Maine Transplant Program

Kidney Paired Donation (KPD)

Living Donor Education and Consent Form

Part I: To be completed by the transplant coordinator and/or other medical professional following completion of the Informed Consent to Become a Living Kidney Donor:

1. Donation as a Personal Choice

The following has been communicated to the potential living donor:

- Potential donor must be willing to donate, free from inducement and coercion.
- Disclosure that it is unlawful for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration.
- In certain cases, donors may be reimbursed for limited travel expenses upon application to the Living Donor Resource Center
- Potential donor is due sufficient time to reflect after consenting to donate.
- Potential donor or candidate may decline to donate for any reason at any time.
- A general, nonspecific statement of unsuitability for donation is available to the potential donor should he/she wish not to proceed with donation.
- An explanation that a potential donor's decision not to proceed with the donation will only be disclosed if authorized by the donor.

2. Donation as an Educated Decision

The following has been communicated to the potential living kidney donor:

- Printed materials that explain all phases of the living donation have been provided to donor in potential donor's native language.
- A disclosure of alternate procedures or courses of treatment for the potential donor and recipient, including deceased donation.
- Education on what remaining organ function and impact on the donor's lifestyle and work has been provided to the potential donor.
- Both national and center-specific outcomes from the most recent reports produced by the Scientific Registry of Transplant. Recipients have been provided to the potential living kidney donor. This information should include, but not be limited to: 1-year patient and graft survival, national 1-year patient and graft survival, and notification and about any and all Medicare outcome requirements not being met by the transplant center.

3. Donation Risks and Benefits

- S/he has received and signed the Informed Consent to Become a Living Kidney Donor which outlines the risks and benefits of donation.
- All potential donor questions have been answered regarding donation risks and benefits.

- It is possible that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery.
- It is possible that the donor's kidney may not be transplanted or the paired donor's matched candidate might not receive a transplant due to unexpected events.

4. Independent Living Donor Advocate

Information on the Independent Living Donor Advocate (ILDA) has been communicated to the potential living donor. The living donor transplant program has provided an ILDA whose responsibilities include, but are not limited to the following:

- Promote the best interests of the potential living donor.
- Advocate for the rights of the potential donor.
- Assist the potential donor in obtaining and understanding information regarding the evaluation and donation process.
- Assist the donor in understanding and obtaining information regarding the informed consent process, medical and psychosocial risks, and follow up requirements.

5. Evaluation of the Donor

The following has been communicated to the potential living donor:

- An evaluation of the potential donor's ability to comprehend the donation process, including procedures employed for both donor and recipient and possible outcomes has been performed.
- The disclosure that the donor will receive thorough medical and psychosocial evaluations.
- The paired donor may require additional testing, including multiple blood draws for crossmatching related to the matching process.

6. Disclosure of Medical Information

The following has been communicated to the potential living donor:

- The potential donor's medical evaluation could reveal health information or conditions (such as HIV and certain infectious diseases) that the transplant center must report to government authorities.
- An explanation that medical information on the potential donor may not be revealed to a
 potential recipient unless authorized by the potential donor. If the potential donor has a
 condition that might harm a recipient, the medical team in charge of his or her evaluation
 will not allow the donation to occur.
- An explanation that the potential donor's identity may be disclosed on recipient's insurance Estimate of Benefits form.
- Potential donor will not be eligible for a KPD match run until s/he consents to share protected health information with all other transplant hospitals in the KPD exchange.

7. Medical Risks

The following medical risks have been communicated to the potential living donor:

- S/he has received and signed the Informed Consent to Become a Living Kidney Donor which outlines the medical risks of donation
- All potential donor questions have been answered regarding the medical risks of donation
- It is possible that the paired donor's paired recipient and the paired donors matched recipient may not have equal outcomes

8. Psychosocial Risks

The following psychosocial risks have been communicated to the potential living donor:

- S/he has received and signed the Informed Consent to Become a Living Kidney Donor which outlines the psychosocial risks of donation
- All potential donor questions have been answered regarding the psychosocial risks of donation

9. Financial Risks

The following financial risks have been communicated to the potential living donor:

- Possibility that the personal expenses of travel, housing, and child care costs and lost wages related to donation might not be reimbursed. However resources might be available to defray some donation related costs.
- S/he has received and signed the Informed Consent to Become a Living Kidney Donor which outlines the potential financial impacts of living donation
- All potential donor questions have been answered regarding potential financial impacts of donation
- Financial counseling and information on financial resources have been offered to the potential donor
- It is possible that the paired donor's name will appear on the matched candidate's insurance Estimate of Benefits

10. Donation Follow Up

- A disclosure that transplant centers are required to report living donor follow-up information for at least two years, and that the donor should expect to be contacted by the transplant program regarding their current health status.
- Any infectious disease or malignancy found during the first two years post donation may need to be reported to public health authorities and will be reported to the recipient transplant center, and the Organ Procurement Transplant Network.
- The agreement of the potential donor to commit to postoperative follow-up testing coordinated by the transplant center that removed the donor's kidney for a minimum of two years.
- A disclosure that living donor follow-up is the best method for the collections of information on the long-term health implications of living donation

11. For Shipped Living Donor Organs

(This section needs to be completed if the potential living donor's kidney may be shipped to another transplant center.)

The following information has been communicated to the potential living donor:

- If the living donor's organ will not be transplanted at the recovery center, there is an increased risk for organ loss associated with transport.
- There is separate consent (included at the end of this document) if the potential living donor is willing for his/her organ to be transplanted at a center other than the recovery center

12. For Non-Directed Donors

(This section needs to be completed for non-directed living donors only.)

If the potential living donor intends to be a non-directed donor, the following information has been communicated to the potential living donor:

- Potential donor has been informed of the option to participate in KPD
- In kidney paired donation, non-directed donors will be matched to candidates by a computer program.
- There is a separate consent (included at the end of this document) for the non-directed donor to participate in a kidney paired donation program.
- Non-directed donations to a candidate waiting for a deceased donor kidney will be done in accordance with UNOS Policy 14.6B: Placement of Non-directed Living Donor Kidneys.
- Any other options available to the non-directed donor

13. Logistics of KPD

- Donor may travel to recipient center or donor kidney may be shipped to recipient center.
- Donor surgeries usually begin at the same time in two-way or three-way exchanges. Recipient surgeries begin after donor surgeries.
- In donor chains, surgeries might not occur simultaneously.
- A donor may help more than one recipient receive a transplant through a paired donation chain.
- A recipient/donor pair can choose to only be matched in two-way or three-way exchanges.
- KPD donors and recipients do not choose their match.
- Donors may need to wait to find a suitable recipient match within a KPD match and/or may need to wait longer to donate after a match has been identified due to logistical issues.
- A KPD donor or candidate may decline a match.
- If the operating room date is not set for a chain at the time of the next match run, but the
 crossmatches have been performed and the donors have been approved up to the point
 where the chain breaks, then the final donor could be entered in the next match run to
 repair the chain. In order for the final donor to be included in the next match run, the
 donor must agree to be in the match run instead of donating to the deceased donor waiting
 list at that time.

Blood type O non-directed donors may be in a position to choose to donate to a shorter chain or to wait for another match run with the possibility of finding a longer chain.

14. Anonymity Between Pairs

The following has been communicated to the potential living donor:

- KPD pairs are kept anonymous prior to transplant.
- The Maine Transplant Program Policy on Information Sharing and Direct Contact between Living Kidney Donors and Recipients has been reviewed.

15. General Information for KPD Donors

The following has been communicated to the potential living donor:

- All living donors, including KPD donors, are evaluated and cleared for donation according to standard medical criteria and program selection criteria.
- Maine Transplant Program Donor selection and matching requirements have been explained.
- Transplant centers will determine if the donor kidney in an exchange is appropriate for the recipient.
- KPD donors will be paired with compatible recipients using an electronic system that
 maximizes the number of matched pairs while providing additional consideration for
 specific populations, such as children and highly sensitized recipients.

16. Possible Untoward Events

- This is not an exhaustive list of possible untoward events. The following has been communicated to the potential living donor:
- An event may occur in the operating room that makes it necessary to stop a donor procedure. In this case, one recipient would not receive a kidney. If a donor or recipient surgery has begun, this surgery will continue even if another surgery in the match must stop.
- If it is necessary to stop a recipient surgery, a kidney would be available. This kidney would be given to a recipient on the deceased donor waiting list according to OPTN policies.
- If the exchange fails, there is no added priority for the paired candidate on the deceased donor wait list.
- It is possible that a donor's kidney could be lost in transport or logistical issues may occur related to shipping a kidney.

17. Commitment of Pairs to Exchange

- Participants may withdraw at any time for any reason
- Donors and potential recipients are strongly encouraged to ask questions and to discuss all
 aspects of the exchange with the transplant team and other health care providers in order
 to make a solid informed decision whether or not to participate.

Recipient/donor pairs should discuss KPD with their caregivers and family.

18. Bridge Donors

- A bridge donor may need to have another medical evaluation at a future time.
- S/he may need to be available to provide blood on multiple occasions for crossmatching.
- How the KPD determines whether a chain ends with a bridge donor
- The bridge donor may decline to donate at any time for any reason
- The bridge donor determines the amount of time the donor is willing to be a bridge donor. The transplant hospital will document in the donor's medical record how long the donor is willing to be a bridge donor. If the bridge donor revises the amount of time the donor is willing to be a bridge donor, the bridge donor's transplant hospital must document that revision in the donor's medical record. The transplant hospital must maintain documentation in the donor's medical record that the donor has verbally consented to remain a bridge donor each time the donor is identified as a bridge donor in an accepted KPD exchange
- All of the bridge donor's options for donation including:
 - Continued participation as a bridge donor in the KPD program
 - O Donation to a candidate waiting for a deceased donor kidney
 - Any other options available to the bridge donor

19. Op	tions		
•	Willing to travel? □ Yes □ No − Explain:		
•	Willing to have their kidney shipped? ☐ Yes ☐ No — Explain:		
•	Will only donate left, right or either kidney \square Left only \square Right only \square Either		
•	Willing to participate in a chain (not as bridge donor)? ☐ Yes ☐ No		
•	Willing to participate as a bridge donor? □ Yes □ No		
•	Willing to participate in : □ KPD □ NKR □ Local		
•	lant Center Representative: reviewed the KPD Program with this patient.		
Signatu	ure of Transplant Care Representative Date 24H Time		

Part II: To be signed by the potential living donor

Maine Transplant Program Informed Consent for KPD (Kidney Paired Donation) Donors

- I understand that I will not be eligible for a KPD match run until I provide a written consent to my Protected Health Information (PHI) with other transplant hospitals in the KPD exchange. By signing this consent, I am agreeing to share my PHI with other transplant hospitals in the KPD exchange.
- I have read, understand, and have signed the Maine Transplant Program Informed Consent to Become a Living Kidney Donor.
- I am aware of and understand the MMC KPD Program's matching requirements and donor selection criteria.
- I understand that KPD donors and candidates do not choose their match and that a KPD donor or candidate may decline a match.
- I understand that by donating my kidney in the KPD program, I may be helping more than one candidate receive a transplant.
- I understand that as a paired donor I may need to wait to find a match and that I may need to wait longer after a match has been identified due to logistical issues.
- I understand that my paired candidate may not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery
- I understand that my kidney may not be transplanted or my paired candidate may not receive a transplant because of unexpected events
- I understand that my matched candidate's insurance may not cover travel costs if I need to travel to the recipient transplant hospital
- I understand that my paired recipient and the recipient I am matched with through KPD might not have equal outcomes
- I understand that my name may appear on the insurance estimation of benefits of the candidate I am matched with
- I understand that there is a possibility that my kidney could be lost in transport or that there may be other potentially negative consequences related to shipment of my kidney
- I understand that I may require additional testing, including multiple blood draws for cross matching.
- I am aware of and understand the Maine Transplant Program *Policy on Information Sharing* and *Direct Contact between Living Kidney Donors and Recipients* which provides guidelines on communication and meetings between matched donors and recipients.
- I understand that if the KPD exchange fails, there are not any additional priority points for my paired candidate on the deceased donor waiting list.

I understand that I can withdraw from participation in the KPD program at any time for any reason. I understand and agree to all points listed above. I have been educated on KPD by the

Maine Transplant Program and wish to participat I can withdraw this consent at any time for any re	•
Signature of Donor	Date 24H Time
Signature of Transplant Care Representative	Date 24H Time
 Additional Non Directed Donor Consents I have been informed of all of my donation on I am aware that I can donate to a candidate of this donation would commence based on UN Living Donor Kidneys. This policy has been expected. 	urrently waiting for a deceased donor kidney. OS Policy 14.6.B Placement of Non-directed
Signature of Donor	Date 24H Time
Signature of Transplant Care Representative	Date 24H Time
 Additional Bridge Donor Consents I understand that I may need to have another available to provide blood on multiple occasion. I understand that I will be informed of the definctuding the size of the chain and planned cholor I understand that I will be informed of the time taken to facilitate donation as quickly as poss. I understand that I must verbally consent to reinto a Kidney Paired Donation chain. 	ons for crossmatching. tails and logistics of the plan for donation nain end. neline on the wait for surgery as steps are ible.
Signature of Donor	Date 24H Time
Signature of Transplant Care Representative	Date 24H Time