Kidney Paired Donation

Pilot Program

Operational Guidelines

(Interim Implementation)

Version 3.0

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Kidney Paired Donation Pilot Program

Operational Guidelines

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Requirements for Participation

1. **Purpose:** To outline the prerequisites that centers must meet to be eligible to participate in the Kidney Paired Donation (KPD) Pilot Program and to outline the criteria that candidates and donors must meet before they are entered in the Program by the transplant center.

2. **Procedures:**

    a. According to the Charlie W. Norwood Living Organ Donation Act (H.R. 710),

    ‘‘(4) The term ‘paired donation of human kidneys’ means the donation and receipt of human kidneys under the following circumstances:

    ‘‘(A) An individual (referred to in this paragraph as the ‘first donor’) desires to make a living donation of a kidney specifically to a particular patient (referred to in this paragraph as the ‘first patient’), but such donor is biologically incompatible as a donor for such patient.

    ‘‘(B) A second individual (referred to in this paragraph as the ‘second donor’) desires to make a living donation of a kidney specifically to a second particular patient (referred to in this paragraph as the ‘second patient’), but such donor is biologically incompatible as a donor for such patient.

    ‘‘(C) Subject to subparagraph (D), the first donor is biologically compatible as a donor of a kidney for the second patient, and the second donor is biologically compatible as a donor of a kidney for the first patient.

    ‘‘(D) If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.

    ‘‘(E) All donors and patients in the group of donor-patient pairs (whether two pairs or more than two pairs) enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.

    ‘‘(F) Other than as described in subparagraph (E), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to in such subparagraph.’’.

b. Transplants centers:

   i. Must be Organ Procurement and Transplantation Network (OPTN) and United Network for Organ Sharing (UNOS) approved to perform kidney transplants and living donor kidney recovery (see UNOS Bylaws, Appendix B, Attachment I, Section XIII on kidney transplant programs)

   ii. Must have a designated contact for the KPD Pilot Program (See KPD Contact Responsibilities Operational Guideline)

   iii. Must agree to abide by all rules set forth in the Kidney Paired Donation Pilot Program Operational Guidelines and the OPTN/UNOS Bylaws and Policies, unless explicitly stated otherwise in the KPD Pilot Program Operational Guidelines. Any potential violations of the KPD Operational Guidelines or any potential violations of policies and bylaws could be referred to the Membership and Professional Standards Committee.

c. Candidates:

   i. Must be registered on the deceased donor kidney waiting list at the transplant center that wishes to enroll the candidate in the KPD Pilot Program

   ii. Must consent in writing to participate in the Kidney Paired Donation Pilot Program.

d. Potential Living Donors:

   i. Must be at least 18 years old

   ii. Must meet the evaluation requirements set forth in the Living Donor Evaluation Section of the Kidney Paired Donation Pilot Program Operational Guidelines

   iii. Must be consented according to the consent process outlined in “The Resource Document for the Informed Consent of Living Donors” and in the Informed Consent Requirements Section of the KPD Pilot Program Operational Guidelines.

   iv. Must consent in writing to participate in the Kidney Paired Donation Pilot Program.

   v. Must not be currently listed as a potential living donor for any other candidate registered in the KPD system

3. Records Required:

- All records below must be maintained and submitted to the OPTN contractor upon request:
    - Record of candidate's informed consent in writing to participate in the Kidney Paired Donation Pilot Program in the candidate's chart
    - Record of the potential living donor's informed consent in writing to participate in the Kidney Paired Donation Pilot Program in the potential living donor's chart
    - Record of the potential living donor's informed consent according to the consent process outlined in "The Resource Document for the Informed Consent of Living Donors" in the potential living donor's chart

Potential Living Donor Evaluation Requirements

1. **Purpose:** To describe the required components of the potential living donor evaluation process

2. **Procedures:**

    a. **Psychosocial Evaluation:** As required by the Bylaws, this evaluation must be performed by a psychiatrist, psychologist or social worker with experience in transplantation. The psychosocial evaluation must:

        i. Review psychosocial issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;

        ii. Attempt to identify factors that warrant educational or therapeutic intervention prior to donation and provide the necessary referrals for further psychological or psychiatric evaluation if current or prior psychiatric disorders are suspected;

        iii. Determine if the potential donor understands the short- and long-term medical risks associated with living donation as currently understood with the information available;

        iv. Allow the transplant program to explore the reason(s) for volunteering to donate to determine that the decision is free of coercion;

        v. Determine if the potential donor is able to make an informed decision and has the ability to cope with the major surgery and related stress. This includes a realistic plan for donation and recovery, with social, emotional and financial support available as needed;

        vi. Review the financial circumstances of the potential donor (employment, insurance coverage, etc) and determine if the potential donor understands the possible financial implications of living donation and the availability of financial resources where applicable;

        vii. Inform the donor that he/she may experience problems in obtaining future disability and health insurance following donation; and

        viii. Inform the donor that health information obtained during their evaluation will be subject to the same regulations as regular medical records and may not be additionally protected.

ix. To protect the potential donor, the most sensitive questions should be asked at the end of the psychosocial evaluation, which prevents recording responses to very sensitive questions in the medical record of inappropriate candidates.

b. **Donor Medical Evaluation:** The Bylaws state that a thorough medical evaluation be performed by a physician or surgeon experienced in living donation. The goal of the medical evaluation is to:

i. Assess the immunologic compatibility of the donor to the recipient;

ii. Assess the general health and surgical risk of the donor including screening for conditions that may predict complications from having one kidney in the future;

iii. Determine if there are diseases present that may be transmitted from donor to recipient; and

iv. Assess the anatomy of the kidneys.

v. Components of the Medical Evaluation

1. **General History:**

a. Evaluate for significant medical conditions such as hypertension, diabetes, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, history of cancer, history of infections, hematologic disorders, and bleeding/clotting disorders

b. Smoking, alcohol and drug use/abuse, including intravenous drug use/abuse and other high risk behavior

c. Active and past medications (nephrotoxic, chronic use of pain medications and NSAIDs, other)

d. Allergies

e. Family history (coronary artery disease, cancer, other)

f. Kidney Specific Personal History:
- Kidney disease, proteinuria
- Kidney injury
- Diabetes
- Chronic infection
- Nephrolithiasis
- Recurrent urinary tract infections
- Gout or other arthritis

- Gestational diabetes

g. Kidney Specific Family History:
   - Kidney disease
   - Diabetes
   - Hypertension
   - Reflux

2. **Social History:** Although a full psychosocial evaluation will be carried out, an evaluation must be part of the medical evaluation to include special emphasis on:

   a. Employment, health insurance status, living arrangements, social stability

   b. Psychiatric illness, depression, suicide attempts

3. **Physical Exam:**

   a. Height, weight, BMI

   b. Examination of all major organ systems

4. **Kidney-Specific:**

   a. Blood pressure (Measure after sitting for 5 minutes, take twice at the same visit, and obtain 2 different assessments of blood pressure on different days). It may however be preferable to perform a 24-hour blood pressure monitor as cohort studies show improved accuracy for determining the correct blood pressure category with 24-hour monitoring

   b. Vascular evaluation (abdominal, femoral, carotid bruits, etc)

   c. Microscopic evaluation

5. **General Laboratory Tests**:

   a. CBC with platelet count

   b. Prothrombin Time/Partial Thromboelastin Time

   c. Comprehensive panel (electrolytes, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)

   d. hCG quantitative pregnancy test for women < 55 years old

   e. Age and gender appropriate cancer screening tests.

f. Chest X-Ray

g. Electrocardiogram (ECG)

h. Evaluation for coronary artery disease, as suggested by the American College of Physicians

i. Pulmonary function tests for smokers, as suggested by the American College of Anesthesiology and American Lung Association

6. **Kidney-Specific Tests:**

a. Urinalysis; microscopy as indicated

b. Urine culture if clinically indicated

c. Measurement of protein excretion

d. Measurement of glomerular filtration rate or creatinine clearance by 24 hour urine collection or equivalent testing

e. Screening for Polycystic Kidney Disease as indicated by family history. If the prospective donor is over age 30, this is usually accomplished with an ultrasound. In those under age 30, genetic testing remains the gold standard.

f. Uric acid

g. GTT in relatives of diabetics as indicated

7. **Immunological Testing:**

a. ABO blood group typing

i. Blood type A and AB must be sub-typed

b. Human Leukocyte Antigen (HLA) typing

8. **Metabolic Focused Testing:**

a. Fasting blood glucose

b. Fasting cholesterol levels (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol) with Fasting Lipid Profile if cholesterol/triglycerides are elevated.

c. Uric acid (High uric acid levels are associated with the metabolic syndrome and independently with reduced kidney function)

d. If the risk of diabetes is higher than the general population by presence of a first degree relative with diabetes or the presence of metabolic syndrome characteristics, but the prospective donor does not meet the definition of diabetes, the potential donor should be counseled that he or she is at an increased risk to develop diabetes and perhaps kidney disease

e. The goal of these tests is to determine the number of elements of the metabolic syndrome present: Donor may be at increased risk of kidney disease if ≥ 3 risk factors (central obesity, high blood pressure BP >130/85, fasting blood glucose ≥ 100mg/dl, triglyceride levels > 150mg/dl, HDL < 40 for a man and <50mg/dl for a woman).

9. **Anatomic Assessment:** This assessment is used to determine which kidney is most anatomically suitable for transplantation (typically dependent upon the number of arteries going to the kidneys) and whether the kidneys are of equal size or have masses, cysts, or stones. The donor should preferably keep the kidney with the fewest issues. Based on these findings, the surgeon will determine 1) the suitability of the organ, and 2) any additional risks associated with anatomical variants. The radiologic imaging may reveal serendipitous findings that will need to be investigated. These finding may be related, or unrelated to the organ of interest.

    - The test of choice will depend upon the local radiological expertise and surgical preference, but may include CT angiogram, MR angiogram or angiogram, used singly or in combination.

10. **Screening for Transmissible Diseases:** This screening is used to identify the risk of passing an infection or disease to a recipient. This screening may also identify a condition that may require donor treatment or may increase the risk of donation. Infectious disease testing typically includes testing for the following:

    - CMV (Cytomegalovirus)
    - EBV (Epstein Barr Virus)
    - HIV 1,2 (Human Immunodeficiency Virus)
    - HTLV I (Human T-cell Lymphotropic Virus) antibody testing

- HBsAg (Hepatitis B surface antigen)
- HBcAb (Hepatitis B core antibody)
- HBsAb (Hepatitis B surface antibody)
- HCV (Hepatitis C Virus)
- RPR (Rapid Plasma Reagin Test for syphilis)
- Tuberculosis
- Other diseases may be tested for depending on program preference and donor risk profile:
    - Strongyloides for donors from endemic areas
    - Trypanosoma cruzi for donors from endemic areas
    - West Nile for endemic areas
    - Toxoplasmosis: Transmission is low if recipients are treated with trimethoprim-sulfamethoxazole

11. **Cancer Screening:** The screening tests follow the practices advised by the American Cancer Society. Screenings to be performed depending upon gender, age, or family history include:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer
- Lung cancer screening is not currently recommended by the American Cancer Society, but could be considered in the older patient with a strong smoking history.

3. Records Required:

- If the potential living donor is registered in the KPD Pilot Program, the transplant center must maintain a record of the potential living donor evaluation in the potential living donor's chart and submit it upon request

Informed Consent Requirements

1. **Purpose:** To outline the process for obtaining informed consent for both the candidate and the potential living donor so that the participant has been given the opportunity to make an informed decision regarding program participation

2. **Procedures:**

    a. For candidates:

        i. A transplant center representative must review the components of the Kidney Paired Donation Pilot Program with the candidate separately from the paired potential living donor. After review, the transplant center will ask the candidate to sign a consent form if he/she agrees to participate.

        ii. The transplant center must maintain documentation of the candidate's informed consent and submit it to the OPTN contractor upon request.

        iii. Consent for the kidney transplant surgery (including the risk that surgery may not occur due to unforeseen events in the operating room such as hypotension, MI, unexpected findings, etc) should take place separately and is the responsibility of the transplant center and attending surgeon.

        iv. If the candidate chooses to accept a shipped kidney, the transplant center must have a signed consent form showing that the candidate has been informed of the potential risks of shipping a kidney.

    b. For potential living donors:

        i. The consent process for the potential living donor must follow the guidelines set in the "Resource Document for the Informed Consent of Living Donors." The consent process for any potential living donor should include, but is not limited to, the following:

            1. The assurance that the potential donor is willing to donate, free from inducement and coercion, and understands that he or she may decline to donate at any time.

            2. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

The medical evaluation will be conducted by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post donation, which will include a screen for any evidence of occult renal and infectious disease and medical co-morbidities which may cause renal disease.

The psychosocial evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion.

3. A disclosure that living donor transplant programs must provide an Independent Donor Advocate (IDA) whose responsibilities include but are not limited to the following:

    - to promote the best interests of the potential living donor
    - to advocate for the rights of the potential donor
    - to assist the potential donor in obtaining and understanding information regarding the:

        (i) consent process

        (ii) evaluation process

        (iii) surgical procedure, and

        (iv) benefit and need for follow-up

4. An evaluation of the potential donor's ability to comprehend the donation process, including procedures employed for both donor and recipient and possible outcomes.

5. The provision of printed materials that explain all phases of the living donation process. Materials should be written at an appropriate reading level and provided in the potential donor's native language. When necessary, independent interpreters should be provided to make certain the potential donor comprehends all phases of living donation and its associated risks and benefits.

6. The provision of education that discusses what remaining organ function will be left after the donation and what the impact on the donor might be.

7. The provision of sufficient time for the potential donor to reflect after consenting to donate.

8. A disclosure of alternate procedures or courses of treatment for the potential donor and recipient, including deceased donation. Pre-existing, life threatening conditions of the potential paired recipient should be disclosed to the potential donor prior to obtaining consent.

9. An explanation that a potential donor's decision not to proceed with the donation can only be disclosed if authorized by the potential donor.

10. A determination that the potential donor understands that he/she will undertake risk and will receive no medical benefit from the operative procedure of donation.

11. A disclosure that the potential donor's medical evaluation could reveal conditions that the transplant center must report to governmental authorities such as HIV or certain venereal diseases

12. 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.

13. A specification of the medical, psychological, and financial risks associated with being a living donor. These risks may be transient or permanent and include, but are not limited to the following:

    a. Potential Medical Risks

    - potential for surgical complications including risk of donor death
    - potential for decreased kidney function in kidney donors. Every kidney donor will experience a decrease in the kidney function compared to pre-donation. The amount will depend upon the potential donor's age and history. The anticipated change in the potential donor's individual kidney function is to be discussed with each donor
    - potential for organ failure and the need for a future organ transplant for the donor
    - potential for other medical complications including long- term complications currently unforeseen

- scars
- pain
- fatigue
- abdominal or bowel symptoms such as bloating and nausea
- increased risk with the use of over the counter medications and supplements

b. Potential Psychosocial Risks

- potential for problems with body image
- possibility of post surgery depression, anxiety, or emotional distress
- possibility of transplant recipient rejection and need for re-transplantation
- possibility that the transplant recipient will have a recurrence of disease
- possibility of transplant recipient death
- potential impact of donation on the donor's lifestyle

c. Potential Financial Risks

- personal expenses of travel, housing, and lost wages related to live donation might not be reimbursed; however, the potential donor should be informed that resources may be available to defray some donation-related costs
- child care costs
- possible loss of employment
- potential impact on the ability to obtain future employment
- potential impact on the ability to obtain or afford health, disability, and life insurance
- health problems experienced by living donors following donation may not be covered by the recipient's insurance

14. A disclosure that transplant centers are required to report living donor follow-up information for at least two years, so the donor should expect to be contacted by the transplant program regarding their current health status.

15. A disclosure that living donor follow-up is the best method for the collection of information on the health implications of living donation.

16. A disclosure that centers will specify who is responsible for the cost of follow-up care.

17. The agreement of the potential donor to commit to postoperative follow-up testing coordinated by the actual recipient's transplant center for a minimum of two years

18. A disclosure that donors may not receive valuable consideration (including without limitation monetary or material gain) for agreeing to be a donor. In certain cases, donors may be reimbursed for limited travel expenses and may receive subsistence assistance.

19. The stipulation that transplant centers will provide potential donors with both national and their center-specific outcomes from the most recent SRTR center-specific report. This information should include, but not be limited to 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

20. A disclosure to all potential non-directed or altruistic living donors of the following:

    a. the transplant program will determine who will receive their organ

    b. the transplant center will take all reasonable precautions to provide anonymity for the donor and recipient

    c. the transplant center should obtain a separate consent to allocate the organ to a paired donation system

    d. the transplant center should disclose there is an increased risk associated with the transport of non-directed living donor organs and obtain additional consent to transplant the organ if it will not be transplanted at the recovery center

ii. A transplant center representative must review the components of the Kidney Paired Donation Pilot Program with the donor separately from the candidate. After review, the transplant center will ask the candidate to sign a consent form if he/she agrees to participate.

iii. The reviewing transplant center representative will acknowledge witness to consent by signing the form.

iv. The transplant center must maintain documentation of the potential living donor's informed consent and submit it to the OPTN contractor upon request.

v. Consent for the donor kidney nephrectomy surgery (including the risk that surgery may not occur due to unforeseen events in the operating room such as hypotension, MI, unexpected findings, etc) should take place separately and is the responsibility of the transplant center and attending surgeon.

vi. If the donor chooses to allow his/her kidney to be shipped, the transplant center must have a signed consent form showing that the candidate has been informed of the potential risks of shipping a kidney.

3. Records Required:

- All records below must be maintained and submitted to the OPTN contractor upon request:
    - Signed consent from the candidate to participate in the Kidney Paired Donation Pilot Program in the candidate's record
    - Signed consent from the potential living donor to participate in the Kidney Paired Donation Pilot Program in the potential living donor's chart
    - Signed consent from the donor to be a living kidney donor in accordance with the "Resource Document for the Informed Consent of Living Donors" in the potential living donor's chart

Histocompatibility Testing Requirements

1. **Purpose:** To define the histocompatibility tests that must be performed on all candidates and potential living donors participating in the Kidney Paired Donation Pilot Program

2. **Procedures:**

    a. For candidates:

        i. HLA-A,-B,-Bw4, 6,-Cw,-DR, and -DQB as well as -DR51, 52, 53 antigen typing is required. Patients with antibodies against HLA-DQA or DPA or DPB must be typed for these specificities so that reliable non-self antibodies are identified.

        ii. Sensitized candidates may have ***unacceptable*** HLA-A,-B,-Cw,-DR,-DQ and DP antigens listed that include those antigens to which the patient is sensitized and would preclude transplantation at the candidate's center with a donor having any one of those antigens. These antigens will be considered unacceptable in all cases.

            1. Antibodies against HLA-DQA or non-HLA antibodies which are considered as a contraindication to transplantation at the recipient transplant center are considered unacceptable for a donor expressing the targets of these antibodies . Determination of donor compatibility in these cases will be the responsibility of the recipient center laboratory.

            2. Sensitization status must be validated quarterly by retesting the candidate in accordance with center protocols.

        iii. Sensitized candidates must have additional, lower level antibodies ("other antibody specificities") against HLA-A,-B, -Bw4,6, -Cw,-DR,-DQ and DP antigens listed that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens. HLA antigen targets of these antibodies will be considered when matching pairs with a minimal risk of positive crossmatch.

            1. Antibody specificities must be updated whenever:

                a. Quarterly antibody screening tests indicate a change in antibody level or specificity

                b. A potentially sensitizing event occurs (e.g. a blood transfusion)

c. A patient who has been inactive for more than 3 months is reactivated.

d. An unexplained positive crossmatch* that precludes transplantation at the recipient center occurs.

iv. Unsensitized patients must be identified as having no detectable anti-HLA antibodies or other unacceptable histocompatibility antigens that would preclude transplantation at the candidate's center.

v. The laboratory must verify the candidate's HLA typing, sensitization status, and low and high stringency antigens before the candidate is eligible for a match run in the KPD Pilot Program.

**Note: An unexplained positive crossmatch is one that is not due to the presence of a reported antibody and its corresponding antigen target.*

b. For donors:

i. HLA-A,-B,-Bw4,6,-Cw,-DR, and -DQ as well as -DR51, 52, 53 antigen typing is required. HLA- DP antigen typing is optional.

ii. The laboratory must verify that the donor HLA type is current and correct before the donor is activated for paired exchange.

iii. Donor HLA typing may be repeated by the candidate laboratory for donor verification in the initial evaluation and must be repeated in the event of an unexplained positive crossmatch. Repeat testing may include additional testing for allele-level antigens, -DQA or other antigens as required to explain the positive crossmatch

c. Exchange of materials:

i. Centers must agree to provide anti-coagulated donor blood to the candidate center for preliminary and final crossmatch testing. (A minimum of two, 10cc ACD tubes and a red top). The crossmatch test will be performed by the candidate center according to their test procedures.

ii. When requested, a candidate serum sample must be provided to the donor center.

iii. Recipient and donor samples should be cryopreserved and stored for future testing for two years.

d. Methods:

i. HLA typing

1. Each participating laboratory must be an OPTN and UNOS member laboratory and must type for HLA-A,-B,-Bw4,6, -Cw,-DR,-DQ and -DP as well as -DR51, 52, 53 antigens at the level of split resolution.

2. The primary HLA typing method must be molecular.

ii. Antibody screening and identification

1. Test sensitivity must be sufficient to reliably detect antibodies that inform the transplant process according to the written agreement between the laboratory and the candidate transplant center.

2. Identification of unacceptable (low stringency) and other high stringency HLA antigens must include at least two methods, one of which must be a solid-phase single phenotypes assay or a solid-phase single-antigen test. It is strongly recommended that specificities for broadly sensitized patients be confirmed by solid-phase single-antigen testing.

3. Patients with IgM antibodies, autoantibodies or other potentially interfering or confounding conditions that might affect the crossmatch tests must be identified and appropriate treatment included in crossmatches.

iii. Referral laboratories

1. When a candidate or donor is listed at a center whose laboratory cannot provide testing at the level specified, testing may be performed at any OPTN and UNOS member laboratory with test expertise documented by recognized external proficiency testing. Centers whose laboratories have repeated failures to perform HLA-typing at the level required or to identify unacceptable antigens that result in positive crossmatches and preclude transplantation may be required to submit their donor and recipient samples to a referral laboratory for testing in order to register candidates and donors for paired exchange.

e. Quality Assurance

i. Laboratories must have a written agreement with their transplant center detailing criteria for histocompatibility testing of potential exchange candidates and donors that meet or exceed those described above.

ii. The candidate center laboratory will be responsible for identifying antibodies causing an unexpected positive crossmatch and for updating the patient's unacceptable antigens to include the new information prior to reactivating the patient for a subsequent match run.

iii. The candidate center laboratory must identify the antibody responsible for any positive crossmatch that precludes an exchange or offer within three weeks of the crossmatch test. Any additional testing of donor or recipient specimens is the responsibility of the candidate center's laboratory and must be performed using available materials. *(The antigen causing the positive crossmatch must be provided with result entry.)*

iv. The candidate laboratory must retain the final cross match serum specimen and the specimen used for the latest solid-phase antibody assay for a minimum of two years.

v. A joint subcommittee of the OPTN/UNOS Kidney Paired Donation Working Group and the OPTN/UNOS Histocompatibility Committee will monitor and review HLA typing discrepancies and all positive crossmatches from potential and actual exchanges to monitor performance by participating laboratories. Laboratories which have 3 or more unexplained positive crossmatches may be required to submit serum samples from sensitized patients to a reference laboratory for parallel solid-phase antibody testing.

3. Records Required:

All records below must be maintained and submitted to the OPTN contractor upon request:

- Documentation that the laboratory has verified the candidate's HLA typing, sensitization status, and low and high stringency antigens. The documentation should be maintained at the laboratory.

Kidney Paired Donation Pilot Program

Operational Guidelines

KPD Contact Responsibilities

1. **Purpose:** To define the duties of the KPD contact

2. **Procedures:**

    a. Each transplant center must designate a primary KPD Contact and an alternate to fulfill the duties described below. (Note: For the purposes of the KPD Contact Responsibilities Operational Guideline, KPD Contact refers to both the primary KPD Contact and the alternate.)

    b. The KPD contact must make sure that his/her contact information (phone number, e-mail address, and mailing address) are up-to-date in the UNOS membership database. Additionally, the KPD Contact must keep the address for the lab or the transplant center where the potential living donor blood sample should be sent for crossmatch updated in the system.

    c. The primary and/or alternate KPD contact must participate in regular conference calls to discuss operations of the KPD Pilot Program. (Attendance at every call is not required, but the contact must attend some calls and will be responsible for obtaining any information communicated during a missed meeting.)

    d. If the KPD contact is not available for any period of time, the contact may designate a proxy from the same center. The proxy will be responsible for all of the normal duties of the KPD contact during this time frame.

    e. The KPD contact is responsible for making sure all data is entered for candidates and potential living donors. The KPD contact will receive an e-mail before each match run is generated with information on which potential living donors and candidates are not eligible to be entered in the match run because of lack of required data. The KPD contact and the alternate will receive an e-mail notification when each match run results are available. The KPD contact is responsible for forwarding this information to anyone else at the transplant center who needs to know this information.

    f. The KPD contact's information (both primary and alternate) will be given to the KPD contact (both primary and alternate) for any candidate/donor pair that has matched to a candidate/donor pair at that center. The primary KPD contact must make sure that someone at the center is in charge of communicating with the matched candidate's or donor's center for each case.

    g. The KPD contact is responsible for coordinating the crossmatch process by making sure the potential living donor blood sample is sent to the matched candidate's center and

by providing an address for where the matched potential living donor's blood sample should be sent.

h. The KPD contact is responsible for making sure acceptances and refusals for matches are entered into the system within the specified time frame (match run time line will be provided before each match run).

3. Records Required:

- The KPD Contact must keep the KPD system updated with correct information for:
    - The KPD Contact's name, address, e-mail address, and telephone number
    - The address where potential living donor blood samples should be shipped for crossmatch (a lab or a transplant center)

Prioritization Points

1. **Purpose:** To describe the candidate characteristics and the match characteristics that receive priority or additional points in the Kidney Paired Donation Pilot Program

2. **Procedures:**

    a. Each match between a candidate and potential living donor receives a base of 200 points.

    b. Zero antigen mismatches between a potential living donor and a candidate receive an additional 200 points.

    c. Highly sensitized (e.g., probability of positive crossmatch≥ 80%) candidates receive an additional 125 points.

    d. Candidates who are prior living organ donors receive an additional 150 points.

    e. Pediatric (i.e., age < 18 years) candidates receive an additional 100 points.

    f. Candidates who have participated in previous match runs but did not receive a transplant receive an additional 2 points per match run.

    g. Matches between candidates and potential living donors who are in the same region receive 25 points in addition to the base number of points.

    h. Matches between candidates and potential living donors who are in the same donation service area (DSA) receive 50 points in addition to the base number of points.

    i. Matches between candidates and potential living donors who are located at the same center receive 75 points in addition to the base number of points.

    j. Matches between candidates and donors who have one or more of the candidate's other antibody specificities receive -5 points.

    k. The waiting list candidate and the non-directed donor in a donor chain will be assigned no points.

Kidney Paired Donation Pilot Program

Operational Guidelines

Donor Chains

1. **Purpose:** To define the requirements for how matching will occur in the context of a donor chain

2. **Procedures:**

   a. **Definitions**

      i. Chains start with a non-directed donor (NDD) and end with a donation to a list recipient.

      ii. A "segment" is a part of a chain that occurs at a different time than other parts of a chain.

   b. **Chain Size and Location**

      i. ~~The chain size will be limited to twenty incompatible pairs or less.~~ There is no limit on the length of the chain.*

      ii. Chains can involve multiple hospitals.

   c. **Logistic Details**

      i. All donor surgeries must occur at the same time within a given segment. The centers involved in the chain can decide how many segments the chain will have and where the segments will break.

      ii. If a transplant center, pair, or potential living donor does not want to be at the end of the segment of a chain, then the segment will not end with that pair. This provision means that the potential living donor would donate on the same day that his or her intended candidate receives a transplant.

      iii. In cases where surgeries are not simultaneous, the candidate must receive a transplant before his or her intended donor donates.

      iv. The scheduled time elapsed between the end of one segment of a chain and the beginning of the next segment in the chain is encouraged to be less than 1 week and must not exceed 3 weeks.

      v. A chain will end with a donation to a candidate on the deceased donor waiting list at the center that entered the NDD that started that chain.

vi. If a transplant center or a pair is unwilling to participate in a chain, they will only be matched in two-way or three-way matches.

d. What to Do When a Chain Breaks

i. If the NDD has a non-O blood type (A, B, AB), then the chain will proceed up to the link where it breaks regardless of the number of transplants that result.

ii. If the NDD has a blood type of O, then

1. If the chain *can reach 5 or more transplants* before breaking (regardless of the total length of the chain), then the chain *will proceed* up to the link where it breaks.

2. If the chain includes less than 6 pairs total and the chain *can reach 50%* of the transplants before breaking, then the chain *will proceed* up to link where it breaks.

3. If a chain includes less than 6 pairs total and the chain *cannot reach 50%* of the transplants before breaking, or if a chain that is 6 or longer *cannot reach 5 transplants*, then the NDD will be given the option to donate to the shorter chain or to enter the next match run with the possibility of finding a longer chain.

4. A NDD will not be asked to wait longer than three months from the match run where a chain started by that NDD was first found before donating to a chain, regardless of the length of the chain. All NDDs must be informed that they 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.

iii. 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. The donor in this situation must agree to be entered in the next match run and must be informed in advance that this situation could arise.

**Effective pending programming*

Eligibility for A_2 and A_2B Matches

1. **Purpose:** To describe in what circumstances a blood type B or blood type O candidate would be eligible to match to blood type A_2 or A_2B donors

2. **Procedures:**

    a. In order for a blood type B candidate to be eligible to be match to a blood type A_2 or blood type A_2B donor, or for a blood type O candidate to be eligible to match to a blood type A_2 donor, all of the following conditions must be met:

        i. The candidate must have a titer value less than 1:8.

        ii. The candidate's titer value and date must be entered in the KPD system.

4. **Records Required:**

    - Records of the titer test and date must be maintained and submitted to the OPTN contractor upon request.

Crossmatching Protocol

3. **Purpose:** To describe the process for conducting a crossmatch once a candidate/donor pair has been matched with another candidate/donor pair

4. **Procedures:**

    a. Preliminary Crossmatch (Candidate to matched potential living donor):

        i. The potential living donor's center must ship the potential living donor blood sample to the matched candidate's center or the laboratory specified by the candidate's center within the amount of time specified in the match timeline sent out before each match run.

        ii. The candidate's center is responsible for running the crossmatch and reporting the results in the Kidney Paired Donation Pilot Program system within the amount of time specified in the match timeline sent out before each match run.

    b. Final Crossmatch (Candidate to matched potential living donor)*:*

        i. In cases where the potential living donor travels and in cases where the donor's kidney is shipped to the matched candidate's transplant center, a final crossmatch must be performed prior to transplantation by the candidate's transplant center according to that transplant center's established crossmatching protocol.

Rules for When Participants Can Meet

1. **Purpose:** To describe the circumstances when donors and candidates participating in the Kidney Paired Donation Pilot Program may meet

2. **Procedures:**

    a. All donors and all recipients must agree to meet.

    b. Meetings must only occur after the transplants have taken place.

    c. Transplant centers must have a written protocol explaining its rules for when participants can meet to include at least:

        i. Timing of the meeting

        ii. What staff must be in attendance at the meeting

    d. Transplant centers must comply with their own written protocol for when participants can meet.

3. **Records Required:**

    - The center's written protocol for when participants can meet must be maintained and submitted to the OPTN contractor upon request.

Rules for Shipping of Kidneys

1. **Purpose:** To outline what procedure must be followed if a living donor kidney is shipped as part of the Kidney Paired Donation Pilot Program

2. **Procedures:**

    a. Any kidney must be shipped in compliance with OPTN/UNOS Policy 12.7 (Responsibility for Transport of Living Donor Organs)

Information Sharing Between Transplant Centers

1. **Purpose:** To define what information the system will allow a transplant center to see about a matched potential living donor and candidate and what information can be shared with the potential living donor and candidate

2. **Procedures:**

    a. HIPAA forms- All participants must sign HIPAA forms to allow centers to share information with other members participating in the KPD Pilot Program.

    b. Prior to matching, no information about candidates or potential living donors will be shared with other centers by the system.

    c. After a match, the system will allow the candidate's center to see the center and the de-identified medical data regarding the matched potential living donor.

    d. After the match, the system will allow the potential living donor's center to see the center of the matched candidate.

    e. All other information may be shared by the centers on a case-by-case basis outside of the KPD system.

Process for Modifying Kidney Paired Donation Pilot Program Operational Guidelines

1. **Purpose:** To outline the process required for any changes to the Kidney Paired Donation Operational Guidelines

2. **Procedures:**

    a. All recommendations for changes to the Kidney Paired Donation Operational Guidelines must be sent to the Kidney Paired Donation Working Group.

    b. The Kidney Paired Donation Working Group will review recommendations and may send recommendations to the Kidney Transplantation Committee for a vote.

    c. Changes must be approved by Kidney Transplantation Committee by a majority vote.

    d. All changes will be reported retrospectively to the OPTN/UNOS Board of Directors.

    e. If necessary, changes to the Kidney Paired Donation Operational Guidelines can be made by a majority vote of the Executive Committee or the Board of Directors.