

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: VISIT - sequence #
 M - SEQNO
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?
DIAGHBSS | (1) | (2)
(INEL) |
| 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"/>
Month Day Year BIRTH_DT | | |
| B. Is the child between 9 and 17 months of age inclusive?
AGEINCL4 | (1) | (2)
(HOLD) |
| <div style="border: 1px solid black; padding: 2px; display: inline-block;">If <u>NO</u>, answer Item 2C.</div> | | |
| C. Will the child be between 9 and 17 months of age inclusive, during the study recruitment period?
WILL1217 | (1)
(HOLD) | (2)
(INEL) |
| 3. Has informed consent been obtained?
CONSNT04 | (1) | (2)
(HOLD) |
| 4. Has HIPAA authorization form been obtained?
HIPAA04 | (1) | (2)
(HOLD) |
| 5. Does the family have telephone service for contact as required?
PHONE04 | (1) | (2)
(HOLD) |

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"/>
	-	

H.	Transcranial doppler	TRNDP_DT	<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"/>	TRNDP_ND	(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: **VISIT** M - **sequence #** **SEQNO**

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

PART II: MEDICAL HISTORY

1. Sick 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" value=""/> <input type="text" value=""/>				
	1. For fever	FEVERBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	FEVER_NA
B.	Dactylitis	DACTBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	DACTBLNA
	1. Age of first dactylitis	AGEDACT	<input type="text" value=""/> <input type="text" value=""/>	months	(1)	N/A	AGEDACNA
C.	Pain	PAINBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	PAINBLNA
D.	Acute chest syndrome	ASCBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	ASCBL_NA
E.	Priapism	PRIAPBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	PRIAPNA
F.	Splenic sequestration	SPLSEQBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	SPLSEQNA
G.	Transfusion	TRNSFBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	TRNS_NA
H.	Bacteremia/sepsis other than meningitis	SEPSISBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	SEPSISNA
I.	Meningitis	MENINBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	MENIN_NA
J.	Aplastic crisis	APLCRBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	APLCR_NA
K.	Transient ischemic attack	TIABL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	TIABL_NA
L.	Seizures (non-febrile)	SEIZNFBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	SEIZNFNA
M.	Seizures (febrile)	SEIZFBL	<input type="text" value=""/> <input type="text" value=""/>		(1)	N/A	SEIZFBNA
N.	Osteomyelitis	OSTEOMBL	<input type="text" value=""/> <input type="text" value=""/>		(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"/> | (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.	PCRTOCPN	(1)		
	<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									
<table border="1" style="display: inline-table; border-collapse: collapse;"> <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; border-collapse: collapse;"> <tr> <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; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>		

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:

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

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)

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

--	--	--

Seq

--	--

-

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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 -

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

ID Number

--	--	--	--

Visit

--	--	--

 -

Seq

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PART I: IDENTIFYING INFORMATION

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

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

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
<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"/>

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** (1) Not Returned (2) Lost **RXNORET**
- B. Approximately how much volume **VOLLFT** cc (1) N/A **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

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

BIOCHND

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: - - (Ideal earliest start date) **VIS_DT**
Month Day Year

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**

*1. Specify: **NODOCSP**

- | | 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**

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: - - ^{VISIT_DT}
 Month Day Year

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) ^{F80I12}

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. 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} ^{SPCPITND}

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:

--	--

 -

--	--

CERT_NO

B. Signature: _____ CERT_SIG

C. General Comments: GEN_CMNT

ID Number

--	--	--	--

Visit Seq

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 -

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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 |
| F. Immunology (record labels on Form 42) | SPC_IMMN | | Yes
(1) No
(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 No
 (1) (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"/> <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
- | | | |
|--|---|--------------------------------|
| | HEIGHT3 <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm | Average Height = HEIGHT |
|--|---|--------------------------------|
- (If #1 and #2 differ by more than 0.5 cm)
- D. Rate hair style interference on child's length
- | | | |
|-----------|-----|-----------------|
| None | (1) | HAIRHGHT |
| 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
- | | | |
|--|--|--------------------------------|
| | WEIGHT3 <input type="text"/> <input type="text"/> . <input type="text"/> kg | Average Weight = WEIGHT |
|--|--|--------------------------------|
- (If #1 and #2 differ by more than 0.2 kg)

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}

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

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} ^{SEQNO}
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 (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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Seq

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PART III: MENTAL SCALE (Continued)

Item No.	Code						Code						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

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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

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MOTPDI 113. PDI Score

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114. 95% CI

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MOT95CIL

MOT95CIH

ID Number

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Visit

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Seq

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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															
	<table border="0" style="width: 100%;"> <tr> <td style="text-align: center;">1</td><td style="text-align: center;">2</td><td style="text-align: center;">3</td><td style="text-align: center;">4</td><td style="text-align: center;">5</td> <td style="text-align: center;">1</td><td style="text-align: center;">2</td><td style="text-align: center;">3</td><td style="text-align: center;">4</td><td style="text-align: center;">5</td> <td style="text-align: center;">1</td><td style="text-align: center;">2</td><td style="text-align: center;">3</td><td style="text-align: center;">4</td><td style="text-align: center;">5</td> </tr> </table>	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
1	2	3	4	5	1	2	3	4	5	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)	13. (1) (2) (3) (4) (5) 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) 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)															
	BEH25 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) BEH30 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: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	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	COM49	49.	O	O	O	O	O			
			25.	O	O	O	O	O		50.	O	O	O	O	O			
COM1	1.	O	O	O	O	O				51.	O	O	O	O	O			
	2.	O	O	O	O	O				52.	O	O	O	O	O			
	3.	O	O	O	O	O				53.	O	O	O	O	O			
	4.	O	O	O	O	O				54.	O	O	O	O	O			
	5.	O	O	O	O	O				55.	O	O	O	O	O			
	6.	O	O	O	O	O				56.	O	O	O	O	O			
	7.	O	O	O	O	O				57.	O	O	O	O	O			
	8.	O	O	O	O	O				58.	O	O	O	O	O			
	9.	O	O	O	O	O				59.	O	O	O	O	O			
	10.	O	O	O	O	O				60.	O	O	O	O	O			
	11.	O	O	O	O	O				61.	O	O	O	O	O			
	12.	O	O	O	O	O				62.	O	O	O	O	O			
	13.	O	O	O	O	O				63.	O	O	O	O	O			
	14.	O	O	O	O	O				64.	O	O	O	O	O			
	15.	O	O	O	O	O				65.	O	O	O	O	O			
	16.	O	O	O	O	O				66.	O	O	O	O	O			
	17.	O	O	O	O	O			COM67	67.	O	O	O	O	O			
	18.	O	O	O	O	O												
	19.	O	O	O	O	O				68.	Raw Domain Score		<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>					
	20.	O	O	O	O	O				69.	Standard Score		<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>					
	21.	O	O	O	O	O				70.	95% Conf. Level		<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>					
	22.	O	O	O	O	O				71.	Percentile Rank		<table border="1" style="display: inline-table; vertical-align: middle;"> <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>					
COM23	23.	O	O	O	O	O	COM48	48.	O	O	O	O	O	O	O			

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	DLS40	40.	0	0	0	0	0
Item No.	Code						20.	0	0	0	0		41.	0	0	0	0	0
	1	2	0	N	DK		21.	0	0	0	0		42.	0	0	0	0	0
DLS1	1.	0	0	0	0		22.	0	0	0	0		43.	0	0	0	0	0
	2.	0	0	0	0		23.	0	0	0	0		44.	0	0	0	0	0
	3.	0	0	0	0		24.	0	0	0	0		45.	0	0	0	0	0
	4.	0	0	0	0		25.	0	0	0	0		46.	0	0	0	0	0
	5.	0	0	0	0		26.	0	0	0	0		47.	0	0	0	0	0
	6.	0	0	0	0		27.	0	0	0	0		48.	0	0	0	0	0
	7.	0	0	0	0		28.	0	0	0	0		49.	0	0	0	0	0
	8.	0	0	0	0		29.	0	0	0	0		50.	0	0	0	0	0
	9.	0	0	0	0		30.	0	0	0	0		51.	0	0	0	0	0
	10.	0	0	0	0		31.	0	0	0	0		52.	0	0	0	0	0
	11.	0	0	0	0		32.	0	0	0	0		53.	0	0	0	0	0
	12.	0	0	0	0		33.	0	0	0	0		54.	0	0	0	0	0
	13.	0	0	0	0		34.	0	0	0	0		55.	0	0	0	0	0
	14.	0	0	0	0		35.	0	0	0	0		56.	0	0	0	0	0
	15.	0	0	0	0		36.	0	0	0	0		57.	0	0	0	0	0
	16.	0	0	0	0		37.	0	0	0	0		58.	0	0	0	0	0
	17.	0	0	0	0		38.	0	0	0	0		59.	0	0	0	0	0
DLS18	18.	0	0	0	0	DLS39	39.	0	0	0	0	DLS60	60.	0	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:

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

PART VI: MOTOR SKILLS

A. Data Rows

1. Starting Row **MSSTROW**

2. Ending Row **MSENDROW**

B. RECORD FORM DATA: MTSK14						1 2 0 N DK					1 2 0 N DK																			
Item No.	1	2	0	N	DK	14.	15.	16.	17.	18.	19.	20.	21.	22.	23.	24.	25.	26.	27.	28.	29.	30.	31.	32.	33.	34.	35.	36.		
						MTSK14																MTSK30								
MTSK1	1.	0	0	0	0		17.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		33.	0	0	0	0	0	0	0
	2.	0	0	0	0		18.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		34.	0	0	0	0	0	0	0
	3.	0	0	0	0		19.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		35.	0	0	0	0	0	0	0
	4.	0	0	0	0		20.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	MTSK36	36.	0	0	0	0	0	0	0
	5.	0	0	0	0		21.	0	0	0	0	0	0	0	0	0	0	0	0	0	0									
	6.	0	0	0	0		22.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		37.	Raw Domain Score	<input type="text"/>					
	7.	0	0	0	0		23.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		MTSKRAW							
	8.	0	0	0	0		24.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		38.	Standard Score	<input type="text"/>					
	9.	0	0	0	0		25.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		MTSKSTRD							
	10.	0	0	0	0		26.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		39.	95% Conf. Level	±	<input type="text"/>				
	11.	0	0	0	0		27.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		MTSK95CL							
	12.	0	0	0	0		28.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		40.	Percentile Rank	<input type="text"/>		.	<input type="text"/>		
MTSK13	13.	0	0	0	0	MTSK29	29.	0	0	0	0	0	0	0	0	0	0	0	0	0	0		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 -

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
 A. Hep B in series - - (1) N/D (2) N/A
- HB2WSEQ** **HB2WDT** **HB2WND**
3. 6-weeks to 2-months of age vaccinations: sequence
 A. DTaP in series - - (1) N/D (2) N/A
- DT6WSEQ** **DT6WDT** **DT6WND**
- 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
 A. DTaP in series - - (1) N/D (2) N/A
- DT4MSEQ** **DT4MDT** **DT4MND**
- 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 - - (1) N/D (2) N/A
 DT6MSEQ DT6MDT DT6MND

B. Hib - - (1) N/D (2) N/A
 HO6MSEQ HO6MDT HO6MND

C. Pneumo-conjugate (PCV 7) - - (1) N/D (2) N/A
 PN6MSEQ PN6MDT PN6MND

6. 6-18 months of age vaccinations:

A. DTaP - - (1) N/D (2) N/A
 DT12MSEQ DT12MDT DT12MND

B. Hib - - (1) N/D (2) N/A
 HO12MSEQ HO12MDT HO12MND

C. IPV - - (1) N/D (2) N/A
 OP12MSEQ OP12MDT OP12MND

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

E. Hep B - - (1) N/D (2) N/A
 HB12MSQ1 HB12MDT1 HB12MND1

F. MMR - - (1) N/D (2) N/A
 MM12MSEQ MM12MDT MM12MND

G. Varicella - - (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) **CD4BLLBL**

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** **Month** - **Day** - **Year** (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 **WETSNITE**
 More than 5 times/week (1)
 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 | DESCLOSL
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

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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

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PART V: CRAWLING AND WALKING

1. Does the child ordinarily walk independently? Yes No **WALKINDE**
(1) (2)
- If No, complete question V-1A, then go to PART VI.
 If Yes, go to question V-1B.

A. CRAWLING AND WALKING (Awake):

(observe child in underclothes or in tight top and shorts).
 Complete 1 through 9, then go to PART VI.

Does Task Does Not Do Task Not Able to Assess

- | | | | | |
|--|-----|-----|-----|-----------------|
| 1. Crawls on four limbs for 9 inches or more | (1) | (2) | (3) | CRWL9IN |
| 2. Pulls-to-stand | (1) | (2) | (3) | PULL2STD |
| 3. Stands alone for at least 3 seconds | (1) | (2) | (3) | STND3SEC |
| 4. Stands alone for at least 30 seconds | (1) | (2) | (3) | STND30S |
| 5. Takes at least 3 steps with support | (1) | (2) | (3) | STEP3SPT |
| 6. Takes at least 3 steps holding onto furniture | (1) | (2) | (3) | STEP3HOL |
| 7. Takes at least 3 steps without support | (1) | (2) | (3) | STEP3ALN |
| 8. Gets up off floor to standing without help | (1) | (2) | (3) | STDUPALN |
| 9. Walks independently for at least 6 feet | (1) | (2) | (3) | WALK6FT |

Codes:

- 1 - Absent
 2 - Present
 8 - Not able to assess

B. GAIT FOR CHILDREN WHO WALK INDEPENDENTLY

Have the child walk a distance of 6' away from examiner, turn around, and walk back. Repeat task, observing from side.

- | | RIGHT | LEFT |
|-------------------------------|--|--|
| 1. Knee flexion | <input type="checkbox"/> KNEEFLXR | <input type="checkbox"/> KNEEFLXL |
| 2. Knee hyperextension | <input type="checkbox"/> KNEHYPER | <input type="checkbox"/> KNEHYPEL |
| 3. Toe walking | <input type="checkbox"/> TOEWALKR | <input type="checkbox"/> TOEWALKL |
| 4. Circumducting gait | <input type="checkbox"/> CIRCGTR | <input type="checkbox"/> CIRCGTL |
| 5. Decreased arm swing | <input type="checkbox"/> DECRSWNR | <input type="checkbox"/> DECRSWNL |
| 6. Cortical arm posture | <input type="checkbox"/> CORARMPR | <input type="checkbox"/> CORARMPL |
- (persistent adduction at shoulder w/flexion at elbow, with/without forearm pronation)

ID Number

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Visit Seq

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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

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

LIVER-SPLEEN SCAN PERFORMANCE

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: - - ^{Month} ^{Day} ^{Year} ^{VISIT_NO}

PART II: SCAN SPECIFICS

1. Camera manufacturer: ^{CAMTYPE}
2. Camera Model: ^{CAMMODEL}
3. Collimator: ^{COLLIMAT}
4. Supplier of TC-sulfur colloid: ^{SUPCOLLD}
5. Dose injected: . mCi ^{DOSINJ4}
6. Time of injection (24-hour clock): ^{INJ44HR} : ^{INJ44MN}
7. Time imaging started: ^{IMSTRHR} : ^{IMSTRMN}
8. Time imaging completed: ^{IMCOMHR} : ^{IMCOMMN}
9. Camera angle: ° ^{CAMANGLE}
10. True Posterior imaging time (min:sec): ^{ANTPOSMN} : ^{ANTPOSSC}
11. Right Posterior Oblique Image Counts: ^{OBLIMCNT}
12. Film Label: ^{LSSCNLBL}

13. Adequacy of Imaging (Answer both questions):

	Yes	No	
A. 400 K Image adequate?	(1)	(2)	^{AOI400K}
B. Timed Image adequate?	(1)	(2)	^{AOITIMED}

If both are **No**, child is ineligible. **Skip** to PART IV.

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

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Visit

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Seq

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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

TSRRTTOT .

2. Counts/pixel

TSRRTCNT .

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

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Seq

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**ABDOMINAL SONOGRAM
(ULTRASOUND) PERFORMANCE**

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: - - ^{Month} ^{Day} ^{Year} ^{VIS_DT}

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}
- _____

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** - **SEQNO**
sequence #
5. Procedure Date: - -
Month Day Year **VISIT_DT**

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

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

INCEX_SP

^B. TCD Label

TCD_LBL

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

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

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} - ^{sequence #} ^{SEQNO}
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}

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ID <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	2. Current Clinic: SITE <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>
3. Patient's Letter Code: INITS <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	4. Preliminary Week #: VISIT sequence # <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> SEQNO
5. Preliminary Event Start Date: <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> Month Day Year	VIS_DT
6. Actual Week Number: <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> ACTVISIT sequence # ACTSEQNO	
7. Actual Event Start Date: <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> Month Day Year	START_DT
8. Actual Event Ending Date: <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> Month Day Year	E_END_DT

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"/>
	-	

***PART III: ADDITIONAL DIAGNOSIS INFORMATION**

If PART II, Item 1C is **YES**, answer 1. Otherwise, skip to 2.

1. Acute Chest Syndrome None 1 lobe > 1 lobe N/A
- A. New Infiltrate ACSNINF (1) (2) (3) (4)
- B. O₂% Saturation on Room Air at Presentation ACSSRAP _____ . _____ %
- C. Oxygen Administered ACSOXADM _____ . _____ L
- Yes No
- D. Mechanical Ventilation ACSMVENT (1) (2)

If PART II, Item 1E is **YES**, answer 2. Otherwise, skip to 3.

2. Splenic sequestration
- A. Spleen size below LCM SPLNSIZE
- | | | | | | |
|-------|--------|--------|--------|-------|-----|
| <2 cm | 2-4 cm | 4-6 cm | 6-8 cm | >8 cm | N/A |
| (1) | (2) | (3) | (4) | (5) | (6) |
- B. Nadir hemoglobin SPLNHMGL _____ . _____ gm/dL
- C. Platelet count at time of nadir hemoglobin SPLPTCNT [] [] [] [] [] k/ μ L

If PART II, Item 1N is **YES**, answer 3. Otherwise, skip to 4.

3. A. Sepsis SEPSBACT (1)* (2)
- *1. Organism genus.species [] . [] [] [] [] [] [] [] [] [] [] [] [] []
- SEPORGGN SEPORGSS
- Yes No
- B. Meningitis (1)* (2)
- *1. Bacterial (1)* MNGTBACT
- *a. Organism genus.species [] . [] [] [] [] [] [] [] [] [] [] [] [] []
- MNGORGGN MNGORGSS
- Viral (2)
- Unknown (3)

If PART II, Item 1Q is **YES**, answer 4. Otherwise, skip to 5.

4. Acute Osteomyelitis Yes No
- A. Organism known ACOSTORG (1)* (2)
- *1. Genus.species [] . [] [] [] [] [] [] [] [] [] [] [] [] []
- AOSORGGN AOSORGSS
- B. Bone Infected []
- ACOSTBON

ID Number Visit Seq

[] [] [] [] [] [] [] [] - [] []

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

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Visit

--	--	--

-

Seq

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^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

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

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 | <input type="text"/> <input type="text"/> <input type="text"/> cc | | | TRVOLWBL |
| | OR | | | |
| 2. Packed Red Cells | <input type="text"/> <input type="text"/> <input type="text"/> cc | | | TRVOLPR2 |
| c. Start Date: | TSTRT_DT | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | - | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| d. Stop Date: | TSTOP_DT | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | - | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
- | | | | | |
|--|-----------------|------|-----|-----|
| 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: - - DEATH_DT
 Month Day Year

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

PEDIATRIC HYDROUREA CLINICAL TRIAL

CONCOMITANT MEDICATIONS

PART I: IDENTIFYING INFORMATION

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

PART II: CON MED COLLECTION REASON

1. Please indicate why this form is being submitted.
- Serious Adverse Event (1) (REASON)
 PK Specimen Collection (2)
2. Date of corresponding event:* (Month) - (Day) - (Year) (EVENT_DT)

* For an SAE, enter the Preliminary Event Start Date from Form 50.
 For PK Specimen Collection, enter the Visit Start Date from Form 22 or the Visit Date from Form 23.

PART III. MEDICATIONS

1. Supplements	SUPPLE			
	YES	NO		
A. Did the patient receive supplements?	(1)*	(2)		
*B. If YES, check all that are applicable for each supplement.	(a) Not Received	(b) Within 3 Days of PK Collection	(c) Within 7 Days of SAE onset	(d) Until close of SAE
1. Ascorbic Acid (Vitamin C)	(1)	(1)	(1)	(1)
2. Folic Acid (Folate)	(1)	(1)	(1)	(1)
3. Multivitamin	(1)	(1)	(1)	(1)

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

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
	(d)		Until close of SAE
*B.	If YES, check all that are applicable for each antibiotic.	Not Received	
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
	(d)		Until close of SAE
*B.	If YES, check all that are applicable for each analgesic.	Not Received	
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								
<table border="1" style="display: inline-table; border-collapse: collapse;"> <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; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>		

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

PEDIATRIC HYDROXYUREA CLINICAL TRIAL
PRE-OPERATIVE TRANSFUSION

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number: 2. Current Clinic:
- 3. Patient's Letter Code: 4. Visit: -
- 5. Transfusion Date: - -

ID

SITE

INITS

VISIT

Sequence #

SEQNO

VIS_DT

PART II: TRANSFUSION

- 1. Transfusion Type: (1) Simple TR_TYPE
(2) Exchange
- 2. Volume (answer A or B):
A. Whole Blood cc TRVOLWBL

OR

B. Packed Red Cells cc TRVOLPR2
- 3. Start Date: - -
Month Day Year TSTRT_DT
- 4. Stop Date: - -
Month Day Year TSTOP_DT
- 5. Transfusion Reason: _____ TR_SP

PART III: COORDINATION

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

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: **ENDCOND**

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 # 0 0 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

STUDY TREATMENT DOSING IRREGULARITY

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:

--	--	--

 -

--	--

 -

--	--	--	--

^{VIS_DT}

Month
Day
Year

PART II: DOSING IRREGULARITY OCCURRENCE

1. Person initiating request:

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

^{PERINREG}

2. Contact Number:

--	--	--

 -

--	--	--

 -

--	--	--	--

^{CONT_NO}

3. Circumstances of dosing irregularity (Answer each item):

	YES	NO	
A. Medical emergency	(1)	(2)	MEDEMERG
B. Non-medical emergency	(1)	(2)	NONMEDEM
C. Possible or real study treatment overdose	(1)	(2)	OVERDOSE
D. Other	(1)	(2)	DOSOTHER
1. If other, specify: _____			

PART III: UNBLINDING OF STUDY TREATMENT

1. Was the patient unblinded?

YES	NO
(1)	(2)

^{UNBLIND}

If NO, skip to Part IV.

2. Unblinding would change the clinical treatment of the patient

YES	NO
(1)*	(2)

^{UNBLCHNG}

3. Unblinding was done by (Answer each item):

	YES	NO	
A. MCC Medical Consultant	(1)	(2)	UNBLMC
B. Medical Coordinating Center	(1)	(2)	UNBLCC

4. Individuals informed of the assigned study treatment (Answer each item):

	YES	NO	
A. Principal Investigator	(1)*	(2)	INDPRINV
B. Clinic Coordinator	(1)*	(2)	INDCOORD
C. Patient/Family	(1)*	(2)	INDPTNT
D. Other	(1)*	(2)	INDOTHER
1. If other, specify: _____			

5. If any*, submit Form 80

(1)	(2)
-----	-----

^{F80III5}

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

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: - - **VIS_DT**
Month Day Year

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

- 1.
- | | | | |
|---|----------------------|---|--|
| Form | Rev | Page | INITIALS
(MCC use only) |
| <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> |
| 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**

MRI READING

PART I: IDENTIFYING INFORMATION

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

PART II: TO BE COMPLETED BY READER

1. Reader [Last Name]: **RDR81**
2. Date read: - - **RDR81_DT**
Month Day Year
3. Film Label **MRI_LBL**
4. SCAN QUALITY
- | | | | |
|--|------------------------------------|-----|---------------|
| | Excellent | (1) | QUAL81 |
| | Slight Artifact/Motion, Adequate | (2) | |
| | Severe Artifact/Motion, Inadequate | (3) | |
5. VOLUMETRICS
- | | | | |
|---------------------|---------------------------------|-----|----------------|
| | Acceptable | (1) | VOLUM81 |
| (Final assessment): | Acceptable after reprocessing | (2) | |
| | Unacceptable after reprocessing | (3) | |
| | Not assessed | (4) | |
6. CURRENT READING STATUS: **STATUS 81**
- | | |
|---|-----|
| Scan is acceptable and reading is complete | (1) |
| Scan is being returned for reprocessing before reading can be performed | (2) |
| Scan is unacceptable and reading will not be completed | (3) |
- F80II5A**
- | | | |
|--------------------------------------|-----|-----|
| A. If (2) or (3), Form 80 submitted? | (1) | (2) |
| | Yes | No |
7. GENERAL APPEARANCE (MARK ONE): **ATROPHY**

- No atrophy (1)
- Atrophy (2)
- Equivocal (3)

If (1), SKIP to Part III.

- A. GENERAL: Yes (1) ATR_GENL
- No (2)

If (2), SKIP to Item 7B.

- 1. Sulcal: Yes (1) ATRGSULC
- No (2)

- 2. Ventricular Yes (1) ATRGVENT
- No (2)

- 3 Level of Severity Mild (1) ATR_SEV
- Moderate (2)
- Severe (3)

- B. FOCAL Yes (1) ATR_FOCL
- No (2)

If (2), SKIP to PART III.

- 1. Sulcal Yes (1) ATRFULC
- No (2)

- 2. Ventricular Yes (1) ATRFVENT
- No (2)

- 3. Specify Area: _____ FOCAL_SP

ID Number	Visit	Seq										
<table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 25px;"></td><td style="width: 25px;"></td><td style="width: 25px;"></td><td style="width: 25px;"></td></tr></table>					<table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 25px;"></td><td style="width: 25px;"></td><td style="width: 25px;"></td><td style="width: 25px;"></td></tr></table> -					<table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 25px;"></td><td style="width: 25px;"></td></tr></table>		

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

 -

2. VASCULAR REGION OF INFARCT
 (Check appropriate sides):

	1. RIGHT		2. LEFT		
	YES	NO	YES	NO	
A. ICC	VRIICC_R	(1) (2)	(1) (2)	VRIICC_L	
B. ICS	VRIICS_R	(1) (2)	(1) (2)	VRIICS_L	
C. MCA	VRIMCA_R	(1) (2)	(1) (2)	VRIMCA_L	
D. ACA	VRIACA_R	(1) (2)	(1) (2)	VRIACA_L	
E. PCA	VRIPCA_R	(1) (2)	(1) (2)	VRIPCA_L	
F. Basilar	VRIBSL	YES (1)	No (2)		
G. Anterior border zone	VRIABZ	(1)	(2)		
H. Posterior border zone	VRIPBZ	(1)	(2)		
I. Centrum semiovale border zone	VRICSB	(1)	(2)		
J. Striatum (lenticulostriates)	VRISTR	(1)	(2)		

4. BONY CHANGES (Mark One):

	Normal (1)	Diffuse thickening (2)	BONY_CHG Focal Abnormality (3)	
A. If (3), Form 80 submitted?			(1) Yes	(2) No F80III4A

	Yes (1)	No (2)	Cannot grade (3)
5. Other lesions OTHLESN	(1)	(2)	(3)
A. If yes, Form 80 submitted?	(1)	(2)	F80III5A

6. Are DWI films available for this review?	(1)	(2)	DWIFAVAI
A. If yes, Form 80 submitted	(1)	(2)	F80III6A

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 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"/>
----------------------	----------------------	----------------------	----------------------

Visit

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

-

Seq

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

LIVER-SPLEEN SCAN CENTRAL 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 - Reader # SEQNO
- 5. Procedure Date: - - VIS_DT

Month
Day
Year

PART II: LIVER-SPLEEN SCAN QUALITY

- 1. Reader's last name RDR84
- 2. Date of reading - -

Month
Day
Year

RD84_DT
- 3. Film label number: LSSCNLBL
- 4. Current status of this reading QUAL84
 - Quality adequate and reading complete (1)
 - Quality inadequate for reading (2)

Yes	No
(1)	(2)

A. If Item 4 is (2), submit Form 80 (1) (2)

If Item 4 is (2), Skip to Part IV. F80II3A

PART III: RESULTS

- 1. Splenic uptake (answer only one): SPLUPT84
 - A. Normal (1)
 - B. Present, but decreased (2)
 - C. Absent (3)

PART IV: COORDINATION (MCC)

- 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 - Reader #
SEQNO
5. Procedure Date: - -
Month Day Year VIS_DT

PART II: EQUIPMENT

1. Reader's last name RDR85
2. Date of reading - -
Month Day Year RDR85_DT
3. Film label number:
4. Current status of this reading STATUS85
- | | | | |
|---|-----|-----|---------|
| Quality adequate and reading complete | (1) | | |
| Returned for reprocessing | (2) | | |
| Quality inadequate for reading after reprocessing (final) | (3) | | |
| | Yes | No | |
| A. If (2) or (3), submit Form 80 | (1) | (2) | F80II3A |
- If (2) or (3), Skip to Part IV.

PART III: RESULTS

- | | | | | |
|----------------|---------|--------|-----|----------|
| | Present | Absent | N/A | |
| 1. Gallbladder | (1) | (2) | (3) | GALBLA85 |
- If not present, SKIP to ITEM 2.
- | | | | | |
|------------------------------|---------|----------|--------|----------------|
| | | | | |
| A. If Present | | | | |
| Normal thin wall | (1) | | | GBWALL85 |
| Thick walled or edema | (2) | | | |
| Not able to assess | (3) | | | |
| | Minimal | Moderate | Marked | N/D |
| B. Color Doppler vascularity | (1) | (2) | (3) | (4)
GBCDV85 |

C. If gallbladder present, answer C1 or
 1. Number of stones **GBNSTN85**
 OR Yes
 2. Multiple stones not countable (1) **GBMSTN85**

D. Largest stone mm **GBLGST85** (1) N/A
GBLGSTNA

E. Stones freely mobile? **GBSFM85** Yes No N/A
 (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)

G. Sludge **GBSLDG85** Present Absent N/A
 (1) (2) (3)

H. Pericholecystic fluid **GBPRFL85** (1) (2) (3)

2. Spleen **SPLEEN85** (1) (2) (3)

If not present, SKIP to ITEM 3.

A. Accessory spleen(s) **ACCSP85** (1) (2) (3)

B. Cephalocaudad length . cm **SPLCLN85**

C. Transverse . cm **SPLTRN85**

D. Anterior - Posterior . cm **SPLANP85**

E. Estimated total spleen volume **SPLVOL85** 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)

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

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

C. Echogenicity	LKECHO85	(1)	(2)	(3)
-----------------	-----------------	-----	-----	-----

1. If abnormal, explain:	_____			LKECEX85
--------------------------	-------	--	--	-----------------

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

B. Signature:	_____	CERT_SIG
---------------	-------	-----------------

C. General Comments:	GEN_CMNT
----------------------	-----------------

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

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

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 _____ ADINFOSP

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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		Yes	No
2. Event Severity			
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
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