REPORTABLE EVENT AND/OR HOSPITALIZATION

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: [ ][ ][ ][ ] ID
2. Current Clinic: [ ][ ] SITE
3. Patient's Letter Code: [ ][ ][ ][ ] INITS
4. Preliminary Week #: [ ][ ][ ] - [ ][ ] VISIT sequence # SEQNO
5. Preliminary Event Start Date: [ ][ ][ ] Month - [ ][ ] Day - [ ][ ][ ][ ] Year VIS_DT
6. Actual Week Number: [ ][ ][ ] - [ ][ ] ACTIVISIT sequence # ACTSEQNO
7. Actual Event Start Date: [ ][ ][ ] Month - [ ][ ] Day - [ ][ ][ ][ ] Year START_DT
8. Actual Event Ending Date: [ ][ ][ ] 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.

*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. O_2% 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/µL

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	BALAMCE	(1)	(2)	(3)
H.	Seizures	SEIZURE	(1)	(2)	(3)
I.	Headache	HEADACHE	(1)	(2)	(3)

6. Results of Imaging Tests:

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

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

ID Number ☐☐☐☐ Visit ☐☐☐ - Seq ☐☐

^PART IV: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

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

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

[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 ☐☐☐ cc TRVOLWBL

OR

2. Packed Red Cells ☐☐☐ cc TRVOLPR2

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.	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 ☐☐

PART VI: MANAGEMENT

		Variable	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	Variable
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 [|]