**Policy: Living Donation for Liver Transplantation**

**Statement: Background**

Since 1989, when 20 – 30% of children were dying on the transplant waiting list due to a lack of available organs for small children, innovative surgical techniques led to the transplantation of a portion of a liver from live donors (left lateral segmentectomy) to children with end-stage liver disease. The left lateral segment, which comprises up to 25% of the donor’s total liver volume, regenerates over time. Today the surgery is considered safe and effective for both the recipient and donor when performed by experienced liver-surgery programs1-3.

In the adult transplant population, it is projected that the disparity between available donor organs from brain dead individuals and those awaiting transplant will continue to grow, secondary to an increased incidence of individuals with end stage liver disease due to viral hepatitis (hepatitis C and B). It has been estimated that viral hepatitis will account for 50% of the liver transplants done in this country over the next 5 years without an increase in deceased donor organs. The demand for livers suitable for transplantation will lead to an even greater shortage of organs, increased waiting times for transplant and subsequently, increased incidence of mortality for those with end-stage liver disease. It is estimated that for adults between the ages of 18 and 55, mortality while awaiting transplant is currently 14.2 % with another 12.6% being dropped from the list due to decompensation4. Efforts to bridge the organ shortage has resulted in 1) the innovative technique of splitting deceased donor livers between two individuals awaiting transplantation, when appropriate, 2) implementation of living donor liver transplantation (LDLT) for adult recipients5, 3) and use of marginal organs from deceased individuals. LDLT for adult recipients requires the removal of approximately 60% of the hepatic mass with a right lobectomy or 70%, with an extended right hepatectomy, with subsequent regeneration of the donated liver mass.

This policy describes the evaluation and informed consent processes by the Emory University Hospital’s Liver Transplant Program (the “Transplant Program”) for all potential living donors for liver transplantation.

**Scope/Procedure:**

It is the policy of the Emory Hospitals that any person who wishes to be a potential living donor must be at least 18 years of age, competent, willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits and alternative treatments available to the recipient. The benefits to both donor and recipient should outweigh the risks associated with the donation and transplantation of a portion of the liver from a healthy living donor. The health and safety of the donor is of critical importance in proceeding with the evaluation and transplantation process. Potential recipients for living liver donation must have previously qualified for liver transplant and listed on the United Network for Organ Sharing (UNOS) wait list. During the evaluation of a potential living donor, the recipient will remain on the waiting list for a deceased donor liver. If an acceptable donor organ becomes available through UNOS before the evaluation or transplantation from a living donor, the deceased donor graft will be used.

**Procedures**

**Initial Communication with Donors**

A. The Transplant Program should not initiate contact with any potential living donor. A potential living donor must initiate contact with the Transplant Program if s/he is interested in becoming a living donor.

B. When a potential living donor for liver transplantation contacts the Transplant Program, s/he should be provided a packet for general information about the procedure by the transplant coordinator (Appendix A). The information is intended to inform the potential donor about the general requirements for evaluation for donation, a brief overview of the evaluation and donation process, the surgical procedure and risks to the donor, expected recovery time, and the risks and benefits of transplantation for both the donor and recipient including future health and life insurance coverage risks. The packet shall also include a standard health questionnaire (Appendix B).

C. If the potential donor is interested in becoming a living donor, s/he should be directed to complete the standard health questionnaire and forward the completed questionnaire to the transplant coordinator. The transplant coordinator will forward the completed questionnaire to the transplant team.

**Preliminary Evaluation of Donor**

A. A potential living donor must be between 18 and 55 years of age, in good physical and mental health, and express a willingness/interest to proceed with the evaluation process. If the potential donor has completed and forwarded the standard questionnaire to the Transplant Program coordinator, and has no absolute medical contraindications to liver donation, the evaluation process will continue.

B. The initial considerations of a potential donor include:

1. The donor may either be a close or distant relative or unrelated to the potential recipient.
2. The donor should be in good physical and mental health.
3. The donation decision should be made by the donor, after being presented with the facts and knowledge of the procedures and the risks and complications, both in the written packet and orally by the transplant team.
4. There should be no evidence of financial gain arising out of the donation.

C. The potential donor should be scheduled for an initial consultation with the liver transplant surgeon: (i) to discuss the possibility, risks and benefits of living donation, (ii) to have an initial physical examination performed and (iii) to discuss the evaluation process, including lab tests, physical examinations, interviews and the surgical procedure. The transplant surgeon should inform the potential donor of the national statistics as well as the Emory Transplant Program’s statistics for the outcomes of living liver donation procedures. The transplant surgeon should also inform the potential donor of the experience of the physician/surgeon members of the Transplant Team.

D. At the initial consultation, the transplant surgeon should present the potential donor with a copy of two consent forms – (i) a consent form to proceed with the medical evaluation process and (ii) a consent form for the partial hepatectomy. The transplant surgeon should discuss/explain the medical evaluation consent form with the potential donor and ask the potential donor to place his/her initials in the left margin of each paragraph and sign the consent form. A copy of the signed evaluation consent form will be provided to the potential donor. The potential donor should not be asked to sign the consent form for the partial hepatectomy at this time, but should be allowed to take a copy of the consent form with him or her to review after completing the initial consultation. Contingent on positive results from the initial consultation, and receipt of the signed medical evaluation consent form, the medical evaluation will begin, with laboratory testing and the scheduling of hepatic, cardiac, and pulmonary work-ups and consultation with the transplant hepatologist.

E. The preliminary medical evaluation should include laboratory testing to confirm the possible donor’s blood type as well as complete routine chemistry, hematology, coagulation, hepatitis screens and viral studies. The potential donor should also be asked to sign a consent form to have an HIV blood test performed. The preliminary medical evaluation should also include a PPD skin test for tuberculosis as well as a urine screen to monitor for substance abuse.

**Psychosocial Evaluation**

In addition to the medical and pre-surgical evaluation, a licensed psychiatrist should perform a psychosocial evaluation. In addition to the standard psychosocial evaluation, the current history should include: a) emphasis on the potential donor’s interest in donation and the desire to be such a donor; b) evidence of the absence of coercion, ambivalence, and prospect of material gain; c) evidence of the absence of psychiatric and/or substance use disorders; d) understanding of the risks and benefits of donation; and, e) other relevant issues. The potential donor should also be evaluated by a social worker to evaluate social needs that the donor may have. The potential recipient should not be present at or involved with the psychosocial evaluation conducted by the licensed psychiatrist or the social worker.

**Independent Donor Advocate**

Because of the inherent conflict of interest in living donation by transplant centers, an independent donor advocate (e.g., internist, clinical ethicist, medical specialist) should be assigned early in the process to assist the potential donor in deciding whether to serve as a living liver donor. The donor advocate’s primary purpose should be to protect and promote the well being of the potential donor, placing the potential donor’s interest above all. The donor advocate must be trained to recognize psychological pressures, both external and family-related, and discuss this with the donor. The donor advocate should be available throughout the evaluation process to weigh the risks and benefits of donation with the individual, review test results, answer questions, and make a written, independent recommendation as to whether the donation should occur.

**Transplant Evaluation Conference**

A. Upon completion of the medical, surgical, social and psychiatric evaluations, the transplant team should meet to review and discuss the potential donor’s candidacy as living donor. The conference should include the surgeon, psychiatrist, hepatologist, social worker and donor advocate. Specific issues to be addressed during the patient screening evaluation and confirmed at a transplant evaluation conference include:

(1) that there are no detected medical or psychological illness which would preclude donation by the potential donor;

(2) the team reasonably believes that the potential donor has a basic understanding of the nature of the procedure, including the risks and benefits to the donor;

(3) the team reasonably believes that the potential donor has a sincere desire to donate;

(4) the team has not detected any evidence of coercion; and

(5) any additional issues as established by the Transplant Program.

B. If the team concludes that the prospective donor remains a candidate for living donation, the potential donor should be informed of the finding of candidacy and be asked to sign an informed consent form to become a living donor.

**Informed Consent Process**

A. Throughout the evaluation process, beginning with the initial request for information, the informed consent process should take place in various stages as described above. The potential donor will be asked to sign two consent forms, and initial each paragraph of the consent forms, along the various stages of the consent process – (i) a consent to proceed with the medical evaluation and (ii) a consent for the actual partial hepatectomy procedure.

B. Upon completion of the evaluation and determination of candidacy for liver donation, should the donor candidate agree to proceed with the living liver donation for transplantation, a family conference should be scheduled at which time the potential recipient, donor and their family members meet with the transplant team, including donor advocate, to review again the surgical procedure, surgical, medical and social risks and benefits to both the donor and recipient, alternative treatments available to the recipient and any methods that may be considered experimental, and answer any questions.

C. Expenses related to the donation should be discussed with the donor. The donor should be reminded that he or she will NOT be compensated by money or material gain of any kind for the liver donation. The evaluation, surgery, hospitalization, and outpatient visits should be pre-authorized and covered by the recipient’s insurance company. In addition, the potential donor may be reimbursed for personal expenses, such as transportation, lodging and lost wages.

D. The potential donor should be informed that he or she will be unable to work for 8-12 weeks after surgery. The potential donor should be informed that, although currently there are no known long term complications related to living liver donation, there may be medical costs related to long-term complications of the surgery and insurance coverage issues as more fully described in the Living Liver Donor Consent Form.

E. The possibility of the unlikely event that the donated portion of the liver cannot be placed in the intended recipient due to intra-operative death should be explained to the donor candidate, giving the donor the opportunity to consent and direct that the liver be placed in another recipient if appropriate.

F. The living donor and recipient will be required to read, understand, initial each paragraph of the consent form, and sign an informed consent form prior to any operative procedure. The informed consent will spell out all possible complications with this procedure including the incidence of death or permanent disability. As with all consents, the donor has the right to withdraw consent at any time. A copy of the signed consent form should be provided to the donor for their files.

G. A withdrawal of consent by the potential donor will not reflect on the recipient’s ability to receive a transplant at Emory from the UNOS deceased organ pool.

H. If the transplant team feels that a potential recipient is too sick to receive an organ from a living donor or if the potential recipient has a diminished chance of survival, the transplant team may re-evaluate the procedure and refuse to proceed forward with the living donation.

**Surgical Coverage and Post-Procedure Guidelines**

A. Prior to scheduling a LDLT and during the transplant admission, the surgical team coverage for both the transplant recipient and donor including names, pager numbers and phone numbers of both patients’ primary surgeon, first physician assistant and attending transplant surgeon on first back-up call will be published and available to the Department of Surgery and Transplant Center leadership; operating room, intensive care and nursing unit staffs.

B. The donor should be hospitalized for approximately 7-10 days after the donation has taken place. If the donor lives outside of the city, s/he should be required to stay in town for several weeks after discharge. The discharge plan should instruct that the donor should not perform any heavy lifting for at least 6 weeks after discharge.

C. After donation, the Transplant Program should continue to monitor the medical condition of the living liver donor. Specifically, the liver donors should be seen in the Emory University Hospital transplant clinic at least once in the three months post-transplant period for physical examination, blood pressure check, serum chemistries, and urinalysis. The living liver donors should then be monitored at least every 3 months with laboratories for one year. The donor will be asked to provide the Transplant Program with information on his/her health for rest of his/her lifetime and should anticipate that such data will be entered into a national donor registry as well.

D. Data on all living donors should be compiled and maintained within the Transplant Program to be available for entry into a national living donor registry once implemented. The Transplant Program and Transplant Center should review aggregate data reports annually with changes in clinical protocols implemented, as indicated.

E. Questions regarding this Policy and Procedure should be directed to the Transplant Program’s administrative leadership.

**References**
1. Millis, JM, Cronin, DC, Brady, LM, et al (2000). Primary living-donor liver transplantation at the University of Chicago: technical aspects of the first 104 recipients. Annals of Surgery, 232: 104-111.

2. Yamaoka, Y, Morimoto T, Inamot T, et al. (1995). Safety of the donor in living-related liver transplantation – an anysis of 100 parental donors. Transplantation, 59: 224-226.

3. Grewal, HP, Thistlethwaite JR, Loss, GE, et al (1998). Complications in 100 living-liver donors. Annals of Surgery, 228: 214-219.

4. UNOS Transplant Patient Data Source web site, <http://www.patients.unos.org>, 1/1/1999 to 12/31/1999.

5. Brown, RS, Russo, MW, Lai, M, Shiffman, ML, et al (2003). A Survey of Liver Transplantation from Living Adult Donors in the United States. New England Journal of Medicine, 348 (9); 818-825.