FORM: LC (LIVING DONOR FOLLOW-UP COMPLICATIONS FORM)

Purpose: To document complications and infections that occurred since previous evaluation, and are not recorded on the Living Donor Follow-up Form (LF) for the current information.

Person(s) Responsible: LTD Clinical Coordinators.

Source(s) of Information: Donor's 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. This form should only be completed as needed to document complications not recorded on the corresponding LF form.

PATIENT ID, TRANSPLANT NO.

The Patient ID and Transplant Number are those of the transplant recipient. 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.1 DATE OF EVALUATION

This is the date that the patient was seen by a physician or contacted by the LTD coordinator for postoperative follow-up. This date should coincide with the evaluation timepoint checked below, and with the date of evaluation recorded on the LF form (Living Donor Follow-up).

Completing Form: Enter the date of evaluation as month, day and year.

I.2 EVALUATION TIMEPOINT

The timepoint for this evaluation should correspond with the protocol data collection timepoint of the LF form. If the date of "death" or "lost to follow-up" coincides with a routine evaluation timepoint, check "death" or "lost to follow-up", rather than the routine follow-up timepoint. Continue these follow-up evaluations up to five years post transplant, or until death, or until the patient is lost to follow-up.

Completing Form: Check the evaluation timepoint to correspond with the evaluation timepoint on the LF form. Check only one timepoint.

II. COMPLICATIONS (since last evaluation)

Any complications or infections the patient may have experienced since the last evaluation that are not included on the LF form, should be documented here. The subsequent information must be provided as defined.

Continuation Status Codes:

1) Existing pre-surgery continuing post-surgery: This is a complication that existed prior to the surgery for the patient, and continues post-surgery.

2) Continuing from last follow-up evaluation: This is to record a post-surgery complication that was present during the previous evaluation period and continuing into this evaluation period. The complication cited must be documented on a previous LC Form.

Date of onset: This is the date the particular complication was first diagnosed within the period of time covered under this evaluation only. For example, the patient may have experienced several upper GI bleeds since his/her surgery. The date recorded here should reflect the first bleed since the "date of evaluation" of the previous evaluation period.

Required surgery: a surgical intervention was required to treat this complication.

Status code at the time of this evaluation: This is the outcome of the complication at the time of this evaluation. **1**: the complication is completely resolved at the time of this evaluation (such as a pneumothorax), or is controlled (such as hypertension, atrial arrhythmia, etc). **2**: the complication is unresolved, continuing and/or worsening. In this case the complication will be noted as a "continuing episode from last follow-up evaluation" at the next evaluation timepoint. **3**: the patient died while experiencing the noted complication, although the complication may not necessarily have contributed to the patient's cause of death.

Completing Form: Check the complications present from the list provided, and complete the information as defined above.

1) Enter "1" if the complication existed pre-surgery and is continuing post-surgery.
Enter a "2" in this column if the complication is continuing from the previous evaluation period. Otherwise leave this space blank.

2) Enter the month, day and year of the date of onset if occurring since the date of the last evaluation.

3) Place a check in this column if the complication required surgery.

4) Enter the status code as defined on the opposite page of the form to indicate the outcome of the complication at the time of this evaluation.

LIVER INJURY

II.1 Bile Duct

Any complication occurring in the bile duct.

Completing Form: Check if bile duct injury occurred and complete remaining columns as instructed on p.2.

II.2 Hepatic Artery

Any injury of the hepatic artery confirmed by diagnostic testing or surgical exploration. If a patient experiences an injury of the hepatic artery and the condition is not treated, note it here with a status code of 1. This complication should not be documented on future follow-up timepoints unless the patient's condition worsens. If needed, record information under "COMMENTS" (section III of the form), starting with the section no. and item name (e.g. II.2 "Injury of hepatic artery . . .").

Completing Form: Check if hepatic artery injury occurred and complete remaining columns as instructed on p.2.

II.3 Portal Vein

Any injury of the portal vein confirmed by diagnostic testing or surgical exploration. If a patient experiences an injury of the portal vein and the condition is not treated, note it here with a status code of 1. This complication should not be documented on future follow-up timepoints unless

the patient's condition worsens. If needed, record additional information under "COMMENTS" (section III of form) as instructed.

Completing Form: Check if injury to the portal vein occurred, and complete remaining columns as instructed on p.2.

II.4 Necrosis

Any necrotic area of the liver or bile ducts.

Completing Form: Check if any area of necrosis is present, and complete remaining columns as instructed on p.2.

II.5 Abscess

A localized collection of pus. Record only liver abscesses here. If there is a positive culture of the abscess available, record it in the "Infections" section of this form also. However, it is possible to have a liver abscess without a positive culture if it is confirmed by surgical exploration, CT, ultrasound or MRI.

Completing Form: Check if abscess was present, and complete remaining columns as instructed on p.2.

ABDOMINAL

II.6 Intra-abdominal bleed

Any bleeding within the abdomen. If a patient experiences a series of bleeds over several days but never fully recovers between them, this constitutes only one "episode". It may be difficult to differentiate between several episodes and one ongoing bleed. In this case consult a physician involved in the patient's care to assess how many separate episodes have occurred.

Completing Form: Check if intra-abdominal bleeding occurred and specify the source(s) of bleeding in the space provided. Complete remaining columns as instructed on p.2.

II.7 GI bleed

Bleeding communicating with the esophagus, stomach or duodenum. If a patient experiences a series of bleeds over several days but never fully recovers between them, this constitutes only one "episode". It may be difficult to differentiate between several episodes and one ongoing bleed. In this case consult a physician involved in the patient's care to assess how many separate episodes have occurred.

Completing Form: Check if upper GI bleeding occurred, and complete remaining columns as instructed on p.2.

II.8 Intra-abdominal abscess/fluid

A localized collection of pus. Record only intra-abdominal abscesses here. If there is a positive culture of the abscess available, record it in the Infections section of this form also. However, it is possible to have an abdominal abscess without a positive culture if it is confirmed by surgical exploration, CT, ultrasound or MRI.

Completing Form: Check if abscess was present, and complete remaining columns as instructed on p.2. If "yes", specify location in the space provided.

II.9 Biliary leak

Any biliary leak from a choledochocholedochostomy, choledochojejunostomy, jejunojejunostomy. Diagnosis is made by contrast radiography or surgical exploration. These types of leaks may result in bile peritonitis.

Completing Form: Check if biliary leak occurred, and complete remaining columns as instructed on p.2. If "yes", specify source in the space provided, then enter the treatment code from opposite page.

CARDIOPULMONARY

II.10 Hypotension

A sustained low blood pressure which has required medical therapy such as vasopressors or IV fluids to maintain adequate tissue perfusion.

Completing Form: Check if hypotension occurred, and complete remaining columns as instructed on p.2.

II.11 Hypertension

A sustained blood pressure greater than 150/95 which has required medical treatment such as drug and/or diet therapy.

Completing Form: Check if hypertension occurred, and complete remaining columns as instructed on p.2.

II.12 Myocardial infarction (MI)

An interruption of blood supply to an area of the myocardium causing necrosis. Diagnosis is made by EKG with positive CPK and MB bands. In the case that an EKG reveals a probable silent MI in the past, check here and record "unk" under "date of first new episode". Record findings under "COMMENTS" (section III of form) as instructed.

Completing Form: Check if myocardial infarction occurred, and complete remaining columns as instructed on p.2.

II.13 Congestive heart failure (CHF)

The inability of the heart to maintain adequate blood flow. This results in congestion of blood in certain veins and organs with an inadequate supply of blood to body tissues.

Completing Form: Check if congestive heart failure occurred, and complete remaining columns as instructed on p.2.

II.14 Pneumothorax (requiring chest tube)

Air or gas in the pleural space. Document only those cases resulting in pressure large enough to require chest tube placement to allow for adequate lung expansion. Pneumothorax is confirmed by chest x-ray.

Completing Form: Check if pneumothorax occurred, and complete remaining columns as instructed on p.2.

II.15 Pleural effusion (requiring thoracentesis)

The presence of fluid in the pleural space. Record only those cases when the effusion was so large and persistent that it required drainage via thoracentesis (also known as thoracocentesis, and pleuracentesis).

Completing Form: Check if pleural effusion occurred, and complete remaining columns as instructed on p.2.

II.16 Cardiopulmonary arrest

A sudden cessation of the heart associated with a lack of respiration. Document only complete cardiopulmonary arrests requiring CPR. Do not check here if the patient suffered only a respiratory arrest that was not accompanied by ventricular fibrillation or ventricular standstill.

Completing Form: Check if cardiopulmonary arrest occurred, and complete remaining columns as instructed on p.2.

II.17 ARDS

Adult respiratory distress syndrome (ARDS) is decreasing pO2 and lung compliance combined with a worsening physiologic shunt due to an increase in microvascular and epithelial permeability in the lung.

Completing Form: Check if ARDS occurred, and complete remaining columns as instructed on p.2.

II.18 Atrial arrhythmia

Any deviation from normal sinus rhythm which originates in the atrium. Examples include frequent PAC's, prolonged sinus tachycardia and bradycardia. The arrhythmia should be prolonged and/or treated to be noted as a complication. Do not record occasional arrhythmias observed on EKG.

Completing Form: Check if atrial arrhythmia occurred, and complete remaining columns as instructed on p.2.

II.19 Ventricular arrhythmia

Any deviation from normal sinus rhythm that originates in the ventricles. The arrhythmia should be prolonged and/or treated to be classified as a complication. Examples of ventricular arrhythmias include frequent PVC's and ventricular tachycardia not associated with cardiopulmonary arrest.

Completing Form: Check if ventricular arrhythmia occurred, and complete remaining columns as instructed on p.2.

II.20 Reintubation

Insertion of an endotracheal tube, nasotracheal tube or tracheostomy to maintain a patent airway for adequate ventilation. Record only episodes of reintubation for respiratory failure. Do not include routine intubation experienced immediately post operatively or when a patient's tracheal tube or site is changed.

Completing Form: Check if reintubation occurred, and complete remaining columns as instructed on p.2.

II.21 Pulmonary edema

Extravascular accumulation of fluid in the lung tissue or air spaces secondary to hydrostatic changes in the capillary permeability. Diagnosis is confirmed by chest x-ray. Document all cases of pulmonary edema, treated or untreated. It may be difficult to differentiate between several episodes of pulmonary edema and one ongoing incident. In this instance contact a physician involved with the patient's care.

Completing Form: Check if pulmonary edema occurred, and complete remaining columns as instructed on p.2.

WOUND COMPLICATION

II.22 Abscess

A localized collection of pus. Record only wound abscesses here. If there is a positive culture of the abscess available, record it in the Infections section of this form also.

Completing Form: Check if abscess was present, and complete remaining columns as instructed on p.2.

II.23 Dehiscence

Any partial or complete separation of a surgical wound. Include any wound dehiscence.

Completing Form: Check if wound dehiscence occurred, and complete remaining columns as instructed on p.2.

II.24 Vein incision

Any complication occurring at vein incision.

Completing Form: Check if any vein incision complications occurred, and complete remaining columns as instructed on p.2.

RENAL

II.25 Renal failure

A sustained creatinine greater than 2.0 mg/dl with or without a urine output less than 10 ml/kg for 24 hours.

Completing Form: Check whether renal failure occurred. If "yes", record creatinine in mg/dl, date of creatinine sample as month/day/year, and check whether dialysis was given.

II.26 Drug reaction

Any serious incident directly caused by a medication administered to the patient. For example, renal failure, bleeding, anaphylactic shock, etc. Do not include minor complaints such as headaches, GI upset, drowsiness, etc.

Completing Form: Check if any drug reaction occurred, and complete remaining columns as instructed on p.2. If "yes", specify the type of reaction in the space provided.

II.27 Neurologic

Any complication affecting the nervous system.

Completing Form: Check if any neurologic complications occurred, and complete remaining columns as instructed on p.2. If "yes", specify the type in the space provided.

II.28-29 Other Complications

Any other complications that are not listed.

Completing Form: Check if any other complications occurred that are not listed and specify in the space provided. If more than two other complications occurred, record the remainder under "COMMENTS" (section III of form) per instruction.

II.30 Treated Infections

Identified infections that warranted treatment, not simply positive cultures. Information must be obtained for site of infection and organism, and date of sample of first positive culture.

Completing Form:

1) Check whether any infections occurred. If "yes", for each infection site, code the site and the organism(s) one per line, using the codes provided on the opposite page. If site is not

listed, code "other"; if organism not listed, code "other" from the correct category of microorganism, e.g. bacterial, viral, fungal, protozoal.

2) Date of sample of first positive culture: Use the date the sample was obtained, not the date the lab reported the results. If this is a continuing infection, record the date of sample for the first positive culture here.

III. COMMENTS

Use this space for any other information that is pertinent to the complications that occurred since the previous evaluation.

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. "II.25 Renal failure: . . .").