ALFSG	Patient Enrollment	____ ____ Center No	_____ _____ Subject Code	Data Collected? ○No ○Yes	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*) Date of assessment

Form 00: Enrollment (Version 8)

Q01	Date of initial hospital admission	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
Q02	Time of initial hospital admission	__ __ : __ __ (*hh:mm 24 hour format*)
Q03	Hospital transfer?	○ No ○ Yes
Q04	If Yes, date of transfer	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
Q05	Date of Birth	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
Q06	Gender	○ Male ○ Female
Q07	Ethnicity	○ Hispanic or Latino ○ Not Hispanic or Latino
Q08	Race (*check all that apply*)	☐ Black/African American ☐ Asian ☐ American Indian/Alaskan Native ☐ White ☐ Native Hawaiian/Other Pacific Islander ☐ Other
Q09	If other, specify	
Q10	Employment status before subject enrollment	○ Employed-full time ○ Employed-part time ○ Medical disability ○ Student ○ Homemaker ○ Self-employed ○ Retired ○ Other capacity ○ Unemployed ○ Unknown
Q11	Years of education completed since starting 1st grade (Do not count repeated grades)	__ __ *years*
Q12	Marital status	○ Never married ○ Married ○ Divorced ○ Separated ○ Widowed ○ Significant Other ○ Unknown
Comments		

Form 00: Enrollment (Version 8)

Q14	Which version of the ALFSG protocol was approved by your IRB at the time of subject enrollment? Please double check. The study visits and CRFs are posted based on the selected protocol version.		O Prior to version 7 O Version 7 or higher
Q13	Subject is participating in the ALFSG-MBT study		O No O Yes
Q25	Version of the ALFSG-MBT protocol approved by your IRB at the time of subject enrollment		O ALFSG-MBT version 2 O ALFSG-MBT version 3 or higher
Q23	*If Q25 is 'ALFSG-MBT 'version 2'*	Primary reason subject is not participating in the ALFSG-MBT study	O Not between 18 and 70 years of age O Pre-existing chronic renal failure O Contraindicated drug consumption O Chronic hemodialysis O Severe shock O Upper GI bleeding O ALF etiology exclusion O Acetaminophen allergy O Caffeine consumption 24 hours prior to enrollment O Inability to obtain informed consent O Consent declined O Other
Q24	*If Q23 is 'Inability to obtain informed consent' , 'Consent decline', or 'Other'*	Details of inability to obtain informed consent, consent declined, or other	
Q26	*If Q25 is 'ALFSG-MBT version 3 or higher'*	Primary reason subject is not participating in the ALFSG-MBT study	O Not between 18 and 80 years of age O Pre-existing chronic renal failure O Contraindicated drug consumption O Chronic hemodialysis O Severe shock O Upper GI bleeding requiring endoscopy or RBC transfusion O ALF etiology exclusion O ALI due to APAP overdose O Acetaminophen allergy O Caffeine consumption 24 hours prior to enrollment O Inability to obtain informed consent O Consent declined O Other
Q27	*If Q26 is 'Inability to obtain informed consent' , 'Consent decline', or 'Other'*	Details of inability to obtain informed consent, consent declined, or other	
Comments			

Form 00: Enrollment (Version 8)

Q15	Subject is participating in the ALFSG-ROTEM study		O No O Yes
Q20	Version of the ALFSG-ROTEM protocol approved by your IRB at the time of subject enrollment		O ALFSG-ROTEM version 1 O ALFSG-ROTEM version 2 or higher
Q16	*If Q20 is 'ALF-ROTEM version 1'*	Primary reason subject is not participating in the ALFSG-ROTEM study	O Site is not currently enrolling in ALF-ROTEM O Subject was not enrolled in ALFSG with hepatic encephalopathy (ALF) O Subject received plasma, platelet, or cryoprecipitate transfusions during the current admission for ALFSG, including at referring hospitals O Inability to obtain informed consent O Consent declined O Other
Q17	*If Q16 is 'Consent declined' or 'Other'*	Specify details for declined consent or other for ALFSG-ROTEM version 1	
Q21	*If Q20 is 'ALFSG-ROTEM version 2 or higher'*	Primary reason subject is not participating in the ALFSG-ROTEM study	O Site is not currently enrolling in ALFSG-ROTEM O Inability to obtain informed consent O Consent declined O Other
Q22	*If Q21 is 'Inability to obtain informed consent', Consent declined' or 'Other'*	Details of inability to obtain informed consent, consent declined, or other for ALFSG–ROTEM version 2 or higher	
Comments			

ALI	Admission	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 01: ALI Admission Form (Version 2)

ALI Study Eligibility Criteria		
1	Acetaminophen: Jaundice/Illness < 2 wks	○ No ○ Yes
2	**Or**, All other: Jaundice/Illness < 26 wks	○ No ○ Yes
3	Previous sedatives	○ No ○ Yes
4	Altered mental status	○ No ○ Yes
5	Previous FFP	○ No ○ Yes
6	INR ≥ 2.0	○ No ○ Yes
7	ALT of ≥ 10X ULN	○ No ○ Yes
8	Tbili ≥ 3.0 mg/dL	○ No ○ Yes
9	Has patient met eligibility criteria?	○ No ○ Yes ○ Protocol exemption granted
10	If protocol exemption, explain.	
Admission		
11	Date of consent/admission to study	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
12	Time of consent/admission to study	__ __ : __ __ (*hh:mm 24 hour format*)
Physical Exam		
13	Peripheral edema	○ No ○ Yes
14	Hepatomegaly	○ No ○ Yes
15	Hyper-reflexia/clonus	○ No ○ Yes
16	Pupillary Dilatation	○ No ○ Yes

Comments

ALF	Admission: Day1	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 02: ALF Admission Form (Version 2)

Acute Liver Failure Study Group PI: William M. Lee M.D. CRF Version 2. February 03, 2011

ALF Study Eligibility Criteria		
1	Jaundice/Illness < 8 wks	○ No ○ Yes
2	**Or**, Jaundice/Illness ≥ 8 wks and < 26 wks	○ No ○ Yes
3	Previous sedatives	○ No ○ Yes
4	Altered mental status	○ No ○ Yes
5	Previous FFP	○ No ○ Yes
6	INR ≥ 1.5	○ No ○ Yes
7	Has patient met eligibility criteria?	○ No ○ Yes ○ Protocol exemption granted
8	If protocol exemption, explain.	
9	History given by (relation to patient)	
Date of onset of hepatic coma grade <u>prior to admission:</u>		
10	Coma grade date I:	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
11	Coma grade date II:	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
12	Coma grade date III:	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
13	Coma grade date IV:	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
Admission		
14	Date of consent/admission to study	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
15	Time of consent/admission to study	__ __ : __ __ (*hh:mm*)
Physical Exam		
16	Peripheral edema	○ No ○ Yes
17	Hepatomegaly	○ No ○ Yes
18	Hyper-reflexia/clonus	○ No ○ Yes
19	Pupillary Dilatation	○ No ○ Yes
Comments		

○ ALI ○ ALF	Patient Enrollment	___ ___ Center No	_ _ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	

Form 03: Medical History (Version 4)

1	History of present illness:	
	Specific symptoms **Please record symptoms that existed prior to enrollment for the subject's current illness.**	
2	Date of onset of first symptom	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
3	Nausea/Vomiting	○ No ○ Yes ○ Unknown
4	Abdominal pain	○ No ○ Yes ○ Unknown
5	Rash	○ No ○ Yes ○ Unknown
6	Headache	○ No ○ Yes ○ Unknown
7	Malaise	○ No ○ Yes ○ Unknown
8	Fever	○ No ○ Yes ○ Unknown
9	Joint pains	○ No ○ Yes ○ Unknown
10	Jaundice	○ No ○ Yes ○ Unknown
11	If Jaundice, date of onset	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
12	Specify other symptoms	
13	Previous health and illnesses (*Check all that apply and specify diagnosis where applicable and known.)*	☐ None ☐ Collagen/vasc diseases _____ ☐ Chronic liver disease_____ ☐ Endocrine/diabetes_____ ☐ Psychiatric disease_____ ☐ Neuro/seizure_____ ☐ Hypertension_____ ☐ Heart disease_____ ☐ Renal disease_____ ☐ Pulmonary disease_____ ☐ Substance abuse_____ ☐ GI disease_____ ☐ HIV/AIDs_____ ☐ IDU at any time in past_____ ☐ Other_____
14	Pre-ALI/ALF Karnofsky score	○ 100 ○ 90 ○ 80 ○ 70 ○ 60 ○ 50 ○ 40 ○ 30 ○ 20 ○ 10 ○ Unknown

Comments

ALFSG	Patient Enrollment	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	

Form 04: Risk Factors and Past Medication (Version 6)

Risk factors in last six months		
1	IDU	○ No ○ Yes
2a	If IDU, check all that apply	☐ Amphetamines ☐ Narcotics ☐ Cocaine ☐ Other
2b	If other, specify IDU	
3	Usual intake of ETOH during the past 6 months *1 drink ETOH =* • *12 oz or 1 can of beer* • *1.5 oz liquor* • *5 oz or 1 glass of wine* • *12 oz or 1 wine cooler*	○ None (less than 1 drink per week) ○ 1 drink per week ○ 2 drinks per week ○ 3 -6 drinks per week ○ 7-14 drinks per week ○ >14 drinks per week
4	Number of weeks using ETOH during the past 6 months	__ __ (*weeks*)
9	Known drug allergies?	○ No ○ Yes
10	Name drug(s)	
11	Type of reaction	○ Hepatocellular ○ Mixed ○ Cholestatic
12	Rash?	○ No ○ Yes
13	Lymphadenopathy	○ No ○ Yes
14	Eosinophilia (i.e., absolute eosinophil count > 500/ml)	○ No ○ Yes
6	Pre-study NAC treatment	○ IV ○ Oral ○ None ○ Unknown
7	Date pre-study NAC started	__ __- __ __ __-__ __ __ __ (*dd-mmm-yyyy*)
15	Was pre-study NAC stopped prior to enrollment?	○ No ○ Yes
8	If 'yes', date pre-study NAC stopped	__ __- __ __ __-__ __ __ __ (*dd-mmm-yyyy*)

Comments

Form 04: Risk Factors and Past Medication (Version 6)

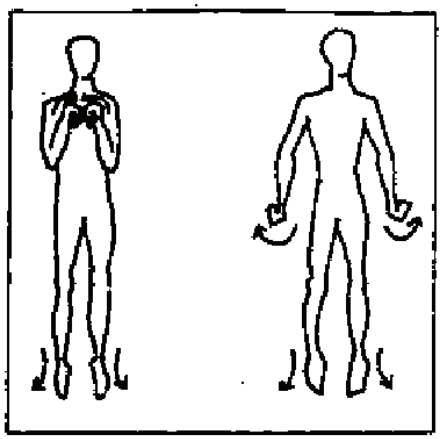
List all medications taken in the 6 months prior to enrollment
including information about acetaminophen overdose, toxins, herbs, mushrooms, OTC meds, vitamins, anesthetics, and anti TB agents.
Combination drugs should be separated and entered on 2 different rows.

No.	A. Medication name (Generic preferred)	B. Date last taken (*dd-mmm-yyyy*)	C. Total dose/ day	D. Dose unit	E. P.R.N.	F. Duration	G. Duration Unit	H. Related to APAP Diagnosis? If 'yes', complete Column I.	I. If APAP, single dose? If 'yes', complete Column J.	J. If 'single dose', enter time taken: (24 hour clock, hh:mm).
5-1		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__
5-2		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__
5-3		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__
5-4		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__
5-5		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__
5-6		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__
5-7		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__
5-8		__-__-____	_____.__	○ mg ○ µg ○ units	○ No ○ Yes	___	○ Days ○ Months ○ Years	○ No ○ Yes	○ No ○ Yes	__:__

○ ALI ○ ALF	Visit:	Center No	Subject Code	Data Collected? ○No ○Yes	(*dd-mmm-yyyy*) Date of assessment

Form 05: Neurological Exam (Version 2)

1	Asterixis	○ (0) absent ○ (1) present
2	Pupillary Reflexes	○ (0) reactive ○ (1) fixed
3	Babinski	○ (0) absent ○ (1) present [up-going great toe]
4	Reflexes-patellar	○ (0) normo-active ○ (1) hypo-reflexia ○ (2) hyper-reflexes
5	Reflexes-biceps	○ (0) normo-active ○ (1) hypo-reflexia ○ (2) hyper-reflexes
6	Posturing-decorticate	○ (0) no posturing ○ (1) posturing
7	Posturing-decerebrate	○ (0) no posturing ○ (1) posturing



Decorticate Decerebrate

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 06: The Orientation Log (O-Log) (Version 2)

If the subject is intubated, select 'No' for "Data Collected" in the header and enter a comment.

Standardized O-Log Cues:

1. What city are you in?
   - -if incorrect first answer, give logical cue according to your city location (for example, for Richmond, VA, "capital of Virginia.")
   - -if incorrect to logical cue, give multiple choices: "are we in Miami, [your city], or Chicago"?
2. What kind of place are we in?
   - -if incorrect first answer, give logical cue: "this is where sick people go to be admitted."
   - -if incorrect to logical cue, give multiple choices: "railway station, airport, hospital."
3. What is the name of this hospital?
   - -if incorrect first answer, make up logical cue for your hospital.
   - -if incorrect to logical cue, give multiple choices: "[your hospital], Georgetown Hospital, Cornell Hospital."

NOTE: Give full credit (6 points) if patient answers both kind of place and hospital name at the same time.

4. What is the name of this month?
   - -if incorrect first answer, give logical cue: "it's the month after [___]".
   - -if incorrect to logical cue, give multiple choices: month before, current month, month after current.
5. What is the date of this month?
   - -if incorrect first answer, give logical clue: "it's the day after [___]".
   - -if incorrect to logical cue, give multiple choices: date before, date after, current date.
6. What is the year?
   - -if incorrect first answer, give logical cue: "it's the year before [___]".
   - -if incorrect to logical cue, give multiple choices: current year, year before, year after
7. What is the day of the week?
   - -if incorrect first answer, give logical cue: "it's the day before [___]".
   - -if incorrect to logical cue, give 3 multiple choices including the correct day of week.
8. What time is it (show clock/watch to patient)?
   For this question, there are no cues, and patient receives 3 points for correct response or 0 points for incorrect response. A correct response should be within 30 minutes of the actual time.

For details of administering and scoring O-log, see: (http://www.tbims.org/combi/olog/olograt.html)

1	City	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response
2	Kind of place	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response
3	Name of hospital	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response
4	Month	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response

Comments

Form 06: The Orientation Log (O-Log) (Version 2)

5	Date	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response
6	Year	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response
7	Day of week	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response
8	Clock time	○ (3) correct spontaneously or upon first free recall attempt ○ (2) correct upon logical cueing ○ (1) correct upon multiple choice cueing ○ (0) unable, incorrect, inappropriate response
9	Total Points (derived variable)	

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○ No ○ Yes	

Form 07: Imaging, EEG, Biopsy (Version 5)

Please document all imaging, EEG, and Biopsies performed from enrollment through the End of Study Visit. Print more worksheets, as needed.

1. Brain CT/MRI

1A. Date of brain CT/ MRI (*dd-mmm-yyyy*)	1B. Brain CT/MRI results	1C. Brain CT/ MRI Application	1D. Cerebral edema?	1E. Intracranial hemorrhage	1F. Other brain CT/MRI abnormal findings
	○ Normal ○ Abnormal	○ CT ○ MRI	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ CT ○ MRI	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ CT ○ MRI	○ No ○ Yes	○ No ○ Yes	

2. EEG

2A. Date of EEG (*dd-mmm-yyyy*)	2B. EEG result	2C. Nonspecific generalized slowing	2D. Triphasic waves	2E. Epileptiform discharges	2F. Other EEG abnormal findings
	○ Normal ○ Abnormal	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	

3. Abdomen CT /MRI

3A. Date of abdomen CT/ MRI (*dd-mmm-yyyy*)	3B. Abdomen CT/MRI result	3C. Abdomen CT/MRI Application	3D. Small liver	3E. Large liver	3F. Nodular contour	3G. Vessels patent	3H. Spleno megaly	3I. Ascites	3J. Other abdomen CT/MRI abnormal findings
	○ Normal ○ Abnormal	○ CT ○ MRI	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ CT ○ MRI	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ CT ○ MRI	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	

Comments

Form 07: Imaging, EEG, Biopsy (Version 5)

4. Abdomen ultrasound

4A. Date of ultrasound of abdomen (*dd-mmm-yyyy*)	4B. Abdomen ultrasound result	4C. Small liver	4D. Large liver	4E. Nodular contour	4F. Vessels patent	4G. Splenomegaly	4H. Ascites	4I. Other abdomen ultrasound abnormal findings
	○ Normal ○ Abnormal	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	

5. Liver biopsy

5A. Date of liver biopsy (*dd-mmm-yyyy*)	5B. Liver biopsy result	5C. Hepatocellular necrosis	5D. If yes, specify %	5E. Inflammation	5F. Cholestasis	5G. Steatosis	5H. Cirrhosis	5I. Other liver biopsy abnormal findings / overall diagnosis
	○ Normal ○ Abnormal	○ No ○ Yes	___ %	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ No ○ Yes	___ %	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	
	○ Normal ○ Abnormal	○ No ○ Yes	___ %	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes	

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	

Form 08: Lab Data (Version 5)

1	Date of blood draw	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
Blood		
2	Hemoglobin	__ __ . ___ *g/dL*
3	Hematocrit	__ __ . __ *%*
4	WBC	__ __ . __ X*1000/mm^3*
5	Differential: PMN	__ __ . __ *%*
6	Differential: Lymphocytes	__ __ . __ *%*
7	Differential: Eosinophils	__ __ . __ *%*
8	Differential: Monos	__ __ . __ *%*
9	Platelet count	__ __ __ X*1000/mm^3*
Liver		
10	Prothrombin time	__ __ . __ *seconds*
11	Is the INR above the limit of detection? If yes, skip to question 14.	○ No ○ Yes ○ Not done
13	INR value:	__ __ . __ (0.5 - 10.0)
14	ALT	__ __ __ __ __ *IU/L*
15	AST	__ __ __ __ __ *IU/L*
16	Alk phos	__ __ __ __ *IU/L*
17	Albumin	__ . __ *gm/dL*
18	Total protein	__ __ . __ *gm/dL*
19	Bilirubin	__ __. __ *mg/dL*
20	Glucose	__ __ __ *mg/dL*
21	Amylase	__ __ __ __ *IU/L*
22	CK	__ __ __ __ __ *IU/L*
23	Lipase	__ __ __ __ __ *IU/L*

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 08: Lab Data (Version 5)

Kidney/Electrolytes		
24	Creatinine	__ __ . __ __ *mg/dL*
25	BUN	__ __ __ *mg/dL*
26	Na	__ __ __ *mmol/L*
27	K	__ . __ *mmol/L*
28	HCO3	__ __ *mmol/L*
29	Chloride	__ __ __ *mmol/L*
30	Phosphate	__ __ . __ *mg/dL*
31	Magnesium	__ . __ *mEq/L*
32	Total calcium	__ __ . __ *mg/dL*
33	Ionized calcium	__ __ . __ *mg/dL*
34	Is the lactate above the limit of detection? If yes, skip to question 37.	○ No ○ Yes ○ Not done
36	Lactate value:	__ __ . __ *mmol/L*
Arterial/Toxins		
37	pH	__ . __ __
38	pO_2	__ __ __ *mmHg*
39	pCO_2	__ __ *mmHg*
40	Standard bicarbonate	__ __ . __ *mEq/L*
41	O_2 saturation	__ __ __ *%*
42	FiO_2	__ __ __ *%*
43	Arterial ammonia	__ __ *umol/L*
44	Venous ammonia	__ __ *umol/L*
45	Toxin screen positive (excluding acetaminophen)	○ No ○ Yes
46	If yes, indicate drug(s)	
47	Is the acetaminophen level below the limit of detection? If yes, skip to question 50.	○ No ○ Yes ○ Not done
49	Acetaminophen level	__ __ __ *mg/L*
50	Date acetaminophen level collected	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
51	Collection Time	__ __ : __ __ (*hh:mm*)

Comments

○ ALI ○ ALF	Patient Enrollment	___ ___ Center No	_ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	

Form 11: Pre-Study Peak Lab Value (Version 2)

	Lab Item	A. Pre-Study Peak Value	B. Date (*dd-mmm-yyyy*)
	Liver		
13	INR	__ __ . __	__ __ - __ __ __ - __ __ __ __
14	ALT	__ __ __ __ __ *IU/L*	__ __ - __ __ __ - __ __ __ __
15	AST	__ __ __ __ __ *IU/L*	__ __ - __ __ __ - __ __ __ __
19	Bilirubin	__ __. __ *mg/dL*	__ __ - __ __ __ - __ __ __ __
	Kidney/Electrolytes		
24	Creatinine	__ __ . __ __ *mg/dL*	__ __ - __ __ __ - __ __ __ __
Comments			

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	

Form 12: Daily Check Up (Version 4)

ICU Checklist

1	In ICU	○ No ○ Yes
2	ICP Monitor	○ No ○ Yes
3	CXR	○ Normal ○ Abnormal ○ Not done
9	Complications (Check all that apply)	☐ None ☐ Seizures ☐ Arrhythmia ☐ GI Bleeding ☐ ARDS ☐ Infection ☐ Other bleeding (specify)
10	If other bleeding, specify	

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 12: Daily Check Up (Version 4)

11	Treatments (Check all that apply)	☐ None ☐ Head up ☐ Acid suppressant ☐ Ventilator ☐ Supplemental O_2 ☐ Lactulose ☐ Rifaximin ☐ Mannitol ☐ Pressors (specify) ☐ Hypertonic saline ☐ Barbiturate ☐ Hypothermia ☐ Anti-convulsant ☐ Sedatives (propofol) ☐ Paralytics ☐ Vitamin K ☐ Transfusion: RBC ☐ Transfusion: Plasma (FFP) ☐ Transfusion: rVIIa ☐ Transfusion: Platelets ☐ NAC oral ☐ NAC IV ☐ ELAD/BAL ☐ Hepatocyte transfusions ☐ Hemodialysis ☐ CVVH
12	If pressors treatments, specify (check all that apply)	☐ Dopamine ☐ Epinephrine ☐ Neosynephrine (Phenylephrine) ☐ Norepinephrine (levophed) ☐ Vasopressin
13	Specific therapies (Check all that apply)	☐ None ☐ Pen G/Silibynin (for mushroom poisoning) ☐ Acyclovir (HSV) ☐ Nucleoside/Nucleotide analogue ☐ Corticosteroids (Autoimmune hepatitis) ☐ Antibiotic Prophylaxis ☐ Antibiotic therapy
If ICP monitored:		
14	Daily Min ICP value	__ __ __ *mmHg*
15	Daily Max ICP value	__ __ __ *mmHg*
16	Type of monitor	○ Epidural ○ Subdural ○ Intraparenchymal ○ Intraventricular ○ Other
21	If other, specify type of monitor	
17	Complications of monitoring	○ None ○ Hemorrhage ○ Infection ○ Other
18	If other, specify complications	
19	Primary reason for ICP withdrawal	○ Malfunction ○ Complications ○ Improvement ○ Other
20	If other, specify primary reason	

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	_ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 13: Vital Signs (Version 3)

1	Pulse	__ __ __ *beats/min*
2	Systolic Blood Pressure	__ __ __ *mmHg*
3	Diastolic Blood Pressure	__ __ __ *mmHg*
4	Respiration	__ __ *breaths/min*
5	Min Temperature (Prior 24 hours)	__ __ . __ *°C*
6	Max Temperature (Prior 24 hours)	__ __ . __ *°C*
7	Height (Day 1 only)	__ __ __ *cm*
8	Weight (Day 1 only)	__ __ __ .__ *kg*
9	Were any imaging, EEGs, or biopsies performed? If this is not the first assessment, document any performed since the last assessment. If yes, include on Form 07: Imaging, EEG, Biopsy posted in the Enrollment visit.	○ No ○ Yes
Comments		

○ ALI ○ ALF	Visit:	___ ___ Center No	_ _ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	

Form 14: Infections (Version 4)

Infections: Indicate positive cultures through day 7 by signifying study day of first positive sample.
Although this form should be capture infections through day 7 and antibiotic treatment through hospitalization, this form should be data entered under the 'admission visit'.

1	Positive cultures? If no, skip to question 9.	○ No ○ Yes

	A. Culture	B. Date (*dd-mmm-yyyy*)	C. Organism (*check all that apply*)							D. Outcome		
			S. aureus	S. epid	Enterococcus	E. coli	Klebsiella	Fungus	Other	Resolved	Cause of death	Unknown importance
2	Blood	__-___-____	☐	☐	☐	☐	☐	☐		○	○	○
3	Tracheal aspirate	__-___-____	☐	☐	☐	☐	☐	☐		○	○	○
4	Urine	__-___-____	☐	☐	☐	☐	☐	☐		○	○	○
5	Catheters (vascular)	__-___-____	☐	☐	☐	☐	☐	☐		○	○	○
6	Wounds	__-___-____	☐	☐	☐	☐	☐	☐		○	○	○
7	Ascites	__-___-____	☐	☐	☐	☐	☐	☐		○	○	○
8	Other evidence infection	__-___-____	Specify: _____							○	○	○

10	Did subject receive antibiotic treatment during hospitalization?	○ No ○ Yes
11	Did subject receive antibiotic prophylaxis during hospitalization?	○ No ○ Yes

Comments

ALFSG	Patient Enrollment	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 15: Transplant Form (Version 4)

Added to waiting list (first time only)		
1	Put on waiting list?	○ No ○ Yes
2	If yes, date first time put on waiting list	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
3	If yes, time first time put on waiting list	__ __ : __ __ (*hh:mm*)
4	If no, primary reason for not being added to waiting list	○ Not sick enough ○ Irreversible brain damage ○ Sepsis ○ Active substance use ○ Inadequate social support ○ Active psychiatric disease ○ Medically unsuitable ○ Other ○ Patient already on list
5	If other, specify reason for not being added to waiting list	
Removed from waiting list (first time only)		
6	Removed from waiting list prior to being transplanted?	○ No ○ Yes
7	If Yes, date first time removed from waiting list	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
8	If Yes, time first time removed from waiting list	__ __ : __ __ (*hh:mm*)
9	If yes, primary reason for being removed from waiting list	○ Improved ○ Irreversible brain damage ○ Sepsis ○ Medically unsuitable ○ Other
10	If other, specify reason for being removed from waiting list	
Liver Transplant (first transplant only)		
11	Transplanted?	○ No (skip to question 28) ○ Yes ○ Unknown
12	If yes, date of first transplant	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
13	If yes, time of first transplant	__ __ : __ __ (*hh:mm*)
14	Type of transplant (Check all that apply)	☐ Orthotopic ☐ Auxiliary ☐ Split liver ☐ Living donor ☐ ABO compatible liver
15	Resected liver weight	__ __ __ __ *gms*
16	Immediate complications during transplant hospitalization	○ PNF (Primary non-function) ○ Biliary ○ None ○ Hepatic artery thrombosis ○ Bleeding ○ Other
17	If 'other', specify:	
Comments		

Form 15: Transplant Form (Version 4)

Immunosuppression associated with first transplant		
18	Immunosuppression used within the first 72 hours of OLT. (Check all that apply)	☐ ATG ☐ Azathioprine ☐ Cyclosporine ☐ Daclizumab ☐ Mycophenolate ☐ OKT3 ☐ Prednisone ☐ Sirolimus ☐ Tacrolimus ☐ Other
19	If other, specify immunosuppression	
Donor Graft #1 associated with first transplant		
20	Recipient Blood Group	○ A ○ B ○ O ○ AB
21	Donor Blood Group	○ A ○ B ○ O ○ AB
22	Biliary anastomosis	○ Duct to duct ○ Roux-en-y
23	Donor Gender	○ Male ○ Female
24	Donor Age	__ __ *years*
25	Cold ischemia time	__ __ : __ __ (*hh:mm*)
26	Warm ischemia time	__ __ : __ __ (*hh:mm*)
27	Narrative Summary	
Re-Transplanted		
28	Re-transplanted?	○ No ○ Yes
29	If yes, date of re-transplant	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)

Comments

○ ALI ○ ALF	Admission: Day 1	___ ___ Center No	_ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 16: Diagnosis (Version 6)

Acetaminophen		
1	Acetaminophen overdose (Medication information regarding APAP overdose is captured on Form 04.) If 'no', skip to question 7.	○ No ○ Yes
2	If yes, specify type If 'suicide attempt', skip to question 7.	○ Suicide attempt ○ Unintentional ○ Unknown
3	If unintentional or unknown, motivation of overdose	○ MD recommended ○ Self initiated
4	If therapeutic intent, primary indication	○ Acute pain syndrome (i.e. < 1 week of symptoms) ○ Infectious process ○ Sub-acute pain (i.e. 1-4 week of symptoms) ○ Chronic pain (> 4 weeks of symptoms) ○ Other
93	If other indication, specify	
Any ALI/ALF in pregnancy		
7	Any ALI/ALF in pregnancy If 'No', skip to question 27.	○ No ○ Yes
8	HELLP?	○ No ○ Yes
9	AFLP?	○ No ○ Yes
10	Weeks gestation at enrollment?	__ __ weeks
11	Delivered? If 'No', skip to question 16.	○ No ○ Yes
12	If delivered, date of delivery	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
13	Fetal status at week 3:Baby	○ Dead ○ Alive (skip to Q15)
14	If death, specify date	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
15	If baby alive, date of hospital discharge	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
16	If not delivered, estimated date of confinement (EDC)	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
17	Gravida	__
18	Para	__
19	Pre-eclampsia?	○ No ○ Yes
20	Eclampsia?	○ No ○ Yes
21	Prior pregnancy: Pre-eclampsia?	○ No ○ Yes
22	Prior pregnancy: Eclampsia?	○ No ○ Yes
23	Complication?	○ No ○ Yes
24	Intra-abdominal hematoma?	○ No ○ Yes
25	Hepatic rupture?	○ No ○ Yes
26	C-Section?	○ No ○ Yes

Form 16: Diagnosis (Version 6)

Autoimmune hepatitis (AIH)		
27	Autoimmune hepatitis (AIH)? If 'No', skip to question 35.	○ No ○ Yes
28	Positive serologies? If 'Yes", should be recorded on Form 29.	○ No ○ Yes
29	Biopsy performed? If 'Yes", should be recorded on Form 07.	○ No ○ Yes
30	Prednisone begun?	○ No ○ Yes
31	If yes, specify prednisone start date	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
32	Other immunosuppressant?	○ No (form is complete) ○ Yes
33	If yes, specify immunosuppressant name	
34	If yes, immunosuppressant start date	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
Budd Chiari Syndrome		
35	Budd Chiari Syndrome? If 'No', skip to question 44.	○ No ○ Yes
36	Risk factor (Check all that apply)	☐ blood dyscrasia ☐ clotting disorder ☐ other cause
37	If other cause, specify:	
38	Specify risk factor of blood dyscrasia	
39	Specify risk factor of clotting disorder	
40	Specify risk factor of other cause	
41	Diagnosis established by (Check all that apply)	☐ Liver biopsy ☐ CT ☐ MRI ☐ Angiography
42	Therapy, other than transplant (Check all that apply)	☐ Anticoagulation ☐ TIPSS ☐ Surgical shunt ☐ Other
43	If other, specify therapy	

Comments

Form 16: Diagnosis (Version 6)

DILI

44	DILI? If 'No', skip to question 52.	○ No ○ Yes

	A. Suspect drug name	B. Prior use of same drug?	C. Duration: Year (i.e., 18 months should be entered as 1 year and 6 months)	D. Duration: Month	E. Causality assessment (See below for details)
45-1		○ No ○ Yes	__ __ years +	__ __ months	○ 1. Definite, ≥95% likelihood ○ 2. Highly likely, 75 to 95% likelihood ○ 3. Probable, 50 to 75% likelihood ○ 4. Possible, 25 to 50% likelihood ○ 5. Unlikely, <25% likelihood ○ 6. Insufficient data, likelihood NA
45-2		○ No ○ Yes	__ __ years +	__ __ months	○ 1. Definite, ≥95% likelihood ○ 2. Highly likely, 75 to 95% likelihood ○ 3. Probable, 50 to 75% likelihood ○ 4. Possible, 25 to 50% likelihood ○ 5. Unlikely, <25% likelihood ○ 6. Insufficient data, likelihood NA
45-3		○ No ○ Yes	__ __ years +	__ __ months	○ 1. Definite, ≥95% likelihood ○ 2. Highly likely, 75 to 95% likelihood ○ 3. Probable, 50 to 75% likelihood ○ 4. Possible, 25 to 50% likelihood ○ 5. Unlikely, <25% likelihood ○ 6. Insufficient data, likelihood NA

Causality assessment

1. Definite, ≥95% likelihood, Liver injury is typical for the drug or herbal ("signature" or pattern of injury, timing of onset, recovery). The evidence for causality is "beyond a reasonable doubt"
2. Highly likely, 75 to 95% likelihood, The evidence for causality is "clear and convincing" but not definite.
3. Probable, 50 to 75% likelihood, The causality is supported by "the preponderance of evidence" as implicating the drug but the evidence cannot be considered definite or highly likely.
4. Possible, 25 to 50% likelihood, The causality is not supported by "the preponderance of evidence" however one can not definitively exclude the possibility.
5. Unlikely, <25% likelihood, The evidence for causality is "highly unlikely" based upon the available information.
6. Insufficient data, likelihood NA, Key elements of the drug exposure history, initial presentation, alternative diagnoses, and/or diagnostic evaluation prevent one from determining a causality score.

Comments

Form 16: Diagnosis (Version 6)

Hepatitis A		
52	Hepatitis A? If 'No", skip to question 55.	○ No ○ Yes
53	Risk factor in past 4 months (Check all that apply)	☐ Food ☐ Water ☐ Household contacts ☐ MSM (Men having sex with men) ☐ Other
54	If other, specify risk factor	
Hepatitis B		
55	Hepatitis B? If 'No", skip to question 55.	○ No ○ Yes
56	Risk factors in past 6 months (Check all that apply)	☐ Multiple sexual partners ☐ IDU ☐ MSM (Men having sex with men) ☐ STD ☐ Other
57	Prior positive HBsAg?	○ No ○ Yes
58	If yes, date of positive HBsAg	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
59	History of hepatitis B	○ No ○ Yes
60	If yes, date of hepatitis B	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
Mushroom intoxication		
61	Mushroom intoxication? If 'No", skip to question 67.	○ No ○ Yes
62	Time of ingestion	__ __ : __ __ (*hh:mm 24 hour format*)
63	Date of ingestion	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
64	Muscarinic symptoms? (vomiting, diarrhea, sweating)	○ No ○ Yes
65	If yes, time of onset	__ __ : __ __ (*hh:mm 24 hour format*)
66	Other persons affected?	○ No ○ Yes
Comments		

○ ALI ○ ALF	Admission: Day 1	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 16: Diagnosis (Version 6)

Shock/ischemia		
67	Shock/ischemia? If 'No", skip to question 78.	○ No ○ Yes
68	Cardiac cause of shock?	○ No ○ Yes
69	If yes, result of Echocardiogram: Left ventricular ejection fraction	__ __ %
70	Mean PA systolic pressure	__ __ mm of Hg
71	Date of echocardiogram	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
72	Arrhythmia	○ Atrial ○ Ventricular ○ No arrhythmia
73	Hypotension (SBP <90 or MAP<50)?	○ No ○ Yes
74	If yes, Date of SBP<90 or MAP<50	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
75	If yes, Time of SBP<90 or MAP<50	__ __ : __ __ (*hh:mm 24 hour format*)
76	Pressors given?	○ No ○ Yes
77	Specify pressor: (check all that apply)	☐ Dopamine ☐ Epinephrine ☐ Neosynephrine (phenylephrine) ☐ Norepinephrine (levophed) ☐ Vasopressin
Comments		

Form 16: Diagnosis (Version 6)

Other viruses		
78	Other viruses? If 'No", skip to question 87.	○ No ○ Yes
79	Virus type If 'Other', specify type in question 80.	○ CMV ○ HSV I ○ EBV ○ VZV ○ HHV 6 ○ Other virus type
80	Specify 'other virus type':	
81	Immunosuppressed?	○ No ○ Yes
82	Skin rash?	○ No ○ Yes
83	Skin biopsy/swab?	○ No ○ Yes
84	Vaginal swab?	○ No ○ Yes
85	Antibody results	
86	DNA quant	_____ IU or copies/mL
87	Primary cause of ALI/ALF	○ Acetaminophen ○ Hepatitis E ○ Any ALI/ALF in pregnancy ○ Mushroom intoxication ○ Autoimmune hepatitis ○ Shock/ischemia ○ Budd-Chiari syndrome ○ Wilson's disease ○ DILI ○ Indeterminate ○ Hepatitis A ○ Other viruses ○ Hepatitis B (+/- delta) ○ Other ○ Hepatitis C
88	Specify 'other' diagnosis if applicable:	
89	How was final diagnosis established? (Check all that apply)	☐ Hx ☐ Tissue/histology ☐ Lab ☐ Other
90	If other, specify	
94	Narrative summary / Interval history	
91	Last name of reviewing site investigator:	
92	Date of site investigator review:	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)

Comments

○ ALI ○ ALF	Discharge	___ ___ Center No	___ ___ ___ ___ ___ Subject Code		__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*) Date of assessment

Form 17: Discharge Summary (Version 4)

Outcome at the end of the inpatient phase

1	Was the subject discharged to home?	○ No ○ Yes
2	If yes, date of discharge home:	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
3	Was the subject discharged to another facility?	○ No ○ Yes
4	If yes, date of discharge to another facility:	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
5	If yes, where?	

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	_ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 18: LTFU Part 1 — Outcome (Version 5)

1	Data collection method (Check all that apply) If chart review, complete this form only with new information since the last visit.	☐ Chart ☐ Phone ☐ Clinic visit
11	If question 1 is 'chart review', what is the most recent date of subject contact documented in the chart?	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*)
	If patient alive:	
2	Was the subject transplanted? (If 'yes', then complete or edit form 15 as necessary.)	○ No ○ Yes ○ Unknown
3	Subject hospitalized since last visit? (Exclude the enrolling event.)	○ No ○ Yes
4	If yes, hospital admission date closest to ALF discharge. If the subject was hospitalized more than once since the last visit, enter the date of hospitalization that occurred first. If more than one hospitalization, then please explain in Comments.	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*)
5	Reason for hospitalization.	
6	Diagnosis as of this visit	○ 1. Acetaminophen ○ 2. Any ALI/ALF in pregnancy ○ 3. Autoimmune hepatitis ○ 4. Budd-Chiari syndrome ○ 5. DILI ○ 6. Hepatitis A ○ 7. Hepatitis B (+/- delta) ○ 8. Hepatitis C ○ 9. Hepatitis E ○ 10. Mushroom intoxication ○ 11. Shock/ischemia ○ 12. Wilson's disease ○ 13. Indeterminate ○ 14. Other viruses ○ 15. Other
8	List DILI agent if applicable	
9	Specify other viruses if applicable	
10	Specify other diagnosis if applicable	
Comments		

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 19: LTFU Part 2 — Complications (Version 4)

Complications since the last visit. If this is the first follow up assessment, enter all complications that have occurred since hospital discharge.
(Check all that apply)

1	Neurological	☐ None ☐ Neuropathy ☐ Seizure ☐ CVA ☐ Headache ☐ Speech ☐ Tremors ☐ Global impairment ☐ Unknown
2	Pulmonary	☐ None ☐ Pneumonia ☐ Effusion ☐ Tracheostomy ☐ Unknown
3	Cardiac	☐ None ☐ Arrhythmia ☐ CHF ☐ MI ☐ Unknown
4	Renal	☐ None ☐ HD < 3 months ☐ HD ≥ 3 months ☐ CVVH ☐ Unknown
5	Liver-Biliary	☐ None ☐ Leak ☐ Stricture ☐ Stone/sludge ☐ PTC ☐ ERCP ☐ Surgical revision ☐ Unknown

Comments

Form 19: LTFU Part 2 — Complications (Version 4)

6	Liver-Vascular	☐ None ☐ HAT ☐ HA stenosis ☐ IVC ☐ Portal vein ☐ Angioplasty/stent ☐ Anti-coagulants ☐ Surgical revision ☐ Unknown
7	Re-operation after transplant	☐ None ☐ Biliary ☐ Vascular ☐ Intra-abd bleed ☐ Intra-abd sepsis ☐ Wound related ☐ Other ☐ Unknown
7t	If other, specify re-operation	
8	CMV disease	☐ None ☐ Blood ☐ Lung ☐ Liver ☐ Other ☐ Unknown
8t	If other, specify CMV disease	
Comments		

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 19: LTFU Part 2 — Complications (Version 4)

9	Bacterial infection	☐ None ☐ Bacteremia ☐ Cholangitis ☐ Hapatic abscess ☐ Intra-abdominal ☐ Other ☐ Unknown
9t	If other, specify bacterial infection	
10	Fungal infection	☐ None ☐ Fluconazole ☐ Amphotericin ☐ Blood ☐ Lung ☐ Other ☐ Unknown
10t	If other, specify fungal infection	
11	Diabetes mellitus	☐ None ☐ Oral agent ☐ Insulin ☐ Diet only ☐ Unknown
12	Hypertension	☐ None ☐ Drug therapy ☐ Diet ☐ Unknown
13	Hyperlipidemia	☐ None ☐ Drug therapy ☐ Diet ☐ Unknown
14	Additional Narrative Summary	
15	Were any imaging, EEGs, or biopsies performed? If this is not the first assessment, document any performed since the last assessment. If yes, include on Form 07: Imaging, EEG, Biopsy posted in the Enrollment visit.	○ No ○ Yes

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	_ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 21: LTFU Part 4 —Substance abuse (Version 2)

Substance abuse since ALF/ALI		
1	Suicidal intent/gesture	○ No ○ Yes ○ Unknown
2	If yes, specify	
3	Suicidal intent/gesture date	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*)
4	Acetaminophen overdose	○ No ○ Yes ○ Unknown
5	Acetaminophen overdose date	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*)
6	Psychiatric illness	○ No ○ Yes ○ Unknown
7	If yes, specify	
8	Alcohol abuse/alcoholism	○ No ○ Yes ○ Unknown
9	CAGE: Cut down	○ No ○ Yes ○ Unknown
10	CAGE: Annoyed	○ No ○ Yes ○ Unknown
11	CAGE: Guilty	○ No ○ Yes ○ Unknown
12	CAGE: Eye opener	○ No ○ Yes ○ Unknown
13	Illicit drug use	○ No ○ Yes ○ Unknown
14	If yes, specify	
Comments		

○ ALI ○ ALF	Visit:	___ ___ Center No	_ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 22: LTFU Part 5 (Version 2)

Acute Liver Failure Study Group PI: William M. Lee M.D. CRF Version 2. February 03, 2011

Demographics

1	Current employment status	○ Employed-full time ○ Self-employed ○ Employed-part time ○ Retired ○ Medical disability ○ Other capacity ○ Student ○ Unemployed ○ Homemaker ○ Unknown
2	Occupation	_ _
3	Current Karnofsky score	○ 100 ○ 80 ○ 60 ○ 40 ○ 20 ○ Unknown ○ 90 ○ 70 ○ 50 ○ 30 ○ 10
4	Current years of education completed since starting 1st grade (Do not count repeated grades)	_ _ *years*
5	Current marital status	○ Never married ○ Separated ○ Unknown ○ Married ○ Widowed ○ Divorced ○ Significant Other
6	Current health insurance (Check all that apply)	☐ No insurance ☐ Private insurance (including HMO, PPO, IPO, etc) ☐ Medicare ☐ Medicaid ☐ Unknown

Liver Histology List

7	☐ Not done	Date (*dd-mmm-yyyy*)	Findings (*check all that apply*)
8-1	#1	_ _ - _ _ _ - _ _ _ _	☐ Hepatitis ☐ Cirrhosis ☐ Rejection
8-2	#2	_ _ - _ _ _ - _ _ _ _	☐ Hepatitis ☐ Cirrhosis ☐ Rejection
8-3	#3	_ _ - _ _ _ - _ _ _ _	☐ Hepatitis ☐ Cirrhosis ☐ Rejection

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*) Date of assessment

Form 22: LTFU Part 5 (Version 2)

9	Fluency	○ No	○ Yes		
10	English as first language	○ No	○ Yes		
11	Vision	○ Normal	○ Impaired		
12	If impaired, specify aides *(check all that apply)*	☐ Glasses ☐ Bifocals ☐ Other __ __ __ __ __			
13	Hearing	○ Normal	○ Impaired		
14	If impaired, specify aides	☐ Left ☐ Right ☐ Other __ __ __ __ __			
15	Ambulation	○ Normal	○ Impaired		
16	If impaired, specify	○ Slow	○ With assistance		
17	If with assistance, specify type *(check all that apply)*	☐ Cane-single footed ☐ Cane 4-footed ☐ Walker ☐ Wheelchair ☐ Transfer			
18	Hand tremors	○ No	○ Yes		
19	If yes, specify arm	☐ Left ☐ Right			
20	Type	○ Rest	○ Intent		
	Trails Test (For clinic visits only)	Time (*mm:ss*)	Errors	Standard Score	Standard Score
21	Test A	__ __ : __ __	__ __	○ Pos ○ Neg	__ __ __ . __
22	Test B	__ __ : __ __	__ __	○ Pos ○ Neg	__ __ __ . __

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 23: RBANS Test (Version 3) **(For clinic visits only)**

1	RBANS test form version	○ Form A ○ Form B
Immediate memory		
2	List learning total score	_ _
3	Story memory total score	_ _
4	Index score	_ _ _
Visuospatial/constructional		
5	Figure copy total score	_ _
6	Line orientation total score	_ _
7	Index score	_ _ _
Language		
8	Picture naming total score	_ _
9	Semantic fluency total score	_ _
10	Index score	_ _ _
Attention		
11	Digit span total score	_ _
12	Coding total score	_ _
13	Index score	_ _ _
Delayed memory		
14	List recall total score	_ _
15	List recognition total score	_ _
16	Story recall total score	_ _ _
17	Figure recall total score	_ _
18	Total score	_ _
19	Index score	_ _ _
Sum		
20	Sum of index Sum = Q4+Q7+Q10+Q13+Q19	_ _ _
21	Total scale score	_ _ _
Comments		

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 24: SF-36 Health Survey (Version 2)

C	Completion method	○ Completed in person ○ Completed at home ○ Completed via phone
1	In general, would you say your health is:	○ Excellent ○ Very good ○ Good ○ Fair ○ Poor
2	**Compared to one year ago**, how would you rate your health in general now?	○ (1) Much better now than one year ago ○ (2) Somewhat better now than one year ago ○ (3) About the same as one year ago ○ (4) Somewhat worse now than one year ago ○ (5) Much worse now than one year ago

	3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?	Yes, limited a lot	Yes, limited a little	No, not limited at all
3a	**Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	○	○	○
3b	**Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○	○	○
3c	Lifting or carrying groceries	○	○	○
3d	Climbing **several** flights of stairs	○	○	○
3e	Climbing **one** flight of stairs	○	○	○
3f	Bending, kneeling, or stooping	○	○	○
3g	Walking **more than one mile**	○	○	○
3h	Walking **several** blocks	○	○	○
3i	Walking **one** block	○	○	○
3j	Bathing or dressing yourself	○	○	○

	4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?	Yes	No
4a	Cut down on the **amount of time** you spent on work or other activities	○	○
4b	**Accomplished less** than you would like	○	○
4c	Were limited in the kind of work or other activities	○	○
4d	Had **difficulty** performing the work or other activities (for example, it took extra effort)	○	○

	5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?	Yes	No
5a	Cut down on the amount of time you spent on work or other activities	○	○
5b	Accomplished less than you would like	○	○
5c	Didn't do work or other activities as carefully as usual	○	○

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code		.

Form 24: SF-36 Health Survey (Version 2)

6	During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	○ Not at all	○ Slightly	○ Moderately	○ Quite a bit	○ Extremely	
7	How much bodily pain have you had during the **past 4 weeks**?	○ None	○ Very mild	○ Mild	○ Moderately	○ Severe	○ Very severe
8	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	○ Not at all	○ Slightly	○ Moderately	○ Quite a bit	○ Extremely	

	9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Non of the time
9a	Did you feel full of pep?	○	○	○	○	○	○
9b	Have you been a very nervous person?	○	○	○	○	○	○
9c	Have you felt so down in the dumps nothing could cheer you up?	○	○	○	○	○	○
9d	Have you felt calm and peaceful?	○	○	○	○	○	○
9e	Did you have a lot of energy?	○	○	○	○	○	○
9f	Have you felt downhearted and blue?	○	○	○	○	○	○
9g	Did you feel worn out?	○	○	○	○	○	○
9h	Have you been a happy person?	○	○	○	○	○	○
9i	Did you feel tired?	○	○	○	○	○	○
10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?	○	○		○	○	○

	11. How TRUE or FALSE is each of the following statements for you?	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
11a	I seem to get sick a little easier than other people	○	○	○	○	○
11b	I am as healthy as anybody I know	○	○	○	○	○
11c	I expect my health to get worse	○	○	○	○	○
11d	My health is excellent	○	○	○	○	○

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	__ __ __ __ __ Subject Code	Data Collected? ○No ○Yes	__ __-__ __ __-__ __ __ __ (*dd-mmm-yyyy*) Date of assessment

Form 25: CDC HRQOL-14 Survey on Health and Well-Being (Version 2)

1	Completion method	○ Completed in person ○ Completed at home ○ Completed via phone
2	Would you say that in general your health is:	○ Excellent ○ Very good ○ Good ○ Fair ○ Poor
3	Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good? *(If none, enter zero)*	__ __ *days*
4	Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good? *(If none, enter zero)*	__ __ *days*
5	During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation? *(If none, enter zero)*	__ __ *days*
6	Are you LIMITED in any way in any activities because of any impairment or health problem? *(If no, skip to question 11)*	○ Yes ○ No
7	What is the MAJOR impairment or health problem that limits your activities?	
8	For HOW LONG have your activities been limited because of your major impairment or health problem? Please give the length of time, for example:6 months, or 3½years, or 2 weeks, etc.	
9	Because of any impairment or health problem, do you need the help of other persons with your PERSONAL CARE needs, such as eating, bathing, dressing, or getting around the house?	○ Yes ○ No
10	Because of any impairment or health problem, do you need the help of other persons in handling your ROUTINE needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?	○ Yes ○ No
11	During the past 30 days, for about how many days did PAIN make it hard for you to do your usual activities, such as self-care, work, or recreation? *(If none, enter zero)*	__ __ *days*
12	During the past 30 days, for about how many days have you felt SAD, BLUE, or DEPRESSED? *(If none, enter zero)*	__ __ *days*
13	During the past 30 days, for about how many days have you felt WORRIED, TENSE, or ANXIOUS? *(If none, enter zero)*	__ __ *days*
14	During the past 30 days, for about how many days have you felt you did NOT get ENOUGH REST OR SLEEP? *(If none, enter zero)*	__ __ *days*
15	During the past 30 days, for about how many days have you felt VERY HEALTHY AND FULL OF ENERGY? *(If none, enter zero)*	__ __ *days*
Comments		

ALFSG	End of Study	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 26: End of Study (Version 5)

3	End of study status: If the subject 'completed study, skip to question 8.		○ Completed study ○ Consent withdrawn ○ Lost to follow-up ○ Death ○ Other
1	*If Q01 is 'Consent withdrawn', 'Death', or 'Other'*	Date of end of study: For subjects who withdraw consent, enter date of withdrawal of consent. For subjects who die, enter date of death.	__ __ -__ __ __ - __ __ __ __ (dd-mmm-yyyy)
4	*If Q01 is 'Consent withdrawn' or 'Other'*	Specify details regarding early termination	
10	*If Q01 is 'Lost to follow-up'*	Date last known to be alive	__ __ -__ __ __ - __ __ __ __ (dd-mmm-yyyy)
5	*If Q01 is 'Death'*	Was an autopsy performed?	○ No ○ Yes ○ Unknown
7	*If Q01 is 'Death'*	Primary cause of death	
6	*If Q01 is 'Death'*	Category of primary cause of death (Check all that apply)	☐ Liver related ☐ Infection/sepsis ☐ Cardiac ☐ Neurological (cerebral edema, cerebral vascular accident) ☐ Multi-organ failure ☐ Intraoperative ☐ Cancer ☐ Other ☐ Unknown

The site PI must review and affirm the accuracy of the information reflected in all of the case report forms for this study participant. Please complete the section below after this review and affirmation is complete.

8	Last name of reviewing principal investigator:		
9	Date of PI review and affirmation:		___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)

Comments

ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	_ _ - _ _ _ - _ _ _ _ (*dd-mmm-yyyy*) Date of assessment

Form 27: Glasgow Coma Scale (Version 3)

1	Was the subject intubated at the time of assessment?	○ Yes (Leave Q6 blank) ○ No
2	Was the subject paralyzed at the time of assessment?	○ Yes ○ No
3	Was the subject sedated at the time of assessment?	○ Yes ○ No
4	Coma grade (best estimate)	○ 0 (no coma) ○ I ○ II ○ III ○ IV
5	Eye opening	○ (4) Spontaneous ○ (3) To voice ○ (2) To pain ○ (1) None
6	Verbal Response	○ (5) Oriented ○ (4) Confused ○ (3) Inappropriate words ○ (2) Incomprehensible sounds ○ (1) None
7	Motor response	○ (6) Obeys commands ○ (5) Localizes pain ○ (4) Withdraw (pain) ○ (3) Flexion (pain) ○ (2) Extension (pain) ○ (1) None
8	Total GCS Score	*(calculated by computer)*
9	Total GCS Score for intubated subjects (using predicted verbal score)	*(calculated by computer)*

Comments

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	

Form 28: Outcome Lab Data (Version 2)

For subjects who discharge, die, or transplant **prior** to Day 7:
At the Outcome visit, please check 'data collected?' as no.

For subjects who discharge, die or transplant **after** Day 7:
At the Outcome visit, please enter the lab data collected prior to discharge, death or transplant, whichever comes first.

At STFU and LTFU visit, this form should be completed if new information is available.

1	Last lab date	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
2	Hemoglobin	__ __ . ___ *g/dL (4-17)*
4	WBC	__ __ . __ X*1000/mm^3*
9	Platelet count	__ __ __ X*1000/mm^3*
10	Prothrombin time	__ __ . __ *seconds*
13	INR	__ __ . __ (0.5-10)
14	ALT	__ __ __ __ __ *IU/L*
15	AST	__ __ __ __ __ *IU/L*
16	Alk phosph	__ __ __ __ *IU/L*
17	Albumin	__ . __ *gm/dL*
19	Total Bilirubin	__ __ . __ *mg/dL*
24	Creatinine	__ __ . ___ *mg/dL*
25	Weight	__ __ __ *kg*

Comments

○ ALI ○ ALF	Patient Enrollment	___ ___ Center No	___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	__ __ - __ __ - __ __ __ __ (*dd-mmm-yyyy*) Date of assessment

Form 29: Serological Exam (Version 1)

Serological Parameters		
1	Anti-HAV (IgM)	○ Positive ○ Negative ○ Not done
2	HBsAg	○ Positive ○ Negative ○ Not done
3	Anti-HBc	○ Positive ○ Negative ○ Not done
4	Anti-HBc (IgM)	○ Positive ○ Negative ○ Not done
5	HBeAg	○ Positive ○ Negative ○ Not done
6	Anti-HBs	○ Positive ○ Negative ○ Not done
7	HBV-DNA	○ Positive ○ Negative ○ Not done
8	If HBV-DNA is positive, specify value	__ __ __ __ __ __ __ __ __ IU/mL
9	Anti-HDV	○ Positive ○ Negative ○ Not done
10	Anti-HCV	○ Positive ○ Negative ○ Not done
11	HCV-RNA	○ Positive ○ Negative ○ Not done
12	If HCV-RNA is positive, specify value	__ __ __ __ __ __ __ __ __ IU/mL
13	Anti-HEV	○ Positive ○ Negative ○ Not done
14	Anti-HIV	○ Positive ○ Negative ○ Not done
15	β-hCG	○ Positive ○ Negative ○ Not done
Miscellaneous		
16	Anti-smooth muscle antibodies (ASMA)	1: __ __ __ or __ . __ ○ Negative ○ Not done
17	Antinuclear antibodies (ANA)	1: __ __ __ or __ . __ ○ Negative ○ Not done
18	Antimitochondrial antibodies (AMA)	1: __ __ __ or __ . __ ○ Negative ○ Not done
19	Anti-liver/kidney microsome (LKM)	1: __ __ __ or __ __ . __ ○ Negative ○ Not done
20	Serum Copper	__ __ __ *µg/ml*
21	Urine Copper	__ __ __ __ *µg/24 hr*
22	Ceruloplasmin	__ __ mg/dL
23	Slit-lamp exam (KF rings)	○ Positive ○ Negative ○ Inconclusive ○ Not done
Comments		

○ ALI ○ ALF	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 32: Acute Rejection (Version 1)

This form should be completed whenever an acute rejection occurs.
Although this form may be collected at various visits, this form should be data entered under the 'admission visit'.

1	Date of acute rejection	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
2	Liver Bx	○ No ○ Yes
3	Steroid pulse	○ No ○ Yes
4	Antilymphocyte antibodies	○ No ○ Yes
5	If yes, specify antilymphocyte antibodies	○ ATG ○ OKT3 ○ Other
6	If other, specify	

Comments

ALI	Visit:	___ ___ Center No	___ ___ ___ ___ ___ Subject Code	Data Collected? ○No ○Yes	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*) Date of assessment

Form 33: STFU Outcome Summary (Version 2)

1	Narrative summary / Interval history	
2	Patient seen for this study visit?	○ No ○ Yes
3	Alive (If no, complete EOS form)	○ No (Skip Q10) ○ Yes
4	Discharged since last assessment	○ No ○ Yes
5	If yes, date of discharge	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
6	Subject transplanted since last visit? (If yes, then complete form 15)	○ No ○ Yes ○ Unknown
7	Subject hospitalized since last visit?	○ No ○ Yes
8	If yes, hospital admission date closest to ALI discharge. (If more than one hospitalization, then please explain in General Comments).	__ __ - __ __ __ - __ __ __ __ (*dd-mmm-yyyy*)
9	Reason for hospitalization.	
10	Patient Status (*as of the date of this form completion*)	○ Improved -follow up at month 3 ○ Not improved –return for next short term follow up visit (Does not apply at week 12 weeks STFU) ○ Met ALF Criteria and moved to ALF protocol
11	Has the diagnosis changed since last assessment? If 'no', skip to question 16.	○ No ○ Yes
12	If yes, what is diagnosis changed to?	○ 1. Acetaminophen ○ 2. Any ALI/ALF in pregnancy ○ 3. Autoimmune hepatitis ○ 4. Budd-Chiari syndrome ○ 5. DILI ○ 6. Hepatitis A ○ 7. Hepatitis B (+/- delta) ○ 8. Hepatitis C ○ 9. Hepatitis E ○ 10. Mushroom intoxication ○ 11. Shock/ischemia ○ 12. Wilson's disease ○ 13. Indeterminate ○ 14. Other viruses ○ 15. Other
13	List DILI agent if applicable	
14	Specify other viruses if applicable	
15	Specify other diagnosis if applicable	
16	Last name of reviewing principal investigator:	
17	Date of PI review and affirmation:	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)

Comments

○ ALI ○ ALF	Patient Enrollment	___ ___ Center No	___ ___ ___ ___ ___ Subject Code		__ __ - __ __ - __ __ __ __ (*dd-mmm-yyyy*) Date of assessment

Form 34: 21 Day Status (Version 1)

1	At 21 days post ALI or ALF admission (whichever comes first), what is the vital status of the subject?	○ Alive ○ Dead ○ Unknown

Comments

ALFSG		___ ___ Site ID	___ ___ ___ ___ Subject ID		

Form 37: ALF-MBT Admission (version 3)

Q55		Protocol under which this subject was enrolled	O Version 2	O Version 3 or higher
MBT Inclusion Criteria				
Q01	*If Q55 is 'Version 2'*	Subject 18 to 70 years of age	O No	O Yes
Q56	*If Q55 is 'Version 3 or higher'*	Subject is 18 to 80 years of age	O No	O Yes
MBT Exclusion Criteria				
Q02		Pre-existing New York Heart Association stage III / IV heart failure	O No	O Yes
Q03		Evidence of pre-existing chronic renal failure requiring hemodialysis	O No	O Yes
Q04		Chronic hemodialysis prior to hospital admission	O No	O Yes
Q05		Severe obstructive lung disease *(FEV_1 <50% of predicted on previous spirometry)*	O No	O Yes
Q06		Severe shock, defined as MAP <70 mmHg despite >15 µg/kg/min dopamine, >0.1 µg/kg/min epinephrine, or >0.1 norepinephrine µg/kg/min	O No	O Yes
Q07		Extensive small bowel resection *(>50 cm)*	O No	O Yes
Q08	*If Q55 is 'Version 2'*	Any evidence of upper GI bleeding at MBT study enrollment	O No	O Yes
Q57	*If Q55 is 'Version 3 or higher'*	Any evidence of upper GI bleeding at study enrollment requiring intervention *Endoscopy or RBC transfusion specifically for upper GI bleeding*	O No	O Yes
Q09		Liver transplantation prior to MBT study enrollment *Listing for LT does not preclude participation in the trial*	O No	O Yes
Q10		Pregnancy or breastfeeding woman *Pregnancy related non-APAP ALI or ALF may be considered for entry following the delivery of the baby and assuming the mother does not wish to breastfeed or collect breast milk during the study period*	O No	O Yes
Q11		Allergic to acetaminophen *(such as Tylenol® or any other acetaminophen-containing medications)*	O No	O Yes
Q12		Participation in other clinical studies evaluating other experimental treatments or procedures? (Participation in observatory studies is not an exclusion.)	O Yes	O Yes
Q13		Patient in whom enteral drugs or fluids are contra-indicated	O No	O Yes
Q14		The patient either does not have an appropriately placed naso/orogastric tube *in situ* or cannot tolerate taking the drug preparation orally (200 ml)	O No	O Yes
Q15		Budd-Chiari Syndrome	O No	O Yes
Q16		Non-APAP ALI or ALF caused by malignancy	O No	O Yes

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

Form 37: ALF-MBT Admission (version 3)

Q17	*If Q55 is 'Version 2'*	ALF caused by known or suspected herpes simplex virus requiring acyclovir therapy	O No	O Yes
Q18		Moderate or severe ARDS, as defined by Berlin Criteria	O No	O Yes
Q19	*If Q55 is 'Version 2'*	Subject received amiodarone or an HMG-CoA reductase inhibitor (Statin) in the 30 days prior to MBT study enrollment	O No	O Yes
Q58	*If Q55 is 'Version 3 or higher'*	Subject received amiodarone in the 30 days prior to MBT study enrollment	O No	O Yes
Q59	*If Q55 is 'Version 3 or higher'*	APAP ALI	O No	O Yes
Q20		Consumption of any food or beverage that contains caffeine in the 24 hours prior to MBT study enrollment	O No	O Yes
Q21		Consumption of alcohol in the 24 hours prior to MBT study enrollment	O No	O Yes
Q22		Smoking cigarettes in the 8 hours prior to MBT study enrollment	O No	O Yes
	Consumption of any of the following drugs that may interfere with the metabolism of ^{13}C-Methacetin in the 48 hours prior to MBT study enrollment			
Q23		Acyclovir (Zovirax) *Consumption of this drug is not an exclusion criteria under protocol version 3 or higher*	O No	O Yes
Q24		Allopurinol (Zyloprim, Aloprim)	O No	O Yes
Q25		Carbamazepine (Tegretol, Tegretol XR , Equetro, Carbatrol, Epitol, Teril)	O No	O Yes
Q26		Cimetidine (Tagamet)	O No	O Yes
Q27		Ciprofloxacin (Cipro, Cipro XR, Proquin XR)	O No	O Yes
Q28		Daidzein (Isoflavone)	O No	O Yes
Q29		Disulfiram (Antabuse, Antabus)	O No	O Yes
Q30		Echinacea (Echinacea purpurea, Echinacea angustifolia)	O No	O Yes
Q31		Eenoxacin (Penetrex)	O No	O Yes
Q32		Famotidine (Pepcid) *Consumption of this drug is not an exclusion criteria under protocol version 3 or higher*	O No	O Yes
Q33		Fluvoxamine (Luvox)	O No	O Yes
Q34		Methoxsalen (Uvadex)	O No	O Yes
Q35		Mexilitene (Mexitil)	O No	O Yes

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

ALFSG		__ __ Site ID	__ __ __ __ Subject ID		

Form 37: ALF-MBT Admission (version 3)

Q36	Montelukast (Singulair)	O No	O Yes
Q37	Norfloxacin (Noroxin)	O No	O Yes
Q38	Phenylpropanolamine (Proin)	O No	O Yes
Q39	Phenytoin (Dilantin)	O No	O Yes
Q40	Propafenone (Rythmol)	O No	O Yes
Q41	Rifampin (Rifadin)	O No	O Yes
Q42	Terbinafine (Lamisil)	O No	O Yes
Q43	Ticlodipine (Ticlid)	O No	O Yes
Q44	Thiabendazole (Mintezol)	O No	O Yes
Q45	Verapamil (Calan, Isoptin)	O No	O Yes
Q46	Zileuton (Zyflo)	O No	O Yes
Q47	Oral contraceptives (Birth control pills)	O No	O Yes
MBT Study Admission			
Q48	Does the subject have gastroparesis?	O No	O Yes
Q49	Subject height	___ ___ ___ . ___	
Q50	Height unit	O inches	O cm
Q51	Legally Authorized Representative (LAR)	O Medical power of attorney O Spouse O Child O Other	
Q52	*If Q51 is 'Other'* — Specify LAR		
Q53	Date of consent/admission to MBT study	___ ___ -___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)	
Q54	Time of consent/admission to MBT study	___ ___ : ___ ___ (24 hour clock, hh:mm)	

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

ALFSG	Visit :	___ ___ Site ID	___ ___ ___ ___ Subject ID	Was this data collected? ○ No ○ Yes	

Form 39: ALF-MBT Administration (version 5)

Q01		MBT device number	___ ___ ___ ___	
Q02		MBT test number	___ ___ ___ ___	
Prior to MBT Substrate Administration				
Study Day Specific ALF-MBT Administration Criteria				
Q03		Is this the "Day 1" MBT test?	○ No	○ Yes
Q68	*If Q03 is 'Yes'*	Informed consent was obtained prior to initiating study procedures	○ No	○ Yes
Q09	*If Q03 is 'No'*	Subject has not smoked on the day of the breath test, prior to the test	○ No	○ Yes
Q10	*If Q03 is 'No'*	Subject has not consumed alcohol in the past 24 hours	○ No	○ Yes
Q11	*If Q03 is 'No'*	Subject has not consumed caffeine within 24 hours prior to test	○ No	○ Yes
Q05		Subject has not ingested oral medications in the last 1 hour	○ No	○ Yes
Q06		Subject has not received general anesthesia in the last 24 hours	○ No	○ Yes
Q07		There is no suspicion that aspiration may occur	○ No	○ Yes
Q08		Subject is not on concurrent use of vasopressors	○ No	○ Yes
Q12		Has the subject ingested acetaminophen-related medications (e.g. Tylenol) within the past 24 hours?	○ No	○ Yes
Q13	*If Q12 is 'Yes'*	Date of last acetaminophen ingestion	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy	
Q14	*If Q12 is 'Yes'*	Time of last acetaminophen ingestion	___ ___ : ___ ___ 24 hour clock, hh:mm	
Q15	*If Q12 is 'Yes'*	Acetaminophen dose administered	__ __ __ mg	
Q16		Is the subject currently on N-acetyl cysteine (NAC)?	○ No	○ Yes
Q17	*If Q16 is 'Yes'*	Route of NAC ingestion	○ Oral	○ Continuous IV
Q18		Date of last meal or tube feeding (must be at least 6 hours prior to MBT test for solid food or 4 hours prior to MBT test for tube feeding)	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy	
Q19		Time of last meal or tube feeding (must be at least 6 hours prior to MBT test for solid food or 4 hours prior to MBT test for tube feeding)	___ ___ : ___ ___ 24 hour clock, hh:mm	
General Comments:				
Name of person who collected data: If this worksheet is a source document, sign/date here:				

Form 39: ALF-MBT Administration (version 5)

Renal Replacement Therapy (RRT)			
Q20	Is the subject on RRT at the time of substrate and/or breath test administration?		○ No ○ Yes
Q21	*If Q20 is 'Yes'*	RRT start date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q22	*If Q20 is 'Yes'*	RRT start time	___ ___ : ___ ___ 24 hour clock, hh:mm
Q23	*If Q20 is 'Yes'*	RRT stop date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q24	*If Q20 is 'Yes'*	RRT stop time	___ ___ : ___ ___ 24 hour clock, hh:mm
Molecular Adsorbent Recirculating System (MARS)			
Q63	Is the subject on MARS at the time of substrate and/or breath test administration?		○ No ○ Yes
Q64	*If Q63 is 'Yes'*	MARS start date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q65	*If Q63 is 'Yes'*	MARS start time	___ ___ : ___ ___ 24 hour clock, hh:mm
Q66	*If Q63 is 'Yes'*	MARS stop date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q67	*If Q63 is 'Yes'*	MARS stop time	___ ___ : ___ ___ 24 hour clock, hh:mm
MBT Coma Grade and Vitals			
Q25	West Haven Scale Grade		○ (0) Normal, no clinical signs or symptoms ○ (1) Trivial lack of awareness (euphoria or anxiety, shortened attention span, impaired performance of addition, inverted sleep pattern) ○ (2) Lethargy or apathy (minimal disorientation for time or place, inappropriate behavior, subtle personality change, impaired performance of subtraction, asterixis) ○ (3) Somnolence to semi-stupor, but responsive to verbal stimuli (confusion, gross disorientation) ○ (4) Coma (unresponsive to verbal or noxious stimuli)
Q26	Systolic blood pressure		___ ___ ___ mm Hg
Q27	Diastolic blood pressure		___ ___ ___ mm Hg
Q28	Heart rate		___ ___ ___ beats / min
Q29	Respiratory rate		___ ___ breaths / min
Q30	Weight		___ ___ ___
Q31	Weight unit		○ lbs ○ kg
General Comments:			
Name of person who collected data: If this worksheet is a source document, sign/date here:			

ALFSG	Visit :	___ ___ Site ID	___ ___ ___ ___ Subject ID	Was this data collected? ○ No ○ Yes	

Form 39: ALF-MBT Administration (version 5)

Q32		Was blood drawn for acetaminophen adduct assay?	○ No ○ Yes
Q33	*If Q32 is 'Yes'*	Date of blood draw for acetaminophen adduct assay (must be prior to substrate ingestion)	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q34	*If Q32 is 'Yes'*	Time of blood draw for acetaminophen adduct assay (must be prior to substrate ingestion)	___ ___ : ___ ___ 24 hour clock, hh:mm
Q35		Is subject receiving supplemental oxygen via nasal cannula?	○ No ○ Yes
Q36	*If Q35 is 'Yes'*	Amount of supplemental oxygen via nasal cannula	___ ___ L / min
Q37	*If Q35 is 'No'*	Is subject receiving supplemental oxygen via face mask / trach mask / ventilator?	○ No ○ Yes
Q38	*If Q37 is 'Yes'*	Amount of FiO2 being delivered	___ ___ ___ %
MBT Baseline Breath Test			
Q39		Start date of baseline breath test	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q40		Start time of baseline breath test	___ ___ : ___ ___ 24 hour clock, hh:mm
Q41		Stop time of baseline breath test	___ ___ : ___ ___ 24 hour clock, hh:mm
Q42		Was the baseline breath test ever interrupted?	○ No ○ Yes
Q43	*If Q42 is 'Yes'*	Explain the baseline breath test interruption	
MBT Substrate Administration			
Q44		Is the subject ventilated?	○ No ○ Yes
Q45		Route of administration of substrate	○ Mouth ○ Naso-enteric tube ○ Orogastric tube
Q46		Substrate ingestion time	___ ___ : ___ ___ 24 hour clock, hh:mm
Q69		Were the entire contents of the substrate ingested? *(If the contents of the substrate were not entirely ingested, the MBT breath collection must not be initiated).*	○ No ○ Yes

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

ALFSG	Visit :	___ ___ Site ID	___ ___ ___ ___ Subject ID	Was this data collected? ○ No ○ Yes	

Form 39: ALF-MBT Administration (version 5)

MBT Breath Collection			
Q47		Was the MBT breath collection initiated?	○ No ○ Yes
Q48	*If Q47 is 'No'*	Explain why the MBT breath collection was not initiated	
Q49	*If Q47 is 'Yes'*	How is the breath being collected?	○ Nasal cannula ○ Endotracheal tube
Q50	*If Q47is 'Yes'*	Does the subject have a nasogastric or dobhoff tube in place?	○ No ○ Yes
Q51	*If Q47 is 'Yes'*	Does subject have an enteric tube in left nostril?	○ No ○ Yes
Q52	*If Q47 is 'Yes'*	Does subject have an enteric tube in right nostril?	○ No ○ Yes
Q53	*If Q47 is 'Yes'*	MBT breath collection start time	___ ___ : ___ ___ 24 hour clock, hh:mm
Q54	*If Q47 is 'Yes'*	MBT breath collection stop time	___ ___ : ___ ___ 24 hour clock, hh:mm
Q55	*If Q47 is 'Yes'*	Was the MBT breath collection ever interrupted?	○ No ○ Yes
Q56	*If Q47 is 'Yes' and Q55 is 'Yes'*	Explain the MBT breath collection interruption	
Q57	*If Q47 is 'Yes'*	Was the MBT breath collection terminated early?	○ No ○ Yes
Q58	*If Q47 is 'Yes' and Q57 is 'Yes'*	Explain why the MBT breath collection was terminated early	
Post MBT Vitals			
Q59	*If Q47 is 'Yes'*	Post MBT Systolic blood pressure	___ ___ ___ mm Hg
Q60	*If Q47 is 'Yes'*	Post MBT Diastolic blood pressure	___ ___ ___ mm Hg
Q61	*If Q47 is 'Yes'*	Post MBT Heart rate	___ ___ ___ beats / min
Q62	*If Q47 is 'Yes'*	Post MBT Respiratory rate	___ ___ breaths / min
General Comments:			
Name of person who collected data: If this worksheet is a source document, sign/date here:			

ALFSG	Visit :	__ __ Site ID	__ __ __ __ Subject ID		

Form 41: ALF-MBT Adverse Event (version 1)

This CRF is optional and should only be completed if the subject experiences an Adverse Event.

Q01	Adverse Event Name *(100 Character max)*	

Grade: Please refer to Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03.

Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

- Grade 1 - Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- Grade 2 - Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental Activities of Daily Living.
- Grade 3 - Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care Activities of Daily Living.
- Grade 4 - Life-threatening consequences; urgent intervention indicated.
- Grade 5 - Death related to AE.

Q02	Grade	○ Grade 1 ○ Grade 2 ○ Grade 3 ○ Grade 4 ○ Grade 5
Q03	Serious?	○ No ○ Yes
Q04	Relatedness to study intervention	○ Unrelated ○ Unlikely ○ Reasonable possibility ○ Definitely
Q05	Date of onset	___ ___ - ___ ___ ___- ___ ___ ___ ___ (dd-mmm-yyyy)
Q06	Time of onset	___ ___ : ___ ___ (24 hour clock, hh:mm)
Q07	Outcome	○ Resolved ○ Resolved w/ sequelae ○ Continuing- Follow up is required ○ Continuing at end of study (No follow up is required) ○ Continuing at time of death ○ Unknown
Q08	*If Q07 is 'Resolved' or 'Resolved w/ sequelae'* — Date of resolution	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

ALFSG	Visit :	__ __ Site ID	__ __ __ __ Subject ID		

Form 41: ALF-MBT Adverse Event (version 1)

Q09	Actions taken with study intervention (check all that apply)		☐ None ☐ Study intervention interrupted ☐ Study intervention discontinued ☐ Study intervention modified
Complete the remainder of the form for SAEs only.			
Q10	*If Q03 is 'Yes'*	Describe the event or problem *(8000 Character max)*	
Q11	*If Q03 is 'Yes'*	Relevant tests / laboratory data, including dates *(1000 Character max)*	
Q12	*If Q03 is 'Yes'*	Other relevant history, including pre-existing medical conditions *(1000 Character max)*	
Q13	*If Q03 is 'Yes'*	Last name of reporting site investigator *(50 Character max)*	
Q14	*If Q03 is 'Yes'*	Date of reporting site investigator signature	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
General Comments:			
Name of person who collected data: If this worksheet is a source document, sign/date here:			

ALFSG	Visit :	__ __ Site ID	__ __ __ __ Subject ID		

Form 43: ALF-MBT Lab Data (version 2)

Q01	Date of blood draw		___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q02	Time of blood draw		___ ___ : ___ ___ 24 hour clock, hh:mm
Q03	WBC		___ ___ . ___ x1000/mm^3
Q04	Platelet count		___ ___ ___ x1000/mm^3
Q05	Is the INR above the limit of detection?		○ No ○ Yes ○ Not done
Q06	*If Q05 is 'No'*	INR value	___ ___ . ___ 0.5 - 10.0
Q16	ALT		__ __ __ __ __ IU/L
Q17	AST		__ __ __ __ __ IU/L
Q07	Bilirubin		___ ___. ___ mg/dL
Q08	Creatinine		___ ___ . ___ ___ mg/dL
Q09	Phosphate		___ ___. ___ mg/dL
Q10	Is the lactate above the limit of detection?		○ No ○ Yes ○ Not done
Q11	*If Q10 is 'No'*	Lactate value	___ ___. ___ mmol/L
Q12	pH		___. ___ ___
Q13	Standard bicarbonate		___ ___. ___ mEq/L
Q14	Arterial ammonia		___ ___ umol/L
Q15	Venous ammonia		___ ___ umol/L

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

ALFSG	ALF Admission: Day 1	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 45: ALFSG-ROTEM Admission (version 2)

ALFSG-ROTEM Exclusion Criteria				
Q01	*If F00Q20 is 'ALF-ROTEM version 1'*	Has the subject received plasma, platelet, or cryoprecipitate transfusions during the current admission for ALF, including at referring hospitals?	○ No	○ Yes
Q02	*If F00Q20 is 'ALF-ROTEM version 1'*	Is the subject enrolled in the STOP-ALF protocol (ornithine phenylacetate)?	○ No	○ Yes
ALFSG-ROTEM Study Admission				
Q03	Date of consent/admission to the ALFSG-ROTEM study		___ ___ -___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)	
Q04	Time of consent/admission to the ALFSG-ROTEM study		___ ___ : ___ ___ (24 hour clock, hh:mm)	
General Comments:				
Name of person who collected data: If this worksheet is a source document, sign/date here:				

ALFSG	Visit:	___ ___ Center No	_ _ _ _ _ _ _ Subject Code	Data Collected? ○No ○Yes	

Form 46: ALFSG-ROTEM Blood Collection (version 3)

Q01	Date of ALFSG-ROTEM blood draw	___ ___ -___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
Q02	Time of ALFSG-ROTEM blood draw	___ ___ : ___ ___ (24 hour clock, hh:mm)
Q03	Is the subject receiving NAC at the time of this ALFSG-ROTEM?	○ No ○ Yes
Q11	ROTEM device number	
Q12	Subject on MARS at the time of blood collection / processing	○ No ○ Yes
Q04	Date of ALFSG-ROTEM sample processing	___ ___ -___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
Q05	Time of ALFSG-ROTEM sample processing	___ ___ : ___ ___ (24 hour clock, hh:mm)
Q06	Type of ALFSG-ROTEM blood collection	○ Daily ○ Post-transfusion

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

Form 46: ALFSG-ROTEM Blood Collection (version 3)

Q13		Sample processing deviation	○ Sample processed outside of window ○ Study coordinator unavailable ○ Equipment / reagents unavailable ○ Device failed quality control ○ Other ○ None
Q14	*If Q13 is 'Other'*	Reason for sample processing deviation	
Q07		Concomitant anticoagulant medication at the time of the ALFSG-ROTEM blood draw	○ None ○ IV heparin ○ SC heparin ○ Enoxaparin ○ Aspirin ○ Warfarin ○ Clopidogrel ○ Other anticoagulant
Q08	*If Q07 is 'Other anticoagulant'*	Specify other concomitant anticoagulation medication at the time of the ALFSG-ROTEM blood draw	
Q09		Any issues or complications?	○ No ○ Yes
Q10	*If Q09 is 'Yes'*	Specify issue or complication	

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

ALFSG	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 47: ALFSG-ROTEM Bleeding / Thrombotic Complication (version 2)

Q01	Complication event		○ Bleeding ○ Thrombotic
Q02	Complication date		___ ___ - ___ ___ ___- ___ ___ ___ ___ (dd-mmm-yyyy)
Q03	Approximate complication time		___ ___ : ___ ___ (24 hour clock, hh:mm)
Q04	Complication event type		○ Spontaneous ○ Post-procedure
Q05	*If Q01 is 'Bleeding'*	Bleeding location (Check all that apply)	☐ Upper GI ☐ Lower GI ☐ CVC ☐ Liver ☐ Intracranial ☐ Other
Q06	*If Q01 is 'Bleeding', and Q05 is 'Other'*	Specify other bleeding location	
Q07	*If Q01 is 'Thrombotic'*	Thrombotic location (Check all that apply)	☐ DVT ☐ Portal vein ☐ CVC / RRT catheter ☐ RRT circuit ☐ Ischemic stroke ☐ Myocardial infarction ☐ Other
Q08	*If Q01 is 'Thrombotic' and Q07 is 'Other'*	Specify other thrombotic location	
Q09	*If Q01 is 'Thrombotic' and Q07 is 'RRT circuit'*	Anticoagulant added to RRT circuit	○ Heparin ○ Citrate ○ Prostacyclin ○ None ○ Other
Q10	*If Q01 is 'Thrombotic' and Q07 is 'RRT circuit' and Q09 is 'Other'*	Specify other anticoagulant added to RRT circuit	

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here:

Form 47: ALFSG-ROTEM Bleeding / Thrombotic Complication (version 2)

Q12	*If Q07 is 'RRT circuit'*	RRT modality	○ CVVH (continuous venovenous hemofiltration) ○ CVVHD (continuous venovenous hemodialysis) ○ CVVHDF (continuous venovenous hemodiafiltration) ○ IHD (intermittent)
Q13	*If Q07 is 'RRT circuit'*	RRT start date	___ ___ - ___ ___ ___- ___ ___ ___ ___ (dd-mmm-yyyy)
Q14	*If Q07 is 'RRT circuit'*	RRT start time	___ ___ : ___ ___ (24 hour clock, hh:mm)
Q15	*If Q07 is 'RRT circuit'*	RRT stop date	___ ___ - ___ ___ ___- ___ ___ ___ ___ (dd-mmm-yyyy)
Q16	*If Q07 is 'RRT circuit'*	RRT stop time	___ ___ : ___ ___ (24 hour clock, hh:mm)
Q17	*If Q07 is 'RRT circuit'*	Any complications of RRT?	○ No ○ Yes
Q18	Required intervention?		○ No ○ Yes
Q19	*If Q01 is 'Bleeding'*	Bleeding treatments (check all that apply)	☐ None ☐ Platelets ☐ FFP ☐ Cryoprecipitate ☐ RBCs ☐ Topical thrombin ☐ Tamponade ☐ Other
Q20	*If Q01 is 'Bleeding' and Q19 is 'Other'*	Specify other bleeding treatments	
Q21	*If Q01 is 'Thrombotic'*	Thrombotic anticoagulation treatments (check all that apply)	☐ None ☐ Enoxaparin ☐ Heparin ☐ Other
Q22	*If Q01 is 'Thrombotic' and Q21 is 'Other'*	Specify other thrombotic anticoagulation treatments	
General Comments:			
Name of person who collected data: If this worksheet is a source document, sign/date here:			

ALFSG	Visit:	___ ___ Center No	___ ___ ___ ___ Subject Code		

Form 48: ALFSG-ROTEM Transfusion / Infusion (version 2)

Q01	Transfusion / infusion date		___ ___ - ___ ___ ___- ___ ___ ___ ___ (dd-mmm-yyyy)
Q02	End time of transfusion / infusion		___ ___ : ___ ___ (24 hour clock, hh:mm)
Q11	Transfusion / infusion occurred prior to ALFSG-ROTEM enrollment		○ No ○ Yes
Q03	Transfusion / infusion type		○ Platelets ○ FFP ○ Cryoprecipitate ○ RBCs ○ rFVIIa ○ Other
Q04	*If Q03 is 'Other'*	Specify other transfusion / infusion type	
Q05	Indication for treatment		○ Bleeding ○ Prophylaxis
Q06	*If Q05 is 'Prophylaxis'*	Reason for prophylaxis	○ Central line ○ Dialysis catheter ○ ICP monitor ○ Liver biopsy ○ Abnormal lab value ○ Other procedure
Q13	*If Q06 is 'Abnormal lab value'*	Specify details of abnormal lab value	
Q07	*If Q06 is 'Other procedure'*	Specify name of other procedure	
Q08	Volume of transfusion		___ ___ units
Q09	Decision for treatment guided by?		○ Standard labs ○ Standard of care TEG / ROTEM ○ Physician discretion ○ Other
Q12	*If Q09 is 'Other'*	Other decision	
Q10	*If Q05 is 'Bleeding'*	CRF ID # corresponding to event (on Form 46: ALFSG-ROTEM Bleeding / Thrombotic Complication)	

General Comments:

Name of person who collected data:
If this worksheet is a source document, sign/date here: