B. Signature: _____

CERT_SIG

C. General Comments:

GEN_CMNT

2. Individual who prescribed or withheld study treatment

		-		
--	--	---	--	--

SCERT_NO

ID Number

--	--	--	--

Visit Seq

		-		
--	--	---	--	--

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: **ID** 2. Current Clinic: **SITE**
3. Patient's Letter Code: **INITS** 4. Visit: **VISIT** - **sequence #** **SEQNO**
5. Scheduled Visit Date: **Month** - **Day** - **Year** (Ideal earliest start date) **VIS_DT**

PART II: REASONS FOR MISSED VISIT

- | | Yes | No | |
|---|-----|-----|-----------------|
| 1. A. Forgot appointment | (1) | (2) | FORGOT |
| B. Scheduling difficulties | (1) | (2) | SCHEDULE |
| C. Transportation | (1) | (2) | TRANSPT |
| D. Child was ill with hospitalization or reportable event | (1) | (2) | ILLCHILD |

If **hospitalized** or reportable event,
COMPLETE Event Form 50

- | | | | |
|---|------|-----|-----------------|
| E. Child was ill - no medical attention | (1)* | (2) | NODOCTOR |
|---|------|-----|-----------------|

NODOCSP

*1. Specify:

- | | Yes | No | N/A | |
|--|-----|-----|-----|-----------------|
| 2. Has Patient/Family Advocate been in touch with the family since last visit? | (1) | (2) | (3) | ADVOCATE |

PART III. COORDINATION:

1. Checked for completeness and accuracy:
- A. Certification number: - **CERT_NO**
- B. Signature: _____ **CERT_SIG**
- C. General Comments: **GEN_CMNT**

**QUARTERLY VISIT
 (3, 9, 15 and 21 Month)**

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: **ID**
 2. Current Clinic: **SITE**
3. Patient's Letter Code: **INITS** 4. Visit: **VISIT**
- **M** - **sequence # SEQNO**
5. Visit Start Date: - -
Month Day Year **VISIT_DT**

PART II: SCHEDULED TESTING

1. A. O₂ saturation (pulse oxymetry) % **O2SAT** (1) N/D*
O2SATND
- B. Second measurement % **O2SATSM** (1) N/D*
O2SATSND
- Yes No
- *2. If not measured, has Form 80 been submitted? (1) (2) **F80II2**

PART III. COORDINATION:

1. Checked for completeness and accuracy:
- A. Certification number: - **CERT_NO**
- B. Signature: _____ **CERT_SIG**
- C. General Comments: **GEN_CMNT**

SIX-MONTH OR 18-MONTH VISIT

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: ^{ID}
- 2. Current Clinic: ^{SITE}
- 3. Patient's Letter Code: ^{INITS}
- 4. Visit: ^{VISIT} M - ^{sequence #} ^{SEQNO}
- 5. Visit Start Date: - - ^{VIS_DT}
 Month Day Year

PART II: BLOOD SPECIMEN COLLECTION

- 1. Pitted Cell Count specimen collected and prepared within 1 hour of collection? ^{(1) N/D*}
 (0.1 ml whole blood in EDTA + gluteraldehyde) ^{SPC_PITC} ^{SPCPTND}

PART III: SPECIAL STUDIES

- 1. Liver (00 if not palpable) cm ^{(1) N/D*}
^{LIVRCM} ^{LIVRCMND}
- 2. A. O₂ saturation (pulse oxymetry) % ^{O2SAT} ^{(1) N/D*}
^{O2SATND}
- B. Second measurement % ^{O2SATSM} ^{(1) N/D*}
^{O2SATSND}
- 3. Form 80 submitted? ^{F80III7} Yes (1) No (2)

PART IV: COORDINATION

- 1. Checked for completeness and accuracy:
 - A. Certification number: - ^{CERT_NO}
 - B. Signature: _____ ^{CERT_SIG}
 - C. General Comments: _____ ^{GEN_CMNT}

TWELVE-MONTH VISIT (52 WEEKS)

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ^{ID}
2. Current Clinic: ^{SITE}
3. Patient's Letter Code: ^{INITS}
4. Visit: ^{VISIT} - ^{sequence #} ^{SEQNO}
5. Visit Start Date: - - ^{VIS_DT}
 Month Day Year

PART II: BLOOD SPECIMEN COLLECTION

1. Pitted Cell Count specimen collected and prepared within 1 hour of collection? (0.1 ml whole blood in EDTA + gluteraldehyde) ^{(1) N/D*} ^{SPC_PITC} ^{SPCPITND}

PART III: SPECIAL STUDIES

1. Liver (00 if not palpable) cm ^{LIVRCM} ^{(1) N/D*} ^{LIVRCMND}
2. A. O₂ saturation (pulse oxymetry) % ^{O2SAT} ^{(1) N/D*} ^{O2SATND}
- B. Second measurement % ^{O2SATSM} ^{(1) N/D*} ^{O2SATSNND}
- | | | Yes | No |
|---|---------------------|-----|------|
| 3. Was TCD (Form 46) performed? | ^{TCD} | (1) | (2)* |
| 4. Was Bayley's (Form 40) administered? | ^{BAYLEYS} | (1) | (2)* |
| 5. Was Vineland (Form 41) administered to parents? | ^{VINELAND} | (1) | (2)* |
| 6. Was Neurological Questionnaire (Form 43) administered? | ^{NRLGQUES} | (1) | (2)* |
| 7. Form 80 submitted? | ^{F80III8} | (1) | (2)* |

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

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 -

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CERT_NO

B. Signature: _____ CERT_SIG

C. General Comments: GEN_CMNT

ID Number

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Visit Seq

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END OF RANDOMIZED STUDY TREATMENT

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: **ID**
 2. Current Clinic: **SITE**
3. Patient's Letter Code: **INITS** 4. Visit: **VISIT** - sequence # **SEQNO**
5. Visit Start Date: - - **VIS_DT**
Month Day Year

PART II: END OF TREATMENT

- | | | | |
|---|-------|-----|-----------------|
| 1. End of Randomized Study Treatment | Yes | No | |
| A. Planned end of randomized treatment at 2-years | (1) | (2) | EOT_PLA |
| B. Inactive follow-up status | (1) * | (2) | EOT_INAC |
| C. Permanent relocation to area with no BABY HUG Clinic | (1) | (2) | EOT_REL |
| D. Withdrew consent | (1) * | (2) | EOT_WCO |
| E. Renal failure or chronic dialysis requiring cessation of study treatment | (1) * | (2) | EOT_KIDN |
| F. Bone marrow status requiring cessation of study treatment | (1) * | (2) | EOT-MD |
| G. Stroke | (1) * | (2) | EOT-STRK |
| H. Placement on chronic transfusion program | (1) * | (2) | EOT_CHT |
| I. Bone marrow transplantation | (1) * | (2) | EOT_BMT |
| J. Death | (1) * | (2) | EOT_DTH |
| K. Other condition requiring end of study treatment | (1) * | (2) | EOT_OTH |
|
 | | | |
| *2. Form 80 submitted? | (1) | (2) | F80II2 |

PART III: BLOOD SPECIMEN COLLECTION

1. Specimen collected:
- | | | | | |
|---|-----------------|---|----------|-----------------|
| A. Hematology (0.5 ml EDTA lavender top) | SPC_HEM | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | (1) N/D* | SPCHEMND |
| B. Biochemistry specimen collected just prior to urine osmolality specimen (1.0 ml red top) | SPC_BIOC | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | (1) N/D* | |
| C. Pitted cell count specimen collected and prepared within 1 hour of collection (0.1 ml EDTA lavender top) | | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | (1) N/D* | SPCPITND |
| | | SPC_PITC | | |
| D. Cytogenetics (4.0 ml Na Heparin green top) | SPC_GYTO | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | (1) N/D* | SPCGYTND |
| E. DNA (3.0 ml EDTA lavender top) | SPC_DNA | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | (1) N/D* | SPCDNAND |
| | | | Yes | No |
| F. Immunology (record labels on Form 42) | SPC_IMMN | | (1) | (2) |
|
 | | | | |
| *2. Form 80 submitted? | F80III2 | | (1) | (2) |

PART IV: SPECIAL STUDIES

1. A. Liver span (00 if not palpable) **LIVRCM** cm (1) N/D* **LIVRCMND**
- B. Spleen (00 if not palpable):
1. Midclavicular line **SPLNMDCL** cm (1) N/D* **SPLNMCND**
2. Anterior axillary line **SPLNINTC** cm (1) N/D* **SPLNICND**
2. Urinalysis
- A. Red cells **REDCELLS**
- Normal dipstick, normal chemistry or less than 3/high-power field (1)
- 3-20/high-power field (2)
- more 20/high-power field (3)
- N/D* (4)
- B. White cells **WHTCELLS**
- Normal dipstick, normal chemistry or less than 3/high-power field (1)
- 3-20/high-power field (2)
- more 20/high-power field (3)
- N/D* (4)
- C. pH **URN_PH** . (1) N/D* **URN_PHND**
- D. Protein **URNPR**
- (1) Negative (2) Trace (3) Small (4) Moderate (5) Large (6) N/D*
- E. Hemoglobin **URNHB**
- (1) Negative (2) Trace (3) Small (4) Moderate (5) Large (6) N/D*
- F. Specific gravity - urine **URINSG** . (1) N/D* **URINSGND**
- G. Date performed - -
 Month Day Year **URIN_DT**
3. A. O₂ saturation (pulse oxymetry) **O2SAT** % (1) N/D* **O2SATND**
- B. Second measurement **O2SATSM** % (1) N/D* **O2SATSNND**
4. Was Form 40 - Bayley's administered? **BAYLEYS** Yes (1) No (2)*
5. Was Form 41 - Vineland administered to parents? **VINELAND** (1) (2)*

ID Number

Visit - Seq

6. Was Form 43 - Neurological Questionnaire administered? **NRLGQUES** (1) (2)*

7. Urine concentrating ability

A. How many hours NPO?

URN_NP

B. Urine osmolality specimen collected just after biochemistry specimen **URINOS**

(1) N/D* **URINOSND**

8. Was liver-spleen scan performed? **LVSPSCAN** Yes (1) No (2)

If YES complete Form 44 Liver-Spleen Scan

A. If No, reason not performed **LVSPSCNP**

- Patient uncooperative (1)
- Parent/guardian refusal (2)
- Other (3)

1. If other, specify: _____ **LVSNP_SP**

9. A. Was abdominal sonogram performed? **EOT_ABDS** (1) (2)

If YES, complete Form 45 Abdominal Sonogram

1. If No, reason not performed **EOTABDNP**

- Patient uncooperative (1)
- Parent/guardian refusal (2)
- Other (3)

a. If other, specify: _____ **ABDNP_SP**

B. How many hours NPO?

ABD_NPO

10. Was transcranial doppler attempted? **EOT_TCD** (1) (2)

If YES, complete Form 46 Transcranial Doppler

A. If No, reason not attempted **EOTTCDNP**

- Patient not available (1)
- Parent/guardian refusal (2)
- Other (3)

1. If other, specify: _____ **TCDNP_SP**

ID Number Visit Seq

 -

- | | | | |
|---|---|----------------|-----|
| | | Yes | No |
| 11. Was Form 22 - DTPA/GFR performed? | FORM22 | (1) | (2) |
| A. If Yes, new study treatment bottle used? | NEW_BTTL | (1) | (2) |
| 1. If yes, record bottle number used | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | TXBOTNO | |
| 12. Form 80 submitted? | F80IV13 | (1) | (2) |

PART V: PHYSICAL EXAMINATION REVIEW

- | | | | |
|--|---|---|----------------------------|
| 1. A. Temperature | TEMP <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | TEMPMEAS
degrees F (1)
degrees C (2) | TEMPND
(1) N/D* |
| B. Pulse | PULSE <input type="text"/> <input type="text"/> /min | | PULSEND
(1) N/D* |
| C. Respiration | RESP <input type="text"/> <input type="text"/> /min | | RESPND
(1) N/D* |
| 2. Child's recumbent length | | | |
| A. Measurement #1 | HEIGHT1 <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm | | (1) N/D* |
| B. Measurement #2 | HEIGHT2 <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm | | HEIGHTND |
| C. Measurement #3
(If #1 and #2 differ by more than 0.5 cm) | HEIGHT3 <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm
Average Height = HEIGHT | | |
| D. Rate hair style interference on child's length | | | HAIRHGHT |
| None | | (1) | |
| Some | | (2) | |
| Not noted | | (3) | |
| 3. Child's weight | | | |
| A. Measurement #1 | WEIGHT1 <input type="text"/> <input type="text"/> . <input type="text"/> kg | | (1) N/D* |
| B. Measurement #2 | WEIGHT2 <input type="text"/> <input type="text"/> . <input type="text"/> kg | | WEIGHTND |
| C. Measurement #3
(If #1 and #2 differ by more than 0.2 kg) | WEIGHT3 <input type="text"/> <input type="text"/> . <input type="text"/> kg
Average Weight = WEIGHT | | |

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	- <input type="text"/> <input type="text"/>

4. Child's head circumference

A. Measurement #1 HEADC1 . cm (1) N/D*
HEADCND

B. Measurement #2 HEADC2 . cm

C. Measurement #3 HEADC3 . cm
 (If #1 and #2 differ by more than 0.4 cm) AVERAGE CHILD'S HEAD CIRCUMFERENCE = HEADC

D. Rate hair style interference on child's head circumference HAIR
 None (1)
 Some (2)
 Not noted (3)

5. Anthropometry measurement date: - - ANM_DT

6. Number of reportable events and/or hospitalizations since last completed study visit? (1) N/A*
N_EVTS V_EVTSNA

If any, complete Form 50, Reportable Event and/or Hospitalization.

7. Since last visit? Yes No N/A FEVER31
 A. Fever more than 101.5 degrees F. (38.4 degrees C.) (1) (2) (3)*
 B. Any vaccinations since last visit VACCINE (1) (2) (3)*
 (including vaccinations given today?)

If yes, update Vaccination Record and Immunology Specimen Collection - Form 42.

8. Routine treatments since last visit? Yes No N/A
 A. Did the child take their night-time dose of twice PENCILN (1) (2) (3)*
 daily prophylactic penicillin last night?
 1. If no, did the child take another antibiotic? ANTIB (1) (2)
 a. Specify: _____ ANTIB_SP

B. How many doses of twice daily prophylactic PENDOSE
 penicillin or similar antibiotic were missed in the
 last week? (1) N/A* PENNA

ID Number Visit - Seq

9 Retrieve study treatment from last visit Not returned Lost

A. Record Rx # **RECORDRX** (1) (2)
RXNORET

B. Approximately how much cc (1) N/A*
 volume is left? **VOLLFT** **VOLNA**

C. Any irregular treatment administration since last visit? Yes No
IRRTRT (1) (2)

If **YES**, complete Form 66 (Study Treatment Dosing Irregularity)

10. Form 80 submitted? **F80V19** Yes No
IRRTRT (1) (2)

PART VI: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: - **CERT_NO**

B. Signature: _____ **CERT_SIG**

C. General Comments: **GEN_CMNT**

ID Number

Visit Seq
 -

LOCAL CBC RESULTS

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ^{ID}

2. Current Clinic: ^{SITE}

3. Patient's Letter Code: ^{INITS}

4. Visit: ^{VISIT} - ^{sequence #} ^{SEQNO}

5. Visit Date: - - ^{VIS_DT}
 Month Day Year

PART II: LAB RESULTS

1. A. Are these lab results for an unscheduled visit that resulted in a toxicity or alert? ^{UNSCHVIS} Yes (1) No (2)

B. Label number put on lab specimens ^{LABEL}

2. A. White Blood Cell Count (WBC) . K/mm³ ^{WBC}

B. Red Blood Cell Count (RBC) . M/mm³ ^{RBC}

C. Hemoglobin . g/dL ^{HB}

D. Hematocrit . % ^{PCV}

E. Platelet Count K/mm³ ^{PLAT}

3. A. Differential Type: ^{DIFFTYPE} (1) Manual (2) Automated

B. Absolute Neutrophil Count . K/mm³ ^{NEUT_CT}

C. Neutrophils (% of WBC) % ^{NEUT_PT}

D. Lymphocytes (% of WBC) % ^{LYMPH_PT}

^{LYMPHOCYTE COUNT =}

E. Monocytes (% of WBC) % ^{MONO_PT}

^{MONOCYTE COUNT =}

F. Nucleated Red Blood Cells (nRBC) * ^{NRBC}

*1. If not 0, Corrected WBC Count[†] . K/mm³ ^{CWBC}

G. Reticulocytes (% of RBC) . % ^{RETIC_PT}

H. Reticulocyte count . K/mm³ ^{RETIC_CT}

I. MCV fL ^{MCV}

PART III: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

		-		
--	--	---	--	--

CERT_NO

B. Signature:

CERT_SIG

C. General Comments:

GEN_CMNT

ID Number

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Visit

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Seq

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HOLD RESTART

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ^{ID}
2. Current Clinic: ^{SITE}
3. Patient's Letter Code: ^{INITS}
4. Visit: - ^{sequence #} ^{VISIT} ^{0 0} ^{SEQN} ^O
5. Visit Restart Date: - - ^{Month} ^{Day} ^{Year} ^{VIS_DT}

PART II: STUDY TREATMENT

1. Is this study restart visit concurrent with a routine study visit? Yes No
(1) (2) **CONCUR**

If **NO**, answer 1A-C
 If **YES**, Skip to Part III

- A. Record bottle number dispensed. ^{TXBOTNO}
- B. Daily dose (use treatment recommendation sent after hold was lifted).
1. . mg ^{TXDDOSMG}
2. . ml ^{TXDDOSML}
- C. Volume dispensed cc ^{VOLDISP}

PART III: COORDINATION

1. Checked for completeness and accuracy:
- A. Certification number: - ^{CERT_NO}
- B. Signature: _____ ^{CERT_SIG}
- C. General Comments: ^{GEN_CMNT}
2. Individual who prescribed or withheld study treatment - ^{SCERT_NO}

BAYLEY'S

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ^{ID}
2. Current Clinic: ^{SITE}
3. Patient's Letter Code: ^{INITS}
4. Visit: M ^{VISIT} - ^{sequence #} ^{SEQNO}
5. Testing Date: - - ^{VIS_DT}
 Month Day Year

PART II: PARTICIPANT

1. Adjustment for Prematurity: ^{ADJ_MO} ^{ADJ_DAYS}
 Months Days
2. Caregiver's Relationship to Child (Darken one): ^{CARE40}
- | | |
|---------------|-----|
| Mother | (1) |
| Father | (2) |
| Grandparent | (3) |
| Aunt or Uncle | (4) |
| Foster Parent | (5) |
| Other | (6) |

PART III: MENTAL SCALE

Record the correct answer codes from the standardized form by checking a number to the right of the item number. The answer codes are **C** (credit), **NC** (no credit), **RF** (refused), **O** (omitted), and **RPT** (caregiver report). If the item was not administered, leave the item below blank.

		MLCHAGYR	MLCHAGMN	MLCHAGDS
		Years	Months	Days
A.	Chronological Age	[]	[] []	[] []
		MLPMAGYR	MLPMAGMN	MLPMAGDS
B.	If premature, Corrected Age	[]	[] []	[] []
C.	1. Starting Row	[] [] []	MLSTROW	
	2. Ending Row	[] [] []	MLENDROW	

D. Record Form Data:

Item No.	Code					MEN24	C	NC	RF	O	RPT	MEN48	C	NC	RF	O	RPT	
	C	NC	RF	O	RPT													
MEN1 1.	(1)	(2)	(3)	(4)	(5)		24.	(1)	(2)	(3)	(4)	(5)	MEN48 48.	(1)	(2)	(3)	(4)	(5)
2.	(1)	(2)	(3)	(4)	(5)		25.	(1)	(2)	(3)	(4)	(5)	49.	(1)	(2)	(3)	(4)	(5)
3.	(1)	(2)	(3)	(4)	(5)		26.	(1)	(2)	(3)	(4)	(5)	50.	(1)	(2)	(3)	(4)	(5)
4.	(1)	(2)	(3)	(4)	(5)		27.	(1)	(2)	(3)	(4)	(5)	51.	(1)	(2)	(3)	(4)	(5)
5.	(1)	(2)	(3)	(4)	(5)		28.	(1)	(2)	(3)	(4)	(5)	52.	(1)	(2)	(3)	(4)	(5)
6.	(1)	(2)	(3)	(4)	(5)		29.	(1)	(2)	(3)	(4)	(5)	53.	(1)	(2)	(3)	(4)	(5)
7.	(1)	(2)	(3)	(4)	(5)		30.	(1)	(2)	(3)	(4)	(5)	54.	(1)	(2)	(3)	(4)	(5)
8.	(1)	(2)	(3)	(4)	(5)		31.	(1)	(2)	(3)	(4)	(5)	55.	(1)	(2)	(3)	(4)	(5)
9.	(1)	(2)	(3)	(4)	(5)		32.	(1)	(2)	(3)	(4)	(5)	56.	(1)	(2)	(3)	(4)	(5)
10.	(1)	(2)	(3)	(4)	(5)		33.	(1)	(2)	(3)	(4)	(5)	57.	(1)	(2)	(3)	(4)	(5)
11.	(1)	(2)	(3)	(4)	(5)		34.	(1)	(2)	(3)	(4)	(5)	58.	(1)	(2)	(3)	(4)	(5)
12.	(1)	(2)	(3)	(4)	(5)		35.	(1)	(2)	(3)	(4)	(5)	59.	(1)	(2)	(3)	(4)	(5)
13.	(1)	(2)	(3)	(4)	(5)		36.	(1)	(2)	(3)	(4)	(5)	60.	(1)	(2)	(3)	(4)	(5)
14.	(1)	(2)	(3)	(4)	(5)		37.	(1)	(2)	(3)	(4)	(5)	61.	(1)	(2)	(3)	(4)	(5)
15.	(1)	(2)	(3)	(4)	(5)		38.	(1)	(2)	(3)	(4)	(5)	62.	(1)	(2)	(3)	(4)	(5)
16.	(1)	(2)	(3)	(4)	(5)		39.	(1)	(2)	(3)	(4)	(5)	63.	(1)	(2)	(3)	(4)	(5)
17.	(1)	(2)	(3)	(4)	(5)		40.	(1)	(2)	(3)	(4)	(5)	64.	(1)	(2)	(3)	(4)	(5)
18.	(1)	(2)	(3)	(4)	(5)		41.	(1)	(2)	(3)	(4)	(5)	65.	(1)	(2)	(3)	(4)	(5)
19.	(1)	(2)	(3)	(4)	(5)		42.	(1)	(2)	(3)	(4)	(5)	66.	(1)	(2)	(3)	(4)	(5)
20.	(1)	(2)	(3)	(4)	(5)		43.	(1)	(2)	(3)	(4)	(5)	67.	(1)	(2)	(3)	(4)	(5)
21.	(1)	(2)	(3)	(4)	(5)		44.	(1)	(2)	(3)	(4)	(5)	68.	(1)	(2)	(3)	(4)	(5)
22.	(1)	(2)	(3)	(4)	(5)		45.	(1)	(2)	(3)	(4)	(5)	69.	(1)	(2)	(3)	(4)	(5)
MEN23 23.	(1)	(2)	(3)	(4)	(5)		46.	(1)	(2)	(3)	(4)	(5)	70.	(1)	(2)	(3)	(4)	(5)
							MEN47 47.	(1)	(2)	(3)	(4)	(5)	MEN71 71.	(1)	(2)	(3)	(4)	(5)

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ID Number

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Visit

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PART III: MENTAL SCALE (Continued)

Item	Code					C	NC	RF	O	RPT		C	NC	RF	O	RPT				
	C	NC	RF	O	RPT															
						98.	(1)	(2)	(3)	(4)	(5)	MEN125	125.	(1)	(2)	(3)	(4)	(5)		
MEN72	72.	(1)	(2)	(3)	(4)	(5)	99.	(1)	(2)	(3)	(4)	(5)		126.	(1)	(2)	(3)	(4)	(5)	
	73.	(1)	(2)	(3)	(4)	(5)	100.	(1)	(2)	(3)	(4)	(5)		127.	(1)	(2)	(3)	(4)	(5)	
	74.	(1)	(2)	(3)	(4)	(5)	101.	(1)	(2)	(3)	(4)	(5)		128.	(1)	(2)	(3)	(4)	(5)	
	75.	(1)	(2)	(3)	(4)	(5)	102.	(1)	(2)	(3)	(4)	(5)		129.	(1)	(2)	(3)	(4)	(5)	
	76.	(1)	(2)	(3)	(4)	(5)	103.	(1)	(2)	(3)	(4)	(5)		130.	(1)	(2)	(3)	(4)	(5)	
	77.	(1)	(2)	(3)	(4)	(5)	104.	(1)	(2)	(3)	(4)	(5)		131.	(1)	(2)	(3)	(4)	(5)	
	78.	(1)	(2)	(3)	(4)	(5)	105.	(1)	(2)	(3)	(4)	(5)		132.	(1)	(2)	(3)	(4)	(5)	
	79.	(1)	(2)	(3)	(4)	(5)	106.	(1)	(2)	(3)	(4)	(5)		133.	(1)	(2)	(3)	(4)	(5)	
	80.	(1)	(2)	(3)	(4)	(5)	107.	(1)	(2)	(3)	(4)	(5)		134.	(1)	(2)	(3)	(4)	(5)	
	81.	(1)	(2)	(3)	(4)	(5)	108.	(1)	(2)	(3)	(4)	(5)		135.	(1)	(2)	(3)	(4)	(5)	
	82.	(1)	(2)	(3)	(4)	(5)	109.	(1)	(2)	(3)	(4)	(5)		136.	(1)	(2)	(3)	(4)	(5)	
	83.	(1)	(2)	(3)	(4)	(5)	110.	(1)	(2)	(3)	(4)	(5)		137.	(1)	(2)	(3)	(4)	(5)	
	84.	(1)	(2)	(3)	(4)	(5)	111.	(1)	(2)	(3)	(4)	(5)		138.	(1)	(2)	(3)	(4)	(5)	
	85.	(1)	(2)	(3)	(4)	(5)	112.	(1)	(2)	(3)	(4)	(5)		139.	(1)	(2)	(3)	(4)	(5)	
	86.	(1)	(2)	(3)	(4)	(5)	113.	(1)	(2)	(3)	(4)	(5)		140.	(1)	(2)	(3)	(4)	(5)	
	87.	(1)	(2)	(3)	(4)	(5)	114.	(1)	(2)	(3)	(4)	(5)		141.	(1)	(2)	(3)	(4)	(5)	
	88.	(1)	(2)	(3)	(4)	(5)	115.	(1)	(2)	(3)	(4)	(5)		142.	(1)	(2)	(3)	(4)	(5)	
	89.	(1)	(2)	(3)	(4)	(5)	116.	(1)	(2)	(3)	(4)	(5)		143.	(1)	(2)	(3)	(4)	(5)	
	90.	(1)	(2)	(3)	(4)	(5)	117.	(1)	(2)	(3)	(4)	(5)		144.	(1)	(2)	(3)	(4)	(5)	
	91.	(1)	(2)	(3)	(4)	(5)	118.	(1)	(2)	(3)	(4)	(5)		145.	(1)	(2)	(3)	(4)	(5)	
	92.	(1)	(2)	(3)	(4)	(5)	119.	(1)	(2)	(3)	(4)	(5)		146.	(1)	(2)	(3)	(4)	(5)	
	93.	(1)	(2)	(3)	(4)	(5)	120.	(1)	(2)	(3)	(4)	(5)		147.	(1)	(2)	(3)	(4)	(5)	
	94.	(1)	(2)	(3)	(4)	(5)	121.	(1)	(2)	(3)	(4)	(5)		148.	(1)	(2)	(3)	(4)	(5)	
	95.	(1)	(2)	(3)	(4)	(5)	122.	(1)	(2)	(3)	(4)	(5)		149.	(1)	(2)	(3)	(4)	(5)	
	96.	(1)	(2)	(3)	(4)	(5)	123.	(1)	(2)	(3)	(4)	(5)		150.	(1)	(2)	(3)	(4)	(5)	
MEN97	97.	(1)	(2)	(3)	(4)	(5)	MEN124	124.	(1)	(2)	(3)	(4)	(5)	MEN151	151.	(1)	(2)	(3)	(4)	(5)

Continued →

ID Number

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Visit

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PART III: MENTAL SCALE (Continued)

Item No.	Code																
	C	NC	RF	O	RPT		C	NC	RF	O	RPT		C	NC	RF	O	RPT
MEN152 152.	(1)	(2)	(3)	(4)	(5)	MEN161 161.	(1)	(2)	(3)	(4)	(5)	MEN170 170.	(1)	(2)	(3)	(4)	(5)
153.	(1)	(2)	(3)	(4)	(5)	162.	(1)	(2)	(3)	(4)	(5)	171.	(1)	(2)	(3)	(4)	(5)
154.	(1)	(2)	(3)	(4)	(5)	163.	(1)	(2)	(3)	(4)	(5)	172.	(1)	(2)	(3)	(4)	(5)
155.	(1)	(2)	(3)	(4)	(5)	164.	(1)	(2)	(3)	(4)	(5)	173.	(1)	(2)	(3)	(4)	(5)
156.	(1)	(2)	(3)	(4)	(5)	165.	(1)	(2)	(3)	(4)	(5)	174.	(1)	(2)	(3)	(4)	(5)
157.	(1)	(2)	(3)	(4)	(5)	166.	(1)	(2)	(3)	(4)	(5)	175.	(1)	(2)	(3)	(4)	(5)
158.	(1)	(2)	(3)	(4)	(5)	167.	(1)	(2)	(3)	(4)	(5)	176.	(1)	(2)	(3)	(4)	(5)
159.	(1)	(2)	(3)	(4)	(5)	168.	(1)	(2)	(3)	(4)	(5)	177.	(1)	(2)	(3)	(4)	(5)
MEN160 160.	(1)	(2)	(3)	(4)	(5)	MEN169 169.	(1)	(2)	(3)	(4)	(5)	MEN178 178.	(1)	(2)	(3)	(4)	(5)

MENRAW 179. Raw Score

MENMDI 180. MDI Score

181. 95% CI -
 MEN95CIL MEN95CIH

ID Number

Visit - Seq

PART IV: MOTOR SCALE

Record the correct answer codes from the standardized form by checking a number to the right of the item number. The answer codes are **C** (credit), **NC** (no credit), **RF** (refused), **O** (omitted), and **RPT** (caregiver report). If the item was not administered, leave the item below blank.

A. Chronological Age MRCHAGYR MRCHAGMN
Years Months Days

B. If premature, Corrected Age MRPMAGYR MRPMAGMN MRPMAGDS

C. 1. Starting Row **MRSTROW**
 2. Ending Row **MRENDROW**

D. Record Form Data:

Item No.	Code					C	NC	RF	O	RPT	C	NC	RF	O	RPT		
MOT1 1.	(1)	(2)	(3)	(4)	(5)	28.	(1)	(2)	(3)	(4)	(5)	MOT56 56.	(1)	(2)	(3)	(4)	(5)
2.	(1)	(2)	(3)	(4)	(5)	29.	(1)	(2)	(3)	(4)	(5)	57.	(1)	(2)	(3)	(4)	(5)
3.	(1)	(2)	(3)	(4)	(5)	30.	(1)	(2)	(3)	(4)	(5)	58.	(1)	(2)	(3)	(4)	(5)
4.	(1)	(2)	(3)	(4)	(5)	31.	(1)	(2)	(3)	(4)	(5)	59.	(1)	(2)	(3)	(4)	(5)
5.	(1)	(2)	(3)	(4)	(5)	32.	(1)	(2)	(3)	(4)	(5)	60.	(1)	(2)	(3)	(4)	(5)
6.	(1)	(2)	(3)	(4)	(5)	33.	(1)	(2)	(3)	(4)	(5)	61.	(1)	(2)	(3)	(4)	(5)
7.	(1)	(2)	(3)	(4)	(5)	34.	(1)	(2)	(3)	(4)	(5)	62.	(1)	(2)	(3)	(4)	(5)
8.	(1)	(2)	(3)	(4)	(5)	35.	(1)	(2)	(3)	(4)	(5)	63.	(1)	(2)	(3)	(4)	(5)
9.	(1)	(2)	(3)	(4)	(5)	36.	(1)	(2)	(3)	(4)	(5)	64.	(1)	(2)	(3)	(4)	(5)
10.	(1)	(2)	(3)	(4)	(5)	37.	(1)	(2)	(3)	(4)	(5)	65.	(1)	(2)	(3)	(4)	(5)
11.	(1)	(2)	(3)	(4)	(5)	38.	(1)	(2)	(3)	(4)	(5)	66.	(1)	(2)	(3)	(4)	(5)
12.	(1)	(2)	(3)	(4)	(5)	39.	(1)	(2)	(3)	(4)	(5)	67.	(1)	(2)	(3)	(4)	(5)
13.	(1)	(2)	(3)	(4)	(5)	40.	(1)	(2)	(3)	(4)	(5)	68.	(1)	(2)	(3)	(4)	(5)
14.	(1)	(2)	(3)	(4)	(5)	41.	(1)	(2)	(3)	(4)	(5)	69.	(1)	(2)	(3)	(4)	(5)
15.	(1)	(2)	(3)	(4)	(5)	42.	(1)	(2)	(3)	(4)	(5)	70.	(1)	(2)	(3)	(4)	(5)
16.	(1)	(2)	(3)	(4)	(5)	43.	(1)	(2)	(3)	(4)	(5)	71.	(1)	(2)	(3)	(4)	(5)
17.	(1)	(2)	(3)	(4)	(5)	44.	(1)	(2)	(3)	(4)	(5)	72.	(1)	(2)	(3)	(4)	(5)
18.	(1)	(2)	(3)	(4)	(5)	45.	(1)	(2)	(3)	(4)	(5)	73.	(1)	(2)	(3)	(4)	(5)
19.	(1)	(2)	(3)	(4)	(5)	46.	(1)	(2)	(3)	(4)	(5)	74.	(1)	(2)	(3)	(4)	(5)
20.	(1)	(2)	(3)	(4)	(5)	47.	(1)	(2)	(3)	(4)	(5)	75.	(1)	(2)	(3)	(4)	(5)
21.	(1)	(2)	(3)	(4)	(5)	48.	(1)	(2)	(3)	(4)	(5)	76.	(1)	(2)	(3)	(4)	(5)
22.	(1)	(2)	(3)	(4)	(5)	49.	(1)	(2)	(3)	(4)	(5)	77.	(1)	(2)	(3)	(4)	(5)
23.	(1)	(2)	(3)	(4)	(5)	50.	(1)	(2)	(3)	(4)	(5)	78.	(1)	(2)	(3)	(4)	(5)
24.	(1)	(2)	(3)	(4)	(5)	51.	(1)	(2)	(3)	(4)	(5)	79.	(1)	(2)	(3)	(4)	(5)
25.	(1)	(2)	(3)	(4)	(5)	52.	(1)	(2)	(3)	(4)	(5)	80.	(1)	(2)	(3)	(4)	(5)
26.	(1)	(2)	(3)	(4)	(5)	53.	(1)	(2)	(3)	(4)	(5)	81.	(1)	(2)	(3)	(4)	(5)
MOT27 27.	(1)	(2)	(3)	(4)	(5)	54.	(1)	(2)	(3)	(4)	(5)	82.	(1)	(2)	(3)	(4)	(5)
MOT55 55.	(1)	(2)	(3)	(4)	(5)	MOT83 83.	(1)	(2)	(3)	(4)	(5)						

Continued →

ID Number

Visit - Seq

PART IV: MOTOR SCALE (Continued)

Item No.	Code						Code						Code				
	C	NC	RF	O	RPT		C	NC	RF	O	RPT		C	NC	RF	O	RPT
MOT84 84.	(1)	(2)	(3)	(4)	(5)	MOT96 96.	(1)	(2)	(3)	(4)	(5)	MOT108 108.	(1)	(2)	(3)	(4)	(5)
85.	(1)	(2)	(3)	(4)	(5)	97.	(1)	(2)	(3)	(4)	(5)	109.	(1)	(2)	(3)	(4)	(5)
86.	(1)	(2)	(3)	(4)	(5)	98.	(1)	(2)	(3)	(4)	(5)	110.	(1)	(2)	(3)	(4)	(5)
87.	(1)	(2)	(3)	(4)	(5)	99.	(1)	(2)	(3)	(4)	(5)	MOT111 111.	(1)	(2)	(3)	(4)	(5)
88.	(1)	(2)	(3)	(4)	(5)	100.	(1)	(2)	(3)	(4)	(5)						
89.	(1)	(2)	(3)	(4)	(5)	101.	(1)	(2)	(3)	(4)	(5)						
90.	(1)	(2)	(3)	(4)	(5)	102.	(1)	(2)	(3)	(4)	(5)						
91.	(1)	(2)	(3)	(4)	(5)	103.	(1)	(2)	(3)	(4)	(5)						
92.	(1)	(2)	(3)	(4)	(5)	104.	(1)	(2)	(3)	(4)	(5)						
93.	(1)	(2)	(3)	(4)	(5)	105.	(1)	(2)	(3)	(4)	(5)						
94.	(1)	(2)	(3)	(4)	(5)	106.	(1)	(2)	(3)	(4)	(5)						
MOT95 95.	(1)	(2)	(3)	(4)	(5)	MOT107 107.	(1)	(2)	(3)	(4)	(5)						

MOTRAW 112. Raw Score

MOTPDI 113. PDI Score

114. 95% CI -

MOT95CIL **MOT95CIH**

ID Number

Visit

Seq

-

PART V: BEHAVIOR RATING SCALE

Record the correct codes from the standardized form by checking a number to the right of the item numbers below. The answer codes are numbers ranging from 1 to 5. If the item was not answered, leave the item below blank.

	BRCHAGYR	BRCHAGMN	
	Years	Months	Days
A. Chronological Age	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
	BRPMAGYR	BRPMAGMN	
B. If premature, Corrected Age	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

C. Record Form Data:	
Item No.	Code
	1 2 3 4 5
BEH1 1.	(1) (2) (3) (4) (5)
2.	(1) (2) (3) (4) (5)
3.	(1) (2) (3) (4) (5)
4.	(1) (2) (3) (4) (5)
5.	(1) (2) (3) (4) (5)
6.	(1) (2) (3) (4) (5)
7.	(1) (2) (3) (4) (5)
8.	(1) (2) (3) (4) (5)
9.	(1) (2) (3) (4) (5)
10.	(1) (2) (3) (4) (5)
11.	(1) (2) (3) (4) (5)
BEH12 12.	(1) (2) (3) (4) (5) BEH24
13.	(1) (2) (3) (4) (5) BEH25
14.	(1) (2) (3) (4) (5)
15.	(1) (2) (3) (4) (5)
16.	(1) (2) (3) (4) (5)
17.	(1) (2) (3) (4) (5)
18.	(1) (2) (3) (4) (5) BEH30
19.	(1) (2) (3) (4) (5)
20.	(1) (2) (3) (4) (5)
21.	(1) (2) (3) (4) (5)
22.	(1) (2) (3) (4) (5)
23.	(1) (2) (3) (4) (5)
24.	(1) (2) (3) (4) (5)
25.	(1) (2) (3) (4) (5)
26.	(1) (2) (3) (4) (5)
27.	(1) (2) (3) (4) (5)
28.	(1) (2) (3) (4) (5)
29.	(1) (2) (3) (4) (5)
30.	(1) (2) (3) (4) (5)
31. Raw Score	<input type="text"/> <input type="text"/> <input type="text"/> BEHRAW
32. Percentile	<input type="text"/> <input type="text"/> BEHPCTL

PART VI: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: - **CERT_NO**

B. Signature: _____ **CERT_SIG**

C. General Comments: _____ **GEN_CMNT**

2. Bayley's Administrator certification number: - **BCERT_NO**

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

PEDIATRIC HYDROXYUREA CLINICAL TRIAL

VINELAND SUMMARY

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: ^{ID}
- 2. Current Clinic: ^{SITE}
- 3. Patient's Letter Code: ^{INITS}
- 4. Visit: M ^{VISIT} - ^{sequence #} ^{SEQNO}
- 5. Testing Date: - - ^{VIS_DT}
Month Day Year

PART II: CAREGIVER CODES:

- 1. Chronological Age: ^{CHRAGEYR} ^{CHRAGEMN} ^{CHRAGEDS}
Years Months Days
- 2. Caregiver's Relationship to Child: ^{CARE41}
 - Mother (1)
 - Father (2)
 - Grandparent (3)
 - Aunt or Uncle (4)
 - Foster Parent (5)
 - Other (6)

PART III: COMMUNICATIONS DOMAIN

INSTRUCTIONS: Record the answer codes from the standardized form in the blanks to the right of the item numbers below for all Vineland domains. The answer codes are: **1** (Sometimes or Partially); **2** (Yes, Usually); **0** (No, Never); **N** (No opportunity); **DK** (Don't Know). Record only letter or number codes and not the response labels.

A. Data Rows

1. Starting Row

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CDSTROW

2. Ending Row

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CDENDROW

RECORD FORM DATA:

Item No.	Code	1	2	0	N	DK	1	2	0	N	DK						
		COM24	24.	O	O	O	O	O	O	O	COM49	49.	O	O	O	O	O
			25.	O	O	O	O	O	O	O		50.	O	O	O	O	O
COM1	1.	O	O	O	O	O						26.	O	O	O	O	O
	2.	O	O	O	O	O						27.	O	O	O	O	O
	3.	O	O	O	O	O						28.	O	O	O	O	O
	4.	O	O	O	O	O						29.	O	O	O	O	O
	5.	O	O	O	O	O						30.	O	O	O	O	O
	6.	O	O	O	O	O						31.	O	O	O	O	O
	7.	O	O	O	O	O						32.	O	O	O	O	O
	8.	O	O	O	O	O						33.	O	O	O	O	O
	9.	O	O	O	O	O						34.	O	O	O	O	O
	10.	O	O	O	O	O						35.	O	O	O	O	O
	11.	O	O	O	O	O						36.	O	O	O	O	O
	12.	O	O	O	O	O						37.	O	O	O	O	O
	13.	O	O	O	O	O						38.	O	O	O	O	O
	14.	O	O	O	O	O						39.	O	O	O	O	O
	15.	O	O	O	O	O						40.	O	O	O	O	O
	16.	O	O	O	O	O						41.	O	O	O	O	O
	17.	O	O	O	O	O						42.	O	O	O	O	O
	18.	O	O	O	O	O					COM67	67.	O	O	O	O	O
	19.	O	O	O	O	O						43.	O	O	O	O	O
	20.	O	O	O	O	O						44.	O	O	O	O	O
	21.	O	O	O	O	O						45.	O	O	O	O	O
	22.	O	O	O	O	O						46.	O	O	O	O	O
	23.	O	O	O	O	O						47.	O	O	O	O	O
COM23							COM48	48.	O	O	O	O	O	O	O	O	O

68. Raw Domain Score **COMRAW**

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69. Standard Score **COMSTRD**

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70. 95% Conf. Level **COM95CL** ±

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71. Percentile Rank **COMPCTL**

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ID NUMBER

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Visit

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Seq

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PART IV: DAILY LIVING SKILLS DOMAIN

A. Data Rows

1. Starting Row

DDSTROW

2. Ending Row

DDENDROW

B. RECORD FORM DATA:

		1	2	0	N	DK						1	2	0	N	DK			
		DLS19	19.	0	0	0	0	0	DLS40	40.	0	0	0	0	0				
Item No.	Code		20.	0	0	0	0	0		41.	0	0	0	0	0				
			21.	0	0	0	0	0		42.	0	0	0	0	0				
DLS1	1.	0	0	0	0	0				43.	0	0	0	0	0				
	2.	0	0	0	0	0				44.	0	0	0	0	0				
	3.	0	0	0	0	0				45.	0	0	0	0	0				
	4.	0	0	0	0	0				46.	0	0	0	0	0				
	5.	0	0	0	0	0				47.	0	0	0	0	0				
	6.	0	0	0	0	0				48.	0	0	0	0	0				
	7.	0	0	0	0	0				49.	0	0	0	0	0				
	8.	0	0	0	0	0				50.	0	0	0	0	0				
	9.	0	0	0	0	0				51.	0	0	0	0	0				
	10.	0	0	0	0	0				52.	0	0	0	0	0				
	11.	0	0	0	0	0				53.	0	0	0	0	0				
	12.	0	0	0	0	0				54.	0	0	0	0	0				
	13.	0	0	0	0	0				55.	0	0	0	0	0				
	14.	0	0	0	0	0				56.	0	0	0	0	0				
	15.	0	0	0	0	0				57.	0	0	0	0	0				
	16.	0	0	0	0	0				58.	0	0	0	0	0				
	17.	0	0	0	0	0				59.	0	0	0	0	0				
DLS18	18.	0	0	0	0	0	DLS39	39.	0	0	0	0	0	DLS60	60.	0	0	0	0

ID Number Visit - Seq

B. RECORD FORM DATA (Continued) :

Item No.	Code						Code				
	1	2	0	N	DK		1	2	0	N	DK
DLS61 61.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	DLS79 79.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
62.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	80.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
63.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	81.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
64.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	82.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
65.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	83.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
66.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	84.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
67.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	85.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
68.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	86.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
69.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	87.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
70.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	88.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
71.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	89.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
72.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	90.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
73.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	91.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
74.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	DLS92 92.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
75.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	93. Raw Domain Score	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	DLSRAW
76.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	94. Standard Score	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	DLSSTRD
77.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	95. 95% Conf. Level ±	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	DLS95CL
DLS78 78.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	96. Percentile Rank	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	DLSPCTL

ID Number

Visit - Seq

PART V: SOCIALIZATION DOMAIN

A. Data Rows

1. Starting Row

SDSTROW

2. Ending Row

SDENDROW

B. RECORD FORM DATA:

		1	2	0	N	DK						1	2	0	N	DK				
							SOC25	25.	0	0	0	0	0	SOC52	52.	0	0	0	0	0
Item No.	Code							26.	0	0	0	0	0		53.	0	0	0	0	0
								27.	0	0	0	0	0		54.	0	0	0	0	0
SOC1		1.	0	0	0	0		28.	0	0	0	0	0		55.	0	0	0	0	0
		2.	0	0	0	0		29.	0	0	0	0	0		56.	0	0	0	0	0
		3.	0	0	0	0		30.	0	0	0	0	0		57.	0	0	0	0	0
		4.	0	0	0	0		31.	0	0	0	0	0		58.	0	0	0	0	0
		5.	0	0	0	0		32.	0	0	0	0	0		59.	0	0	0	0	0
		6.	0	0	0	0		33.	0	0	0	0	0		60.	0	0	0	0	0
		7.	0	0	0	0		34.	0	0	0	0	0		61.	0	0	0	0	0
		8.	0	0	0	0		35.	0	0	0	0	0		62.	0	0	0	0	0
		9.	0	0	0	0		36.	0	0	0	0	0		63.	0	0	0	0	0
		10.	0	0	0	0		37.	0	0	0	0	0		64.	0	0	0	0	0
		11.	0	0	0	0		38.	0	0	0	0	0		65.	0	0	0	0	0
		12.	0	0	0	0		39.	0	0	0	0	0	SOC66	66.	0	0	0	0	0
		13.	0	0	0	0		40.	0	0	0	0	0							
		14.	0	0	0	0		41.	0	0	0	0	0		67. Raw Domain Score	<input type="text"/>	<input type="text"/>	<input type="text"/>		
		15.	0	0	0	0		42.	0	0	0	0	0		SOCRAW					
		16.	0	0	0	0		43.	0	0	0	0	0		68. Standard Score	<input type="text"/>	<input type="text"/>	<input type="text"/>		
		17.	0	0	0	0		44.	0	0	0	0	0		SOCSTRD					
		18.	0	0	0	0		45.	0	0	0	0	0		69. 95% Conf. Level	±	<input type="text"/>	<input type="text"/>		
		19.	0	0	0	0		46.	0	0	0	0	0		SOC95CL					
		20.	0	0	0	0		47.	0	0	0	0	0		70. Percentile Rank	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	
		21.	0	0	0	0		48.	0	0	0	0	0		SOCCTL					
		22.	0	0	0	0		49.	0	0	0	0	0							
		23.	0	0	0	0		50.	0	0	0	0	0							
SOC24		24.	0	0	0	0	SOC51	51.	0	0	0	0	0							

PART VI: MOTOR SKILLS

A. Data Rows

1. Starting Row

MSSTROW

2. Ending Row

MSENDROW

B. RECORD FORM DATA:

		1	2	0	N	DK						1	2	0	N	DK		
MTSK14		14.	O	O	O	O	MTSK30					30.	O	O	O	O	O	
Item No.	Code	15.	O	O	O	O	O	O	O	O	31.	O	O	O	O	O		
MTSK1	1.	O	O	O	O	O	17.	O	O	O	O	O	O	O	O	O		
	2.	O	O	O	O	O	18.	O	O	O	O	O	O	O	O	O		
	3.	O	O	O	O	O	19.	O	O	O	O	O	O	O	O	O		
	4.	O	O	O	O	O	20.	O	O	O	O	O	O	O	O	O		
	5.	O	O	O	O	O	21.	O	O	O	O	O	O	O	O	O		
	6.	O	O	O	O	O	22.	O	O	O	O	O	O	O	O	O		
	7.	O	O	O	O	O	23.	O	O	O	O	O	O	O	O	O		
	8.	O	O	O	O	O	24.	O	O	O	O	O	O	O	O	O		
	9.	O	O	O	O	O	25.	O	O	O	O	O	O	O	O	O		
	10.	O	O	O	O	O	26.	O	O	O	O	O	O	O	O	O		
	11.	O	O	O	O	O	27.	O	O	O	O	O	O	O	O	O		
	12.	O	O	O	O	O	28.	O	O	O	O	O	O	O	O	O		
MTSK13	13.	O	O	O	O	O	MTSK29	29.	O	O	O	O	O	O	O	O		
												37. Raw Domain Score	<input type="text"/>					
												MTSKRAW						
												38. Standard Score	<input type="text"/>					
												MTSKSTRD						
												39. 95% Conf. Level	±	<input type="text"/>				
												MTSK95CL						
												40. Percentile Rank	<input type="text"/>					
												MTSKPCTL						

PART VII: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

CERT_NO

B. Signature: _____

CERT_SIG

C. General Comments:

GEN_CMNT

2. Vineland Administrator certification number:

VCERT_NO

ID Number

Visit

Seq

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: 2. Current Clinic: **SITE**
- ID**
3. Patient's Letter Code: **INITS** 4. Visit: **M** - **SEQNO**
- VISIT** sequence #
5. Date Form Started: - - **VIS_DT**
- Month Day Year

PART II: IMMUNIZATIONS and IMMUNOLOGIC REACTIVITY TESTING

1. Date of birth: - - **DOB_IMMU**
- Month Day Year
2. 0-2 weeks vaccination: sequence
in series - - (1) N/D (2) N/A
- Month Day Year
- HB2WSEQ** **HB2WDT** **HB2WND**
3. 6-weeks to 2-months of age vaccinations: sequence
in series - - (1) N/D (2) N/A
- Month Day Year
- DT6WSEQ** **DT6WDT** **DT6WND**
- A. DTaP
- B. Hib (Hemophilus influenza B: PRP-D, HbOC, PRP-OMP, PRP-T) - - (1) N/D (2) N/A
- HO6WSEQ** **HO6WDT** **HO6WND**
- C. IPV - - (1) N/D (2) N/A
- OP6WSEQ** **OP6WDT** **OP6WND**
- D. Pneumo-conjugate (PCV 7) - - (1) N/D (2) N/A
- PN6WSEQ** **PN6WDT** **PN6WND**
- E. Hep B - - (1) N/D (2) N/A
- HB6WSEQ** **HB6WDT** **HB6WND**
4. 4-months of age vaccinations: sequence
in series - - (1) N/D (2) N/A
- Month Day Year
- DT4MSEQ** **DT4MDT** **DT4MND**
- A. DTaP
- B. Hib - - (1) N/D (2) N/A
- HO4MSEQ** **HO4MDT** **HO4MND**
- C. IPV - - (1) N/D (2) N/A
- OP4MSEQ** **OP4MDT** **OP4MND**
- D. Pneumo-conjugate (PCV 7) - - (1) N/D (2) N/A
- PN4MSEQ** **PN4MDT** **PN4MND**

5. 6-months of age vaccinations:

A. DTaP
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 DT6MSEQ DT6MDT DT6MND

B. Hib
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 HO6MSEQ HO6MDT HO6MND

HO6MND
 C. Pneumo-conjugate (PCV 7) Month: - Day: - Year: (1) N/D (2) N/A
 PN6MSEQ PN6MDT PN6MND

6. 6-18 months of age vaccinations:

A. DTaP
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 DT12MSEQ DT12MDT DT12MND

B. Hib
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 HO12MSEQ HO12MDT HO12MND

C. IPV
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 OP12MSEQ OP12MDT OP12MND

D. Pneumo-conjugate (PCV 7) Month: - Day: - Year: (1) N/D (2) N/A
 PN12MSEQ PN12MDT PN12MND

E. Hep B
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 HB12MSQ1 HB12MDT1 HB12MND1

HB12MND1
 F. MMR
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 MM12MSEQ MM12MDT MM12MND

G. Varicella
 sequence in series: Month: - Day: - Year: (1) N/D (2) N/A
 VR12MSEQ VR12MDT VR12MND

7. Yearly influenza vaccines

A. - - INFLU1

B. - - INFLU2

C. - - INFLU3

D. - - INFLU4

ID Number

Visit - Seq

IMMUNOLOGIC REACTIVITY TESTING SPECIMEN COLLECTION

8. Study Entry (Pre-treatment)

A. Serum Opsonophagocytic + pneumococcal antibody **OPBLDT** - - (1) N/D **OPBLND**

B. Tube label (3.0 cc in red tube) **OPLLBL**

C. Naive and memory CD4/CD8 **CD4BLDT** - - (1) N/D **CD4BLND**

D. Tube label (0.5 cc in purple tube) **CD4LLBL**

9. 2-6 weeks after MMR vaccination (regardless of age):

A. Antibody to MMR **MMA12MDT** - - (1) N/D **MMA12MND**

B. Tube label (1.2 cc in red tube) **MMA12MLB**

10. 23-month-of-age blood samples: **PCAB2YDT** - - (1) N/D **PCAB2YND**

A. Antibody response to pneumo 23 **PCAB2YLB**

C. Antibody response to MMR **MMA2YDT** - - (1) N/D **MMA2YND**

D. Tube label (1.2 cc in red tube) **MMA2YLBL**

E. Naive and memory CD4/CD8 **CD42YDT** - - (1) N/D **CD42YND**

F. Tube label (0.5 cc in purple tube) **CD42YLBL**

IMMUNIZATION RECORD

11. 24-month-of-age vaccination: sequence in series - - (1) N/D **PN2YSEQ** **PN2YDT** **PN2YND**

ID Number Visit - Seq

IMMUNOLOGIC REACTIVITY TESTING SPECIMEN COLLECTION

12. 2-8 weeks after 24-month of age vaccinations:

- A. Serum Opsonophagocytic + pneumococcal antibody **OC2YDT** - - (1) N/D **OC2YND**
- B. Tube label (3.0 cc in red tube) **OC2YLBL**

IMMUNOLOGIC REACTIVITY TESTING SPECIMEN COLLECTION

13. Study Exit:

- A. Serum Opsonophagocytic + pneumococcal antibody **OCAEOSDT** - - (1) N/D **OCAEOSND**
- B. Tube label (3.0 cc in red tube) **OCAEOSLB**
- C. Antibody response to MMR **MMAEOSDT** - - (1) N/D **MMAEOSND**
- D. Tube label (1.2 cc in red tube) **MMAEOSLB**
- E. Naive and memory CD4/CD8 cells: **CD4EDSDT** - - (1) N/D **CD4EDSND**
- F. Tube label (0.5 cc in purple tube) **CD4EDSLB**

PART III: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number: - **CERT_NO**
- B. Signature: _____ **CERT_SIG**
- C. General Comments: **GEN_CMNT**

ID Number

Visit - Seq

NEUROLOGICAL EXAMINATION AND QUESTIONNAIRE

(Adapted from Chiriboga, Kairam, Kline 1991)

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ^{ID}

2. Current Clinic: ^{SITE}

3. Patient's Letter Code: ^{INITS}

4. Visit: M ^{VISIT} - ^{sequence #} ^{SEQNO}

5. Testing Date: - - ^{VIS_DT}

Month Day Year

PART II: QUESTIONNAIRE FOR THE CHILD'S CARETAKER

1. Which hand does your child prefer to Right (1) **HANDED**
 Left (2)
 No preference (3)
 Not able to assess (4)

2. How would you describe your child's ability to swallow? **SWALLOW**
 Normal (1)
 Abnormal, no intervention needed (2)
 Abnormal, requires modification of food consistency (3)
 Abnormal, swallowing impossible, tube or parenteral feedings (4)
 Not able to assess (5)

3. How would you describe your child's ability to walk and climb stairs? **WALKCLMB**
 Walks and climbs stairs without assistance, and alternates feet upon stair climbing (1)
 Walks and climbs stairs without assistance, but does not alternate feet upon stair climbing (2)
 Walks unassisted, but cannot climb stairs without support (3)
 Walks only with assistance, or walks unassisted only with leg braces or other supporting device (4)
 Non-ambulatory despite supporting devices (5)
 Not old enough (6)

4. How would you describe your child's toileting? Yes No N/A **DIAPNITE**
 A. Routinely wears diapers at night (1) (2) (3)
 B. Wets at night
 More than 5 times/week (1) **WETSNIITE**
 1-5 times/week (2)
 1/week to 1/month (3)
 Less than 1/month (4)
 N/A (5)

- | | Yes | No | N/A | |
|---|-----|-----|-----|----------|
| C. Routinely wears diapers in daytime? | (1) | (2) | (3) | DIAP_DAY |
| 1. If NO, currently experiencing wetting accidents? | | | | |
| Often | (1) | | | WET_ACC |
| Occasionally | (2) | | | |
| Rarely | (3) | | | |
| N/A | (4) | | | |
| 5. Does your child have tingling, numbness, pins and needles, "electric shock" or a burning sensation in his/her hands or feet? | | | | |
| No | | | (1) | TINGNUMB |
| Yes, sometimes | | | (2) | |
| Yes, often | | | (3) | |
| Not able to assess | | | (4) | |
| Question not age appropriate | | | (5) | |
| 6. Has your child ever had a seizure or convulsion? | | | | |
| No | | | (1) | SEIZURE |
| Yes, with fever | | | (2) | |
| Yes, without fever | | | (3) | |
| Yes, both febrile and afebrile | | | (4) | |
| Not able to assess | | | (5) | |

PART III: QUESTIONS COMPLETED BY THE EXAMINER

- | | | | | |
|---|-----|-----------|-----------|----------|
| 1. Does the child have sensory loss or sensory diminishment? | Yes | No | N/A | |
| | (1) | (2) | (3) | SENSLOSS |
| If <u>NO</u> or <u>N/A</u> , skip to PART III, Question 2 | | | | |
| A. Which best describes the change? | | DESCLOS R | DESCLOS L | |
| Decrease or loss of pain/temperature/position sense/vibration in great toes | | (1) | (1) | |
| Decrease or loss of pain/temperature/position sense/vibration in ankles | | (2) | (2) | |
| Decrease or loss of pain/temperature/position sense/vibration in knees | | (3) | (3) | |
| Not able to assess | | (4) | (4) | |

ID Number	Visit	Seq

2. Does the child have loss or diminishment of motor function? Yes No **LOSSSTRG**
(1) (2)

If NO, skip to PART IV, Question 1

- A. Which best describes the loss of strength? **LOSSSTRU**
1. Right Upper
 - Mild weakness (1)
 - Moderate weakness (2)
 - Severe weakness (3)
 - No change. (4)
 - Not able to assess (5)
 2. Left Upper **LOSSSTLU**
 - Mild weakness (1)
 - Moderate weakness (2)
 - Severe weakness (3)
 - No change. (4)
 - Not able to assess (5)
 3. Right Lower **LOSSSTRL**
 - Mild weakness (1)
 - Moderate weakness (2)
 - Severe weakness (3)
 - No change. (4)
 - Not able to assess (5)
 4. Left Lower **LOSSSTLL**
 - Mild weakness (1)
 - Moderate weakness (2)
 - Severe weakness (3)
 - No change. (4)
 - Not able to assess (5)
 5. Nonfocal impairment of gross motor development **LOSSGMTR**
 - Abnormal quality without delay in skills relative to age. (1)
 - Mild delay in skills relative to age (2)
 - Moderate or severe delay in skills relative to age (3)
 6. Nonfocal impairment of fine motor skills **LOSSFMTR**
 - Abnormal quality without delay in skills relative to age. (1)
 - Mild delay in skills relative to age (2)
 - Moderate or severe delay in skills relative to age (3)
- B. Which best describes the change in tone? **LOSSTONE**
- Proximal decrease (1)
 - Proximal increase (2)
 - Distal decrease (3)
 - Distal increase (4)
 - Proximal and distal decrease (5)
 - Proximal and distal increase (6)
 - Proximal decrease and distal increase (7)

ID Number Visit Seq

-

PART IV: REFLEXES

Reflex Codes¹

- 1 = Muscle contraction without limb displacement
- 2 = Muscle contraction with limb displacement
- 3 = Muscle contraction accompanied by clonus
- 4 = No reflex elicited
- 8 = Not able to assess

		RIGHT	LEFT
1.	Biceps reflex ¹ :	<input type="checkbox"/> RFLXBICR	<input type="checkbox"/> RFLXBICL
2.	Knee jerk ¹ :	<input type="checkbox"/> RFLXKJR	<input type="checkbox"/> RFLXKJL
3.	Ankle jerk ¹ :	<input type="checkbox"/> RFLXAJR	<input type="checkbox"/> RFLXAJL
4.	Ankle clonus: Codes: 1 - Clonus absent 2 - (1-4) beats on 2 trials 3 - (\geq 5) beats on at least 1 of 2 trials 4 - Spontaneous clonus 8 - Not able to assess	<input type="checkbox"/> RFLXACR	<input type="checkbox"/> RFLXACL
5.	Crossed adductor response: Codes: 1 - Absent 2 - Present 8 - Not able to assess	<input type="checkbox"/> RFLXARR	<input type="checkbox"/> RFLXARL
6.	Upgoing toe: Codes: 1 - Absent 2 - Present 3 - Two informative trials not obtained	<input type="checkbox"/> RFLXUPTR	<input type="checkbox"/> RFLXUPTL

ID Number

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Visit Seq

			-		
--	--	--	---	--	--

PART VI: CLINICAL NEUROLOGICAL DIAGNOSIS

¹ Distribution		² Severity Codes	
1	-None	1	- None
2	-General	2	- Mild
3	-Axial	3	- Moderate
4	-Limb	4	- Severe
Distribution ¹		Severity ²	
<input type="checkbox"/>	HYPOTOND	<input type="checkbox"/>	HYPOTONS
<input type="checkbox"/>	HYPRTOND	<input type="checkbox"/>	HYPRTONS

1. TONE

A. Hypotonia

B. Hypertonia

2. DIAGNOSIS BY STUDY EXAMINER:

Are any of the diagnoses listed below present today?

Yes
(1)

No
(2) **DIAGNOS**

If Yes, code diagnoses below.
 If No, go to question PART VII-1.

*These diagnoses require demarcation of "side involved."



¹Diagnosis Codes

²Side Involved

11 -Ataxia, specify	29 -Static Encephalopathy (etiology)	1 -Right
* 12 -Cranial Nerve Abnormality, Specify	30 -Static Encephalopathy (etiology)	2 -Left
* 13 -Headaches (muscular contraction)	31 -Attention Deficit Hyperactivity	3 -Bilateral
* 14 -Headaches (vascular)	32 -Epilepsy (idiopathic)	4 -Side
15 -HIV-Associated Progressive	33 -State Abnormality < 6 months	
23 -Macrocephaly (> 95% for sex and	34 -Newborn Drug Withdrawal < 3	
24 -Microcephaly (< 5% for sex and	40 -Stroke, neurological deficit	
* 25 -Myelopathy, specify	41 -TIA	
* 26 -Myopathy, specify	88 -Other Neurological Condition	
* 27 -Peripheral Neuropathy or		

Diagnosis ¹	Side ²	Specify:
A. <input type="checkbox"/> <input type="checkbox"/> DIAGN_A	<input type="checkbox"/> DIAGN_AS	DIAGNASP
B. <input type="checkbox"/> <input type="checkbox"/> DIAGN_B	<input type="checkbox"/> DIAGN_BS	DIAGNBSP
C. <input type="checkbox"/> <input type="checkbox"/> DIAGN_C	<input type="checkbox"/> DIAGN_CS	DIAGNCSP
D. <input type="checkbox"/> <input type="checkbox"/> DIAGN_D	<input type="checkbox"/> DIAGN_DS	DIAGNDSP

ID Number Visit Seq

 -

PART VII: NEUROLOGIC STATUS BY STUDY EXAMINER

1. From a neurological standpoint, what do you think the status of the patient is since the last assessment? NEURSTA1

1-Improved

2-Stable/unchanged

* 3-Deteriorated

* 4-Unable to assess

5-No previous assessment

2. From a neurological standpoint, what do you think the status of the patient is since the initial (baseline) assessment? NEURSTA2

1 - Improved

2 - Stable/unchanged

* 3 - Deteriorated

* 4 - Unable to assess

5 - No previous

3. Summary findings	Yes	No	N/A	
A. New stroke	*(1)	(2)	(3)	NEW_STRK
B. New TIA	*(1)	(2)	(3)	NEW_TIA

If either Yes, complete Form 50.

4. *Form 80 submitted? (1) (2) F80VII4

PART VIII: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: - CERT_NO

B. Signature: _____ CERT_SIG

C. General Comments: _____ GEN_CMNT

2. Neurological examiner certification number: - NCERT_NO

ID Number

Visit Seq

-

PART III: QUANTITATIVE ASSESSMENT

1. 400K Image

A. Anterior View

1. Spleen

a. total counts

KASPLTOT

--	--	--	--	--	--

b. # pixels in ROI

KASPLPIX

--	--	--	--	--

c. counts/pixel

KASPLCNT

--	--	--

2. Liver

a. total counts

KALIVTOT

--	--	--	--	--	--

b. # pixels in ROI

KALIVPIX

--	--	--	--	--

c. counts/pixel

--	--	--

B. Posterior View

1. Spleen

a. total counts

KPSPLTOT

--	--	--	--	--	--

b. # pixels in ROI

KPSPLPIX

--	--	--	--	--

c. counts/pixel

--	--	--

2. Liver

a. total counts

KPLIVTOT

--	--	--	--	--	--

b. # pixels in ROI

KPLIVPIX

--	--	--	--	--

c. counts/pixel

--	--	--

C. Spleen/Liver Ratio

1. Total counts

KSLRTTOT

--	--	--	--

2. Counts/pixel

KSLRTCNT

--	--	--	--

ID Number

--	--	--	--

Visit

--	--	--

Seq

--	--

-

2. Timed Image

A. Left Anterior Oblique View

1. Spleen

a. total counts

TASPLTOT

--	--	--	--	--	--

b. # pixels in ROI

--	--	--	--	--

c. counts/pixel

TASPLCNT

--	--	--

2. Liver

a. total counts

TALIVTOT

--	--	--	--	--	--

b. # pixels in ROI

TALIVPIX

--	--	--	--	--

c. counts/pixel

TALIVCNT

--	--	--

B. Right Posterior Oblique View

1. Spleen

a. total counts

TPSPLTOT

--	--	--	--	--	--

b. # pixels in ROI

--	--	--	--	--

c. counts/pixel

--	--	--

2. Liver

a. total counts

TPLIVTOT

--	--	--	--	--	--

b. # pixels in ROI

TPLIVPIX

--	--	--	--	--

c. counts/pixel

--	--	--

C. Spleen/Liver Ratio

1. Total Counts

TSLRTTOT

		.		
--	--	---	--	--

2. Counts/pixel

TSLRTCNT

		.		
--	--	---	--	--

ID Number

--	--	--	--

Visit

--	--	--

Seq

--	--

-

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: -

CERT_NO

B. Signature: _____

CERT_SIG

C. General Comments:

GEN_CMNT

ID Number

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------

Visit

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Seq

<input type="text"/>	<input type="text"/>
----------------------	----------------------

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: **ID**
2. Current Clinic: **SITE**
3. Patient's Letter Code: **INITS**
4. Visit: **VISIT** sequence #
 M - **SEQNO**
5. Procedure Date: **VIS_DT**
 - -
Month Day Year

PART II: EQUIPMENT AND QUALITY

1. Equipment **ABDSEQPT**
2. Transducer **ABDSTRNS**
3. Sonographer's last name **RDR45**
4. Quality of study **STATUS45**
 Adequate (1)
 Inadequate (2)
5. Film Label **SONO_LBL** **SONO_LBL**

PART III: COORDINATION

1. Checked for completeness and accuracy:
- A. Certification number: **CERT_NO**
 -
- B. Signature: **CERT_SIG**

- C. General Comments: **GEN_CMNT**

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ^{ID}
2. Current Clinic: ^{SITE}
3. Patient's Letter Code: ^{INITS}
4. Visit: M ^{VISIT} - ^{sequence #} ^{SEQNO}
5. Procedure Date: - - ^{VISIT_DT}
Month Day Year

PART II: EQUIPMENT

1. TCD examiner's last name ^{RDR46}
2. TCD machine serial number ^{TCDMNUM}
3. Patient's position during exam ^{PTNTPOS}
- Sitting (1)
 - Lying on exam table (2)
 - Other (3)*

*A. Specify: ^{POS_SP}

PART III: EXAMINATION PERFORMANCE

1. Patient's cooperativeness during the exam (answer each item)
- | | Yes | No | |
|---------------------|-----|-----|---------------------|
| A. Calm | (1) | (2) | ^{PTNTCALM} |
| B. Very Active | (1) | (2) | ^{PTNTCACT} |
| C. Crying/Screaming | (1) | (2) | ^{PTNTCRY} |

2. Completeness of exam COMPEXAM

- Attempted, but no data collected (1)*
- Started, but aborted with some data (2)^*
- Complete exam given (3)^

*A. Reason for incomplete exam INCEXAM

- Patient uncooperative (1)
- Other (2)**

**1. Specify

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

^B. TCD Label

TCD_LBL

INCEX_SP

PART IV: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number:

--	--

 -

--	--

CERT_NO
- B. Signature: _____ CERT_SIG
- C. General Comments: GEN_CMNT

ID Number		Visit		Seq								
<table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>					-	<table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>			-	<table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>		

MRI/MRA ELIGIBILITY READING

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: ID 2. Current Clinic: **SITE**
- 3. Patient's Letter Code: **INITS** 4. Visit: VISIT M - **SEQNO**
sequence #
- 5. Film Date: - - **VIS_DT**
Month Day Year

PART II: LOCAL READING

- | | | |
|-----------------------|----------------|----------------------|
| | Yes | No |
| 1. MRI Interpretable? | MRI (1) | (2)
(INEL) |

2. MRI film label

MRI_LBL

3. MRA Interpretable?

MRA (1)* (2)

If **No**, **Skip** to Item 4.
If **Yes**, answer 3.A.

*A. Greater than 50% stenosis?

STENOSIS (1) (2)
(INEL)

4. MRA film label

MRA_LBL

PART III: COORDINATION

- 1. Checked for completeness and accuracy:
 - A. Certification number: - **CERT_NO**
 - B. Signature: _____ **CERT_SIG**
 - C. General Comments: _____ **GEN_CMNT**

REPORTABLE EVENT AND/OR HOSPITALIZATION

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number:	ID	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	2. Current Clinic:	SITE	<input type="text"/> <input type="text"/>
3. Patient's Letter Code:	INITS	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	4. Preliminary Week #:	VISIT	<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <small>sequence #</small>
5. Preliminary Event Start Date:		<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			SEQNO
		<small>Month Day Year</small>			VIS_DT
6. Actual Week Number:	ACTVISIT	<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>		<small>sequence #</small>	ACTSEQNO
7. Actual Event Start Date:		<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			START_DT
		<small>Month Day Year</small>			
8. Actual Event Ending Date:		<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			E_END_DT
		<small>Month Day Year</small>			

PART II: DIAGNOSIS/ES OR PROBLEM

- | | | | |
|-----------------------------------|-------|-----|-----------------|
| 1. Please indicate all diagnoses: | YES | NO | |
| A. Dactylitis | (1)^ | (2) | HXDACTY |
| B. Pain | (1)^ | (2) | HX_PAIN |
| C. Acute chest syndrome | (1)*^ | (2) | HX_ACS |
| D. Priapism | (1)^ | (2) | HX_PRIAP |
| E. Splenic sequestration | (1)*^ | (2) | HXSPLSEQ |
| F. Splenomegaly | (1)*^ | (2) | HXSPLEN |
| G. Biliary obstruction | (1)^ | (2) | HXBILOB |
| H. Hepatopathy | (1)^ | (2) | HYHEPATH |
| I. Hepatic sequestration | (1)^ | (2) | HXHEPSEQ |
| J. Pancreatitis | (1)^ | (2) | HXPANCR |
| K. Fever >101.5°F (38.4°C) | (1)^ | (2) | HXFEVNC |

1. Reason:

HXFEVNCR

- | | | | |
|----------------------------|-------|-----|-----------------|
| L. Acute renal failure | (1)^ | (2) | HXAREFAI |
| M. Permanent renal failure | (1)^ | (2) | HXPREFAI |
| N. Sepsis or Meningitis | (1)*^ | (2) | HXSEPSIS |
| O. Severe neutropenia | (1)^ | (2) | HXSEVNEU |

1. Please indicate all diagnoses (Continued):

- | | YES | NO | |
|------------------------------------|-------|-----|----------|
| P. Aplastic crisis | (1)^ | (2) | HXAPLCRI |
| Q. Acute osteomyelitis | (1)*^ | (2) | HXACOSTE |
| R. Stroke, with neurologic deficit | (1)*^ | (2) | HXSTROK |
| S. Transient ischemic attack | (1)*^ | (2) | HXTIA |
| T. Upper respiratory infection | (1)^ | (2) | HXUPRESP |
| U. Otitis Media | (1)^ | (2) | HXOTITIS |
| V. Skin infection, bacterial | (1)^ | (2) | HXSKIN_B |
| W. Skin infection, fungal | (1)^ | (2) | HXSKIN_F |
| X. Gastroenteritis | (1)^ | (2) | HXGASTRO |
| Y. Constipation | (1)^ | (2) | HXCONST |
| Z. Viral Syndrome | (1)^ | (2) | HXVRLSYN |
| AA. Other 1 | (1)^ | (2) | HXOTHER |

1. Specify: HXOTH_SP

BB. Other 2 (1)^ (2) HXOTHER2

1. Specify: HXOT2_SP

CC. Other 3 (1)^ (2) HXOTHER3

1. Specify: HXOT3_SP

DD. Other 4 (1)^ (2) HXOTHER4

1. Specify: HXOT4_SP

- | | YES | NO | |
|-------------------------------------|-----|-----|-----|
| 2. Does this Form 50 report an SAE? | (1) | (2) | SAE |

If **YES**, complete Form 51: Concomitant Medication.

ID Number	Visit	Seq
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

If PART II, Items 1R or 1S is **YES**, answer 5-7. Otherwise, skip to Part IV.

5. Findings of Stroke/TIA:		YES	NO	N/A
A. Loss of consciousness	LOS_CONS	(1)	(2)	(3)
B. Change in mental status	CHG_MENT	(1)	(2)	(3)
C. Loss of or difficulty with speech or vocalization	SPEECH	(1)	(2)	(3)
D. Paralysis or weakness	PARALYS	(1)	(2)	(3)
E. Difficulty with swallowing	DIFFSWAL	(1)	(2)	(3)
F. Difficulty with vision	DIFF_SEE	(1)	(2)	(3)
G. Loss of balance or dizziness	BALANCE	(1)	(2)	(3)
H. Seizures	SEIZURE	(1)	(2)	(3)
I. Headache	HEADACHE	(1)	(2)	(3)

6. Results of Imaging Tests:		NORMAL	ABNORMAL	NOT DONE
A. MRI of brain	F50MRI	(1)	(2)	(3)
B. CT scan of brain	F50CTBR	(1)	(2)	(3)
C. PET scan of brain	F50PTBR	(1)	(2)	(3)
D. MRA cerebral vasculature	F50MRA	(1)	(2)	(3)
E. Transcranial Doppler	F50TCD	(1)	(2)	(3)
F. Arteriogram	F50ARTGR	(1)	(2)	(3)

7. Was a Neurological Questionnaire (Form 43) completed? F50NEUR YES (1) NO (2)

ID Number

--	--	--	--

Visit

--	--	--

-

Seq

--	--

^PART IV: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

Complete PART IV for each item in PART II checked YES.

1.	2.	3.	4.	5. ² Attribution to	6. ³ Diagnosis

- | | | |
|--|--|---|
| <p>¹Severity</p> <p>1 Mild</p> <p>2 Moderate</p> <p>3 Severe</p> <p>4 Life threatening</p> <p>5 Disabling</p> <p>6 FATAL</p> <p>7 Unknown</p> | <p>²Attribution to Study Treatment</p> <p>1 Definite (clearly related)</p> <p>2 Probable (likely related)</p> <p>3 Possible (may be related)</p> <p>4 Unlikely (doubtfully related)</p> <p>5 Unrelated (definitely not related)</p> | <p>³Diagnosis Unexpected</p> <p>1 Yes</p> <p>2 No</p> <p>3 N/A</p> |
|--|--|---|

PART V: REPORTABLE TREATMENTS

1. Answer each item:
- | | | | |
|--|-----|----|-----|
| | YES | NO | N/A |
|--|-----|----|-----|
- A. Transfusion TRANSFUS
- | | | | |
|--|-----|-----|-----|
| | (1) | (2) | (3) |
|--|-----|-----|-----|
1. If yes,
- a. Transfusion Type: (1) Simple (2) Exchange TR_TYPE
- b. Volume, answer b 1 or 2.
1. Whole Blood cc TRVOLWBL
- OR
2. Packed Red Cells cc TRVOLPR2
- c. Start Date: TSTRT_DT - -
- Month Day Year
- d. Stop Date: TSTOP_DT - -
- B. Placement on chronic transfusion therapy* CHRTRAN (1)* (2) (3)
- C. Bone marrow transplantation* BMT (1)* (2) (3)
- D. Splenectomy SPLCTMY (1) (2) (3)
- E. Cholecystectomy CHOLCTMY (1) (2) (3)
- F. Parenteral antibiotics PAR_ANTI (1) (2) (3)
- G. Butyrate BUTYRATE (1) (2) (3)
- H. Other treatment contraindicated for HU CONTRAHU (1) (2) (3)
- I. Dialysis, limited course DIALYS_L (1) (2) (3)
- J. Dialysis, chronic* DIALYS_C (1)* (2) (3)
- K. Renal transplant or candidate* RENTRANS (1)* (2) (3)

*Complete Form 36 - End of Randomized Treatment and Form 64 - Stop Treatment Order.

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	- <input type="text"/> <input type="text"/>

PART VI: MANAGEMENT

		Yes	No
1. Out patient	OUT_PT	(1)	(2)
2. Hospitalization	HOSPTLZD	(1)	(2)
3. Prolonged hospitalization (>7 days)	LONGHOSP	(1)	(2)
4. ICU admission	ICU	(1)	(2)

PART VII: HOSPITAL

1. Hospital Name: **HOSPNAME** _____

2. City: **HOSPCITY** _____

3. State: **HOSP_ST** **HOSP_ZIP** 4. Zip:

5. Admission Date: **ADM_DT** - -
 Month Day Year

6. Discharge Date: **DISCH_DT** - -
 Month Day Year

PART VIII: OUTCOMES

	Yes	No	
1. Significant new disability	(1)	(2)	SNEWDISA
2. Persistent new disability	(1)	(2)	PNEWDISA
3. Permanent new disability	(1)	(2)	PERMDISA
4. Death	(1)	(2)	DEATH

A. Date of Death: - -
 Month Day Year **DEATH_DT**

B. Location **DTH_LOC**

In-patient (1)

In community (2)

PART IX: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: - **CERT_NO**

B. Signature: _____ **CERT_SIG**

C. General Comments: _____ **GEN_CMNT**

ID Number Visit Seq

 -

ANTIBIOT

2. Antibiotics

		YES (1)*	NO (2)
A.	Did the patient receive antibiotics?		
	(a)	(b)	(c)
		Within 3 Days of PK Collection	Within 7 Days of SAE Onset
*B.	If YES, check all that are applicable for each antibiotic.	Not Received	Until close of SAE
1.	Amoxicillin (e.g., Amoxil, Prevpac, Trimox)	(1)	(1)
2.	Amoxicillin and Clavulante Potassium (e.g. Augmentin)	(1)	(1)
3.	AmpicillinSodium and Sulbactam Sodium (e.g., Unasyn)	(1)	(1)
4.	Azithromycin (e.g., Zithromax)	(1)	(1)
5.	Cetaclor (e.g., Ceclor)	(1)	(1)
6.	Cefotaxime (e.g., Claforan)	(1)	(1)
7.	Ceftriaxone (e.g., Rocephin)	(1)	(1)
8.	Cefuroxime (e.g., Ceftin)	(1)	(1)
9.	Clindamycin (e.g. Cleocin, Clinda-Derm, Clindagel)	(1)	(1)
10.	Co-trimoxazole (e.g., Bactrim, Septra, Sulfatrim)	(1)	(1)
11.	Erythromycin (e.g., ERYC, PCE)	(1)	(1)
12.	Penicillin (e.g., Pfizerpen)	(1)	(1)
13.	Vancomycin (e.g., Vancocin)	(1)	(1)

If the patient is receiving an antibiotic not listed above, enter this information in Section 7.

ANALGES

3. Analgesics

		YES (1)*	NO (2)
A.	Did the patient receive analgesics?		
	(a)	(b)	(c)
		Within 3 Days of PK Collection	Within 7 Days of SAE Onset
*B.	If YES, check all that are applicable for each analgesic.	Not Received	Until close of SAE
1.	Acetaminophen (e.g., Tylenol, Panadol, Aspirin-Free Anacin)	(1)	(1)
2.	Acetaminophen with Codeine	(1)	(1)
3.	Aspirin (Acetylsalicylic acid)	(1)	(1)
4.	Codeine (e.g., Brontex)	(1)	(1)
5.	Fentanyl (e.g., Actiq)	(1)	(1)
6.	Ibuprofen (e.g., Advil, Genpril, Haltran, IBU, Motrin)	(1)	(1)
7.	Ketorolac (e.g., Toradol)	(1)	(1)
8.	Morphine Sulfate (e.g., MS Contin, Duramorph, Infumorph, Roxanol)	(1)	(1)
9.	Nalbuphine (e.g., Nubain)	(1)	(1)
10.	Oxycodone (e.g., Endocodone, Oxycontin, Roxicodone)	(1)	(1)
11.	Oxycodone and Acetaminophen	(1)	(1)

If the patient is receiving an analgesic not listed above, enter this information in Section 7.

ID Number Visit Seq
 -

4. Pulmonary

PULMONAR

A. Did the patient receive pulmonary medications?

Yes (1)* No (2)

(a) (b) (c) (d)

*B. If YES, check all that are applicable for each pulmonary medication.

	Not Received	Within 3 Days of PK Collection	Within 7 Days of SAE Onset	Until close of SAE
1. Albuterol (e.g., Proventil, Ventolin, Volmax)	(1)	(1)	(1)	(1)
2. Budesonide Inhalation Powder (e.g., Entocort, Pulmicort)	(1)	(1)	(1)	(1)
3. Fluticasone (e.g., Flovent, Advair)	(1)	(1)	(1)	(1)
4. Levalbuterol (e.g., Xopenex)	(1)	(1)	(1)	(1)
5. Montelukast (e.g., Singulair)	(1)	(1)	(1)	(1)

If the patient is receiving a pulmonary medication not listed above, enter this information in Section 7.

5. Topicals

TOPICALS

A. Was the patient using topical medications?

Yes (1)* No (2)

(a) (b) (c) (d)

*B. If YES, check all that are applicable for each topical medication.

	Not Received	Within 3 Days of PK Collection	Within 7 Days of SAE Onset	Until close of SAE
1. Clomazole (e.g., Lotrimin, Mycelex)	(1)	(1)	(1)	(1)
2. Medicated Shampoo ^1. Specify: _____	(1)	(1)^	(1)^	(1)^
3. Nystatin (e.g., Mycostatin, Nystop, Ped-Dri)	(1)	(1)	(1)	(1)
4. Nystatin and Triamcinolone (e.g., Mycogen II, Mycolog-II, Myconel, Myco-triacet II, Mytrex, Tri-Statin)	(1)	(1)	(1)	(1)
5. Steroid ^1. Specify: _____	(1)	(1)^	(1)^	(1)^

If the patient is receiving a topical medication not listed above, enter this information in Section 7.

6. Other

OTHER

A. Was the patient using any other medications?

Yes (1)* No (2)

(a) (b) (c) (d)

*B. If YES, check all that are applicable for each medication.

	Not Received	Within 3 Days of PK Collection	Within 7 Days of SAE Onset	Until close of SAE
1. Diphenhydramine (e.g., Benadryl)	(1)	(1)	(1)	(1)
2. Hydroxyzine (e.g., Anx, Atarax, Visaril)	(1)	(1)	(1)	(1)
3. Promethazine (e.g., Phenergan, Promacot, Promethegan)	(1)	(1)	(1)	(1)
4. Rantidine (e.g., Tritec, Zantac)	(1)	(1)	(1)	(1)

ID Number Visit Seq
 -

7. Additional Medications

Please list all other prescriptions, over-the-counter (OTC) medications, vitamins and herbs not specified in Items 1-6 that the child received during the time period of interest. Record the type of concomitant medication. Check all time periods that are applicable for each medication.

	(a) Type of Con Med ¹	(b) Within 3 Days of PK Collection (1)	(c) Within 7 Days of SAE Onset (1)	(d) Until Close of SAE (1)
A. _____	<input type="checkbox"/>	(1)	(1)	(1)
B. _____	<input type="checkbox"/>	(1)	(1)	(1)
C. _____	<input type="checkbox"/>	(1)	(1)	(1)
D. _____	<input type="checkbox"/>	(1)	(1)	(1)
E. _____	<input type="checkbox"/>	(1)	(1)	(1)
F. _____	<input type="checkbox"/>	(1)	(1)	(1)
G. _____	<input type="checkbox"/>	(1)	(1)	(1)
H. _____	<input type="checkbox"/>	(1)	(1)	(1)
I. _____	<input type="checkbox"/>	(1)	(1)	(1)
J. _____	<input type="checkbox"/>	(1)	(1)	(1)
K. _____	<input type="checkbox"/>	(1)	(1)	(1)
L. _____	<input type="checkbox"/>	(1)	(1)	(1)
M. _____	<input type="checkbox"/>	(1)	(1)	(1)
N. _____	<input type="checkbox"/>	(1)	(1)	(1)
O. _____	<input type="checkbox"/>	(1)	(1)	(1)

¹Type of concomitant medication

- | | |
|--------------|-------------|
| 1 Supplement | 4 Pulmonary |
| 2 Antibiotic | 5 Topical |
| 3 Analgesic | 6 Other |

ID Number Visit Seq
 -

PART IV. COORDINATOR INFORMATION

1. Checked for completion and accuracy:

A. Certification Number: -

CERT_NO

B. Signature: _____

CERT_SIG

C. General Comments:

GEN_CMNT

ID Number Visit - Seq

TREATMENT STOP ORDER

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: ID
- 2. Current Clinic: SITE
- 3. Patient's Letter Code: INITS
- 4. Visit: VISIT - sequence # SEQNO
- 5. Date of Order: - - VIS_DT
 Month Day Year

PART II: INITIATION OF STOP ORDER

- 1. Stop order initiated by: STOPBY
 - Clinical Center staff (1)
 - Medical Coordinating Center (2)
 - Operations Committee (3)
- 2. Type of stop order:
 - Temporary stop/automatic restart (1) TPSTOPTX
 - Temporary stop/conditional restart (2)
 - Permanent stop/never restart (3)
- 3. Is Clinical Center staff directed to contact the patient's caregiver and instruct him/her to stop giving study medication to the patient? YES NO CCSTOPTX
 - (1) (2)

If NO, Skip to PART IV.

PART III: STOP ORDER IMPLEMENTATION

1. Did the Clinical Center staff contact the patient's caregiver? YES NO **CCCONTPT**
 (1) (2)

IF YES, ANSWER: **CCCNTDT**

A. Date - -
 Month Day Year

B. Military time: :
CONTHR **CONTMN**

SKIP TO ITEM 3.

2. IF NOT CONTACTED:

A. How many attempts were made to contact the patient's caregiver? **ATTMCONT**

B. Date and time contact attempts ended: **ENDCONDNT**

1. Date - -
 Month Day Year

2. Military time: :
ENDCONHR **ENDCONMN**

SKIP TO PART IV.

3. Did the patient's caregiver agree to stop giving study treatment to the patient? YES NO **PTAGR**
 (1) (2)
4. Did the patient's caregiver agree to return all unused study medication at the next BABY HUG Clinic Visit? YES NO **PTAGRTRN**
 (1) (2)

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: - **CERT_NO**

B. Signature: _____ **CERT_SIG**

C. General Comments: **GEN_CMNT**

ID Number

Visit - Seq

RESTART TREATMENT ORDER

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: ID
- 2. Current Clinic: SITE
- 3. Patient's Letter Code: INITS
- 4. Visit: VISIT - sequence # - SEQNO
- 5. Date of Order: - - VIS_DT

Month
Day
Year

PART II:

- 1. Type of restart RESTRTTY
 - Wait until next clinic study visit (1)
 - Restart now with present prescription (2)
- 2. Did patient's caregiver receive and understand instruction? (1) (2) PATUNSTN
YES NO

PART III. COORDINATION

- 1. Checked for completeness and accuracy:
 - A. Certification number: - CERT_NO
 - B. Signature: _____ CERT_SIG
 - C. General Comments: _____ GEN_CMNT

PART IV. COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

--	--

 -

--	--

CERT_NO

B. Signature: _____

CERT_SIG

C. General Comments:

GEN_CMNT

ID Number

--	--	--	--

Visit

--	--	--

 -

--	--

Seq

ADDITIONAL INFORMATION FORM

PART I: IDENTIFYING INFORMATION (same as form being documented)

1. Patient's ID Number:

--	--	--	--

^{ID} 2. Current Clinic:

--	--

SITE
3. Patient's Letter Code:

--	--	--

INITS 4. Visit:

--	--	--

^{VISIT} -

--	--

^{sequence #} SEQNO
5. Date of Referenced Form:

--	--	--

Month -

--	--

Day -

--	--	--	--

Year VIS_DT

PART II: DOCUMENTATION FOR FORM/ITEM FOR THE CAPTIONED PATIENT

1.

Form	Rev	Page	INITIALS (MCC use only)								
<table border="1" style="width: 100%; height: 20px;"><tr><td style="width: 50%;"></td><td style="width: 50%;"></td></tr></table>			<table border="1" style="width: 100%; height: 20px;"><tr><td style="width: 100%;"></td></tr></table>		<table border="1" style="width: 100%; height: 20px;"><tr><td style="width: 50%;"></td><td style="width: 50%;"></td></tr></table>			<table border="1" style="width: 100%; height: 20px;"><tr><td style="width: 33%;"></td><td style="width: 33%;"></td><td style="width: 33%;"></td></tr></table>			
FORM 2	REV2	PAGE	INITS2								
2. Narrative/comments/explanation/other: CMNT

PART III: COORDINATION

1. Checked for completeness and accuracy:
- A. Certification number:

--	--

 -

--	--

CERT_NO
- B. Signature: _____ CERT_SIG

PART III: READING

1. DISCREET FINDINGS **FINDINGS** Yes No
(1) (2)

If (2), SKIP to Item 2.

Complete the table for up to 7 lesions using the codes below.

SIDE:	TYPE	SIZE	LOCATION CODES
R = Right	H = Hemorrhage	0 = Small (Punctate) (Few mm)	0 = Frontal
L = Left	I = Infarct	1 = Medium (ovoid) (0.5 - 1.5cm)	1 = Temporal
		2 = Large (geographic) (\geq 1.5cm)	2 = Parietal
			3 = Occipital
			4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus)
			5 = Capsular/Corona
			6 = Centrum semiovale
			7 = Brain stem
			8 = Cerebellum

	_SID	_TYP	_SIZ	_LC1	_LC2	_LC3	_LC4	
LESION	SIDE	TYPE	SIZE	1 st	Location(s)			4 th
					2 nd	3 rd		
LSNA	A.	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>
LSNB	B.	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>
LSNC	C.	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>
LSND	D.	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>
LSNE	E.	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>
LSNF	F.	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>
LSNG	G.	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>	<input style="width: 40px; height: 20px;" type="text"/>

ID Number Visit Seq

-

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: -

CERT_NO

B. Signature: _____

CERT_SIG

C. General Comments:

GEN_CMNT

ID Number

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Visit

Seq

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>
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PART III: CENTRAL REVIEW INTERPRETATION (Answer items 1-8 using the codes below.)

a. OVERALL RATING	b. DESCRIPTION OF ABNORMALITY	d. INVOLVED SEGMENTS
1 = Normal	1 = Stenosis, Mild (25% to 50% narrowing)	1 = Supraclinoid
2 = Equivocal	2 = Stenosis, Moderate (50% to 75% narrowing)	2 = Pre- or Juxtapellar
3 = Abnormal	3 = Stenosis, Severe (75% to 99% narrowing)	3 = Petrous
	4 = Occlusion	4 = Distal cervical

	OVERALL RATING	DESCRIPTION OF ABNORMALITY (IF OVERALL RATING=3)	LENGTH OF STENOTIC SEGMENT (mm)	INVOLVED SEGMENT (INDICATE ALL THAT APPLY IF RATING =3)
1. Right ICA	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	INVSEGR1 <input type="text"/> d1 <input type="text"/> INVSEGR2 <input type="text"/> d2 <input type="text"/> INVSEGR3 <input type="text"/> d3 <input type="text"/> INVSEGR4 <input type="text"/> d4 <input type="text"/>
	ORRICA	ABRICA	LSSRICA	
2. Right MCA	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	
	ORRMCA	ABRMCA	LSSRMCA	
3. Right ACA	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	
	ORRACA	ABRACA	LSSRACA	
4. Left ICA	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	INVSEGL1 <input type="text"/> d1 <input type="text"/> INVSEGL2 <input type="text"/> d2 <input type="text"/> INVSEGL3 <input type="text"/> d3 <input type="text"/> INVSEGL4 <input type="text"/> d4 <input type="text"/>
	ORLICA	ABLICA	LSSLICA	
5. Left MCA	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	
	ORLMCA	ABLMCA	LSSLMCA	
6. Left ACA	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	
	ORLACA	ABLACA	LSSLACA	
7. Basilar	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	
	ORBASIL	ABBASIL	LSSBASIL	

	OVERALL RATING	DESCRIPTION OF ABNORMALITY (IF OVERALL RATING=3)	LENGTH OF STENOTIC SEGMENT	INVOLVED SEGMENT (INDICATE ALL THAT APPLY IF RATING =3)
8. OVERALL MRA	a <input type="text"/>	b <input type="text"/>	c <input type="text"/> <input type="text"/>	d1 <input type="text"/> INVSEG1 <input type="text"/> d2 <input type="text"/> INVSEG2 <input type="text"/> d3 <input type="text"/> INVSEG3 <input type="text"/> d4 <input type="text"/> INVSEG4 <input type="text"/>
	ORMRA	ABMRA	LSSMRA	

ID Number

Visit - Seq

9. Collateral Blood Vessels (Mark One):
- | | | | | | |
|--|--------------|-------------|-------------|--------------------|----------------|
| | Right
(1) | Left
(2) | Both
(3) | Not Present
(4) | BLDVSLs |
| | | | Yes | No | |
10. If narrative provided, complete Form 80
- | | | | |
|--|-----|-----|-----------------|
| | (1) | (2) | FM80III7 |
|--|-----|-----|-----------------|

PART IV: COORDINATION

1. To Be Completed by Radiology Technician:

- A. Certification number: - **CERT_NO**
- B. Person completing form: [Name] _____ **CERT_SIG**
- C. General Comments: **GEN_CMNT**

ID Number

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Visit

<input type="text"/>	<input type="text"/>	<input type="text"/>
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-

Seq

<input type="text"/>	<input type="text"/>
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C. If gallbladder present, answer C1 or					
1. Number of stones		<input type="text"/>	<input type="text"/>		GBNSTN85
	<input type="text"/> OR <input type="text"/>			Yes	
2. Multiple stones not countable				(1)	GBMSTN85
					N/A
D. Largest stone		<input type="text"/>	<input type="text"/>	mm	GBLGST85 (1)
					GBLGSTNA
				Yes	
				No	
				N/A	
E. Stones freely mobile?	GBSFM85			(1)	(2) (3)
F. Dilation				Dilated	Normal N/A
1. Common bile duct	GBCBD85			(1)	(2) (3)
2. Pancreatic duct	GBPAND85			(1)	(2) (3)
3. Intrahepatic ducts	GBIHEP85			(1)	(2) (3)
				Present	Absent N/A
G. Sludge	GBSLDG85			(1)	(2) (3)
H. Pericholecystic fluid	GBPRFL85			(1)	(2) (3)
<hr/>					
2. Spleen	SPLEEN85			(1)	(2) (3)
<input type="text"/> If not present, SKIP to ITEM 3. <input type="text"/>					
A. Accessory spleen(s)	ACCSP85			(1)	(2) (3)
B. Cephalocaudad length		<input type="text"/>	<input type="text"/>	.	<input type="text"/> cm SPLCLN85
C. Transverse		<input type="text"/>	<input type="text"/>	.	<input type="text"/> cm SPLTRN85
D. Anterior - Posterior		<input type="text"/>	<input type="text"/>	.	<input type="text"/> cm SPLANP85
E. Estimated total spleen volume	SPLVOL85	<input type="text"/>	<input type="text"/>	<input type="text"/>	cu cm (1) N/D SPLVOLND
F. Homogeneity					SPLHOM85
		Homogeneous		(1)	
		Inhomogeneous		(2)	
		N/A		(3)	
1. If inhomogeneous, submit Form 80:				Yes	No F80III2F
				(1)	(2)
<hr/>					

Label Number

ID Number

Visit Seq
 -

		Present	Absent	N/A
3. Right Kidney	RKIDN85	(1)	(2)	(3)

If not present, SKIP to ITEM 4.

A. Estimated volume		<input type="text"/> <input type="text"/> <input type="text"/>	cu cm	RKVOL85
---------------------	--	--	-------	----------------

B. Renal parenchyma	RKRPAR85	Normal (1)	Abnormal (2)	N/A (3)
---------------------	-----------------	---------------	-----------------	------------

1. If abnormal, explain:	_____			RKRPEX85
--------------------------	-------	--	--	-----------------

C. Echogenicity	RKECHO85	(1)	(2)	(3)
-----------------	-----------------	-----	-----	-----

1. If abnormal, explain:	_____			RKECEX85
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		Present	Absent	N/A
4. Left Kidney	LKID85	(1)	(2)	(3)

If not present, SKIP to ITEM 5.

A. Estimated volume		<input type="text"/> <input type="text"/> <input type="text"/>		LKVOL85
---------------------	--	--	--	----------------

B. Renal parenchyma	LKRPAR85	Normal (1)	Abnormal (2)	N/A (3)
---------------------	-----------------	---------------	-----------------	------------

1. If abnormal, explain:	_____			LKRPEX85
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C. Echogenicity	LKECHO85	(1)	(2)	(3)
-----------------	-----------------	-----	-----	-----

1. If abnormal, explain:	_____			LKECEX85
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		Yes	No	N/A
5. Liver enlarged	LVREN85	(1)	(2)	(3)

		Yes	No	N/A
6. Any other abdominal abnormalities	ABDABN85	(1)	(2)	(3)
A. If YES, submit Form 80	F80III5A	(1)	(2)	

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:	<input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/>	CERT_NO
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B. Signature:	_____	CERT_SIG
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C. General Comments:	GEN_CMNT
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Label Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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ID Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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Visit	<input type="text"/> <input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/>
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CLINICAL EVENTS CLASSIFICATION

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: ID
- 2. Current Clinic: SITE
- 3. Patient's Letter Code: INITS
- 4. Week #: - sequence VISIT SEQNO
- 5. Event Start Date: - - VIS_DT
Month Day Year

PART II: CLASSIFICATION

- 1. Reviewer: TK MS CON MED REVIEWER
(1) (2) (3) (4)
- 2. Date of review - - REVIEWDT
Month Day Year
- 3. Classification decision CLASSDEC
Final (1)
Pending (2)
- If **FINAL**, Skip to PART III
- 4. Additional information requested? Yes No ADINFO
(1)* (2)

*a. Specify _____

PART III: BODY SYSTEM(S) AFFECTED CLASSIFICATION

		Yes	No
1. Blood and lymphatic system disorders	SOC_01	(1)	(2)
2. Cardiac disorders	SOC_02	(1)	(2)
3. Congenital, familial and genetic disorders	SOC_03	(1)	(2)
4. Ear and labyrinth disorders	SOC_04	(1)	(2)
5. Endocrine disorders	SOC_05	(1)	(2)
6. Eye disorders	SOC_06	(1)	(2)
7. Gastrointestinal disorders	SOC_07	(1)	(2)
8. General disorders and administration site conditions	SOC_08	(1)	(2)
9. Hepatobiliary disorders	SOC_09	(1)	(2)
10. Immune system disorders	SOC_10	(1)	(2)
11. Infections and infestations	SOC_11	(1)	(2)
12. Injury, poisoning and procedural complications	SOC_12	(1)	(2)
13. Investigations	SOC_13	(1)	(2)
14. Metabolism and nutrition disorders	SOC_14	(1)	(2)
15. Musculoskeletal and connective tissue disorders	SOC_15	(1)	(2)
16. Neoplasms benign, malignant and unspecified (incl cysts and polyps)	SOC_16	(1)	(2)
17. Nervous system disorders	SOC_17	(1)	(2)
18. Pregnancy, puerperium and perinatal conditions	SOC_18	(1)	(2)
19. Psychiatric disorders	SOC_19	(1)	(2)
20. Renal and urinary disorders	SOC_20	(1)	(2)
21. Reproductive system and breast disorders	SOC_21	(1)	(2)
22. Respiratory, thoracic and mediastinal disorders	SOC_22	(1)	(2)
23. Skin and subcutaneous tissue disorders	SOC_23	(1)	(2)
24. Social circumstances	SOC_24	(1)	(2)
25. Surgical and medical procedures	SOC_25	(1)	(2)
26. Vascular disorders	SOC_26	(1)	(2)

PART IV: FINAL CLASSIFICATION OF OUTCOME EVENT

1. Event Type		Yes	No
A. Severe splenic sequestration	SEVSPLSQ	(1)	(2)
B. Stroke	STROKE	(1)	(2)
C. Transient ischemic attack	TIAFCL	(1)	(2)
D. Acute chest syndrome	ACUTE	(1)	(2)
E. Death	DEATH	(1)*	(2)

*1. Immediate cause

DEATHIMM

*2. Primary underlying cause

DEATHPRM

F. Other

FCLOTHR

(1)*

(2)

*1. Specify event/diagnosis

FCLOTHSP

ID Number

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Visit

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Seq

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2. Event Severity		Yes	No
A. Serious adverse event [†]	SERIOUS	(1)	(2)
B. Severity	SEVER		
Mild		(1)	
Moderate		(2)	
Severe		(3)	
Life threatening		(4)	
Disabling		(5)	
Fatal		(6)	
Unknown		(7)	
C. Attribution to study treatment	ATTRIB		
Definite		(1)	
Probable		(2)	
Possible (may be related)		(3)	
Unlikely (doubtfully related)		(4)	
Unrelated (definitely not related)		(5)	

PART V: COORDINATION

1. Checked for completeness and accuracy:
- A. Certification number: - **CERT_NO**
- B. Signature: _____ **CERT_SIG**
- C. General Comments: _____ **GEN_CMNT**

[†]Defined to be death, life-threatening event, hospitalization (initial or prolonged), severe splenic sequestration, stroke, TIA, acute chest syndrome or disability.

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	- <input type="text"/> <input type="text"/>