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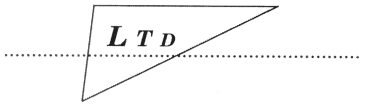

NIDDK

Liver Transplantation Database

POST-TRANSPLANT FOLLOW-UP FORM

LONG-TERM CLINICAL & LABORATORY DATA

02/12/1991

FORM KEYS

Patient ID _____

Transplant No. _____

Evaluation Timepoint _____

COMPLETION LOG

Data Collector ID _____-_____
Center Initials

DATE

Data Collection _____/_____/_____

Data Entry _____/_____/_____

Sysid _____

Verification _____/_____/_____

Cleaned _____/_____/_____

Transfer _____/_____/_____
MM DD YY

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POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT ID _____-
_____

TRANSPLANT NUMBER _____

To be completed by the clinical coordinator at follow-up collection times (4 and 12 months and yearly thereafter) post-transplant. If the patient has returned home, the data are to be obtained from the local caretaking physician mail-in form and/or via telephone contact with the local physician or with the patient. If the patient has returned to the clinical center for this evaluation, the data are to be obtained from the examining physician or from the records at the clinical center.

I. 1. DATE OF EVALUATION/PATIENT CONTACT _____/_____/_____
MM DD YY

2. EVALUATION TIMEPOINT (check one)

__ 9. Four months
__10. Year 1
__11. Year 2
__12. Year 3
__13. Year 4
__14. Year 5

3. Was PATIENT AT CLINICAL CENTER for evaluation? Yes__ No__

IF NO, specify source of information (check one)

__ 1. Physician Mail-In Form
__ 2. Physician contacted by LTD coordinator
__ 3. Patient contacted by LTD coordinator

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PATIENT ID _____-
_____

II. CURRENT MEDICAL STATUS (Physician's Assessment)

1. Was PHYSICAL EXAMINATION performed? Yes__ No__

IF YES

1.1 Height _____cm ____ins x 2.54

1.2 Weight _____kg ____lbs) 2.2

1.3 Nutritional status (check one)

__ 1. Excellent (well nourished)

__ 2. Fair (mild/moderate depletion or partially repleted)

__ 3. Poor (severe depletion)

1.4 Muscle wasting Yes__ No__

1.5 Is patient a pediatric case (age < 16 years)? Yes__ No__

IF YES, COMPLETE for PEDIATRIC PATIENTS ONLY

1.5.1 Percentile height for age (NCHS chart) _____

1.5.2 Percentile weight for age (NCHS chart) _____

1.5.3 Head circumference (for patients ≤ 3 years of age) ____cm ____ins x 2.54

1.5.3.1 Percentile for age (NCHS chart) _____

2. KARNOFSKY SCALE (check one)

__ 1. Normal, no complaints, no evidence of disease. (Does not look or act like he/she has liver disease and, in the case of adults, admittedly feels fine).

__ 2. Able to carry on normal activity, minor signs or symptoms of disease. (Works/attends school/ plays normally in spite of slight or intermittent evidence of disease, e.g. fatigue).

__ 3. Normal activity with effort, some signs or symptoms of disease. (Works/attends school/plays normally but chronically does not feel well, e.g. chronic fatigue, chronic pruritus).

__ 4. Cares for self (consistent with age) but unable to carry on normal activity or to do active work/ school/play. (Has had to quit usual work duties (in or outside of the home)/can no longer attend school/play is more passive than active at this point).

__ 5. Requires occasional assistance (beyond general age appropriate level) but is able to care for most of own needs. (Experiences periods of time when activities of daily living are not possible for him/her to accomplish (appropriate for age). This is the younger child who usually can walk or sit by self but periodically cannot do this independently).

__ 6. Requires considerable assistance and frequent medical care. (Can, at best, only assist with activities of daily living appropriate for age. This is the infant who now needs considerable help with feedings that formerly had been easy. Also has need of frequent clinic and/or hospital visits for management of signs/symptoms of end-stage disease (ie., recurrent cholangitis, encephalopathy, chronic unrelieved pruritus, ascites that is difficult to manage)).

__ 7. Disabled, requires special care and assistance. (Requires total care of most of his/her needs including specialized needs that might include: hemodialysis, tube feeding, home hyperalimentation, etc.).

__ 8. Severely disabled, hospitalization is indicated although death not imminent. (Is not well enough to be managed safely or completely at home any longer).

__ 9. Hospitalization necessary, very sick, active support treatment necessary. (Constant medical and/or surgical intervention to keep patient alive such as: FFP infusions/exchange transfusions to control coagulopathy, frequent infections requiring one or more antibiotics, treatment of variceal bleeds, may or may not need ventilator assistance but probably requires O_2).

__10. Moribund, fatal processes progressing rapidly. (May include the following: multiple infections, hepatic coma, active bleeding, and labile BP requiring vasopressors).

3. Was PROTOCOL BIOPSY performed? Yes__ No__

(Note: Biopsy date may be $\pm$ 2 months of one-year follow-up timepoint.)

IF YES | 3.1 DATE _____/_____/_____ MM DD YY

4. DRINKING HISTORY

4.1 Ever drink alcohol since most recent transplant or since last followup evaluation?

Yes__ No__ Unk__

IF YES

4.1.1 Currently drink? Yes__ No__ Unk__

IF YES — 4.1.1.1 Number of drinks during a typical week _____

IF NO — 4.1.1.2 When did patient stop drinking? _____/_____ MM YY

4.1.1.3 Previous number of drinks during a typical week _____

4.1.2 Has patient ever thought or been told that he/she may have a drinking problem?

Yes__ No__ Unk__

III. MEDICATIONS on day of follow-up evaluation

(check all that apply)

1. Immunosuppressives

	Total Daily Dose (mg)
__ 1.1 Cyclosporine	_____
__ 1.2 FK506	_____
__ 1.3 Imuran	_____
__ 1.4 ALG	_____
__ 1.5 Prednisone	_____
__ 1.6 Prednisolone	_____
__ 1.7 Solumedrol	_____
__ 1.8 OKT3	_____
__ 1.9 Other _____	_____
__1.10 Other _____	_____
__1.11 Other _____ (specify (30 char))	_____

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
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_____

2. OTHER MEDICATIONS Yes__ No__

IF YES, code as specified in Appendix I

	CODE	NAME (30 characters)	Check here if Other med.
1.	____ ____ ____	_____	____
2.	____ ____ ____	_____	____
3.	____ ____ ____	_____	____
4.	____ ____ ____	_____	____
5.	____ ____ ____	_____	____
6.	____ ____ ____	_____	____
7.	____ ____ ____	_____	____
8.	____ ____ ____	_____	____
9.	____ ____ ____	_____	____
10.	____ ____ ____	_____	____
11.	____ ____ ____	_____	____
12.	____ ____ ____	_____	____
13.	____ ____ ____	_____	____
14.	____ ____ ____	_____	____
15.	____ ____ ____	_____	____
16.	____ ____ ____	_____	____
17.	____ ____ ____	_____	____
18.	____ ____ ____	_____	____

IV. LABORATORY DATA

1. HEMATOLOGY Date of sample _____/_____/_____ (MM DD YY) Not Done (-2)

1.1 Hemoglobin (HGB)	___ ___.___g/dl	____
1.2 Hematocrit (HCT)	___ ___.___%	____
1.3 Platelet count x 10^3	___,___ ___ ___cells/mm^3	____
1.4 White blood cells (WBC) x 10^3	___ ___.___cells/mm^3	____
1.5 Prothrombin time (PT)	__ __.__/__ __.__secs. (Patient Control)	____
1.6 Partial thromboplastin time (PTT)	__ __ __.__/__ __ __.__secs. (Patient Control)	____

2. IMMUNOSUPPRESSIVE MEDS. LEVELS

2.1 CYCLOSPORINE LEVEL Date of sample _____/_____/_____ (MM DD YY) ____

IF DONE

2.1.1 Specimen type: 1. Whole blood __ 2. Serum __

2.1.2 Trough level obtained at: 1. 6 hr __ 2. 8 hr __ 3. 12 hr __
4. 24 hr __ 5. Cont. Infusion __ 6. Other _____ (specify (30 char))

		Not Done (-2)
2.1.3 HPLC level	_____ ng/ml	____
2.1.4 RIA level	_____ ng/ml	____
2.1.5 TDX level	_____ ng/ml	____
2.1.6 Monoclonal RIA	_____ ng/ml	____

2.2 FK506 LEVEL Date of sample _____/_____/_____ (MM DD YY) ____

IF DONE

2.2.1 Method _____ (specify (30 char))

2.2.2 Level _____ ng/ml

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3. CLINICAL CHEMISTRY Date of sample _____/_____/_____ (MM DD YY) Not Done (-2)

3.1 Alkaline phosphatase	__ __ __ __U/L	____
3.2 Total bilirubin	___ ___.__mg/dl	____
3.3 Direct bilirubin	___ ___.__mg/dl	____
3.4 SGOT (AST)	__ __ __ __ __U/L	____
3.5 SGPT (ALT)	__ __ __ __ __U/L	____
3.6 Gamma GTP	__ __ __ __U/L	____
3.7 Albumin	___.___g/dl	____
3.8 Alpha feto-protein	__ __ __ __ __ng/ml	____
3.9 Bicarbonate	__ __ __mEq/L	____
3.10 Blood urea nitrogen	__ __ __.___mg/dl	____
3.11 Calcium	__ __.___mg/dl	____
3.12 Chloride	__ __ __mEq/L	____
3.13 Cholesterol	__ __ __ __mg/dl	____
3.14 Creatinine	__ __.__mg/dl	____
3.15 Glucose	__ __ __mg/dl	____
3.16 Potassium	__.__mEq/L	____
3.17 Sodium	__ __ __mEq/L	____
3.18 Total protein	__ __.__g/dl	____

4. URINE STUDIES (at 4 mos and at yearly intervals) Date of sample _____/_____/_____ (MM DD YY)

Not Done (-2)

4.1 Creatinine clearance	__ __ __ ml/min	____
Number of hours _____		

OR

4.2 GFR (glomerular filtration rate)	__ __ __ ml/min	____

5. CULTURES

	RESULTS Pos	Neg	Date of Sample	
5.1 CMV - blood	____	____	_____/_____/_____	____
5.2 CMV - urine	____	____	_____/_____/_____ (MM DD YY)	____

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		RESULTS Pos	Neg	Date of Sample	Not Done (-2)
6.	INFECTION SCREEN				
	Viral serologies				
	6.1 Anti-CMV IgG	____	____	_____/_____/_____ MM DD YY	____
	Titer _____				
	6.2 Anti-CMV IgM	____	____	_____/_____/_____	____
	6.3 Anti-EBV (VCA) IgG	____	____	_____/_____/_____	____
	6.4 Anti-EBV (VCA) IgM	____	____	_____/_____/_____	____
	6.5 Anti-HSV	____	____	_____/_____/_____	____
	6.6 Anti-HAV	____	____	_____/_____/_____	____
	6.7 Anti-HAV IgM	____	____	_____/_____/_____	____
	6.8 HBsAg	____	____	_____/_____/_____	____
	6.9 Anti-HBc	____	____	_____/_____/_____	____
	IF HBsAg POSITIVE				
	6.10 Anti-HBc IgM	____	____	_____/_____/_____	____
	6.11 HBeAg	____	____	_____/_____/_____	____
	6.12 Anti-HBe	____	____	_____/_____/_____	____
	6.13 Anti-HDV	____	____	_____/_____/_____	____
	6.14 Anti-HBs	____	____	_____/_____/_____	____
	6.15 Anti-HCV	____	____	_____/_____/_____	____
**	6.16 Anti-HIV	____	____	_____/_____/_____	____
	IF HIV POSITIVE				
**	6.17 Western Blot	____	____	_____/_____/_____	____
**	6.18 Anti-HTLV1	____	____	_____/_____/_____	____

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PATIENT ID _____-
_____

V. COMMENTS: Yes__ No__

IF YES

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(60 char/line)