

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

**FORM: DF (DONOR FORM)**

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- Purpose: To document: 1) the demographic information and medical history of the donor.
- 2) the cause of death and the occurrence of events (cardiac arrest, hypoxemia, acidosis, etc.) from the time of injury/illness to the time of harvest.
- 3) the laboratory test results for blood drawn at (or closest to) the time of selection as a donor.
- Person(s) Responsible: LTD Clinical Coordinators, organ procurement personnel.
- Source(s) of Information: Donor chart from the donor hospital; documentation obtained by the organ procurement team; information obtained from a phone call to the donor hospital or to the donor's family.
- General Instructions: Complete the form using information from the donor chart brought back to the LTD Center from the donor hospital or from information obtained by the procurement team. If a donor chart is not available or does not include all the information necessary to complete this form, call the donor hospital to obtain as much missing data as possible.

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**I. RECIPIENT ID, TRANSPLANT NO.**

The Recipient ID and Transplant Number will be recorded/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 Recipient ID and Transplant Number.

**I.1 DATE OF START OF HEPATECTOMY**

This is the date that the incision was made for the donor liver hepatectomy.

Completing Form: Record the date of the start of the hepatectomy as month, day, year.

**I.2 WAS MEDICAL CHART AVAILABLE?**

Determine whether a copy of the donor's medical chart was made available to the procurement personnel.

Completing Form: Indicate "yes" or "no".

**II. DEMOGRAPHIC DATA**

Exact birthdate is preferred; use age in years and months only when birthdate is unobtainable. Note that height and weight are to be recorded in metric units. If inches and pounds were given in the chart, convert to cm and kg as instructed. Race by definition distinguishes the black and white categories only; the remaining categories are ethnic origins, but are considered important enough to be identified separately. Ethnic by definition is a large group of people classified according to common traits and customs. Those individuals of mixed racial/ethnic background should be categorized as the individual would classify himself/herself.

Completing Form: Birthdate - enter month/day/year, if obtainable. If not obtainable, record "UNK" for birthdate and enter donor's age to the closest month. If any part of the birthdate is unknown, record known parts, mark unknown parts "UNK". If year is unknown, record "UNK" in all parts. If donor is less than two weeks old and the birthdate is unknown, enter 0 for years and 0 for months.

Check the appropriate sex of the donor.

Height and Weight - if inches and/or pounds are obtained from the chart, record in the boxes, convert to metric using the formulas provided, and record the cm and/or kg equivalents.

Check one category for each item (blood type, and Rh factor).

Check the appropriate race/ethnic background of the donor. If "other" is checked, specify in the space provided.

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Note the "UNK" (unknown) category for race. This is to be used when race is unobtainable.

**III. HOSPITALIZATIONS**

Date of admission for injury/illness: There are times when donors present at one hospital and then are transferred to the current hospital. When this happens, record the date of admission to the first hospital.

Total duration in ICU for this injury/illness: If more than one hospital is involved, count total ICU days at all hospitals. Any part of a day should be considered one full day.

Completing Form: Enter month/day/year for date of admission.

Check if donor was ever in the ICU. If "yes", record total duration in days. If information is unknown or missing, check "UNK".

**IV. CAUSE OF DEATH**

Incident/disease leading to death. If there is any conflicting information, confirm cause of death with the PI. It is the responsibility of the PI to contact the other physicians involved and resolve the conflict.

Completing Form: Check only one cause of death. In the event of anoxia with a cause other than those listed, check #10 "anoxia, other" and specify the cause of the anoxia. In the event of a narcotics overdose, specify the drug. If the cause of death is other than those listed, check "Other", and specify in the space provided.

**V. PRE-EXISTING/COEXISTING CONDITIONS**

**V.1-2 DRUGS/TOXINS**

"Acute intoxication" for alcohol should be confirmed by a positive blood alcohol level, and "current use" of drug should be confirmed by a positive toxicology screen. Chronic use of alcohol or drugs can only be obtained from the medical history.

Completing Form: Check whether there was documentation of alcohol and/or drug abuse as defined above. If information is unknown or missing, check "unk".

**V.3-4 CIRCULATORY**

3. Cardiac disease (preexisting): presence of formerly diagnosed heart disease (e.g. coronary artery disease, history of prior MI, etc).
4. Hypertension: History of hypertension as noted in donor chart.

Completing Form: Check whether there was documentation of cardiac disease or hypertension. If "yes" for hypertension, indicate whether treated or not treated with antihypertensives/diuretics. If

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information is unknown or missing, check "unk".

**V.5-6      CNS**

5.    CNS malignancy: brain or spinal cord malignancy
6.    Seizure disorder: requiring medication

Completing Form: Check whether there was documentation of CNS malignancy or seizure disorder (treated). If information is unknown or missing, check "unk".

**V.7-8      INFECTIONS**

7.    Hepatitis (history of clinical): means diagnosed hepatitis (A, B, B & D, C) with measurable signs of disease.
8.    Other current infections: as diagnosed by a physician and documented in the medical record (if available).

Completing Form: Check whether there was documentation of a history of hepatitis or other current infections. 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 X) starting with the section no. and item name (e.g. "V.8.5. Other current infections: . . ."). If information is unknown or missing, check "unk".

**V.9          CONGENITAL ANOMALIES**

Any single birth defect or group of defects (syndrome) documented as an anomaly in the medical record.

Completing Form: Check whether there was documentation of congenital anomalies. If "yes", specify. If there is more than one type, record the remainder under "COMMENTS" (Section X) starting with the section no. and item name (e.g. V.9. Congenital anomalies: . . ."). If information is unknown or missing, check "unk".

**V.10        DIABETES MELLITUS**

Insulin dependent or non-insulin dependent.

Completing Forms: Check whether there was documentation of diabetes mellitus. If "yes", indicate whether or not insulin is used. If information is unknown or missing, check "unk".

**V.11        HYPERGLYCEMIA (UNTREATED)**

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Abnormally increased content of sugar in the blood. Condition must be clearly documented in the medical record.

Completed Form: Check whether there was documentation of untreated hyperglycemia. If information is unknown or missing, check "unk".

**V.12 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 whether there was documentation of pulmonary disease. If information is unknown or missing, check "unk".

**V.13 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 whether there was documentation of renal disease. If information is unknown or missing, check "unk".

**V.14 NUTRITIONAL SUPPORT**

Patient has received nutritional support either via a central venous catheter (hyperalimentation) or into the gastrointestinal tract via a feeding tube (enteral alimentation).

Completing Form: Check whether there was documentation of nutritional support. If "yes", check hyperalimentation and/or enteral and record the duration in days for each. If information is unknown or missing, check "unk".

**V.15 OTHER**

Any other preexisting or coexisting condition that is noted in the donor chart and does not fall in the categories provided.

Completing Form: Check "yes", if there was documentation of other conditions, and specify type(s) in space provided, one condition/line. If there are more than 4 types, record the remainder under "COMMENTS" (Section X) starting with the section no. and item name (e.g. "V.15.5 Other: . . .").

**VI. PRE-HARVEST EPISODES**

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Any occurrence of the following from time of injury/illness until donor incision time.

1. Cardiac arrest - pulseless
2. Acidosis -  $\text{pH} < 7.3$
3. Hypothermia -  $< 32.5^{\circ}\text{C}$
4. Hyperthermia -  $> 38.5^{\circ}\text{C}$
5. Hypoxemia -  $\text{PaO}_2 < 60 \text{ mmHg}$  on  $\text{FiO}_2 > 70\%$
6. Lowest systolic blood pressure/accompanying diastolic (sustained for at least 1/2 hour)

Completing Form: For each category, check whether there was an occurrence in the given time frame. For blood pressure, record only the lowest systolic and accompanying diastolic blood pressure sustained for at least 30 minutes. Occasionally only a systolic blood pressure is recorded. Indicate diastolic as "UNK" in that case. If systolic is "palpable", record 0 for systolic and "UNK" for diastolic.

**VII. MEDICATIONS GIVEN FROM TIME OF INJURY/ILLNESS**

Includes infusions and scheduled medications as well as unscheduled medications. Does not include maintenance IV, hyperalimentation, intralipids, albumin, antacids, topicals and multivitamins. Refer to Appendix 3 "Medications Not to be Used" for the list of drugs to exclude. If two separate institutions are involved (as in a transfer) and the medications given at the first hospital are clearly documented, include those here also.

Completing Form: Check whether medications were given. If "yes", record the medication(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.

**VIII. BLOOD TRANSFUSIONS (WB or PRBC) FROM TIME OF INJURY/ILLNESS**

Whole blood or packed red blood cells given from time of injury/illness until donor incision time. Include data from all institutions if more than one is involved.

Completing Form: Check whether whole blood or packed red blood cells were used in the given timeframe. If information is unknown or missing, check "UNK".

**IX. 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. These results will usually be from the donor center.

Completing Form: Record date of sample as month, day and year.

GENERAL INSTRUCTIONS for completing laboratory data:

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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  $\geq 5$ ).

**IX.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.

**IX.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.

**IX.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.

**IX.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 From:

1. Record as \_ \_ \_ \_ \_ U/L.

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2. If not done, check the "Not Done" column.

**IX.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:  $BUN = \text{urea} \div 2.14$ .

Completing Form:

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

**IX.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.

**IX.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 the highest value given for the normal range as provided by the donor hospital. If the normal range is not obtainable, enter control as "UNK".
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.



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**IX.8 BLOOD ALCOHOL TEST DONE AT TIME OF ADMISSION**

This is the blood alcohol level that was obtained at time of admission to the donor hospital, if the test was done. Results from the medical chart or lab report must be converted to mg% when recording (mg%=g/dl x 1000).

Completing Form: Check whether a blood alcohol was obtained at time of admission. If "yes" record the date the sample was obtained as month, day and year, and record the blood alcohol level as \_\_\_ mg%.

**IX.9 TOXICOLOGY SCREEN DONE AT TIME OF ADMISSION**

Any tests that were done at the time of admission to the donor hospital to screen for the presence of drugs such as codeine, marijuana, cocaine, LSD, etc., in the blood.

Completing Form: Check whether a toxicology screen was obtained at time of admission. If "yes" record the date the sample was obtained as month, day and year, and whether positive results were obtained. If results were positive, specify the drugs that showed positive results as they appear on the record, one drug/line. If there are more than 4 drugs, record the remainder under "COMMENTS" (Section X) starting with the section no. and item name (e.g. "IX.9.2.5 Toxicology screen: . . .").

**IX.10 INFECTIOUS DISEASE SCREEN**

This infectious disease screen may be done either at the donor hospital, or the blood may be brought back to the recipient hospital to be run.

Completing Form:

1. Record the date of the blood sample as month, day, year.
2. For each test check whether the results were positive or negative, if the test was done. If the test was not done, check the "not done" column.

- |      |   |
|------|---|
| 10.1 | Anti-CMV IgG and the titer obtained for positive results. |
| 10.2 | HBsAg   |
| 10.3 | Anti-HBs  |
| 10.4 | Anti-HBc  |
| 10.5 | Anti-HCV  |
| 10.6 | Anti-HIV  |
| 10.7 | Anti-HTLV1  |
| 10.8 | Routine Blood Culture                                     |

- |        |   |
|--------|---|
| 10.8.1 | 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 X) starting with the section no. and item name (e.g. "IX.10.8.1 Bacteria: . . ."). |
|--------|---|

- |          |   |
|----------|---|
| 10.8.2-3 | Other - specify any other organism(s) that show positive results for blood cultures, one organism/line. If there are more than 2 types, record the remainder under "COMMENTS" (Section X) starting with the section no. and item name (e.g. |
|----------|---|

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"IX.10.8.4. Other organism: . . .").

**IX.11.1 IMMUNOLOGY, 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. These tests are usually run at the recipient hospital.

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).

**IX.11.1.4-8 IMMUNOLOGY, HISTOCOMPATIBILITY, TESTING - OPTIONAL TESTS.**

These HLA tests (Bw4/6; C; DRw 52/53; DQ and DP) are optional, but record each test that was performed.

Completing Form: Record results as given on the donor record.

**X. COMMENTS**

Use this space for any other information that is pertinent to the donor's medical history that has not already been mentioned elsewhere in this form.

Completing Form: Check whether there are any comments to be made. If "yes", write in any comments that are pertinent to the donor's medical history. If comment pertains to a specific item on the form, precede comment with section and item number (e.g. "V.15.5 Other miscellaneous condition: . . .").