To describe the process of education and obtaining informed consent, ensuring medical, psychosocial, and financial appropriateness of potential living kidney donor candidates in accordance with the center's established selection criteria.

I. Policy Statement

All potential living kidney donor candidates shall undergo a multidisciplinary evaluation to ascertain the psychological and physiological status of the donor separately from the potential recipients(s). This includes, but not limited to, a medical, psychosocial, and financial evaluation prior to donation. Potential living kidney donors may be ruled out at any time during the evaluation process for any medical or psychosocial contraindication that may be identified.

Candidates must be approved in accordance with the center's established selection criteria.

II. Roles and Responsibilities of the Living Donor Team

1. **Living Donor Nurse Coordinator**
   - Directs, coordinates and facilitates the evaluation process
   - Provides education regarding the donor evaluation process, the risks of donation, treatment options available to the recipient, the surgical procedure, post op care and patient rights.
   - Obtains laboratory test results to rule out obvious exclusions, which would rule out donation.
   - Compiles and presents all results, reports, and recommendations to the selection committee.
   - Notifies the potential transplant recipient's nephrologist of the plan to proceed with living donor transplant.
2. **Donor Surgeon**
   - Directs and coordinates the evaluation process in conjuncture with the Living Donor Nurse Coordinator
   - Interviews the potential donor to assess motivation to donate and medical suitability
   - Reviews results of all laboratory and diagnostic testing to assess for the need for further evaluation and to determine medical suitability
   - Provides education regarding the donor surgery, risks and benefits of surgery as well as pre- and post-op care instructions
3. **Nephrologist**
   All donors will be cleared medically by a nephrologist or primary care physician who is not involved with any direct activities involving the transplant recipient.
   - Advises on the evaluation process in conjuncture with the Living Donor Nurse Coordinator and Donor Surgeon
   - Interviews the potential donor to assess motivation to donate and medical suitability
   - Reviews results of all laboratory and diagnostic testing to assess for the need for further evaluation and to determine medical suitability
   - Provides education regarding kidney health, risks, and benefits of donation
4. **Social Worker**
   - Completes a psychosocial evaluation of the living kidney donor
5. **Dietitian**
   Nutritional Assessments and diet counseling services will be provided by a qualified dietitian during all phases of the donation process and may be phased out if no

interventions are recommended by the dietitian. Any member of the multidisciplinary team will note any further clinical needs identified after phase-out and notify the dietitian if there is a need for any further intervention.

6. **Pharmacist**
   Pharmacological assessments will be provided by a qualified pharmacist during all phases of the donation process
7. **Independent Living Donor Advocate**
   The Living Donor Team has identified a team of individuals who function independently and are not involved in the routine activities of the transplant center to serve in the role of Independent Living Donor Advocate (ILDA) to advocate for and ensure protection of the rights of any potential living donors and living donors. The ILDA will not be involved in the evaluation, selection or care of potential transplant recipients.

III. Education and Informed Consent of Potential Living Kidney Donors

Potential donors and their families are provided education through a variety of media to meet their learning needs, abilities, and preferences. These include, but are not limited to digital media, written material; pictorial handouts; interpreters, to aid in communication over language barriers; recognized website material (OPTN/UNOS); and class instruction. The living donor team will provide education prior to the start of the evaluation related to the informed consent process, and it will be documented in the electronic medical record (EMR) under the “notes” tab. The living donor team shall provide ongoing opportunities for discussion and education at all stages of the potential donor candidate’s evaluation.

The completed and signed informed consent for the potential donor candidate’s evaluation will also be stored in the EMR under the “media” tab, where it can be readily accessed by all members of the living donor team.

IV. Patient Confidentiality

Strict privacy and confidentiality shall be given to each potential donor candidate during the evaluation, surgery, and post-op process.

The transplant multidisciplinary team shall assess the non-directed donor and recipient’s position regarding anonymity. In all cases, anonymity between the donor and the recipient shall be maintained until at least after the transplant. The transplant team shall facilitate a meeting between the donor and recipient only if agreed upon by both parties.

V. Evaluation of Potential Living Kidney Donors

All potential living kidney donor candidates shall undergo a multidisciplinary evaluation to ascertain the psychological and physiological status of the donor separately from the potential recipients(s). This includes, but not limited to, a medical, psychosocial, and financial evaluation prior to donation.

a. Medical Evaluation

If the potential donor meets the initial acceptability criteria the living donor candidate will complete testing. The following tests will be ordered:

LABORATORY TESTING
ABO typing (X 2),
HLA tissue typing

Cytotoxic and flow crossmatching with the recipient • A second cytotoxic/flow crossmatch, and HIV test within 28 days of surgery • Living Donors can be considered for the ABO Incompatible Program or positive crossmatch (XM) Program if appropriate. • If XM is positive and ABO blood type is compatible patient falls into HLA incompatible category.
CMP, CBC, PT, PTT
Electrolytes
Lipid panel
Urinalysis with reflex to culture
Hepatitis panel HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery
HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery
RPR/Syphilis
CMV IgG and IgM
Urine drug screen
24-hour urine for microalbumin, CrCl, and Protein
PSA for males > 40 years of age
Pregnancy test for females 18-55 years of age
Epstein Barr virus

DIAGNOSTIC TESTING
Blood pressure taken on at least two separate occasions or 24-hour or overnight BP monitoring
Chest X-ray
EKG
CTA abdomen and Pelvis
Abdominal Ultrasound
Quantiferon TB Gold
The American Cancer Society recommends screening for lung cancer with a low-dose CT (LDCT) scan for people aged 50 to 80 years who: • Smoke or used to smoke AND • Have at least a 20 pack-year history of smoking
Colonoscopy > 45 years of age

Pap smear for women > 21 years of age As recommended for the general population by American Cancer Society and US Preventative Services Task Force.
Bilateral mammogram for women > 40 years of age or family history of breast cancer
In the event of the following:
Any donor with a BMI > 28, Elevated level of fasting glucose or family history of diabetes: Two-hour Glucose Tolerance test
Any donor with a history of kidney stone(s): Will complete kidney stone evaluation under MD discretion.
Any donor with family history of PKD: Renal testing and genetic testing under MD discretion
Any donor suspect to exposure to toxoplasmosis: Immunoglobulin G IgG and IgM
Any donor suspect for geographically endemic disease such as Coccidiomycosis, Strongyloides, Trypanosoma cruzi, Malaria, HHV-8, West Nile Virus and HHV- 6: Serology and nucleic acid (NAT) testing
CTA Abd and Pelvis, genetic testing on all donors
If imaging identifies 4 or more cysts in either kidney, this will be deemed a relative contraindication to donation and will be further reviewed and decided on a case-by-case basis.

b. Psycho-Social Evaluation

The psychosocial evaluation is conducted by a Licensed Clinical Social Worker with experience in transplantation to determine if there are any pre- or post-donation emotional concerns or needs, to assess decision making capacity, screen for any potential mental health issues and to evaluate for potential coercion.

The psychosocial evaluation must include the following components:

- Assess for any psychosocial (including mental health) issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome.
- Assess for the presence of risk criteria behaviors as defined by the US Public Health Service (PHS) that have the potential to increase the risk of disease transmission to the recipient.
- Assess history of smoking, alcohol, and drug use/abuse and dependency.
- Identify factors that warrant educational or therapeutic intervention prior to final donation decision.
- Determine that the potential donor understands the short and long-term medical and psychosocial risks associated with living donation, for both donor and recipient.
- Assess whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reason(s) for volunteering to donate and the nature of the relationship (if any) to the transplant candidate.
- Assess the potential donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes the potential donor having a realistic plan for donation and recovery, with social, emotional, and financial support available as recommended; and
- Review the occupation, employment status, health insurance status, living arrangements, and social support of the potential donor and determine if the potential donor understands the potential financial implications of living donation.
- Recommends a psychiatric consult for anonymous donors and for other donors as determined during psychosocial assessment.
- Summarizes the psychosocial assessment and makes recommendations to the transplant team

c. Selection Committee

All donors will be presented at the Transplant Selection Committee for review. A donor may be presented to the Transplant Selection Committee at any time in the process by any member of the interdisciplinary team.

The living donor team may determine that a potential donor is not a suitable candidate at any time during the evaluation, based on the established selection criteria. Each transplant center has its own set criteria for potential living donors; therefore, even if a potential donor is deemed unsuitable by the living donor team at UCI Health, they may qualify for donation at another center.

VI. Selection Criteria

The following criteria will be used for identifying acceptable living kidney donors:

- At least 18 years of age. Potential donors must be of legal age and have sufficient intellectual ability to understand the procedure and give informed consent.
- Potential donors who are felt, or known to be, coerced will be excluded.
- Potential donors must be mentally and emotionally competent to make an informed decision regarding donation. Donors with history of psychosocial or mental health issues are evaluated on a case-by-case basis.
- No active substance abuse within the past 3-6 months, marijuana use can be made on a case-by-case basis.

- Obesity/ Body Mass Index (BMI) > 32 cannot be donors, exceptions can be made on a case-by-case basis by the surgeon.
- Potential donors must have the ability and willingness to comply with long-term post-operative follow-up care.
- Potential donors with uncontrollable hypertension or history of hypertension with evidence of end stage organ damage will be excluded.
- Potential donors with a personal history of diabetes will be excluded.
- Potential donors with active infection will be excluded, at minimum until the infection resolves.
- Donors prohibiting blood or blood products will be excluded.
- HIV positive donors will be excluded
- Donors with previous solid tumor malignancies must be disease free for two years.
- Potential donors with a history of Lymphoproliferative malignancies will be excluded.
- Potential donors with Autosomal Dominant Polycystic Kidney Disease (ADPKD) in the immediate family shall be excluded if the potential donor is under the age of 30 years, except for genetically unaffected family members, such as an unaffected parent, aunt, uncle, etc.

REFERENCES:

CMS, Conditions of Participation, 482.9 “Patient and Living Donor Selection”
CMS, Conditions of Participation, 482.102 “Patient and Living Donor Rights”
CMS, Conditions of Participation, 482.98 “Human Resources”

OPTN, Policy 14.2.A “ILDA Requirements for Kidney Recovery Hospitals”
OPTN, Policy 14.2.B “ILDA Required Protocols for Kidney Recovery Hospitals”
OPTN Policy 3, “Candidate Registrations, Modifications and Removals”