

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

Form 025
Revision 1

Tue Sep 22 10:32:16 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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- 5. Admission Date
- 6. Discharge Date

ADM_DT
DISCH_DT

PART VIII: OUTCOMES

- 1. Significant new disability
- 2. Persistent new disability
- 3. Permanent new disability
- 4. Death
 - A. Date of Death
 - B. Location

SNEWDISA
PNEWDISA
PERMDISA
DEATH
DEATH_DT
DTH_LOC

PART IX: COORDINATION

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

CERT_NO
CERT_SIG
GEN_CMNT

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PART VI: REPORTABLE TREATMENTS

1. Answer each item

A. Transfusion

TRANSFUS

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

a. Transfusion Type

TR_TYPE

b. Volume, answer b 1 or 2.

1. Whole Blood

TRVOLWBL

OR

2. Packed Red Cells

TRVOLPR2

c. Start Date

TSTRT_DT

d. Stop Date

TSTOP_DT

B. Placement on chronic transfusion therapy

CHRTRAN

C. Splenectomy

SPLCTMY

D. Parenteral antibiotics

PAR_ANTI

E. Dialysis, limited course

DIALYS_L

PART VII: HOSPITALIZATION

1. Hospital Name:

HOSPNAME

2. Hospital City:

HOSPCITY

3. Hospital State:

HOSP_ST

4. Hospital Zip:

HOSP_ZIP

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- H. Seizures
- I. Headache
- 5. Results of Imaging Tests

SEIZURE
HEADACHE

- A. MRI of brain
- B. CT scan of brain
- C. PET scan of brain
- D. MRA cerebral vasculature
- E. Transcranial Doppler
- F. Arteriogram

F50MRI
F50CTBR
F50PTBR
F50MRA
F50TCD
F50ARTGR

PART V: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

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

	Diagnosis/Problem	Date of Onset	Number of Days	Severity	Attribution to Study Treatment	Diagnosis Unexpected
1	PROBLEM	ONSET_DT	NUMDAYS	SEVERITY	ATTR_TRT	DIAGUNXP

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- B. Spleen size below LCM during SAE
- C. Nadir hemoglobin (in gm/dl)
- D. Platelet count at time of nadir hemoglobin (in k/ul)

SPLNSIZE_DURING
SPLNHMGL
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
 - A. Loss of consciousness
 - B. Change in mental status
 - C. Loss of or difficulty with speech or vocalization
 - D. Paralysis or weakness
 - E. Difficulty with swallowing
 - F. Difficulty with vision
 - G. Loss of balance or dizziness

LOS_CONS
CHG_MENT
SPEECH
PARALYS
DIFFSWAL
DIFF_SEE
BALANCE

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PART III: SAE

1. Please indicate all diagnoses:

- A. Acute chest syndrome
- B. Splenic Sequestration Crisis
- C. Prolonged Hospitalization (greater than 7 days)
- D. Stroke or TIA
- E. Life Threatening Event
 - 1. Specify
- F. Death
- G. ICU Admission

HX_ACS
HXSPLSEQ
LONGHOSP
HX_STROKE_TIA
LIFE_THREAT_EVT
LIFE_THREAT_EVT_SP
HX_DEATH
ICU

PART IV: ADDITIONAL DIAGNOSIS INFORMATION

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

1. Acute Chest Syndrome

- A. New Infiltrate
- B. O2% Saturation on Room Air at Presentation
- C. Oxygen Administered (in Liters)
- D. Mechanical Ventilation

ACSNINF
ACSSRAP
ACSOXADM
ACSMVENT

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

2. Splenic Sequestration

- A. Spleen size below LCM prior to SAE

SPLNSIZE_PRIOR

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1. Report Date: VISIT_DT

PART II: EVENT PERIOD

1. Date of Event

A. Event Start Date

START_DT
E_END_DT

B. Event Ending Date

**2. Qualifying Procedure (Event must have occurred during the 5 days following a 24 month assessment procedure.)
Please note all that apply:**

A. DTPA/GFR

DTPA_DT

or

DTPA_NA

B. Liver/Spleen Scan

LIVER_SPLEEN_DT

or

LIVER_SPLEEN_NA

C. Abdominal
Sonogram

ABD_SONO_DT

or

ABD_SONO_NA

D. WPPSI

WPPSI_DT

or

WPPSI_NA

E. Blood Specimens

BLOOD_SPEC_DT

or

BLOOD_SPEC_NA
