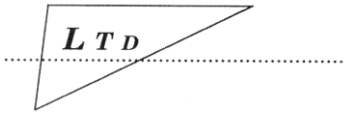
LT



NIDDK

Liver Transplantation Database

LONG-TERM FOLLOW-UP FORM

CLINICAL & LABORATORY DATA

2/10/2000
Version 4.0

FORM KEYS

Patient ID _____ - _____

Evaluation Timepoint _____

COMPLETION LOG

Data Collector ID_____ - _____
Center Initials

Data Collection Date _____/_____/_____
MM DD YY

FOR CLINICAL CENTER USE ONLY

LT Entry Date: ___/___/___

LX Entry Date: ___/___/___

LB Entry Date: ___/___/___
MM DD YY

LONG-TERM FOLLOW-UP FORM
NIDDK Liver Transplantation Database

LT

PATIENT ID _____-_____

To be completed by the clinical coordinator at yearly follow-up, or at time of death or retransplantation. If the patient was retransplanted or died since the last follow-up evaluation during the operational phase of the LTD (June 30, 1995), this follow-up evaluation should be completed to capture information up to the time of retransplantation or death.

I. 1. EVALUATION TIMEPOINT ***(check one):***

__ 1.1 Initial follow-up

__ 1.2 Year 2 follow-up

__ 1.3 Year 3 follow-up

__ 1.4 Year 4 follow-up

__ 1.5 Retransplantation Date of Retx: ___/___/___ ***(complete PP, PG forms)***

__ 1.6 Death Date of Death: ___/___/___ ***(complete MD, PP, PG forms)***
MM DD YY (pathology forms if possible)

2. Is there any new information on this patient since the last evaluation? Yes___ No ___

2.1 **IF NO** give reason (e.g. lost to follow-up) _____
(30 char)
DO NOT PROCEED WITH THE REST OF THIS FORM

3. METHOD OF EVALUATION ***(check all that apply):***

__ 3.1 Telephone interview - patient

__ 3.2 Telephone interview - other: specify relationship to patient _____
(30 char)

__ 3.3 Clinic visit

__ 3.4 Current hospitalization

__ 3.5 Medical chart

__ 3.6 Computer database

__ 3.7 Nursing dictation

__ 3.8 Other, specify _____
(30 char)

4. Date of latest contact/information during this evaluation period: ___/___/___
MM DD YY

5. PATIENT STATUS ***(at time of evaluation or most recent)***: DATE

5.1 Karnofsky scale ***(use codes on opposite page)*** ____ ___/___/___

5.2 Height _____ cm | ___ ins x 2.54 | ___/___/___

5.3 Weight _____ kg | ___ lbs) 2.2 | ___/___/___

5.4 Blood pressure _____ / _____ ___/___/___
systolic diastolic MM DD YY

5.5 Is the patient currently on hypertension medication? Yes ___ No ___

6. EVER DRINK ALCOHOL since last follow-up evaluation? Yes ___ No ___ Unk ___

IF YES

6.1 Currently drink? Yes ___ No ___

IF YES Number of drinks during a typical week ____

IF NO When did patient last drink? ____/____ MM YY

6.2 Has patient ever thought or been told that he/she may have a drinking problem?
Yes ___ No ___ Unk ___

7. Number of BIOPSIES done at this evaluation or since the last evaluation: _____ ***(enter 0 if none)***.

Dates of Biopsies:

7.1	___/___/___	7.5	___/___/___
7.2	___/___/___	7.6	___/___/___
7.3	___/___/___	7.7	___/___/___
7.4	___/___/___	7.8	___/___/___
	MM DD YY		MM DD YY

☐ ***Check here if additional biopsies, and document in COMMENTS section. Use the keywords MORE BIOP to precede the comments.***

8. Number of CHOLANGIOGRAMS done at this evaluation or since the last evaluation: _____ ***(enter 0 if none)***.

Dates of Cholangiograms:

8.1	___/___/___	8.5	___/___/___
8.2	___/___/___	8.6	___/___/___
8.3	___/___/___	8.7	___/___/___
8.4	___/___/___	8.8	___/___/___
	MM DD YY		MM DD YY

☐ ***Check here if additional cholangiograms, and document in COMMENTS section. Use the keywords MORE CHOL to precede the comments.***

9. Number of ULTRASOUNDS done at this evaluation or since the last evaluation: _____ ***(enter 0 if none)***.

Dates of Ultrasounds:

9.1	___/___/___	9.5	___/___/___
9.2	___/___/___	9.6	___/___/___
9.3	___/___/___	9.7	___/___/___
9.4	___/___/___	9.8	___/___/___
	MM DD YY		MM DD YY

☐ ***Check here if additional ultrasounds, and document in COMMENTS section. Use the keywords MORE ULTRA to precede the comments.***

LONG-TERM FOLLOW-UP FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

II. Number of **HOSPITALIZATIONS** since last evaluation: _____ ***(enter 0 if none)***.
(Note: Include only those that lasted at least three days or terminated in death)

Provide information for each hospitalization:

	Admission Date (MM/DD/YY)	Days in ICU	Discharge Date (MM/DD/YY)	Reason(s) for Hospitalization Check all that apply ***(see codes below)***	Other, specify (30 char)
1.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____
2.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____
3.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____
4.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____
5.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____
6.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____
7.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____
8.	___/___/___	_____	___/___/___	1__ 2__ 3__ 4__ 5__ 6__ 7__	_____

☐ ***Check here if additional hospitalizations, and document in COMMENTS section. Use the keywords MORE HOSP to precede the comments.***

Reason(s) for Hospitalization

1. Follow-up evaluation
2. Recurrent disease
3. Acute rejection
4. Chronic rejection
5. Infection
6. Retransplantation
7. Other, specify

LONG-TERM FOLLOW-UP FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

III. MEDICATIONS given during this evaluation period. ***(Note: Only those medications listed on opposite page are to be included.)***

For each medication given during this evaluation period, provide the code (from list on opposite page), name, date that medication was started, and code for reason medication was given. If the medication was discontinued during this evaluation period, record the date of termination and reason. If the medication was continued from the previous evaluation, record "NA" in the space for START DATE. If the medication is continuing at the time of evaluation, record "NA" in the space for STOP DATE. If reason for initiation or termination of medication is not provided in the list, record code for OTHER, and specify reason.

Med. code	Medication name (30 char)	INITIATION Start Date (MM/DD/YY)	Reason (code)	IF OTHER, specify (30 char)	TERMINATION Stop Date (MM/DD/YY)	Reason (code)	IF OTHER, specify (30 char)
IMMUNOSUPPRESSANTS							
1. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
2. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
3. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
4. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
5. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
6. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
7. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
8. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
OTHER MEDICATIONS							
1. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
2. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
3. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
4. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
5. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
6. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
7. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____
8. _____	_____	___/___/___	_____	_____	___/___/___	_____	_____

☐ ***Check here if additional medications from list, and document in COMMENTS section. Use the keywords MORE MEDS to precede the comments.***

LONG-TERM FOLLOW-UP FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

IV. GRAFT DYSFUNCTION requiring diagnostic or therapeutic intervention since last evaluation. Number of causes: ____ ***(enter 0 if none)***.

Provide the information for each cause of dysfunction, using the codes provided for underlying cause and outcome/current status. Specify as required.

	Cause ***(code)***	**If neoplasm, biopsy complic., or other,** specify(30 char)	Cont. from prev. eval **(check if Yes)**	Onset Date (MM/DD/YY)	How was dysfunction determined? ***(check all that confirmed dysfunction, enter ND if not done)***						Recur. disease ***(check if yes)***	Outcome /current status ***(code)***	**If resolved, reLT, or died** Date (MM/DD/YY)
					Bioch	Histol	Serol	Radiol	Clinical	Toxicol			
1.				/ /									/ /
2.				/ /									/ /
3.				/ /									/ /
4.				/ /									/ /
5.				/ /									/ /
6.				/ /									/ /
7.				/ /									/ /
8.				/ /									/ /

Underlying cause of dysfunction:

1. Uncertain
2. Acute rejection
3. Chronic rejection
4. Biliary strictures/obstruction/stones (obstructive cholangiopathy)
5. Alcohol abuse
6. Primary biliary cirrhosis
7. Primary sclerosing cholangitis
8. Autoimmune hepatitis
9. Neoplasm, specify
10. Viral hepatitis A
11. Viral hepatitis B
12. Viral hepatitis B&D
13. Viral hepatitis C
14. Viral hepatitis E
15. Viral hepatitis unknown
16. Steatosis
17. Primary non/dysfunction (within 1st 7 days posttx without HAT)
18. Liver biopsy complication, specify
19. Other, specify

Outcome/current status code:

1. Resolved/controlled
2. Unresolved/continuing/worsening
3. Retransplantation
4. Died
5. Cannot determine

☐ ***Check here if additional graft dysfunction, and document in COMMENTS section. Use the keywords MORE GRAFT to precede the comments.***

LONG-TERM FOLLOW-UP FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

V. Any **NEOPLASIA** present during this evaluation period? Yes ___ No ___

Use codes from opposite page for site, type, and treatment.
For neoplasms that occurred more than once, list each occurrence separately (one per line).
For PTLD/lymphoma(s), list each treatment separately (one per line).

	Site Code	Type Code *(skin or PTLD/lymphoma only)*	**If Other**, specify (30 char)	Cont. from prev. eval *(check if yes)*	**If new**, Date of Diagnosis (MM/DD/YY)	Primary/ Metast. *(circle one)*	**TREATMENT (PTLD/LYMPHOMA ONLY)** Code	Start date (MM/DD/YY) *(Enter –2 if began before eval. period)*	Stop date (MM/DD/YY) *(Enter –2 if not ended)*
1.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
2.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
3.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
4.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
5.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
6.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
7.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
8.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
9.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
10.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
11.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___
12.	_____	_____	_____	_____	___/___/___	**P M**	_____	___/___/___	___/___/___

LONG-TERM FOLLOW-UP FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

13. _____ _____ _____ _____ ___/___/___ **P M** _____ ___/___/___ ___/___/___

14. _____ _____ _____ _____ ___/___/___ **P M** _____ ___/___/___ ___/___/___

15. _____ _____ _____ _____ ___/___/___ **P M** _____ ___/___/___ ___/___/___

16. _____ _____ _____ _____ ___/___/___ **P M** _____ ___/___/___ ___/___/___

☐ ***Check here if additional neoplasms, and document in COMMENTS section. Use the keywords MORE NEO to precede the comments.***

LONG-TERM FOLLOW-UP FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

VI. Any new **RECURRENCE OF DISEASE** since last evaluation? Yes ___ No ___

IF diagnosed during this evaluation period, check all that apply.
(Refer to definitions on opposite page. For any given disease, ALL CRITERIA MUST BE MET.)

	Date of Onset (MM/DD/YY)
__ 1. Primary biliary cirrhosis	___/___/___
__ 2. Primary sclerosing cholangitis	___/___/___
__ 3. Autoimmune hepatitis	___/___/___
__ 4. Neoplasm	___/___/___

IF YES
4.1 Type _____
specify (30 char)

4.2 Site: 1. Intrahepatic__ 2. Extrahepatic __

__ 5. Hepatitis ___/___/___

IF YES ***check type(s):***

- __ 5.1 Viral A
- __ 5.2 Viral B
- __ 5.3 Viral B & Delta
- __ 5.4 Viral C
- __ 5.5 Unknown (cryptogenic)
- __ 5.6 Non-alcoholic steato-hepatitis
- __ 5.7 Other _____ specify (30 char)

__ 6. Alcoholic liver disease (ALD) ___/___/___

__ 7. Hemochromatosis ___/___/___

__ 8. Other, code liver disease diagnosis _____ ___/___/___
(see back of page)

_____
specify as required (30 char)

DATA ENTRY USE ONLY

Data Entry	___/___/___
Sysid	_____
Verification	___/___/___
Cleaned	___/___/___
Transfer	___/___/___ MM/DD/YY