Name of Policy:	**Informed Consent Process/Confidentiality**
Policy Number:	3364-140-33
Department:	Kidney Transplant Administration (Nursing Service)
Approving Officer:	Chief Nursing Officer Director, Renal Transplant Program
Responsible Agent:	Transplant Coordinator
Scope:	The University of Toledo Medical Center

THE UNIVERSITY OF TOLEDO 1872

Effective Date: May 1, 2021

Initial Effective Date: December 27, 2007

_____ New policy proposal
_____ Major revision of existing policy
__X__ Minor/technical revision of existing policy
_____ Reaffirmation of existing policy

(A) Policy Statement

All prospective living donors will be informed of all aspects of and potential outcomes from living donation.

(B) Purpose of Policy

To ensure that all prospective donors are fully informed of all aspects of living donation.

(C) Procedure

1. Once a prospective living donor makes initial contact with the living donor coordinator, a general information packet will be provided to the prospective living donor.
2. Upon identification of intended living donor (in the case of multiple prospective donors), the living donor coordinator will meet with intended donor to review informed consent literature.
3. Once literature has been reviewed and discussed and the donor coordinator feels that the donor understands the material presented, the intended donor will consent to proceed with living donation by way of consent form that will remain in the potential donor chart.
4. All prospective living donors are informed of confidentiality upon initial contact either in person or via telephone during medical screening by way of general information packet provided. Once the intended living donor is identified, confidentiality is addressed during review of informed consent.
5. The evaluation process consists of the following items to be discussed with living donor:
   a. Results of physical evaluation with discussion of how any current medical issues or medication regimen could be affected by donation, or could affect recovery from donation.
   b. Suitability for donation
   c. Results of laboratory and donor specific diagnostic testing
   d. Relevance of any psychosocial issues related to donation
   e. Financial responsibilities resulting from the living donation as well as expenses, including potential out of pocket expenses if the donor has complications from surgery, needs medication following discharge, or is expected to undergo follow-up testing or a physical exam so that the program can report donor statistics to the OPTN.
   f. Donor's ongoing health status after donation is reported to the OPTN at the time of donation, 6 months, 1 year, and 2 years after donation.
   g. Requirement of blood specimen at time of donation and storage of this specimen for 10 years at the recovery hospital. It would only be used for investigation of potential donor-derived disease.
6. The surgical process is addressed initially in general information packet and a more detailed discussion during informed consent, and also with the donor surgeon at the time of evaluation. The discussion of the surgical process will include:

a. Risks associated with surgery
b. Risks and effects of general anesthesia
c. Possible need for blood transfusion and the risks involved with the use of blood or blood products.
d. Expected post-surgical course and discomforts.
e. Termination of the surgery with any indication that he/she is at significant risk of complications or death during the surgery.

7. All potential living donors will be advised of alternative treatments to organ transplantation, and will have the ongoing option of changing their mind regarding donation.

8. All potential living donors will discuss potential medical and psychosocial risks to include:
   a. Infection of surgical sites or urinary tract
   b. Pneumonia
   c. Blood clot formation
   d. Arrhythmias and cardiovascular collapse (cardiac arrest)
   e. Organ failure
   f. Potential need for organ transplant later on in life
   g. Death
   h. Depression
   i. Post-traumatic stress disorder (PTSD)
   j. General anxiety
   k. Anxiety regarding dependence on others
   l. Possible feelings of guilt
   m. Hernia or nerve injury
   n. Hemorrhage or need for blood transfusion
   o. Consequences of surgery (pain, fatigue, scars, nausea, vomiting, constipation)

9. All potential donors will be informed of national and transplant center specific outcomes for recipients and national and center specific outcomes for living donors.

10. All potential living donors will be informed that the donation procedure and future health problems related to the donation may not be covered by his/her insurance carrier. The potential donor will also be advised that attempts to obtain medical, disability, and life insurance in the future may also be jeopardized and there is the possibility of denial of coverage.

11. All potential living donors will be notified that 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.

Approved by:	**Review/Revision Date:**
/s/ Todd Stec, RN Interim Chief Nursing Officer — Date /s/ Michael Rees, MD Transplant Program Director — Date	1/1/2009 4/21/2009 1/12/2010 8/7/2012 1/7/15 5/22/2017 5/1/2018 5/3/2021
Review/Revision Completed By: *Transplant Coordinator* *Transplant Administrator*	**Next Review Date:** 5/1/2024
Policies Superseded by This Policy:	