Maine Medical Center Transplant Program Policies and Procedures Policy on Informed Consent for Kidney Transplant Patients

Purpose

To define the policy and procedures for obtaining the informed consent of potential kidney transplant candidates throughout the transplant experience.

Policy

The Maine Transplant Program provides potential kidney transplant candidates with all the necessary information to make an informed decision about treatment options. Informed consent is a multistep educational process that takes place over time and with the input of multidisciplinary team providers. In the implementation of this Policy, the Transplant Program will maintain full compliance with the Maine Health Policy: "Consent to Treat for Procedures, Interventions, and Treatment Policy"

Procedure for Kidney Transplant Candidates

- 1. All potential kidney transplant candidates are required to complete an initial educational class. This class, which is presented in a PowerPoint format, and offered either on line, via DVD, or in person, gives potential candidates information about the following:
 - Transplant team and their roles
 - ESRD and treatment options
 - Transplant process and pathway to transplantation
 - Inclusion and exclusion criteria
 - Recipient and donor matching
 - Evaluation process and testing
 - Surgery and what to expect
 - Possible risks and complications
 - Post-transplant medications and side effects
 - Post-transplant follow-up
 - Financial risks/concerns
 - Living donation, including exchange programs
- 2. Following the educational class, candidates who chose to go forward with evaluation will be scheduled for a clinic visit, where they will meet one-on-one with select members of the multidisciplinary team which may include:
 - Nephrologist
 - Surgeon
 - Social worker
 - Pre-transplant RN Coordinator
 - Financial counselor
 - Transplant Registered Dietitian
 - Transplant Pharmacist

Multidisciplinary visits may be conducted virtually or by phone, with the exception of the Social Work psychosocial assessment, which will be done in person unless extenuating circumstances exist.

3. Candidates attending the class are also provided with written information about living kidney donation and required maintenance health screenings. At their Clinic visit, candidates will meet with the Pre

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Transplant RN Coordinator and review the *Consent to Participate in the Kidney Transplant Program.* This Consent will inform candidates about the evaluation process, alternative treatments, potential medical or psychosocial risks, center specific outcomes (SRTR), organ donor risk factors, his or her right to refuse transplantation, and the fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect his/her ability to have immunosuppressive drugs paid for under Medicare Part B. This consent will direct patients to a separate surgical consent for specific and more detailed information regarding surgical risks and benefits. The signature on this document will be considered informed consent to begin the evaluation process and participate in the Transplant Program.

4. Prior to listing, the Pre Transplant Coordinator will review several additional and important documents including the *Kidney Waitlist Patient Form*, which further highlights understanding of the listing process and acceptance of non-standard deceased donor organs (DCD, KDPI>85, Hepatitis B core Antibody positive, Hepatitis C Antibody positive and paired donation).

Additional documents provided at this Visit include the program's most recent SRTR Program Summary, Coverage Policy, Kidney Recipient Rights, and Program Inactivity, Withdrawal and Termination Policy. The signed forms are completed and filed in the electronic medical record.

After listing, a patient may be consented for receiving a Hepatitis C NAT positive (HCV+) kidney by signing the *Accepting a Kidney from a Hepatitis C Virus NAT Positive Deceased Donor* consent form, if he/she meets the HCV+ Kidney Transplant Selection Criteria per the *Hepatitis C Virus* (HCV) and Kidney Transplantation Policy.

5. Prior to the transplant surgery, the candidate reviews and signs the *Kidney Transplant Surgery Consent* with the transplant surgeon or his designee (i.e. surgical consent).

References

MTP Kidney Waitlist Form
MTP Coverage Policy
Kidney Recipient Rights
Kidney Transplant Surgery Consent
Consent to Participate in the Kidney Transplant Program
Program Inactivity, Withdrawal and Termination Policy
Accepting a Kidney from a Hepatitis C Virus NAT Positive Deceased Donor Consent

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