

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

PART IV: SPECIAL STUDIES

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

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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**

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- | | | | |
|---|---|----------------|-----|
| | | 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 | |
|--|----------------|---|----|--|
- (If #1 and #2 differ by more than 0.5 cm) **Average Height = HEIGHT**
- 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 | |
|--|----------------|--|----|--|
- (If #1 and #2 differ by more than 0.2 kg) **Average Weight = WEIGHT**

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

4. Child's head circumference

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

B. Measurement #2 HEADC2 . cm

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

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

5. Anthropometry measurement date: - - ANM_DT

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

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

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

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

8. Routine treatments since last visit? Yes No N/A
 A. Did the child take their night-time dose of twice PENCILN (1) (2) (3)*
 daily prophylactic penicillin last night?

1. If no, did the child take another antibiotic? ANTIB (1) (2)
 a. Specify: _____ ANTIB_SP

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

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- 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
(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**

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