FORM: IO (INTRA-OPERATIVE PROCEDURE)

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<u>Purpose</u>: To record the status of the patient and any complications that may have occurred

during the intra-operative procedure.

<u>Person(s) Responsible</u>: LTD Clinical Coordinator, anesthesiologist.

Source(s) of Information: Intra-operative record.

General Instructions: This form is completed for each transplant performed for each patient.

Transplants are numbered consecutively if a patient undergoes more than one transplant. Note that only patients who receive(d) a first liver transplantation as an LTD patient should be considered. Care should be taken to record the correct dates for the surgical timepoints as the date of incision may be before the date of

close incision. The date of transplant should be this latter date.

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TRANSPLANT NUMBER

This is the transplant number for the current liver transplantation (OLTX) for this patient.

Completing Form: Record whether this is the 1st, 2nd, 3rd, ... OLTX for this patient.

DATE OF TRANSPLANT

The date of closure for the operation (end of case as recorded by the anesthesiologist) should be recorded, and not the date of initial incision (which may occur the day before).

Completing Form: Record the date of closure for the transplant as month, day, year.

I. RETRANSPLANTATION

A second or subsequent liver transplant. Note that this is permissible only for patients who received a first liver transplantation as an LTD patient. The reason for retransplantation should be recorded.

<u>Completing Form</u>: Check "yes" if this is not the first liver transplant. If "yes", check appropriate reason for retransplantation. If reason is not one of the listed reasons, check "other" and specify in the space provided.

II. BYPASS USED

Bypass is veno venous bypass.

<u>Completing Form</u>: Check the appropriate response, "yes" or "no" to indicate whether bypass was used.

III. SURGICAL TIME POINTS

These times should be obtainable from the anesthesia record. If not available, they should be added to the routine data collection done by the anesthesiologist.

Completing Form: For each item record time as military time on a 24 hour clock.

III.1 INCISION

The "cut skin" time.

Completing Form: Use military time and record the time as hours and minutes, and date (month,

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day, year) of the initial incision. The date is necessary as it may differ from the date of closure.

III.2 LIVER CROSS CLAMPED

The time at which the hepatic vena cava is clamped.

<u>Completing Form</u>: Record the time as hours and minutes (military time) that the liver is cross clamped.

III.3 DONOR LIVER REMOVED FROM ICE

The time the donor liver was removed from ice to be placed in the recipient. This is the start of warm ischemia time.

<u>Completing Form</u>: Record the time as hours and minutes (military time) the liver was removed from ice to be placed in the recipient.

III.4 INITIAL FLOW RESTORED: 1. VENOUS (PORTAL VEIN) AND 2. ARTERIAL (HEPATIC ARTERY)

Completion of 1) the portal vein anastomosis and restoration of blood flow and 2) the hepatic artery anastomosis and restoration of blood flow.

<u>Completing Form</u>: Record the time as hours and minutes (military time) that: 1) portal vein anastamosis was completed and flow was restored; 2) hepatic artery anastomosis was completed and flow was restored.

III.5 CLOSE INCISION

The end of procedure as recorded by the anesthesiologist.

<u>Completing Form</u>: Record the time as hours and minutes (military time) and date (month, day, year) that the anesthesiologist considers the procedure ended. This date may be one day later than the date of incision.

IV. INTRAOPERATIVE COMPLICATIONS

- A) Stage I (Hepatectomy): from incision time to cross clamp time.
- B) Stage II (Anhepatic): from cross clamp time to release of portal vein.
- C) Stage III (Reperfusion): from reperfusion of portal vein to end of procedure.

<u>Completing Form</u>: This section requests data on intraoperative events that occurred during the 3 stages as defined. Occurrence of each complication should be recorded for each of the three stages of the procedure.

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IV.1 VENTRICULAR ARRHYTHMIA

An irregular heart rhythm originating in the ventricle, also known as a "lethal" arrhythmia.

<u>Completing Form</u>: Check "yes" if a ventricular arrhythmia occurred. Check "no" if no ventricular arrhythmia occurred. Answer separately for each stage.

IV.2 CPR PERFORMED

Cardiopulmonary resuscitation.

<u>Completing Form</u>: Check "yes" if CPR was performed, check "no" if CPR was not performed. Answer separately for each stage.

IV.3 HYPOXEMIA

Insufficient oxygenation of the blood defined as PaO₂ < 60 mmHg on any FiO₂.

<u>Completing Form</u>: Check "yes" if hypoxemia occurred. Check "no" if no hypoxemia occurred. Answer separately for each stage.

IV.4 CLINICALLY SIGNIFICANT EMBOLISM: AIR

An air embolus (due to air bubbles entering the veins after trauma or surgical procedure) that is considered clinically significant.

<u>Completing Form</u>: Check "yes" if a clinically significant air embolus occurred. Check "no" if a clinically significant air embolus did not occur. Answer separately for each stage.

IV.5 CLINICALLY SIGNIFICANT EMBOLISM: CLOT

A clot embolus that is considered clinically significant.

<u>Completing Form</u>: Check "yes" if a clinically significant clot embolus occurred. Check "no" if a clinically significant clot embolus did not occur. Answer separately for each stage.

IV.6 HYPOTENSION

Defined as a systolic blood pressure < 70 mmHg for 15 minutes or more in adults and at least a 30% decrease in systolic blood pressure for 15 minutes or more in pediatric patients.

Completing Form: Check "yes" if hypotension occurred. Check "no" if hypotension did not

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occur. Answer separately for each stage.

V. BLOOD USAGE

Transfusion of blood or blood products.

<u>Completing Form</u>: For each of the listed blood products, record the total volume in cc's given during the entire procedure. Do not leave blanks: for example, if no cell saver units were transfused, enter 0. If units are recorded, convert to cc's before recording.

VI. URINE OUTPUT

Urine output should be recorded in cc's for each of the 3 stages listed.

Completing Form: Record the urine output in cc's for each of the 3 stages.

VII. HEMODYNAMICS

The hemodynamic measurements requested are to be recorded for each of the specified timepoints: at the time of incision, at 5 minutes prior to the anhepatic phase, at 10 minutes into the anhepatic phase, at 5 minutes before reperfusion, at 15 minutes after reperfusion, and at 70 minutes after reperfusion. Note that pulmonary artery pressures, capillary wedge pressures and cardiac outputs cannot be obtained in children or in adults transplanted without Swan-Ganz catheterization. ICP (intracranial pressure) monitoring, if used, should be recorded as well as any treatment given at each of the timepoints.

<u>Completing Form</u>: Record in the designated units the measurements for each of the hemodynamic parameters at each of the six timepoints. Check whether ICP monitoring was done. If yes, record the reading at each timepoint, and check whether any of the treatments listed were given at these timepoints.

VIII. COAGULATION FACTORS

The three coagulation parameters listed (PT, PTT, and platelet count) should be recorded at each of the six timepoints. Note that the PT and PTT control values must be recorded. Use the actual values 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 the control value). A corrected PT control variable has been added to the dataset and replaces the PT control value recorded by the centers. Refer to the corrected PT control list.

For PT, normal range is 9.5 to 15.9 seconds for the patient; edit range is 9.0 to 50.0 seconds for the patient, 10.0 to 15.0 seconds for the control.

For PTT, normal range is 23.0 to 60.0 seconds for the patient; edit range is 15.0 to 150.0 seconds for the patient, 15.0 to 50.0 seconds for the control.

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<u>Completing Form</u>: Record in the designated units the measurement of each of the coagulation factors at each of the six timepoints.

IX. PRESSORS

Record the specific pressor agents that were given during each of the six designated timepoints.

X. PERSONNEL: ANESTHESIOLOGIST OF RECORD

This is the ID of the anesthesiologist of record during the transplant surgery.

<u>Completing Form</u>: Record the center number and the first 3 letters of the anesthesiologist's last name.

XI. GENERAL COMMENTS ON THE INTRAOPERATIVE COURSE

This space is for any additional pertinent information or explanation to further describe the surgery.

<u>Completing Form</u>: Check whether there are any comments to be made. If "yes" write the comments in the designated space. If a comment pertains to a specific item in the form, precede the comment with the section and item numbers, (e.g. "IX.4. Pressors . . .").