

<p>Name of Policy: <u>Informed Consent for Potential Transplant Candidates</u></p> <p>Policy Number: 3364-140-32</p> <p>Department: Transplant Administration (Nursing Service)</p> <p>Approving Officer: Chief Nursing Officer Director, Renal Transplant Program Director, Pancreas Transplant Program</p> <p>Responsible Agent: Transplant Coordinator</p> <p>Scope: The University of Toledo Medical Center</p>	 <p>Effective Date: July 1, 2024</p> <p>Initial Effective Date: 12/27/2007</p>
<p><input type="checkbox"/> New policy proposal</p> <p><input checked="" type="checkbox"/> Major revision of existing policy</p>	<p><input checked="" type="checkbox"/> Minor/technical revision of existing policy</p> <p><input type="checkbox"/> Reaffirmation of existing policy</p>

(A) Policy Statement

All potential transplant candidates will review, understand and undergo a multifaceted informed consent process.

(B) Purpose of Policy

To provide potential transplant patients with information on transplantation.

(C) Procedure

Information on transplantation will be given during the pre-evaluation and initial evaluation clinic visit process, after receiving the initial referral. All potential transplant candidates are required to attend a mandatory orientation class. In this class, the following topics are discussed by the transplant coordinator and/or transplant social worker:

1. Patient selection criteria
2. Patient work up needs
3. Description of expected procedures to be done during surgery
4. Risk of general surgery
5. The possible need for blood transfusion and the risks involved with use of blood or blood products
6. Expected post-surgical course and discomforts, i.e., possible need for artificial ventilation, pain, bleeding and infection
7. Benefits associated with transplant surgery for the transplant candidate relative to other alternatives
8. Alternative treatments, i.e., dialysis (kidney) or insulin (pancreas)
9. Discuss potential medical risks including:
 - a. Wound infection
 - b. Pneumonia
 - c. Blood clots

- d. Organ rejection, failure or re-transplant
- e. Lifelong immunosuppressant therapy
- f. Arrhythmias and cardiovascular collapse
- g. Multi-organ failure
- h. Death

10. Discuss potential psychosocial risks, depression, post traumatic stress disorder, generalized anxiety, anxiety regarding dependence on others and feelings of guilt.
11. Discuss that future health problems related to the transplantation may not be covered by his/her insurance carrier and if needed, alternative financial resources should be discussed/explored.
12. Discuss transplant program's outcomes in regard to current one year post transplant patient survival rate, how these rates compare to national averages, and whether the latest report outcome measures comply with Medicare's outcome requirements.
 - a. Patient is provided with website (www.srtr.org).
13. Organ donor risk factors that could affect the success of the graft or health of the patient including but not limited to:
 - a. Medical/social history and age of donor
 - b. Condition of organ
 - c. Risk of contracting HIV, Hepatitis B, Hepatitis C, Malaria or other infectious pathogens if donor is infected.
14. After organ offer is made for a patient, the on-call organ offer team, transplant coordinator, transplant surgeon or other member of the transplant team must discuss the possible risks associated with transplantation of that organ for the patient.
 - a. The patient will be informed if the donor meets risk criteria as defined by the CDC. Documentation that the patient was informed and willing to proceed with the organ offer will be in the patient medical record.
 - b. Hepatitis C: UTMC will offer Hepatitis C NAT positive organ offers. At time of organ offer the patient will be informed that the donor is Hepatitis C NAT positive. Documentation that the patient was informed and willing to proceed with the organ offer will be in the patient medical record. All patients that receive a Hepatitis C NAT positive organ will have routine follow up with the gastroenterologist.
15. Patient's right to refuse transplant.
16. If a transplant is not provided in a Medicare-approved transplant center it could affect transplant recipient's ability to have his/her immunosuppressive drugs paid for under Medicare Part B.
17. In an effort to keep patients informed, the Program (On-Call) Coverage plan will be shared with patients as part of the evaluation process and a copy will be mailed to them at the time of listing with UNOS.
18. In the unlikely event that no surgical coverage is available for acceptance of organs and transplant related activities, the Transplant Program Director or his designee will notify the OPO and the transplant coordinator on call, who will change all actively listed patients to Status 7. Patients will be returned to active status when the medical staffing situation has been resolved. Patients will be notified by letter of their change to inactive status, the reason for the change, and the date on which they will return to active status.

Approved by:	Review/Revision Date:
<p>/s/ Kurt Kless, MSN, MBA, RN, NE-BC Chief Nursing Officer/CNO</p>	<p>1/26/2009 2/17/2009 1/12/2009 12/4/2012 12/17/14 3/24/15 3/24/18 3/24/2021 1/16/2024 3/1/2024</p>
<p>/s/ Michael Rees, MD Director, Renal Transplant Program</p>	
<p>/s/ Kunal Yadav, MD Director, Pancreas Transplant Program</p>	
<p><i>Review/Revision Completed By: Transplant Surgeon, Transplant Administrator</i></p>	<p>Next Review Date: 7/1/2027</p>
<p>Policies Superseded by This Policy:</p>	