| The Transplant Institute<br>METHODIST DALLAS<br>**Methodist Dallas Medical Center** | **Title:**<br>Medical Evaluation Policy for Living Donor Kidneys Recovered at MDMC<br>**Section:**<br>Kidney – Living Donation | **Effective Date:**<br>02/01/2013 |
|---|---|---|
| **Approved by:**<br>Amna Ilahe, M.D., Living Donor Medical Director<br>Alejandro Mejia, M.D., Primary Living Donor Surgeon<br>Melody Holder, Director of Transplant Clinical Operations | | **Revision Date(s):**<br>06/27/2013; 10/16/2015; 12/11/2018; 06/23/2020; 05/2021; 08/31/2021; 01/13/2022; 3/3/2023; 11/2024; 05/2026<br>**Next review Date:**<br>05/2029 |

**Purpose:** To describe the criteria and process for evaluating a potential kidney living donor. This applies to all donors whose kidney is recovered at Methodist Dallas Medical Center whether the organ is transplanted into a recipient at this center or shipped to another center as in the case of paired/non directed donation.

**Policy:** The evaluation of the potential donor will be performed by Methodist Dallas Medical Center. This medical evaluation may include information obtained from other consultants and specialists. Documentation of the evaluation is maintained in the donor record.

**Process:**

The goal of the medical evaluation is to:

- Assess the immunologic compatibility of the donor to the recipient
- Assess the general health and surgical risk of the donor, including screening for conditions that may predict complications from having one kidney in the future
- Determine if there are diseases present that may be transmitted from donor to recipient
- Assess the anatomy and function of the kidneys

Key elements of the medical evaluation include:

1) General history:
   - Evaluation for a personal history of significant medical conditions which include, but are not limited to:
     - Hypertension
     - Diabetes
     - Lung disease
     - Heart disease
     - Gastrointestinal disease
     - Autoimmune disease
     - Neurologic disease
     - Genitourinary disease
     - Hematologic disorders
     - Bleeding or clotting disorders
     - History of cancer including melanoma
     - History of infections
   - Evaluation for a kidney-specific personal history of:

- Genetic renal diseases
- Kidney disease
- Proteinuria
- Kidney injury
- Diabetes (including gestational diabetes)
- Nephrolithiasis
- Recurrent urinary tract infections

- Evaluation for active and past medications (with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medications and NSAIDs)
- Allergy history
- Evaluation for coronary artery disease

2) Family history of coronary artery disease and cancer

3) Kidney-specific family history of:
   - Kidney disease
   - Diabetes
   - Hypertension
   - Kidney cancer

4) Social history: Although a full psychosocial evaluation will be carried out, an evaluation must be part of the medical evaluation to include specific emphasis on:
   - Occupation, employment status, health insurance status, living arrangements and social support
   - Smoking, alcohol and drug use/abuse
   - Behavior that meets risk identified criteria as defined by US PHS Guideline
   - Psychiatric illness, depression, suicide attempts

5) Physical Exam:
   - Height, weight, BMI, vital signs
   - Examination of all major organ systems
   - Blood pressure - Taken on at least two different occasions; or
     Ambulatory blood pressure monitoring will be obtained for those with an abnormal BP during examination or at the discretion of the examining Transplant Nephrologist. Potential donors with a 24-hour average >135/85, a daytime average of 140/90, a nighttime average of 125/75 or failure to dip by 10% during sleep will not be accepted for donation

6) General tests to include:
   - CBC with differential and platelet count
   - Prothrombin time (PT) and International Normalized Ratio (INR)
   - Partial Thromboplastin Time (PTT)
   - Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin,
   - HCG quantitative pregnancy testing for premenopausal women without surgical sterilization
   - Chest x-ray
   - Electrocardiogram (ECG)

7) Blood type and subtype (an additional blood type will be drawn before the donor is entered into the UNet system). If subtyped *and* pre-red blood cell transfusion samples are available, then subtyping must be completed according to the table below:

| Subtyping Requirements by First Subtype Result | |
|---|---|
| **If the donor's primary blood type is:** | **A second subtyping must be completed if the first subtype result is:** |
| A | Blood type A, non-$A_1$ |
| AB | Blood type AB, non-$A_1B$ |

Living donor blood samples for subtyping must:

- Be tested using pre-red blood cell transfusion samples
- Be drawn on two separate occasions
- Have different collection times
- Be submitted as separate samples

All subtype results reported to the OPTN must be from two separate tests indicating the same result. **If there are conflicting or indeterminate subtype results, the subtype results must not be reported to the OPTN and living donor transplant compatibility or allocation must be based on the primary blood type.**

8) Other metabolic testing
   - Fasting blood glucose
   - Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol)
   - Glucose tolerance test and/or glycosylated hemoglobin in first degree relatives of diabetics and high-risk individuals.
   - ANA for patients with a first degree relative with SLE
   - Hgb electrophoresis for patients with a first degree relative with sickle cell disease

9) Kidney-specific tests to include:
   - Urinalysis and urine microscopy
   - Urine culture, if clinically indicated
   - Measurement of urinary protein and albumin excretion
   - Measurement of kidney function by glomerular filtration rate by isotopic methods or creatinine clearance calculated from a 24 hour urine collection
   - Screening for polycystic kidney disease or other inherited renal disease as indicated by family history

     - Potential donors from a family with polycystic kidney disease who are less than the age of 30 must have a renal sonogram. If sonogram is negative or equivocal, an MRI will be required. If the MRI is negative, genetic testing is indicated (at the donor's expense)
     - Potential donors from a family with polycystic kidney disease who are >30 must have a renal ultrasound or other imaging tests to determine if PKD is present. Screening criteria that would suggest the potential donor has PKD as follows:
       - In patients <30 years of age, at least two cysts (on one or both kidneys) are seen with ultrasound
       - In patients age 30-59, at least two cysts are seen in each kidney with ultrasound
       - In patients>60 years of age, four or more cysts are seen in each kidney with ultrasound

- Potential donors with a personal history of kidney stones must have a 24-hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine, and sodium excretion

    - These patients will be considered if the following criteria are met:
        - Has only passed one stone
        - Has not had any episodes of stones for > 10 years
        - Has a negative stone risk profile
- Anatomic assessment to determine whether the kidneys are of equal size or have masses, cysts, or stones or other anatomical defects and to determine which kidney is more anatomically suitable for transplantation.

- 3-D CT scan of the abdomen

- Screening for transmissible diseases:
    - CMV IgG
    - EBV IgG
    - VZV IgG
    - RPR (Rapid Plasma Reagin test for syphilis)
    - HBsAb (Hepatitis B surface antibody)
    - Screening for latent TB using via PPD testing, Quantiferon Gold or T Spot
    - HIV Antibody (anti-HIV) testing OR HIV Antigen/Antibody (Ag/Ab combination test) testing as close as possible but within 28 days prior to organ recovery
    - HIV ribonucleic acid (RNA) by nucleic acid testing (NAT) as possible but within 28 days prior to organ recovery
    - HBsAg (Hepatitis B surface antigen) as close as possible but within 28 days prior to organ recovery
    - HBcAb (Hepatitis B core antibody - **total**) as close as possible but within 28 days prior to organ recovery
    - HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible but within 28 days prior to organ recovery
    - Hepatitis C antibody as close as possible but within 28 days prior to organ recovery
    - HCV RNA by nucleic acid test (NAT) as close as possible but within 28 days prior to organ recovery
    - West Nile Virus by nucleic acid testing (NAT) all donors whose recoveries occur between July 1 and October 31- as close as possible but within 14 days prior to the recovery
    - Trypanosoma cruzi screening (for potential donors from Mexico, South America, and Central America)
    - Strongyloides screening (for potential donors from Southeast Asia, Central America)
    - Schistosoma (for donors from Africa and Southeast Asia)

10) Cancer screening per American Cancer Society protocols:

- Females between the ages of 21-29 must have a Pap smear within the last 3 years
- Females between the ages of 30-65 must have a Pap smear within the last 3 years or co-testing (Pap smear and HPV testing) within the last 5 years if both initial tests were negative.
- Females >65 who have had adequate negative prior screening (3 consecutive pap smears or 2 consecutive co-tests within the previous 10 years) are not required to have a pap smear.

- Older females who have not been adequately screened must have a Pap smear within the last 2 years or co-tests within the last 5 years.
- Females 40 years and over or with any family history of breast cancer or ovarian cancer in a first degree relative will have mammogram within the past year.
- Exceptions to this will be based on the recommendations of the patient's gynecologist.
- Prostate cancer: PSA level (within the past year) on all males >40
- Colon cancer: Colonoscopy for patients >45 years of age
- Skin cancer: Periodic health exam
- Lung cancer: Low-dose Chest CT scan for potential donors who meet all of the following criteria:
  - >30 pack-year smoking history
  - Either still smoking or have quit smoking within the last 15 years
  -

11) Consultations
- Transplant Nephrologist
- Licensed Master Social Worker (or Psychologist)
- Dietitian
- Independent Living Donor Advocate
- Transplant Surgeon
- Infectious Diseases Physician consult/screening
- Transplant Psychologist for all donors under age 21, non-directed donors and if recommended by social worker, Nephrologist or Selection Committee
- Transplant Coordinator (Education Session)
- Stress echocardiogram and cardiology consult (for patients >50 years of age, those with an abnormal ECG, or those with any cardiac history)
- Gastroenterology (for patients with a history of peptic ulcer disease colon problems, occult blood positive stools, or other GI diseases)
- Pulmonary (for patients with an abnormal chest x-ray).
  - Potential donors with a new finding of a positive TB test and a clear CXR will require treatment but can continue with the evaluation process. Donation will not be permitted until 2 months of treatment is completed; donors must then continue treatment after donation for a total treatment time as determined by Infectious Diseases physician

- Psychiatry (at the discretion of the Transplant Nephrologist or Selection Committee)
- Hepatology Consult with Fibrosis Assessment (for patients with abnormal LFTs)
- Other consultations as indicated by nephrologist, surgeon or Selection Committee

12) Donors who have a history of hypertension may be considered if:
- >50 years of age
- Taking no more than two hypertension medications
- Hypertension has been well controlled for at least two years
- Does not use tobacco-based products
- BMI 35 or less
- Have their own health insurance

If patient meets the above criteria and is cleared initially by nephrologist, additional testing will include:
- 24-hr ambulatory BP monitoring
- HgbA1C
- Genetic testing

13) Exclusion Criteria:

Absolute exclusion criteria for potential living donors include the following:

- Age less than 18 years
- Age 18-21, unless the potential living donor has undergone a psychological evaluation and been approved by the Selection Committee to proceed with the living donor evaluation
- Mentally incapable of making an informed decision
- Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage
- Kidney stones (see above)
- HIV
- Diabetes
- Active malignancy or an incompletely treated malignancy
- High suspicion of donor coercion
- High suspicion of illegal financial exchange between donor and recipient
- Evidence of acute symptomatic infection, until that infection is resolved
- Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
- 24-hour urine protein >300 mg/24 hours. Individuals with a total urine protein of 150-300 mg/24 hours may warrant additional evaluation.
- Creatinine Clearance < 80cc/min
- Lupus
- Significant cardiovascular disease
- Significant liver disease
- Morbid obesity. Potential donors with a BMI of 35-39 may be accepted with the recommendations of the Transplant Surgeon
- Ongoing substance dependency or substance abuse. Potential donors who use marijuana will be discussed/approved on an individual basis by the Selection Committee

Reference: OPTN/UNOS Policy 14.0- Living Donation