


Name of Policy: <u>Living Renal Donor (CMS-X057)</u> Policy Number: 3364-140-01 Department: Renal Transplant Program Approving Officer: Chief Nursing Officer Director, Renal Transplant Program Responsible Agent: Director, Renal Transplant Program Transplant Coordinator Scope: The University of Toledo Medical Center	 Effective Date: March 1, 2025 Initial Effective Date: October 23, 2007				
<table> <tr> <td><input type="checkbox"/> New policy proposal(for Med Staff)</td> <td><input checked="" type="checkbox"/> Minor/technical revision of existing policy</td> </tr> <tr> <td><input type="checkbox"/> Major revision of existing policy</td> <td><input type="checkbox"/> Reaffirmation of existing policy</td> </tr> </table>		<input type="checkbox"/> New policy proposal(for Med Staff)	<input checked="" type="checkbox"/> Minor/technical revision of existing policy	<input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Reaffirmation of existing policy
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(A) Policy Statement

It is important that all potential living donors receive a medical and psychosocial evaluation that is completely independent of the recipient evaluation. The potential living donor evaluation will be completed in a systematic manner prior to donation and to address medical suitability for donation. The evaluation will also consider the donor's current health issues that could be affected by donation.

(B) Purpose of Policy

To properly assess and evaluate the adequate candidacy of all potential living donors.

(C) Scope

This policy applies to members of the medical staff involved with living donor transplantation procedures at the University of Toledo Medical Center, UTMCI Personnel and any other persons involved in the transplantation programs of the University of Toledo.

(D) Procedure

1. All living donor work-up is considered current for a time period of one year except:
 - a. HLA is considered current for five years
 - b. Colonoscopy will be repeated as recommended by the GI specialist, or at the discretion of the Transplant Committee, based on patient clinical information
2. Identified potential donor will be referred to the Renal Transplant Donor Coordinator for initiation of the following workup. All information will be documented in the living donor's medical record, including donor's suitability for transplant.
3. Medical screening will be conducted by the Renal Transplant Donor Coordinator using "Potential Living Kidney Donor Medical History Screening Form."
 - a. Donor Surgeon will review form to determine suitability for kidney donation.
 - b. Absolute contraindications identified in history exclude further evaluation.
4. Determination of blood type. The Donor Surgeon will order laboratory testing to determine blood type. If incompatible, this would exclude direct donation for the intended recipient, but would not exclude

further evaluation for the paired exchange program. These potential donors are given the opportunity to participate in paired exchange program.

- a. Donor will have blood for ABO drawn on at least 2 separate occasions prior to generation of the donor ID in UNOS for living donation.
 - b. The blood samples will be drawn on 2 separate occasions, have different collection times, and be submitted as separate samples. Subtyping will be determined on blood samples that are pre-red blood cell transfusion, will also be drawn on 2 separate occasions with different collection times, be submitted as separate samples and the results indicating the same subtype.
 - c. In the event results of the blood type determination are conflicting or indeterminate, the Transplant coordinator will review with the physician and repeat testing will be performed for verification of the actual result.
 - d. The Data Coordinator and Transplant Coordinator, or 2 Transplant Coordinators will independently verify and report the ABO of the donor using all known available blood type and subtype determination source documents (medical record lab results of the blood type samples) and complete the Donor Feedback Form on the UNOS website.
5. Initial laboratories obtained and reviewed by donor surgeon will include:
- a. Initial cross match and tissue typing with ABO and sub-typing as needed
 - b. Complete blood count with differential
 - c. Complete metabolic panel
 - d. Coagulation profile (PT/PTT/INR)
 - e. Urinalysis (send for culture if symptoms present or abnormal u/a results.)
 - f. Fasting Lipid profile
 - g. Serologies to include but not limited to: HIV, Hep Panel, RPR, CMV, EBV, WNV (if living in area of endemic) If WNV is positive, a WNV NAT will need to be completed.
 - h. Phosphorus
 - i. Uric Acid
 - j. HcG quantitative pregnancy test in women < 55 years and non-sterilized.
 - k. TSH
 - l. PSA in males > 40.
 - m. Microalbumin-albumin excretion.
 - n. Urine tox screen.
6. Blood pressure monitoring is required.
- a. Two blood pressure readings on two separate occasions.
 - b. Hypertension is acceptable only if the blood pressure is well controlled with one oral agent. The potential donor must then get medical clearance from his/her Primary Care Physician, and/or a UPMC Nephrologist.
 - c. All donors with a diagnosis of HTN will undergo 24 hour blood pressure cuff
 - d. All donors with HTN will undergo a cardiac echo.
 - e. All donors with HTN and >50 will undergo a cardiac stress and cardiac echocardiogram.
7. The potential donor will meet with the Renal Transplant Donor Coordinator. The Donor Coordinator and potential donor will review and sign the living donor informed consent. The consent form for potential living kidney donors will provide the potential donor with the telephone number for reporting grievances to the OPTN.
8. Testing required for living donor candidates is ordered by the Donor Surgeon. The testing results are reviewed by the Donor Surgeon and the Renal Transplant Donor Coordinator. Testing will include:
- a. Two separate 24 hours urine collections for Protein and Creatinine Clearance and/or nuclear renal scan for GFR, Chest x-ray, and EKG.

- b. Psychosocial evaluation with a social worker; see policy for psychosocial evaluation of potential living kidney donors (#3364-140-05).
 - c. Pelvic exam and/or pap smear for all women according American Cancer Society Guidelines.
 - d. Mammogram for women > 40 years of age or as appropriate based on family risk factors or MD preference.
 - e. Colonoscopy for all donors > 50 years of age, or as appropriate based on family risk factors.
 - f. Cardiovascular testing:
 - i. Cardiac Clearance as needed
 - ii. Cardiac Stress test for all donors > age 50.
 - iii. Additional cardiac testing at the discretion of the cardiologist or donor surgeon
 - g. Polycystic Kidney Disease (PKD) Genetic testing will be ordered for all donors, with a known family history of PKD under the age of 30 and at the discretion of the donor surgeon. After compatibility is determined, a CT angiogram and/or ultrasound will be obtained to rule out evidence of PKD in the donor.
 - h. APOL1 Genetic Testing (to evaluate for risk of potential renal issues) will be ordered for all donors that are African American. This is not a contraindication to donation. It will be used for risk stratification and donor education.
 - i. Tuberculin Test and/or TB Quantiferon Gold test as determined by risk factor.
 - j. CT Angiogram of Abdomen and Pelvis on all donors
 - k. 24-hour urine Stone panel (Litholink) as required for all donors with a history of nephrolithiasis or nephrolithiasis >3mm found on imaging. Panel must include: Calcium, Oxalate, Uric Acid, citric Acid, Creatinine and Sodium.
 - l. DM testing: Fasting blood glucose and Glucose tolerance test or glycosylated hemoglobin
 - m. Interview with donor and donor surgeon:
 - i. This could take place in the early stages especially if the donor has many questions related to risks of surgery or work up or if there are questions of suitability of a person to be a donor.
 - ii. This could take place after all the work up is completed but preferably before doing the angiogram.
 - iii. After interview with donor surgeon, the donor surgeon and/or living donor coordinator will inform the potential donor of any referrals needed for other procedures and/or consults. Follow-up for any additional procedures and/or consults will be followed up by the living donor coordinator.
9. Once all of the tests are completed and found acceptable, the donor surgeon reviews findings. Patient is then presented at Transplant Committee. Arrangements should be made to proceed with live donor transplantation if donor is found to be acceptable.
10. All donors undergoing living kidney donation will be required to have updated serologies that are within 28 days of donation. Serologies that need updated include: HIV, Hep B Surf Ag, Hep B Core Ab, Hep C and RPR. Donor NAT will also be done within 28 days of donation: including Hep B DNA, Hep C RNA and HIV RNA. The recovery hospital will obtain blood specimens for serological and NAT testing from the living donor within 24 hours prior to organ recovery (this will take place in Pre-operative holding prior to donation) and will store for 10 years. This specimen will only be used for investigation of potential donor-derived disease. The type of sample will be documented in the living donor medical record.
11. Donors who intend for their organs to be procured at a facility other than UTMC and transported to UTMC for transplant, as part of a paired exchange, will be reviewed by the UTMC selection committee and will need to meet UNOS Policy for Living donation. Once all results are found to be acceptable, arrangements for living donor transplant may proceed.

12. In the event a donor is from out of town, for either direct donation or donation made possible through kidney paired exchange, and it is not practical for the donor to meet the ILDA and surgeon prior to the donor evaluation committee meeting, then the living donor committee can evaluate such cases on an individual basis and determine if a potential donor is acceptable to move forward assuming nothing untoward is identified upon an in-person evaluation. All donors must see the ILDA and donor surgeon prior to undergoing nephrectomy. However, the ILDA will need to complete a phone interview prior to the initiation of the donor evaluation process.
13. Cancer screening for age appropriate and/or risk determination according to ACS guidelines to include, but not limited to:
- Cervical cancer - pap smears every three years.
 - Breast cancer - yearly mammogram to age 55, then every two years if desired.
 - Prostate cancer – PSA at age 40.
 - Colon cancer – colonoscopy age 45.
 - Lung cancer – low dose CT scan of chest for those at high risk for lung cancer. High risk is 30 pack year smoking history and still smoking or quit in the past 5 years.
14. Endemic transmissible diseases will be considered for all donors. This will include, but are not limited to; strongyloides, or Trypanosoma cruzi. If a donor is identified as being from an endemic area testing will be complete. If a donor tests positive, the donor will be required to get clearance from infectious disease prior to proceeding.

Approved by:		Review/Revision Date:	
/s/		12/7/07	5/22/17
Kurt Kless, MSN, MBA, RN, NE-BC	Date	2/21/08	5/11/2018
Chief Nursing Officer		12/3/2008	2/1/2020
		2/6/2009	3/1/2021
		1/12/2010	3/14/2022
		1/21/2011	1/21/2025
		8/31/12	
/s/		10/10/12	
Michael Rees, MD	Date	9/30/14	
Transplant Program Director		12/5/14	
		5/21/15	
		5/11/16	
		2/22/17	
<i>Review/Revision Completed By:</i> <i>Transplant Program</i>			
		Next Review Date: 3/1/2028	
Policies Superseded by This Policy: Prior Living Renal Transplant Policy 3364-140-01 that was departmental only			