

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 1 of 11

Purpose: To document:

- 1) the demographic information and medical history of the living donor.
- 2) the intra-operative events and complications that occurred during the donor liver hepatectomy procedure.
- 3) the laboratory test results for blood drawn at (or closest to) the time of selection as a donor.
- 4) assessment of the donor liver and graft assessment in recipient.

Person(s) Responsible: LTD Clinical Coordinators.

Source(s) of Information: Hospital medical records, information obtained from a phone call to the donor, physician(s), laboratory and other test results.

General Instructions: Complete the form using information obtained directly from the donor or from information documented in the medical record.

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 2 of 11

PATIENT ID, TRANSPLANT NO.

The Patient ID and Transplant Number as pertaining to the recipient will be recorded as assigned by the Clinical Center Coordinator before entry. The transplant number should be the 1st, 2nd or 3rd, etc., transplant for this recipient.

Completing Form: Record the Patient ID and Transplant Number.

I. DEMOGRAPHIC DATA

I.1 BIRTHDATE

Completing Form: Enter donor's birthdate as month/day/year.

I.2 SEX

Completing Form: Check the appropriate sex of the donor.

I.3- I.4 HEIGHT / WEIGHT

Note that height and weight are to be recorded in metric units. Conversion formulas are provided to convert measurements recorded in inches and pounds to cm and kg as needed.

Completing Form: If inches and/or pounds are obtained from the chart, record in the boxes. Then use the conversion formulas provided to record the cm and/or kg equivalents.

I.5- 1.6 BLOOD TYPE / Rh FACTOR

Completing Form: Check one category for each item.

1.7 RACE/ETHNIC BACKGROUND

Race/ethnic background includes both racial and ethnic origin classifications. Both are considered important enough to be listed separately. Ethnicity is defined as the classification of a large group of people sharing common cultural traits and customs. Those individuals of mixed racial/ethnic background should be categorized as the individual would classify himself/herself.

Completing Form: Check the appropriate race/ethnic background of the donor. If "other" is checked, specify in the space provided. Note the "UNK" (unknown) category for race to be used when race is unobtainable.

1.8 RELATION TO RECIPIENT

Completing Form: Record the donor's relation to the recipient. If "other" is checked, specify the relationship in the space provided.

II. PRE-EXISTING/COEXISTING CONDITIONS

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 3 of 11

II.1 HISTORY OF ALCOHOL USE

Indicate whether the donor has a history of alcohol consumption. One drink = one 12 oz. beer = one 6 oz. glass of wine = one ounce of hard liquor.

Completing Form: Check the appropriate response to indicate whether the donor has ever consumed any type of alcoholic beverages. If "yes", enter the number of years of alcohol use. Then, indicate the total number of all alcoholic drinks consumed in a typical week. If the donor does not regularly consume any alcohol during a typical week or rarely consumes alcohol, enter 0 for "number of drinks in a typical week". Enter the date of most recent alcohol consumption in month/day/year format.

II.2 HISTORY OF DRUG USE

Indicate whether the donor has a history of illicit drug use.

Completing Form: Check the appropriate response to indicate whether the donor has ever used any illicit drugs. If "yes", enter the total number of years of drug use. Then, record the date of most recent drug use in month/day/year format.

II.3 HYPERTENSION

History of hypertension.

Completing Form: Check the appropriate response to indicate whether there was documentation of the condition in the medical record.

II.4 SEIZURE DISORDER(TREATED)

History of seizure disorder requiring medication.

Completing Form: Check the appropriate response to indicate whether there was documentation of the condition in the medical record.

II.5 DIABETES MELLITUS

History of diabetes mellitus, whether insulin dependent or non-insulin dependent.

Completing Form: Check the appropriate response to indicate whether there was documentation of the condition in the medical record.

II.6 PULMONARY DISEASE

Any disease pertaining to the lung. Examples include asthma, adult respiratory distress syndrome (ARDS), aspiration, chronic obstructive pulmonary disease (COPD), lung abscesses, pulmonary embolism etc. Exclude malignancies. Conditions must be clearly documented in the medical record.

Completing Form: Check the appropriate response to indicate whether there was documentation

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 4 of 11

of the condition in the medical record.

II.7 RENAL DISEASE

Functional impairment or anatomic abnormality of the kidney and/or urinary tract as documented in the medical record. Includes diseases such as acute tubular necrosis (ATN), glomerulonephritis, etc. Do not include renal lithiasis, malignancies or renal failure.

Completing Form: Check the appropriate response to indicate whether there was documentation of the condition in the medical record.

II.8 HEPATITIS (HISTORY OF CLINICAL)

Diagnosed hepatitis (A, B, B & D, C) with measurable signs of disease.

Completing Form: Check the appropriate response to indicate whether there was documentation of hepatitis in the medical record. Specify type in the space provided.

II.9 INFECTIONS (CURRENT)

Current infections other than hepatitis as diagnosed by a physician and documented in the medical record.

Completing Form: Check whether there was documentation of current infections other than hepatitis. For other current infections, specify site(s) and organism(s), one infection/line. If there are more than 4 types, record the remainder under "COMMENTS" (Section XV) starting with the section no. and item name (e.g. "II.9.5 Current infections: . . .").

III. ANTIBIOTICS GIVEN (PRE-OP ONLY)

Includes infusions and scheduled antibiotics as well as unscheduled antibiotics.

Completing Form: Check whether antibiotics were administered in the pre-op period. If "yes", record the antibiotic(s) given and provide code as specified in the Medications List (Appendix I). If a medication is not coded on the list, check with your PI regarding its indication, and whether it should be documented. If so, inform the Coordinating Center as soon as possible to assign a code for this medication.

IV. LABORATORY DATA AT TIME OF SELECTION AS DONOR

For all laboratory data, total bilirubin through prothrombin time - use the results given at time of selection as donor. Record the date of sample for these tests.

GENERAL INSTRUCTIONS for completing laboratory data:

1. If units differ from those stated on the form, conversion to the correct units must be made.
2. If results show more decimal digits than required on the form, round to the appropriate number of decimal places (ie. drop if less than 5, round up to next digit if ≥ 5).

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 5 of 11

Completing Form: Record date of sample in month/day/year format.

IV.1 TOTAL BILIRUBIN

1. Normal range: 0.0 to 1.2 mg/dl.
2. Edit range: 0.0 to 3.0 mg/dl.

Completing Form:

1. Record as _._ mg/dl.
2. If not done, check the "Not Done" column.

IV.2 DIRECT BILIRUBIN

1. Normal range: 0.0 to 0.3 mg/dl.
2. Edit range: 0.0 to 1.0 mg/dl.

Completing Form:

1. Record as _._ mg/dl.
2. If not done, check the "Not Done" column.

IV.3 SGOT (AST)

1. Normal range for SGOT is method dependent and will vary with each institution.
2. Edit range: 0 to 2,100 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

IV.4 SGPT (ALT)

1. Normal range for SGPT is method dependent and will vary with each institution.
2. Edit range: 2 to 400 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

IV.5 BUN

1. Normal range: 5.0 to 24.0 mg/dl.
2. Edit range: 1.0 to 60.0 mg/dl.
3. If BUN is not done and urea is available, convert urea to BUN using the formula: $BUN = \text{urea} \div 2.14$.

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 6 of 11

Completing Form:

1. Record as _ _ _ _ mg/dl.
2. If not done, check the "Not Done" column.

IV.6 CREATININE

1. Normal range: 0.2 to 1.4 mg/dl.
2. Edit range: 0.1 to 3.0 mg/dl.

Completing Form:

1. Record as _ _ _ mg/dl.
2. If not done, check the "Not Done" column.

IV.7 PROTHROMBIN TIME (PT) PATIENT AND PT CONTROL

1. Record actual laboratory result for patient value.
2. For "control" time use actual value if available; otherwise, record value used at hospital.
3. Normal range: 9.5 to 15.9 seconds.
4. Edit range: 9.0 to 20.0 seconds for patient; 10.0 to 15.0 seconds for control.

Completing Form:

1. Record as _ _ _ seconds for actual PT.
2. Record as _ _ _ seconds for control (if data not available, record as UNK).
3. If not done, check the "Not Done" column.

V. INFECTIOUS DISEASE SCREEN

The infectious disease screen should be run at the transplant center prior to the donor partial hepatectomy.

Completing Form:

Record the date of the blood sample as month, day, year.

For each test check whether the result was positive or negative, if the test was done. If the test was not done, check the "not done" column.

1. Anti-CMV IgG and the titer obtained for positive results.
2. HBsAg
3. Anti-HBs
4. Anti-HBc
5. Anti-HCV
6. Anti-HIV
7. Anti-HTLV1
8. Routine Blood Culture

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 7 of 11

- 8.1 Bacteria - if test result is positive, specify the organism in the space provided. If there is more than one organism or a second positive blood culture, record the organism(s) under "COMMENTS" (Section XV) starting with the section no. and item name (e.g. "V.8.1.2 Bacteria: . . .").
- 8.2 - 8.3 Other - specify any other organism(s) that are not bacterial that show positive results for blood cultures, one organism/line. If there are more than 2 types, record the remainder under "COMMENTS" (Section XV) starting with the section no. and item name (e.g. "V.8.4 Other organism: . . .").

VI. HISTOCOMPATIBILITY TESTING (HLA-A, HLA-B and HLA-DR)

HLA donor results return as a letter and one or two numbers following, eg. A2 or B11. There are usually (but not always) two results per category, eg. HLA-A = A1 and A3. The three HLA categories that should be tested are HLA-A, HLA-B and HLA-DR.

Completing Form:

1. Record the date of the blood sample as month, day, year.
2. Record results as given on the donor record for HLA-A, HLA-B and HLA-DR. If the test is not done, code -2 on the appropriate lines (eg. HLA-A -2/-2). If test was done but result is left blank, code as -3 on appropriate line (eg. HLA-A 1/-3).

VII. PRE-OPERATIVE MORPHOLOGY ASSESSMENT

Completing Form:

- VII.1** Liver scan performed: Check the appropriate response.
- VII.2** Normal parenchyma (CT or MRI): Check the appropriate response.
- VII.3** Segments to be removed: Check the appropriate response. If other than the specified segments, check "other", and specify in the space provided.
- VII.4** Pre-operative graft volume: Enter total volume in cc's.
- VII.5** Pre-operative graft weight: Enter weight in kg.
- VII.6** Arteriogram performed: Check the appropriate response. If "yes", check the classification of the arterial anatomy. If "other variant" is checked, specify type in the space provided.
- VII.7** Replaced right hepatic: Check the appropriate response.

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 8 of 11

VIII. DONOR RECOVERY

VIII.1 PARTIAL HEPATECTOMY START TIME

Date and time of the start of the partial hepatectomy procedure, according to the time zone of the LTD Clinical Center in military time.

Completing Form: Record the date as month, day, year; record the time as hours and minutes using military time.

VIII.2 PARTIAL HEPATECTOMY FLUSH TIME

Date and time of the flushing of the liver with preservation solution according to the time zone of the LTD Clinical Center in military time. Note that the date may be different than that given for the partial hepatectomy start time.

Completing Form: Record the date as month, day, year; record the time as hours and minutes using military time.

VIII.3 PARTIAL HEPATECTOMY END TIME

Date and time of the end of the partial hepatectomy procedure, according to the time zone of the LTD Clinical Center in military time. Note that the date may be different than that given for the start and flush times of the partial hepatectomy procedure.

Completing Form: Record the date as month, day, year; record the time as hours and minutes using military time.

VIII.4 ARTERIAL DISSECTION

Completing Form: Record the appropriate response(s) and enter the diameter (s) in mm. If "other" is checked, specify in the space provided.

VIII.5 GRAFT USED

Completing Form: Check the corresponding graft segments used. If "other", specify type in the space provided.

VIII.6 PORTAL VEIN

Completing Form: Enter the length and diameter in mm.

VIII.7 HEPATIC VEIN

Completing Form: Check the appropriate response, whether single or multiple veins.

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 9 of 11

VIII.8 BILE DUCT CHOLANGIOGRAM PERFORMED

Completing Form: Enter the appropriate response. If "yes" complete which type. If "full left" or "common channel" is checked, enter the diameter in mm. If "separate ducts 2 and 3" is checked, enter the diameter of segment 2 and segment 3 in mm.

VIII.9 GRAFT VOLUME DISPLACEMENT

Completing Form: Enter the total volume in cc's.

VIII.10 DONOR VEINS RETRIEVED

Completing Form: Check the appropriate response(s) and enter the diameter(s) in mm. Enter the length of the saphenous vein in mm. If "other" is checked, specify in the space provided.

IX.1 FLUSH TYPES

This includes flush solutions and additives used for portal vein, artery and preservation solution. The commonly used solutions are the UW solution (Viaspan), LR (Lactated Ringers), and OTAR.

Completing Form: For the UW solution, Lactated Ringers, and OTAR check whether used as portal vein flush, artery flush or preservation solution, and record the total volume (cc) used. If not used, enter 0. Record the total volume in cc's. If a solution other than the UW solution, Lactated Ringers, or OTAR is used, specify the solution and check the category(ies) for which it was used. Record the total volume in cc's. If more than one "other" is used, record the remainder under "COMMENTS" (Section XV) starting with the section no. and item name (e.g. IX.1.4 Other flush types...").

IX.2 WERE MEDICATIONS ADDED TO FLUSH

This includes medications added to the portal vein and/or artery flush. Commonly used medications include: 1) Calciparine, 2) D50, 3) Heparin, 4) Mannitol, 5) Solumedrol (dexamethasone/decadron), 6) insulin, 7) penicillin.

Completing Form: Check whether medications were added to flush. If "no", proceed to section X. If "yes", proceed to the boxed medications list. For each medication listed, check whether it was added to portal vein flush or artery flush. If not used, leave columns blank. For medications other than those listed, specify type under "Other", one medication/line, and check the appropriate column(s). If more than two "other" medications are used, record the remainder under "COMMENTS" (Section XV) as instructed.

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 10 of 11

X. INTRA-OPERATIVE

X.1 INTRA-OPERATIVE COMPLICATIONS

Completing Form: Check whether any intraoperative complications occurred. If "yes", check the specific complication(s). If "Damage to structure of Donor" is checked, check the specific type of damage(s) that occurred. If "Damage to other organ" is checked, specify type in the space provided.

X.2 BLOOD LOSS

Intra-operative blood volume loss.

Completing Form: Record whether blood loss occurred. If "yes", record the total volume in cc's lost during the procedure.

X.3 REPLACEMENT BLOOD GIVEN

Completing Form: Record whether replacement blood was given. If "yes", for each of the listed blood products listed, record the total volume in cc's given during the entire procedure. If units are recorded, convert to cc's before recording.

XI. ANTIBIOTICS USED DURING SURGERY

Completing Form: Check whether antibiotics were administered during surgery. If "yes", record the antibiotic(s) given and provide code as specified in the Medications List (Appendix I). If a medication is not coded on the list, check with your PI regarding its indication, and whether it should be documented. If so, inform the Coordinating Center as soon as possible to assign a code for this medication.

XII. ASSESSMENT OF LIVER

Subsections 1, 2, 3 are self-explanatory to the surgeon.

Completing Form:

1. Check whether 1) Consistency/texture was normal; 2) Perfusion/color was well perfused; 3) Injury/trauma was present at the time of incision and at the time of cross-clamp or flush.
2. Check one category to describe how well the liver flushed.
3. Check one category to describe the overall quality of the liver.

XIII. IMPLANTATION: GRAFT ASSESSMENT IN RECIPIENT

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION**

FORM: LD (LIVING DONOR FORM)

Page 11 of 11

Record the graft type, and diameter, and length were applicable, at time of implantation.

Completing Form: Record the appropriate graft and diameter(mm) for Hepatic Vein, Portal Vein, and Hepatic Artery. Record length in mm for Portal Vein graft type. Check whether Roux Y anastomosis was performed. Record the total number of ducts used.

XIV. SURGEON ID

The ID of the most senior surgeon should be used.

Completing Form: Record the LTD center prefix and first 3 letters of surgeon's last name.

XV. COMMENTS

Use this space for any other information that is pertinent to the donor's medical history or the intra-operative procedure that has not already been included in this form that would be considered to be of relevance.

Completing Form: Check whether there are any comments to be made. If "yes", write in any pertinent comments. If comment pertains to a specific item on the form, precede comment with section and item number (e.g. "XI.11 Other antibiotics used: . . .").