BABY HUG FOLLOW-UP STUDY II
SERIOUS ADVERSE EVENT
(ACTIVE GROUP ONLY)

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: ___ ___ ___ ___ SUBJECT_ID
2. Current Clinic: ___ ___ SITE_ID
3. Patient's Letter Code: ___ ___ ___ LETTER_CD
4. Reporting Date: VISIT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
   Month Day Year

PART II: EVENT PERIOD

1. Date of Event
   A. Event Start Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ START_DT
   Month Day Year
   B. Event End Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ E_END_DT
   Month Day Year
2. Qualifying Procedure (Event must have occurred during the 5 days following an "Active" assessment procedure.) Please note all that apply:
   A. Liver/Spleen Scan LIVER_SPLEEN_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year (1) N/A LIVER_SPLEEN_NA
   B. Abdominal Sonogram ABD_SONO_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year (1) N/A ABD_SONO_NA
   C. WISC IV WISC4 ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year (1) N/A WISC4_NA
   D. Blood Specimens BLOOD_SPEC_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year (1) N/A BLOOD_SPEC_NA
   E. TCD TCD_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year (1) N/A TCD_NA
   F. PFT PFT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year (1) N/A PFT_NA
   G. Cardiac Echocardiogram CARDIAC_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year (1) N/A CARDIAC_NA

H.	MRI	MRI_DT	___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year	(1)	N/A MRI_NA
I.	MRA	MRA_DT	___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year	(1)	N/A MRA_NA
J.	Vineland	VINELAND_DT	___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year	(1)	N/A VINELAND_NA
K.	Connor CPT II	CONNORCPT2_DT	___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year	(1)	N/A CONNORCPT2_NA
L.	Peds QOL	PEDSQOL_DT	___ ___ ___ - ___ ___ - ___ ___ ___ ___ Month Day Year	(1)	N/A PEDSQOL_NA

PART III: SAE

			YES	NO
1.	Please indicate all diagnoses:			
A.	Acute Chest Syndrome	HX_ACS	(1)	(2)
B.	Splenic Sequestration Crisis	HXSPLSEQ	(1)	(2)
C.	Prolonged Hospitalization (greater than 7 days)	LONGHOSP	(1)	(2)
D.	Stroke or TIA	HX_STROKE_TIA	(1)	(2)
E.	Life Threatening Event	LIFE_THREAT_EVT	(1)	(2)
	1. Specify: _____	LIFE_THREAT_EVT_SP		
F.	Death	HX_DEATH	(1)	(2)
G.	ICU Admission	ICU	(1)	(2)

PART IV: ADDITIONAL DIAGNOSIS INFORMATION

If PART III, Item 1A is YES, answer 1. Otherwise, skip to 2.

		None	1 Lobe	>1 Lobe	N/A	
1.	Acute Chest Syndrome					
A.	New Infiltrate	(1)	(2)	(3)	(4)	ACSNINF
B.	O_2% Saturation on Room Air at Presentation	_____	_____	. _____%		ACSSRAP
C.	Oxygen Administered	_____	_____	. _____L		ACSOXADM
D.	Mechanical Ventilation	Yes (1)		No (2)		ACSMVENT

If PART III, Item 1B is YES, answer 2. Otherwise, skip to 3.

ID Number

2. Splenic Sequestration

A. Spleen size below LCM **prior** to SAE SPLNSIZE_PRIOR

<2 cm	2-4 cm	4-6 cm	6-8 cm	>8 cm
(1)	(2)	(3)	(4)	(5)

B. Spleen size below LCM **during** SAE SPLNSIZE_DURING

<2 cm	2-4 cm	4-6 cm	6-8 cm	>8 cm
(1)	(2)	(3)	(4)	(5)

C. Nadir hemoglobin ___ ___ . ___ gm/dL SPLNHMGL

D. Platelet count at time of nadir hemoglobin ___ ___ ___ ___ k/µL SPLPTCNT

If PART III, Item 1C is YES, answer 3. Otherwise, skip to 4.

3. Prolonged Hospitalization

A. Reason: LONGHOSP_SP

_____

_____

_____

If PART III, Item 1D is YES, answer 4-5. Otherwise, skip to Part V.

4. (Stroke or TIA) Findings of		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)

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5. 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)

PART V: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

Complete PART V for each item in PART III checked YES.

PROBLEM	ONSET_DT	NUMDAYS	SEVERITY	ATTR_TRT	DIAGUNXP
1. Diagnosis/ Problem	2. Date of Onset	3. Number of Days	4. [1]Severity	5. [2]Attribution to Study Treatment	6. [3]Diagnosis Unexpected

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

ID Number

PART VI: REPORTABLE TREATMENTS

1. Answer each item		YES	NO	N/A
A. Transfusion	TRANSFUS	(1)	(2)	(3)

1. If yes, complete a. – d. Otherwise, skip to B.

a. Transfusion Type: TR_TYPE (1) Simple (2) Exchange

b. Volume, answer b 1 or 2.

1. Whole Blood TRVOLWBL ____ ____ ____ cc

OR

2. Packed Red Cells TRVOLPR2 ____ ____ ____ cc

c. Start Date: TSTRT_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

d. Stop Date: TSTOP_DT ___ ___ ___ - ___ ___ - ___ ___ ___ ___
Month Day Year

		YES	NO	N/A
B. Placement on chronic transfusion therapy	CHRTRAN	(1)	(2)	(3)
C. Splenectomy	SPLCTMY	(1)	(2)	(3)
D. Parenteral antibiotics	PAR_ANTI	(1)	(2)	(3)
E. Dialysis, limited course	DIALYS_L	(1)	(2)	(3)

PART VII: HOSPITALIZATION

1. Hospital Name: _____ HOSPNAME

2. City: _____ HOSPCITY

3. State: ____ ____ HOSP_ST 4. Zip Code: ___ ___ ___ ___ ___ HOSP_ZIP

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

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

ID Number

PART VIII: OUTCOMES

			YES	NO
1.	Significant new disability	SNEWDISA	(1)	(2)
2.	Persistent new disability	PNEWDISA	(1)	(2)
3.	Permanent new disability	PERMDISA	(1)	(2)
4.	**DEATH**	DEATH	(1)	(2)

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

B. Location: DTH_LOC

1. Inpatient (1)
2. 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
