## Maine Transplant Program Maine Medical Center Policies and Procedures Living Donor Evaluation Protocol

- 1. Potential living kidney donors complete required registration and health history forms.
- 2. Medical Record Review for medical suitability performed by Living Donation Coordinator and a Transplant physician.
  - Potential living donors must have had a physical exam within the past 1-2 years and have all
    up to date age and gender appropriate cancer screenings consistent with American Cancer
    Society Guidelines
  - b. Exclude for hypertension treated with more than one blood pressure medications, chronic hematuria, symptomatic kidney stone (see Appendix C: Kidney Stone Algorithm), diabetes, obesity noted in medical record (see Living Donor Selection Criteria). Records must include 3 separate, documented blood pressure readings.
  - c. Other medical conditions reviewed on case-by case basis
  - d. If excluded, the potential living donor is sent a letter from the coordinator explaining the reason.
- 3. HLA Genetic Testing to determine ABO and genetic compatibility between recipient and potential living donor.
  - a. If incompatible, potential living donor notified, offered opportunity to participate in one or more KPD (Kidney Paired Donation) programs.
  - b. If compatible or interested in KPD, potential living donor begins medical evaluation.
- 4. Living Donor Medical Evaluation will meet all requirements of UNOS Policy 14.4.A and 14.4.B and be documented in the donor medical record.
- 5. Potential Living Donor Medical Testing includes the following:
  - a. Lab testing for general health and kidney function:
    - GLOFIL test <u>or</u> two separated 24 hour urine collections for measured creatinine clearance.
    - Two spot urine specimens to determine Microalbumin/Creatinine ratio or one 24 hr urine collection for determination of Albumin excretion rate.
    - CBC
    - CMP
    - Phosphorous
    - Uric acid
    - Lipid Panel
    - 2 Separate Urinalysis with microscopic exam
    - Urine for Culture &Sensitivities when appropriate.
    - Pre-diabetes screening test: Fasting glucose and Hemoglobin A1C.
    - 2 hour glucose tolerance test (GTT): will be ordered if any of above pre-diabetes screening tests are abnormal or the potential donor has family history of Type 2 diabetes.
    - Will use Maine Living Kidney Donor Program DM screening algorithm to determine suitability (See Appendix A of Living Donor Selection Criteria).
    - If sibling of a Type I DM testing to include:
      - 1. Fasting baseline blood specimen for:
        - a. Fasting blood glucose
        - b. Glutamic acid

Maine Transplant Program Maine Medical Center Policies and Procedures Living Donor Evaluation Protocol Page 2 of 4

- c. Insulin level
- d. Insulin Antibodies
- 2. 2 hour blood specimen for:
  - a. Blood glucose
  - b. Insulin level
- Infectious disease screening:

To include HIV, Hepatitis B and C panel, CMV, EBV and RPR antibody testing. Tuberculosis screening will be performed either by Gold Quantiferon or PPD.

- Second ABO testing to be done by MMC blood bank.
- Any history of DVT or other clotting issue testing to include:
  - 1. Factor V Leiden
  - 2. Anticardiolipin AB
  - 3. Prothrombin Gene Mutation
  - 4. Lupus AC
  - 5. B2 Glycoprotein
  - 6. Homocysteine
- b. Renal Ultrasound if a direct blood relative with Polycystic Kidney Disease (PKD)
- c. 24 hour ambulatory blood pressure monitoring for any person demonstrating borderline hypertension to diagnose "white-coat" hypertension vs. true pre-hypertension, use B/P algorithm to determine suitability (See Appendix B of Living Donor Selection Criteria)
- d. Any living donor biologically related to the recipient whose renal insufficiency is related to a disease process that is genetically transmitted, the program will specifically consider the potential for the donor to be susceptible to that genetic disease.
- e. Any other testing required as determined by the transplant team based on testing results and medical history.
- f. If testing within normal limits, appointment made for Living Donor Evaluation at the Transplant Program.
- g. If excluded, potential living donor notified by phone and in writing. Primary care physician also notified in writing.
- 6. Living Donor Evaluation includes:
  - a. Education class/review of Living Kidney Donor Handbook with Living Donation Coordinator
  - b. Meeting with Independent Living Donor Advocate
  - c. Consultation with Financial Counselor
  - d. Psychosocial evaluation with transplant social worker
  - e. Nutrition evaluation with transplant RD (either in person or by record review)
  - f. Pharmacist review of medical records and further evaluation as needed
  - g. Vital signs (including 3 separate blood pressure readings)
  - h. H&P with transplant surgeon and transplant nephrologist, including review for up to date cancer screenings for gender and age group according to the American Cancer Society Guidelines for the following cancers:
    - Breast Cancer
    - Cervical Cancer
    - Prostate Cancer Colon Cancer
    - Skin Cancer screening: All donors will receive a skin exam at the time of evaluation and will be questioned regarding any history of skin malignancies or suspicious skin lesions. Due to the lack of evidence supporting the practice, skin self-exams are NOT required, nor are any other skin examinations or dermatology consultations required (US Preventative Services Task Force:
      - http://www.uspreventiveservicestaskforce.org/uspstf/uspsskca.htm).
    - Lung cancer

Maine Transplant Program Maine Medical Center Policies and Procedures Living Donor Evaluation Protocol Page 3 of 4

- i. EKG
- j. All donors age 65 and above will require stress testing. Type of testing ordered will depend on EKG results and review of the records by the transplant nephrologist.
- k. Living Kidney Donor Rights, SRTR data, Public Health System Questionnaire to review donor's risk criteria for transmission of infectious diseases, and MMC forms and consents reviewed with Living Donation Coordinator and signed.
- l. Paired exchange programs reviewed with donor (as indicated)
  - Program explained included donor responsibility
  - Consent obtained using Potential Kidney Paired Donation (KPD) Living Donor Education Form, including discussion and description of willingness of donor to: travel, have kidney shipped, donate specific kidney, participate in a chain, etc.
  - Medical release consent obtained
- m. Chest x-ray
- n. Abdominal CT
- o. Any additional testing required by transplant team as determined by physical exam, CT results and medical history.
- Asymptomatic kidney stones noted on CT will require further evaluation testing and determination of suitability (See Appendix C: Kidney Stone Algorithm of Living Donor Selection Criteria)
- 7. Living donor is presented at Transplant Candidate Review for committee approval.
  - a. Must have multi-disciplinary evaluation prior to presentation that includes:
    - Living Donor Coordinator
    - Independent Living Donor Advocate
    - Transplant Social Worker
    - Transplant Dietician
    - Transplant Nephrologist
    - Transplant Surgeon
    - Financial Counselor
    - Pharmacy Review as needed
  - b. If participating in an exchange, the exchange donor selection will be dependent upon meeting recipient's pre-selection criteria.
- 8. If donor participating in exchange program potential donor registered in appropriate program through program website
  - a. If possible match is identified, blood specimen for cross-matching with potential recipient is obtained from donor
  - b. If match is possible, logistics and possible surgery dates discussed with donor
- 9. Plan for Living Donor Nephrectomy surgery:
  - a. Living donor must have pre-surgery visit with Transplant Surgeon (surgical consent), Living Donation Coordinator and Pre-Admission Unit (anesthesia consent) typically 1-2 weeks prior to donation surgery.
    - Pre-Op teaching completed by LD Coordinator, Living Donor Surgery Information reviewed and given to donor
  - b. If possible, a tour of R5 and hospital with R5 RN educator.
  - c. Pre-op labs include (unless previous labs done within 28 days of surgery):
    - CBC
    - BMP
    - INR
    - X-match for 2 units RBCs

Maine Transplant Program Maine Medical Center Policies and Procedures Living Donor Evaluation Protocol Page 4 of 4

- HCG for women of child-bearing age & ability
- d. Final Cross-match between recipient and donor will be repeated within 28 days of intended donation surgery date.
- e. Screening for potential transmissible infectious diseases by organ donation (PHS 2020 guidelines). Testing <u>must</u> be performed at below indicated time window before donation surgery date/time.
  - HIV: Antigen/Antibody and NAT. (within 28 days )
  - Hepatitis B: Surface antigen, Core antibody and NAT. (within 28 days).
  - Hepatitis C: antibody and NAT. (within 28 days)
  - Additional serum specimen (10 ml Red Top and a 6 ml Lavender Top tubes) for future serologic and NAT testing. (day of surgery in pre op holding). This specimen will be stored at -80° C for at least 10 years at the HLA laboratory.
- f. Other infectious disease screenings as appropriate for donors from endemic areas or time of year and location associated risk:
  - Western Nile Virus: all donors will be tested within 28 days of donation.
  - Strongyloides: For donors from South Eastern United States.
  - Trypanosoma cruzi: For donors from tropical countries.
- g. Mandatory Donor information will be entered into UNET and UNOS ID obtained.
- h. Living donor chart will be reviewed by a Transplant Physician for final suitability for surgery.
  - Pre-Op checklist completed and signed by Transplant Surgeon and Living Donor Coordinator.

Original Date: 05/07/2008

Review Dates: 12/29/2008, 04/06/2012, 8/8/2013, 9/18/2013, 11/25/13, 12/16/13, 4/16/14, 1/12/15, 7/22/15, 8/5/15, Additions added 01/21/16 to meet current practice RMT, 4/25/18, 10/8/18, 4/12/19, 2/2/21, 5/11/21, 10/12/22, 7/28/23

Protocol Champion: Juan Palma-Vargas, MD, Director of Living Donation