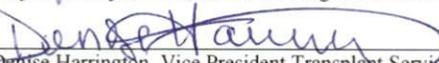
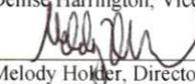


 Methodist Dallas Medical Center	Title: Informed Consent Policy	Effective Date: 07/2008
	Section: Liver, Kidney and Pancreas	
Approved by:  Alejandro Mejia, M.D., Executive Program Director		Revision Date(s): 07/2011; 07/2014 01/2015; 09/2019; 09/2022; 11//2025
 Denise Harrington, Vice President Transplant Services		
 Melody Holder, Director of Transplant Clinical Operations		
		Next review Date: 11/2028

Purpose: To provide solid organ transplant recipients information about the transplant process.

Policy: Methodist Dallas Transplant Institute shall provide information to protect and promote the rights of transplant patients

Procedure:

- 1) The transplant coordinator initiates education regarding informed consent with the first phone call or in the first clinic visit or encounter that may occur in a clinic setting, classroom, or other designated areas of the hospital
- 2) The transplant coordinator educates the transplant recipient during evaluation and prior to surgery
- 3) The transplant coordinator will continue instruction in subsequent phone call or clinic visits and prior to transplantation
- 4) The transplant coordinator documents education and patient understanding of education in the patient's medical record

Methodist Dallas Transplant Institute shall provide each patient with the following transplant information regarding the transplantation process (see transplant specific informed consent)

The process for evaluating patients for transplant begins at the time an individual is identified as a potential candidate and continues until the time the individual is placed on the waiting list. The following topics are discussed with the patient:

- 1) Results of the physical evaluation
- 2) Patient selection criteria and suitability for transplant
- 3) Results of laboratory and transplant specific diagnostic testing
- 4) Relevance of any psychosocial issues to the success of the transplant
- 5) Financial responsibilities resulting from the transplant
- 6) Necessity of following a strict medical regimen post-transplant

Surgical Procedure and Potential Risks for Transplantation

The following topics are discussed with the patient:

- Risks associated with the surgery
- Description of the expected procedures to be performed during the surgery
- Risks and effects of general anesthesia
- Possible need for blood transfusion and the risks involved with the use of blood or blood products

- Expected post-surgical course and discomforts (e.g. possible need for artificial ventilations, pain, bleeding, and infection)
- Benefits associated with transplant surgery for the transplant candidate relative to other alternatives

Alternative Treatments

This discussion occurs before the placement on the OPTN/UNOS waiting list, if there are significant changes in the patient's medical condition, or if other alternative treatments become available

Potential Medical and/or Psychosocial Risks

This discussion occurs early in the evaluation process and with any changes in the patient's medical or psychological condition.

The following medical risks are discussed with the patient:

- Wound infection
- Pneumonia
- Blood clot formation
- Organ rejection, failure, or re-transplantation
- Lifetime immunosuppressant therapy
- Arrhythmias and cardiovascular collapse
- Multi-organ failure
- Death

The following psychosocial risks must be discussed with the patient:

- Depression
- Post-Traumatic Stress Disorder
- Generalized anxiety
- Anxiety regarding dependence on others
- Feelings of guilt

Insurance Coverage

The following topics must be discussed with the patient:

- Future health problems related to transplantation may not be covered by their insurance carrier and if applicable, alternative financial resources should be explored
- Attempts to obtain medical, disability and life insurance in the future may be jeopardized and that denial of coverage is a possibility

National and Center Specific Outcomes

The most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report must be discussed with the patient including (but not limited to):

- Methodist Dallas Transplant Institute's observed and expected one-year post transplant patient and graft survival rate
- National one-year patient and graft survival rate
- Notification of all Medicare outcome requirements not being met by Methodist Dallas Transplant Institute

Organ Donor Risk Factors

Risk factors of the organ donor that could affect the success of the transplant or health of the patient, including but not limited to:

- Organ donor's history
- Condition or age of the organs used
- The risk of contracting HIV, hepatitis B, hepatitis C, malaria and other infectious diseases if the disease cannot be detected at the time of donation

Right to Refuse Transplantation

- The patient is advised of the right to withdraw consent for transplantation at any time

Medicare Approved Facility

- The fact that if a transplant is performed in a facility that is not Medicare-approved, it could affect the patient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B

Waiting Time Transfer and Multiple Listing

- The option of being listed at multiple transplant centers
- Ability to transfer time to another transplant center without loss of accrued time

Complaints and Grievances

- OPTN/UNOS patient services number will be provided to the patient

Reference: OPTN/UNOS Policy 3.2