

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS AND PROCEDURES**

FORM: CI (POST-TRANSPLANT SHORT-TERM FOLLOW-UP)

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<u>Purpose:</u>	To document the patient's post-transplant medical status at specified timepoints (Day 1, Day 3, and weekly for six weeks).
<u>Person(s) Responsible:</u>	LTD Clinical Coordinator.
<u>Source(s) of Information:</u>	Medical chart, physician(s) caring for the patient, laboratory test reports, patient.
<u>General Instructions:</u>	This form is completed at the specified timepoints, using information that falls within the allowable range of days for each timepoint. Data collected that are specific to the day of assessment include patient's location, mental status, weight, intubation status. Laboratory test results may be those from any blood draw closest to the day of assessment within the allowable window.

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I. ASSESSMENT DATE

This is the date of evaluation and data collection at protocol timepoints for the first 6 weeks post-transplant. Note that "allowable days" indicates the time frame allowed for each designated timepoint.

Completing Form: Record the date of data collection as month, day, year (e.g. 04/01/90).

II. PATIENT LOCATION

1. In ICU: in the ICU or a step-down unit at the Clinical Center.
2. In Hospital: on the floor (not ICU or step-down unit) at the Clinical Center.
3. Outpatient: at a facility located close to the Clinical Center that is not the patient's home.
4. Outpatient (at home): the patient has returned to usual place of residence.

Completing Form: Use the designated code (1 = In ICU, 2 = In hospital, 3 = Outpatient, 4 = Outpatient (at home)) to indicate the patient's location on the day of the assessment.

III.1 MENTAL STATUS

This information is best obtained by personal observation. For consistency, record a morning observation.

Completing Form: Use the designated code (1 = alert/oriented, 2 = lethargic/slow to respond, 3 = disoriented, 4 = comatose, 5 = anesthetized, 6 = sedated, 7 = unable to assess/not assessed) to indicate the appropriate description of the patient's mental status on the morning of the assessment day.

III.2 WEIGHT

If the patient's weight was recorded in pounds, convert to kilograms by dividing the weight in pounds by 2.2 ($\text{kg} = \text{lbs} \div 2.2$).

Completing Form: Enter weight in kilograms.

III.3 INTUBATED

Refers to the state of having an endotracheal tube in place to allow for better ventilation/oxygenation. The tubes can be placed from the nose to the trachea, mouth to the trachea, directly into the trachea and into the larynx. Note intubation for the entire day (24 hrs.) of this assessment.

Completing Form: Circle "Y" if the patient has an endotracheal tube in place during the entire 24 hr period. Circle "N" if at any time during this period the patient was extubated.

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III.4 BLOOD USAGE

Transfusion of blood or blood products. Report blood and blood products in "cc's" and not "units". If units are recorded, convert to cc's. Report blood and blood product usage during the entire timeframe (ie. since the previous assessment date to the current assessment date).

Completing Form: Circle "Y" to indicate if the patient has received any blood or blood products during this report period. If "yes", enter the total number of cc's received for each category. If none were received in a certain category, enter "0". If no blood or blood products were transfused, circle "N".

III.5 INTERIM DIALYSIS

A process of removing urea and other waste products from the body when a person suffers from renal failure. Include any form of dialysis (hemodialysis, peritoneal dialysis, etc.).

Completing Form: Circle "Y" if the patient required any form of dialysis since the previous evaluation timepoint. If no dialysis was performed, circle "N".

IV. LABORATORY DATA

Refer to individual tests.

GENERAL INSTRUCTIONS

1. Use the blood/urine test results of samples drawn closest to the actual day or week specified within the allowable window. Day 1 labs should always be the first blood draw of Day 1 after the transplant. Day 1 begins after the first midnight post-transplant.
2. Record the date of sample in the appropriate boxes as month, day, year (e.g. 04/01/90).
3. If units differ from those stated on the form, conversion to the correct units must be made.
4. If results show more decimal digits than required, round to the appropriate number of decimal places (ie. drop if < 5, round up to the next digit if ≥ 5).

IV.1 HEMOGLOBIN (HGB)

1. Normal range: 9.0 to 25.0 g/dl.
2. Edit range: 3.0 to 31.0 g/dl.

Completing Form:

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1. Record as __. __ g/dl.
2. If not done, mark "ND" in the box.

IV.2 HEMATOCRIT (HCT)

1. Normal range: 28.0% to 67.0%.
2. Edit range: 15.0% to 67.0%.

Completing Form:

1. Record as __. __ %.
2. If not done, mark "ND" in the box.

IV.3 PLATELET COUNT

1. Normal range: 140×10^3 to 451×10^3 cells/mm³.
2. Edit range: 10×10^3 to 600×10^3 cells/mm³.

Completing Form:

1. Record as __. __. __ $\times 10^3$ cells/mm³.
2. If not done, mark "ND" in the box.

IV.4 WHITE BLOOD COUNT (WBC)

1. Normal range: 3.4×10^3 to 38.0×10^3 cells/mm³.
2. Edit range: 1.0×10^3 to 71.0×10^3 cells/mm³.

Completing Form:

1. Record as __. __. __ $\times 10^3$ cells/mm³.
2. If not done, mark "ND" in the box.

IV.5 PROTHROMBIN TIME (PT) PATIENT AND PT CONTROL

1. Record actual laboratory result under PT.
2. For "control" time, use actual value if available; otherwise record the highest value given for the "Normal" range at your center (e.g. if normal range is 10.9 to 12.8, record 12.8 as control value).
3. Normal range: 9.5 to 15.9 seconds.
4. Edit range: 9.0 to 50.0 seconds for patient; 10.0 to 15.0 seconds for control value.

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Completing Form:

1. Record as _ _ . _ seconds for actual PT.
2. Record as _ _ . _ seconds for control.
3. If not done, mark "ND" in the box.

IV.6 PARTIAL THROMBOPLASTIN TIME (PTT) PATIENT AND PTT CONTROL

1. Record actual laboratory result under PTT.
2. For "control" time, use actual value if available; otherwise, record the highest value given for the "normal" range at your center (ie. if normal range is 25.0 to 41.0, record 41.0 under control).
3. Normal range: 23.0 to 60.0 seconds.
4. Edit range: 15.0 to 150.0 seconds for patient; 15.0 to 50.0 for control value.

Completing Form:

1. Record as _ _ _ . _ seconds for actual PTT.
2. Record as _ _ _ . _ seconds for control.
3. If not done, mark "ND" in the box.

IV.7 ALKALINE PHOSPHATASE (AP)

1. Normal range for alkaline phosphatase is method dependent, and will vary with each center (usual range: 30 to 530 U/L).
2. Edit range: 30 to 5000 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, mark "ND" in the box.

IV.8 TOTAL BILIRUBIN

1. Normal range: 0.0 to 1.2 mg/dl.
2. Edit range: 0.0 to 76.0 mg/dl.

Completing Form:

1. Record as _ _ . _ mg/dl.
2. If not done, mark "ND" in the box.

IV.9 DIRECT BILIRUBIN

1. Normal range: 0.0 to 0.3 mg/dl.
2. Edit range: 0.0 to 50.0 mg/dl.

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Completing Form:

1. Record as _ _ _ mg/dl.
2. If not done, mark "ND" in the box.

IV.10 SGOT (AST)

1. Normal range for SGOT is method dependent, and will vary with each center (usual range: 0 to 40 U/L).
2. Edit range: 0 to 10,000 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, mark "ND" in the box.

IV.11 SGPT (ALT)

1. Normal range for SGPT is method dependent, and will vary with each center (usual range: 2 to 56 U/L).
2. Edit range: 1 to 5,000 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, mark "ND" in the box.

IV.12 GAMMA GTP (GGT)

1. Normal range for GGT is method dependent, and will vary with each center (usual range: 6 to 85 U/L).
2. Edit range: 1 to 1,500 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, mark "ND" in the box.

IV.13 ALBUMIN

1. Normal range: 3.4 to 5.0 g/dl.
2. Edit range: 1.0 to 6.0 g/dl.

Completing Form:

1. Record as _ _ g/dl.
2. If not done, mark "ND" in the box.

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IV.14 ALPHA FETO-PROTEIN

1. Normal range: 0 to 15 ng/ml.
2. Edit range: 0 to 1,000 ng/ml.

Completing Form:

1. Record as _ _ _ _ _ ng/ml.
2. If not done, mark "ND" in the box.

IV.15 BICARBONATE

1. Normal range: 18 to 32 mEq/L.
2. Edit range: 11 to 50 mEq/L.

Completing Form:

1. Record as _ _ _ mEq/L.
2. If not done, mark "ND" in the box.

IV.16 BLOOD UREA NITROGEN (BUN)

1. If BUN is not available and urea is available, convert urea to BUN; ie. $\text{urea} \div 2.14 = \text{BUN}$.
2. Normal range: 5.0 to 24.0 mg/dl.
3. Edit range: 1.0 to 180.0 mg/dl.

Completing Form:

1. Record as _ _ _ . _ mg/dl.
2. If not done, mark "ND" in the box.

IV.17 CALCIUM

1. Normal range: 6.5 to 11.5 mg/dl.
2. Edit range: 2.0 to 12.0 mg/dl.

Completing Form:

1. Record as _ _ . _ mg/dl.
2. If not done, mark "ND" in the box.

IV.18 CHLORIDE

1. Normal range: 95 to 115 mEq/L.
2. Edit range: 70 to 125 mEq/L.

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Completing Form:

1. Record as _ _ _ mEq/L.
2. If not done, mark "ND" in the box.

IV.19 CHOLESTEROL

1. Normal ranges for cholesterol vary depending on age and sex, as well as on method for assay (may vary by 15%).
2. Edit range: 30 to 1,000 mg/dl.

Completing Form:

1. Record as _ _ _ _ mg/dl.
2. If not done, mark "ND" in the box.

IV.20 CREATININE

1. Normal range: 0.2 to 1.4 mg/dl.
2. Edit range: 0.1 to 15.0 mg/dl.

Completing Form:

1. Record as _ _ . _ mg/dl.
2. If not done, mark "ND" in the box.

IV.21 GLUCOSE

1. Normal fasting range: 45 to 130 mg/dl.
2. Edit range: 5 to 500 mg/dl.

Completing Form:

1. Record as _ _ _ mg/dl.
2. If not done, mark "ND" in the box.

IV.22 POTASSIUM (K+)

1. Normal range: 3.5 to 6.2 mEq/L.
2. Edit range: 2.0 to 8.0 mEq/L.

Completing Form:

1. Record as _ . _ mEq/L.
2. If not done, mark "ND" in the box.

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IV.23 SODIUM

1. Normal range: 134 to 145 mEq/L.
2. Edit range: 110 to 150 mEq/L.

Completing Form:

1. Record as _ _ _ mEq/L.
2. If not done, mark "ND" in the box.

IV.24 TOTAL PROTEIN

1. Normal range: 4.2 to 8.5 g/dl.
2. Edit range: 2.0 to 10.0 g/dl.

Completing Form:

1. Record as _ _ _ g/dl.
2. If not done, mark "ND" in the box.

IV.25 CREATININE CLEARANCE

1. Normal range: 40 to 140 ml/min (varies with age).
2. Edit range: 5 to 190 ml/min.

Completing Form:

1. Record as _ _ _ ml/min.
2. Record the number of hours for creatinine clearance.
3. If not done, mark "ND" in the box.

IV.26 GLOMERULAR FILTRATION RATE (GFR) OR IOTHALMATE (SHORT RENAL CLEARANCE)

1. Normal range for this test varies with age.
2. Edit range: 5 to 150 ml/min.

Completing Form:

1. Record as _ _ _ ml/min.
2. If not done, mark "ND" in the box.

V.1-7 CsA OR FK506 LEVEL

1. Cyclosporine or FK506 levels can be obtained via many different methods. Each center

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must check with its own laboratory to determine the method used. Trough levels are determined by how many hours previously the person had received a CsA or FK506 dose (eg. if CsA was given BID -12 hours apart- the trough level would be obtained 12 hours after a dose, but prior to the next dose).

2. Normal values differ with each method of test.
3. Edit range: 0 to 99999 ng/ml.

Completing Form:

1. Circle "CsA" if a cyclosporine blood level was obtained; "FK506" if an FK506 blood level was obtained; otherwise circle "ND". If either the "CsA" or "FK506" level was obtained, then complete the following.
2. Code the appropriate specimen type: whole blood, serum or plasma.
3. Code the time point that the trough level was obtained in the space provided. If "other", specify the time.
4. Record the test result under the appropriate level type for CsA trough level (V.3 - V.6). More than one method may be used and recorded. Enter "ND" for level types not used. For FK506 trough level, record the level obtained and specify the method used (V.7.1). If the FK506 method used was enzyme immunoassay then code as EIA.

VI.1 CMV - BLOOD CULTURE

1. The assessment date for the CMV blood culture is the date of blood draw within the window, for 1) the first positive result, if any; or 2) if there are no positive results, for the most recent negative result.
2. Any positive culture results for the entire period, beginning with the previous assessment date, and ending with the current assessment date should be indicated as a positive culture.
3. The results of CMV cultures are either positive or negative. Criteria for pos/neg results are center specific. Check with clinical center lab.

Completing Form: Circle "+" for positive culture, "-" for negative culture, and "ND" for cultures not done.

VI.2 CMV - URINE CULTURE

1. The assessment date for the CMV urine culture is the date of the urine sample, within the window, for 1) the first positive result, if any; or 2) if there are no positive results, for the most recent negative result.
2. Any positive culture results for the entire period, beginning with the previous

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assessment date, and ending with the current assessment date should be indicated as a positive culture.

3. Results will return as positive or negative.

Completing Form: Circle "+" for positive culture, " -" for negative culture, and "ND" for cultures not done.

VII. PROTOCOL BIOPSY

Protocol biopsies are to be done post transplant on Day 0 or Day 1, at Week 1 and at Week 3. The Post-Transplant Pathology Form is to be completed at this time also. Note "Allowable Days" or windows for defining protocol timepoints are different from those in the rest of the form.

Prior to February 12, 1991, the Week 1 biopsy was to be completed between days 1 to 14 and the Week 3 biopsy between days 15 and 28.

Completing Form:

1. Record the biopsy date as month, day and year.
2. If biopsy was not done, enter "ND" on the line and specify the reason in the space provided.

VIII. COMMENTS

Use this space for any other information that is pertinent to this evaluation period that has not been recorded elsewhere in this form.

Completing Form: Check whether there are any comments to be made. If "yes" write in the comments that are pertinent to this evaluation period, identifying the comments for each evaluation period by the appropriate timepoint.