Transplant Services
University of Virginia Health System

Transplant Services Policy No. 6.0

A. SUBJECT: Living Donor - Referral, Intake & Screening Process

B. EFFECTIVE DATE: May 1, 2010

C. POLICY:

The University of Virginia Transplant Center and living donation program, maintains standard procedures for initiating the process of living donation. All living donor candidates must personally reach out to the living donor coordinator in order to initiate the process. The UVA Transplant Center does not make the first contact with a possible donor.

D. PROCEDURE:

I. The process for living donor evaluation from point of referral to the decision to list is outlined in the *Living Donation Process Flowsheet* (Appendix I).

II. Referral (Initiating Contact)

1. How Referrals are Made – referrals for living donation are made through the Living Donor Coordinator (LDC) by the potential donor ONLY, in the following manner:
    a. Phone referrals
    b. Electronic Mail
    c. Facsimile
    d. Presentation to Clinic
        i. Potential donors who present to clinic along with their intended recipient are referred to the LDC.
        ii. The LDC takes the potential donor to a separate consult room to perform the initial screening and interview.
    e. Recipients who contact the transplant program with a contact method for a donor are given contact information for the Living Donor Coordinator and informed that the donor themselves must initiate contact with the transplant center.

III. Initial Interview/Intake – During the initial interview or intake (which may happen in clinic or via telephone), the LDC obtains information necessary to determine whether the individual is a candidate for living donor evaluation. The following is documented on the *Living Kidney* or the *Living Liver Donor Evaluation Intake Form.*

1. Demographic and social information – the Living Donor Coordinator obtains the following:
    a. Name, address and contact numbers
    b. Gender
    c. Age / Date of Birth

   d. Social Security Number
   e. Primary Care Physician Name & Contact Information
   f. Employment Status
   g. Insurance Status
2. Living Donation Education Materials – The LDC provides the living donor candidate with information regarding donation including:
   a. Living Kidney or Liver Donation Patient Education Handbook (is reviewed with patient via phone or in person & mailed if over phone)
   b. *Living Kidney Donor Agreement of Understanding* or *Living Liver Donor Agreement of Understanding* (is reviewed with patient via phone or in person & mailed if over phone)
   c. Websites (www.transplantliving.org and http://www.healthsystem.virginia.edu/internet/transplant/)
   d. UNOS Living Donation Brochure
3. Determination of relation to the intended recipient
4. Basic Vital Signs (when intake occurs in clinic)
   a. Blood pressure
   a. Temperature
   b. Heart Rate
   c. Respiratory Rate
5. Basic Medical History
   a. Height, Weight and BMI
   b. ABO (if known by donor)
   c. Allergies
   d. Past Surgical History
   e. Any current medications, prescription or over the counter
   f. Herbal supplements or vitamins
   g. Previous drug reactions / reactions to anesthesia
6. Review of Systems
   a. Neurological
      i. Seizures
      ii. Chronic Headaches, Migraines
      iii. Cerebro-vascular incidents
      iv. Any other neurological or brain diagnoses
   b. Cardio-Vascular
      i. Myocardial Infarctions
      ii. Chest Pains, angina
      iii. History of Hypertension
      iv. Any other cardiac or vascular diagnoses
   c. Respiratory
      i. Any shortness of breath or dyspnea on exertion
      ii. Chronic cough
      iii. Asthma
      iv. Any Lung Disease
      v. Pneumonias

vi. Tuberculosis exposure / positive TB Skin Test
vii. Smoking History (pack / year history, continued smoking)
viii. Any other pulmonary diagnoses

d. Gastro-Intestinal
   i. Nausea / Vomiting
   ii. Constipation / Diarrhea
   iii. Upper or lower GI bleeding
   iv. Ulcers / GERD
   v. Hepatitis
   vi. Any other liver disease
   vii. Any family history of liver disease
   viii. Colonoscopies (have they had recently/when/results)
   ix. Any other GI diagnoses
e. Genito-Urinary
   i. Urinary Tract Infections
   ii. Kidney Stones
   iii. Sexually Transmitted Diseases
   iv. In Males – Any prostate issues
   v. Any history of diabetes (including gestational for females) or pancreatic diagnoses
   vi. Any immediate family history of diabetes (parent(s) and/or sibling(s) or child)
f. For Females – Gynecological History
   i. Last Menses, any irregularities
   ii. Menopause – if applicable
   iii. Pregnancies, spontaneous or therapeutic abortions
   iv. Use of Birth Control
   v. Last PAP Smear
   vi. Last Mammogram
   vii. Any other gynecological issues or diagnoses
g. Integumentary System
   i. Skin condition, rashes, lesions
   ii. Dental condition
   iii. Herpes
   iv. Any other skin conditions / diagnoses
h. Neoplasms
   i. Careful questioning for presence of neoplasms
   ii. Skin cancer, abnormal PAP smears
   iii. Biopsies

7. <u>Psycho-social history</u>
   a. Family support structure
      i. Family knowledge of desire to donate
      ii. Family level of support for donation
      iii. Number of children in household
      iv. Ability to receive post-donation care

b. Any history of Substance Use
    i. Type, duration and time since last use
c. Any history of depression, anxiety or other mental health issues

8. Additional Factors – The LDC will also note other factors to pass on to Donor Evaluation Team, as appropriate, for review and further evaluation. These may include, but are not limited to:
    a. Affect during interview
        i. Anxious about donation
        ii. Apparent cognizance of potential risks of donation
    b. Understanding of donation process
        i. Has the potential donor reviewed material prior to the interview
        ii. Cognitive ability to understand process
    c. Coercion
        i. Does the potential donor present as being altruistic?
        ii. Does the donor make any statements leading the Coordinator to believe they are under coercion?
9. Mailings – when the initial interview/intake is done via telephone (and not in person) the living donor coordinator will mail to the candidate the following:
    a. *Living Kidney Donation Patient Education Handbook* or the *Living Liver Donation Patient Education Handbook*
    b. Most Recent SRTR Patient Education Sheet (Reference *Kidney-Living Donor & Liver-Living Donor Transplant Outcomes for our Patients Education Sheet*)
    c. *Living Kidney Donor Agreement of Understanding* Form or *Living Liver Donor Agreement of Understanding* Form
    d. Living Donor Coordinator Contact Information
    e. Lab Orders for Blood Typing (when indicated)
    f. UNOS Living Donation Brochure
    g. OPTN/UNOS Your Resource for Organ Transplant Information Sheet

IV. Screening – Screening is performed by the Living Donor Coordinator under the direction of the Transplant Team. Screening is defined as basic testing to ascertain initial suitability to donate to the intended recipient and / or as an altruistic donor (no designated recipient.)

1. CDC High Risk Screening
    a. Potential donors are mailed or provided with the Living Donor Screening for High Risk Behaviors form.
    b. Donors that wish to proceed with the donor evaluation must sign the form , which provides consent to share the donors high risk status should they be deemed high risk.
    c. Once the form is received, the Living Donor Coordinator contacts the potential donor to complete the screening (reference form *OP036 Living Donor Screening for High Risk Behaviors*).

2. When Screening Tests Are Performed
    a. Screening tests are only performed after the potential candidate is fully educated and signs the Living Donation Agreement of Understanding. This occurs in various ways including the following:
        i. If the donor reviews information prior to the initial interview, screening tests may be performed directly after the interview process.
        ii. If the donor does not review information and/or presents as having reservations regarding the donation process in the interview, screening may be performed after information has been provided and the donor has reviewed the provided information and returned the Agreement of Understanding.

3. Screening tests

    Testing for potential **Kidney donors** includes, but is not limited to the following:
    a. ABO Typing (#1 – this is the first of two required)
    b. HLA Testing
    c. Comprehensive Metabolic Panel
    d. 24 hour Urinalysis
        i. Creatinine Clearance
        ii. Total Urine Protein
        iii. Micro-Albumin
    e. Random Urinalysis
        i. Microscopic UA
        ii. Albumin/creatinine ratio
    f. HgB A1C (as appropriate based on history)
    g. Glucose Tolerance Test (as appropriate if first degree family member with DM and/or personal history of gestational diabetes)
    h. Screening for polycystic kidney disease or other inherited renal disease as guided by family history
        i. Is the potential donor at risk for polycystic kidney disease (PCKD)?
        ii. If yes, imaging (u/s or CT scan depending on scenario)
        iii. If 0-2 cysts and less than 30 years old, genetics counseling and genetics testing
        iv. If 3 or more cysts (unilateral or bilateral), decline as a donor
        v. If age 30-59 and no renal cysts, can proceed with evaluation
        vi. If age 30-59 with 1-3 cysts, genetics counseling and testing should be done

vii. If a PCKD mutation is found, decline as a donor
viii. Each individual situation will be reviewed and discussed with the multidisciplinary team

Testing for potential **Liver donors** includes but is not limited to the following:

a. ABO Typing (must be compatible with intended recipient)
b. Hepatic chemistry panel (as indicated based on patient history)
c. Hepatitis panel (as indicated based on patient history)
d. Inconclusive Tests or tests incompatible with the clinical picture are repeated to better clarify the patient's medical status
e. Short Renal Clearance-Iothalamate Testing – potential kidney donors with suboptimal repeat calculations of GFR based on comprehensive metabolic panel, which can vary widely, may be referred for Short Renal Clearance-Iothalamate testing for more accurate measurement. Reference *Short Renal Clearance-Iothalamate Testing Protocol*.

2. Contraindications to living donation
    a. Less than 18 years of age
    b. Greater than 70 years of age (Kidney)
    c. Greater than 55 years of age (Liver)
    d. HIV infection
    e. Pregnancy
    f. BMI greater than 35 (Kidney)
    g. BMI greater than 30 (Liver)
    h. Diabetes
    i. Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage
    j. Microalbuminuria
    k. Inability to give consent/mentally incapable of making an informed decision
    l. Evidence of coercion
    m. Evidence of illegal financial exchange between donor and recipient
    n. Major psychiatric disorder, not under adequate control, including evidence of suicidality
    o. History and/or treatment of major organ disease
    p. Evidence of acute symptomatic infection (until resolved)
    q. Hepatitis C+
    r. Coronary Artery Disease
    s. History of CVA
    t. Active Substance Abuse
    u. History of Melanoma
    v. History of cancer within the past 5 years
    w. Active malignancy, or incompletely treated malignancy

3. Protocol for Clinical Findings that are not absolute

The following table includes potential clinical findings and/or contraindications with appropriate actions that can be taken to further assess a potential donor's candidacy

Clinical Finding	Action	Comment
BMI of >35 (Kidney) BMI of >30 (Liver)	Provide weight goal	May present again following attaining goal weight
Bilateral recurrent renal calculi	Rule out as potential Kidney donor	
Unilateral renal calculi (kidney donors)	24-hour urine stone panel; Confirm with additional imaging	May discuss with Transplant Team to donate the kidney with calculi
Calculated GFR<80 or low Creatinine Clearance	Repeat test and review with Transplant Team	If second test is unequivocal and no other relative contraindications exist, may perform Iothalamate study
Iothalamate GFR of <80	Rule out as potential donor	
Positive urine micro-albumin	If combined with elevated creatinine or low GFR/ creatinine clearance, rule out as potential donor.	If isolated result, may repeat test. Two positive tests result in potential donor being ruled out.
Active infectious disease process	Rule out as potential donor	May present for re-screening following resolution of infection.
Cardiac Disease	Any cardiac disease which has resulted in surgical intervention or cardiac arrest is an automatic rule out.	Asymptomatic cardiac diagnoses may be reviewed with the DET to determine eligibility to donate.

Clinical Finding	Action	Comment
Hypertension	If uncontrolled (as defined by having wide variability in BP measurements) or requiring more than one medication to control, potential donor is ruled out.	If controlled with only one, or no medication may be reviewed with DET and Transplant Teams for eligibility. Must have three months stability on medication regime as well as favorable 24-hr ambulatory blood pressure monitoring prior to evaluation.
Current Liver Disease	Any current liver disease is a rule out for donation.	Exception is Gilbert's Disease. Patients with Gilbert's disease without episodes of jaundice may be eligible to donate.
Elevated Blood Glucose/ history of gestational diabetes	2-hour GTT performed and if abnormal (with diagnosis of Diabetes or glucose intolerance),donor is ruled out	Potential donors who have a family history of Diabetes will have GTT and / or HbA1C done to ascertain current glucose tolerance and be re-assessed.
Pulmonary Diagnoses	COPD, Emphysema, Asthmas with frequent admissions or pneumonias or any other pulmonary issue resulting in a need for supplemental oxygen; the donor will be ruled out.	
Inability to rule out potential familial / genetic disease	If a genetic relative of the intended recipient presents for donation, must be able to rule out disease in donor.	These cases are reviewed with the Transplant team and/or the DET team.
Laboratory Values out of normal range	Results of screening laboratory tests that are out of range may be repeated at the discretion of the coordinator.	Values that are significantly out of range and or consistently out of range will be reviewed with the Transplant team / DET by the Coordinator prior to determination of eligibility.

4. <u>Completion of Screening</u>
    a. Upon completion of the initial screening the LDC either begins the donor evaluation (for potential donors that are clearly good candidates and compatible w/ their potential recipient);

b. Or presents the potential donor to the Selection Committee (Reference Selection Screening section in policy *6.2 Transplant Services Living Donor Selection Process*)
c. The committee determines whether the potential donor appears to be a candidate and whether to move forward with completing the donor evaluation/work up.
d. Standard donation – If potential donor meets initial eligibility criteria and still wishes to proceed with donation the Living Donor Coordinator will reinforce to the potential donor their right to decline to donate and will refer the potential donor to the Donor Evaluation Team.
e. Desensitization
    i. If the potential donor meets initial eligibility criteria but is not compatible with the intended recipient, the Selection Committee may decide to discuss desensitization with the potential donor.
    ii. In this case the donor will be provided with additional education regarding the desensitization process for donation.
    iii. If the potential donor still wishes to proceed with donation the Living Donor Coordinator will reinforce to the potential donor their right to decline to donate and will refer the potential donor to the Donor Evaluation Team.
f. Paired Exchange/Non-direct Donation
    i. If the potential donor meets initial eligibility criteria but is not compatible with the intended recipient, the Selection Committee may decide to discuss Paired Exchange/Non-direct donation with the potential donor.
    ii. The donor is provided with detailed education regarding the paired exchange program and registries (Reference the *Paired Donor Exchange Program Education Handbook*).
    iii. If the potential donor still wishes to proceed with donation they sign the *University of Virginia Paired Donor Exchange Program Agreement Form.* The Living Donor Coordinator will reinforce to the potential donor their right to decline to donate and will refer the potential donor to the Donor Evaluation Team.

SIGNATURE: Signature on File
Robert E. Teaster RN, MBA, CPTC Director of Transplant Services

Signature on File
Kenneth L. Brayman, MD/PhD Transplant Center Medical Director

References:
CMS Conditions of Participation: §482.94 Patient & Living Donor Management
CMS Conditions of Participation: §482.102 Patient & Living Donor Rights
UNOS Policy 12.3.1. ABO Identification
OPTN Guidance for the Informed Consent of Living Donors
OPTN Guidance for the Development of Program Specific Living Kidney Donor Medical Evaluation Protocols

Other Pertinent Information:
6.2 Transplant Services Living Donor Selection Process
6.5 Transplant Services Living Donor Advocate Policy
PE015 Living Kidney Donation Patient Education Handbook
PE016 Living Liver Donation Patient Education Handbook
OP034 Living Kidney Donor Evaluation Intake Form
OP035 Living Liver Donor Evaluation Intake Form
OP036 Living Donor Screening for High Risk Behaviors
MC081178 Living Kidney Donor Agreement of Understanding Form
MC081183Living Liver Donor Agreement of Understanding Form
PE028 Paired Donor Exchange Program Education Handbook
PE029 Paired Donor Exchange Program Participation Form
Appendix I – Living Donation Process Flowsheet

Version #	Revision Date	Implementation Date
1	04/23/2010	05/01/2010
2	02/21/2011	02/21/2011
3	04/29/2012	05/01/2012
4	01/23/2013	