

At-a-Glance

Kidney Paired Donation (KPD) Histocompatibility Testing Policies

- **Affected/Proposed Policy:** Policy 13: (Kidney Paired Donation (KPD)); 13.5 (Histocompatibility Testing); 13.6 (Matching within the OPTN KPD Program); 13.7 (KPD Screening Criteria); and 13.10 (Crossmatching Protocol)

- **Kidney Transplantation Committee**

This proposal includes requirements for histocompatibility testing on donors and recipients in the OPTN KPD Program. It includes required methods for HLA typing, antibody screenings, and crossmatching; a list of HLA types that must be reported for donors and candidates; and processes that must be followed for identifying unacceptable antigens and in the event of unacceptable positive crossmatches.

- **Affected Groups**

Histocompatibility Laboratory Directors/Supervisors
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members

- **Number of Potential Candidates Affected**

As of January 6, 2014, there were 390 candidates in the OPTN KPD Pilot Program.

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal is intended to further the OPTN strategic goal of promoting transplant safety by preventing negative graft outcomes through more effective donor screening and quality testing for donor and recipient histocompatibility.

Kidney Paired Donation (KPD) Histocompatibility Testing Policies

Affected/Proposed Policy: Policy 13: (Kidney Paired Donation (KPD)); 13.5 (Histocompatibility Testing); 13.6 (Matching within the OPTN KPD Program); 13.7 (KPD Screening Criteria); and 13.10 (Crossmatching Protocol)

Kidney Transplantation Committee

Public comment response period: March 14, 2014 – June 13, 2014

Summary and Goals of the Proposal

The OPTN/UNOS Kidney Transplantation Committee (“Kidney Committee”) recommends this proposal with the goal of promoting efficiency and transplant safety in the OPTN KPD Pilot Program (“OPTN KPD program”). The proposal includes the changes below. Please note that some of the changes are already required through programming or in the OPTN KPD pilot program guidelines required to participate in the program, and this change simply moves those requirements into OPTN policy. Items that are new are highlighted in the below list.

- HLA typing is required for donors and candidates in order to be eligible for match runs in the OPTN KPD Program
- The potential donor’s hospital is responsible for all HLA reporting requirements on the donor
- The transplant hospital registering the candidate in the OPTN KPD program is responsible for all HLA reporting requirements on the candidate
- HLA typing for donors and candidates must be performed using molecular methods (New)
- The following HLA types are required to be reported for potential donors in the OPTN KPD program: HLA-A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, DPB (New)
- The following types are required to be reported for candidates in the OPTN KPD program: HLA-A, B, Bw4, Bw6, and DR (New)
- If a candidate has unacceptable antigens listed for the following, these additional types are required to be reported for the candidate: HLA-C, DR51, DR52, DR53, DQA, DQB, and DPB (New)
- The candidate’s transplant hospital is responsible for retyping a matched donor to confirm the donor’s HLA information (New)
- The candidate’s transplant hospital is responsible for all antibody screening requirements on the candidate
- Candidates must be screened for antibodies using a method at least as sensitive as the crossmatch method and using a solid phase assay (New)
- Antibody screenings are required 1) every 90 days, 2) when a potentially sensitizing event occurs, 3) if the candidate has been reactivated after being inactive for more than 90 days, and 4) if an unacceptable positive crossmatch occurs that precludes transplantation (New)
- The candidate’s physician or surgeon (or designee) and the affiliated histocompatibility laboratory director (or designee) must review and confirm the unacceptable antigens reported for a candidate (New)
- The candidate’s transplant hospital is responsible for performing a physical crossmatch before the donor’s nephrectomy is scheduled and a final crossmatch prior to the

transplant. The candidate's transplant hospital must report crossmatch results to the matched donor's hospital and the OPTN Contractor (New)

- If an unacceptable positive crossmatch occurs between a candidate and a matched donor, the candidate's transplant hospital must inactivate the candidate before the next scheduled match run, review and update the candidate's unacceptable antigens, and report a reason for the unacceptable crossmatch to the OPTN Contractor within 7 days of the date that the crossmatch results were received by the candidate's transplant hospital. (New)

Background and Significance of the Proposal

Since becoming operational in 2010, the OPTN KPD pilot program has largely been governed by a set of rules called Operational Guidelines. The Operational Guidelines are requirements for transplant programs who wish to participate in the OPTN KPD pilot program. In March 2012, the Kidney Committee released a public comment proposal converting several sections of the Operational Guidelines into OPTN policy in an effort to move toward making the OPTN KPD program permanent. Among these sections were proposed policies governing histocompatibility testing in the OPTN KPD program. The majority of the March 2012 proposal received support, but there were a number of opposing comments pertaining to the histocompatibility policy sections. For this reason, the Kidney Committee opted to recommend reserving these sections for further deliberation as other sections of the OPTN KPD policies went forward. The Kidney Committee and KPD Workgroup formed a Histocompatibility Advisory Committee (HAC) to discuss the feedback received and make recommendations for how the policy proposal should be amended.

Around the same time that the Kidney Committee distributed the original public comment proposal, a number of professional transplant societies convened a KPD consensus conference. This consensus conference brought together physicians, histocompatibility experts, allied health professionals, transplant administrators, representatives from current KPD programs, insurers, and patients to address dynamic challenges and complexities in KPD.

The recommendations in this proposal incorporate comments and recommendations from:

- comments received during the spring 2012 public comment period
- the 2012 KPD consensus conference findings related to histocompatibility testing
- the OPTN/UNOS Histocompatibility Committee

The Kidney Committee has incorporated the following recommendations in this proposal:

Expanding the list of HLA types required to be reported for OPTN KPD donors: The original public comment proposal did not include a requirement to report HLA-DQA and HLA-DPB for KPD donors. Many of the public comments expressed concern that this would result in unexpected positive crossmatches. The requirement also aligns with the recommendations in the KPD consensus conference findings. Therefore, the proposal now includes an expanded list of donor HLA types that the donor's transplant hospital must report to be eligible for OPTN KPD match runs.

Expanding the list of HLA types required to be reported for OPTN KPD candidates: The original public comment proposal did not include a requirement for reporting HLA-C, -DR51, -DR52, or -DR53 for candidates. Many of the public comments suggested that these types are important in

cases where the candidate has anti-HLA antibodies to these types. Therefore, the proposal now includes a requirement for these types to be reported on the candidate in instances where unacceptable antigens are reported by the candidate's transplant hospital. HLA-DQA and HLA-DPB were included in the list of types to be reported in the original proposal and remain as required in the current proposal if the candidate has unacceptable antigens reported.

Molecular typing required for donors and candidates: In the original public comment proposal, molecular typing was the primary method required for both donors and candidates. Some public comments expressed concern about the need for molecular typing on all candidates, and they suggested that molecular typing should be required only for further interpretation of a positive crossmatch or where a candidate has anti-HLA antibodies. During the post-public comment discussion, members of the KPD Workgroup and Kidney Committee also expressed concern that requiring molecular typing for all candidates will add unnecessary expense with little benefit. Members of the HAC responded to these concerns, asserting that molecular typing, a superior form of typing, is important when comparing the patient's HLA with the potential donor's HLA, especially when the patient is making anti-HLA antibodies. The KPD consensus conference findings also recommend that all HLA typing be done by molecular methods. The majority of the Kidney Committee members agreed with the recommendation to require molecular typing on both donors and candidates.

Confirming HLA type of the donor: The original public comment proposal did not include a requirement for the candidate's transplant hospital to confirm the donor's HLA type. Several of the public comments received raised concern that this should be a requirement in order to ensure patient safety. The HAC agreed that this additional typing is needed in the KPD program in order to detect HLA typing discrepancies and prevent incompatible transplants and unexpected positive crossmatches.

Antibody Screenings—methods and frequency: The original public comment proposal did not include specific requirements for antibody identification. The American Society for Histocompatibility and Immunogenetics (ASHI) recommended that policy state that the antibody screening method be at least as sensitive as the crossmatch method. In addition, the KPD consensus conference recommended quarterly antibody screenings with a solid phase immunoassay. Some members of the KPD Workgroup and the Kidney Committee voiced concern that requiring antibody screenings on *all* candidates quarterly will be expensive and burdensome to participating programs. Members of the HAC responded that quarterly screenings are common practice and are especially important in the KPD program to detect antibodies if any sensitizing events have occurred. The majority of the Kidney Committee members agreed that all of these recommendations are important, and therefore, the proposal contains all of these new requirements for antibody screenings.

Joint review of unacceptable antigens: The original public comment proposal did not contain a requirement for a joint review (between the candidate's physician or surgeon and the affiliated histocompatibility director) of the unacceptable antigens entered for a candidate. However, the KPD consensus conference strongly recommended regular communication between the candidate's transplant hospital and the histocompatibility laboratory. Members of the HAC expressed the view that this communication is most important for review and determination of unacceptable antigens. In addition, a joint review of unacceptable antigens will be required with implementation of the new deceased donor kidney allocation system when a candidate's CPRA score is greater than 98% (candidates in this category will receive additional allocation priority if the joint review and approval occurs). Given the large number of sensitized patients in the

OPTN KPD program and the risk that comes with breaking a chain with an unexpected positive crossmatch, the HAC recommended that this joint review be required in OPTN policy.

Crossmatching protocol: The original public comment proposal required the candidate's hospital to perform a preliminary crossmatch prior to the matched donor's recovery procedure. Several public comments pointed out that federal regulations require histocompatibility laboratories to perform a final crossmatch and have the results available prior to transplant for kidney transplants and multi-organ transplants involving a kidney. The current proposal specifies that the candidate's transplant hospital is responsible for performing a physical crossmatch before the donor's nephrectomy is scheduled and a final crossmatch prior to transplant. The candidate's hospital must report the results to the OPTN Contractor and the matched donor's transplant hospital.

Process for addressing unacceptable positive crossmatches: The original public comment proposal did not specify any new requirements with regard to addressing positive crossmatches that occur between a candidate and matched donor that preclude transplantation and break a chain. The HAC regularly reviews reported reasons for positive crossmatches. In response to these reports, the HAC recommended that transplant hospitals inactivate a candidate within two days of the positive crossmatch and report the reason to the OPTN Contractor within seven days of the positive crossmatch. This requirement is intended to prevent tying up donors who could potentially match other candidates until the candidate can be screened for antibodies and the unacceptable antigens listed can be updated.

Some members of the KPD Workgroup and the Kidney Committee expressed concern with this measure, stating that it seemed punitive to candidates and would be burdensome for transplant hospitals participating in the OPTN KPD program. The HAC responded that unexpected positive crossmatches have the ability to affect many candidates and donors in a chain and create deficiencies in the overall paired exchange program. The Kidney Committee members discussed whether the OPTN Contractor should automatically inactivate a candidate after an unacceptable positive crossmatch occurs, alleviating some burden from the individual programs. Some members thought that allowing the transplant hospital to inactivate the candidate and then reactivate once unacceptable antigens have been updated gives transplant hospitals *more* flexibility in the process. The majority of the Kidney Committee members agreed to maintain a requirement for the transplant program to inactivate the candidate before the next match run (instead of within two days) and reactivate the candidate once the unacceptable antigens have been updated. The Kidney Committee members hope to gain insight through the public comment process on whether transplant hospitals find this solution to be more or less burdensome than requiring the OPTN Contractor to automatically inactivate the candidate when unacceptable positive crossmatches occur.

In December 2013, the Kidney Committee recommended incorporating these recommendations into this proposal and distributing the proposed policies for public comment.

Supporting Evidence and/or Modeling

The match success rate is defined as the percentage of candidate/donor match offers in the OPTN KPD pilot program (KPDPP) that end up resulting in a transplant. The sharp increase in the number of transplants facilitated through the KPDPP in 2013 is attributable to a rise in match offers in conjunction with an increase in the match success rate. Though the rate has gone up, it still remains at approximately 10%, which implies that 90% of match offers currently do not result in a transplant.

Increasing match success rates, a challenge reportedly faced not just by the OPTN KPDPP but by other KPD programs as well, is vital to increasing the number of patients that receive transplants and remains a key goal of the Kidney Committee and KPD Workgroup. In a survey about barriers to KPD participation sent to living donor transplant programs in 2013, when asked what could be done to improve the KPDPP, several respondents submitted responses such as “match success rates,” “more transplants,” “(reduce) potential matches falling through,” and “better matching of highly sensitized patients.”

Due to the interdependencies among matches within the same 2-way, 3-way, or chain exchange, the consequence of one match failure is that all of the matches in the exchange do not result in a transplant. If match failures occur more than a week after initially being accepted, candidates and donors end up missing out on subsequent match runs and additional matching opportunities. This interdependency between matches, coupled with the relatively low match success rate, led the Kidney Committee’s KPD Workgroup in 2012 to remove long chains from the program in favor of chains of length 4 or less. Prior to this switch, long chains of as many as 16 links were repeatedly falling apart, leading to a large number of unrealized transplant opportunities.

Matches can fail for a variety of reasons. According to the “OPTN KPD Pilot Program Cumulative Match Report (CMR), for KPD Match Runs Oct 27, 2010 – Apr 15, 2013,” 52% of failed matches were not actually refused, but could not have proceeded to transplant due to refusals of other matches in the same exchange. Of the matches that were refused, 30% were refused due to either “positive crossmatch” or “unacceptable antigens.” An analysis of KPDPP data through September 30, 2013 showed that crossmatch or antibody-related issues continue to account for approximately 30% of refusal reasons. Of the crossmatch-related refusals, about 1/3 were due to an actual positive crossmatch, while 2/3 were due to unacceptable antigens.

In match runs through June 3, 2013, 61 transplant programs had accepted at least one match offer for which the entire exchange subsequently fell through. Some programs had more than 20 such futile acceptances. Seven programs receiving at least 10 offers had refused more than half of them. The report indicates that one program refused 19 matches due to crossmatch-related reasons (“positive crossmatch” or “unacceptable antigens”). For one other program, 4 of 5 (80%) refusals were due to crossmatch-related reasons. However, though some programs may have had a disproportionate number of crossmatch-related refusals, the report also reveals that the problem is not isolated to a few institutions: 39 programs refused at least one match offer due to a crossmatch related reason.

On August 8, 2012, the HAC started requesting information from centers that refused match offers due to a virtual (unacceptable antigens) or actual positive crossmatch to identify underlying causes and possible solutions to prevent similar match failures in the future. Given the transplant center’s ability in the KPD system to prevent unwanted offers by entering unacceptable antigens as well as using the donor pre-refusal tool, understanding whether these match failures could have been avoided is paramount in determining whether education, system enhancements, policy changes, or other solutions are needed.

Additional information discovered about refusals due to actual positive crossmatches included the following:

- Donor DPB antigens not listed
- Typo in donor’s HLA-DQ (had no effect on crossmatch prediction)

- Candidate had newly identified antibodies and increased MFI for existing antibodies
- Cumulative strength of multiple moderate-level antibodies
- Donor has DPB 16, but no bead to detect DPB antibody and no way to report it to UNOS
- No sample sent in last quarter to retest patient for unacceptable antigens

Additional information discovered about virtual positive crossmatches refusals (unacceptable antigens) included the following:

- DQ5 antibodies too high
- Patient had allele-level antibodies to DPB
- Two moderately high unacceptable antigens
- Education issue: center did not realize that unacceptable antigen updates in Waitlist did not carry over to the KPD system
- No data entry field for DPB unacceptable antigen
- Inadvertent omission of flow-level unacceptable antigens in candidate's KPD record

At the inception of the OPTN KPDPP, entry of DPB antigens was required for all donors. However, to reduce the burden on transplant centers, the KPD Work Group decided to make entry of DPB antigens optional in April 2011. Subsequent to relaxing the requirement to enter DPB antigens, the percentage of donors for whom DPB antigens were entered dropped from 100% to just over 80% within just 3 months. Table 6 of the most recent Cumulative Match Report (CMR) shows that (in aggregate for all match runs from Oct 27, 2010 through Apr 15, 2013) DPB antigens were not reported for about 27% of donors entered into match runs.

Expected Impact on Living Donors or Living Donation

This proposal requires additional histocompatibility testing on living donors in the OPTN KPD program.

Expected Impact on Specific Patient Populations

This proposal will impact all candidates and potential donors in the OPTN KPD Pilot Program. However, it will be especially beneficial to sensitized patients listed in the program. As of January 6, 2014, 61% of the patients listed in the OPTN KPD program (236 out of 390) were highly sensitized (had CPRA scores $\geq 80\%$).

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule

This proposal is intended to further the OPTN strategic goal of promoting transplant safety by preventing negative graft outcomes through more effective donor screening and quality testing for donor and recipient histocompatibility.

Plan for Evaluating the Proposal

The Kidney Committee will evaluate the effect of this proposal 1 and 2 years post-implementation.

This proposal is intended to promote efficiency and transplant safety in the OPTN KPD pilot program through more effective donor screening and quality testing for donor and recipient histocompatibility. The Committee's hypothesis is that following implementation of this proposal,

offer refusals and match failure rates due to positive crossmatch and unacceptable antigens will decrease. Since external factors and other changes in transplant policy can have an influence on the post-implementation period, interpreting the apparent impact of the additional optional fields based on “before vs. after” analysis must be done with caution.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

- Has the number and the percentage of KPD match offers refused due to a positive crossmatch or unacceptable antigens decreased?
- Has the match failure rate due to positive crossmatch or unacceptable antigens decreased?

The following performance metrics, and any others subsequently requested by the Committee, will be compared against the data before and after implementation to evaluate the proposal:

- The number and percentage of KPD match offers refused due to a positive crossmatch or unacceptable antigens.
- Match failure rate due to positive crossmatch or unacceptable antigens.

The committee will also evaluate the effect of the policy on specific patient populations (e.g. pediatric, minority, and sensitized candidates).

Additional Data Collection

Additional data collection will be required as part of this proposal:

- Transplant programs entering a potential donor in the OPTN KPD pilot program will be newly required to report HLA-DQA and HLA-DPB as part of this proposal.
- If a candidate has unacceptable antigens listed to the following, these additional types are required to be reported for the candidate: HLA-C, DR51, DR52, DR53, DQA, DQB, and DPB.
- If an unacceptable positive crossmatch occurs between a candidate and a matched donor, the candidate’s transplant hospital must report a reason for the unacceptable crossmatch to the OPTN Contractor within 7 days of the date that the crossmatch results were received by the candidate’s transplant hospital.

These new requirements are proposed to ensure that members are complying with the histocompatibility testing requirements for candidates and donors in the OPTN KPD program.

Expected Implementation Plan

If public comment is favorable, this proposal will be submitted to the Board of Directors in November 2014 and, if approved will be effective pending programming and notice to the OPTN membership.

Compliance Monitoring

During its compliance reviews of transplant hospitals, UNOS may request and review KPD candidate records to verify documentation showing compliance with the policy requirements

listed pertaining to candidate antibody screening, required reporting to the OPTN contractor, required process and documentation of verification of data entry, candidate antibody retesting when indicated, documentation of antibody screening results in the candidate record, and placement of the candidate on inactive status when indicated.

UNOS may request and review donor records to verify documentation showing compliance with policy requirements pertaining to required reporting to the OPTN contractor, documentation of the required joint review prior to declining a KPD match offer due to unacceptable antigens, submission of explanation to the OPTN contractor if declining due to either a positive crossmatch or unacceptable antigens, and performance and verification of HLA type of the matched donor prior to transplant.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Policy 13: Kidney Paired Donation (KPD)

13.5 Histocompatibility Testing

Reserved

13.5.A HLA Typing Requirements for OPTN KPD Candidates:

1. Before a candidate can appear on an OPTN KPD match run, the transplant hospital registering the KPD candidate is responsible for reporting molecular typing results for all of the following (at the level of serological splits) to the OPTN Contractor:
 - HLA-A
 - HLA-B
 - HLA-Bw4
 - HLA-Bw6
 - HLA-DR

2. If the candidate has antibodies against the following HLA types, then the candidate's transplant hospital is responsible for reporting molecular typing results for all of the following (at the level of serological splits) to the OPTN Contractor before a candidate can appear on an OPTN KPD match run.
 - HLA-C
 - HLA-DR51
 - HLA-DR52
 - HLA--DR53
 - HLA-DPB
 - HLA-DQA
 - HLA-DQB

13.5.B Antibody Screening Requirements for OPTN KPD Candidates:

1. Transplant hospitals must test their candidates for antibodies using a method at least as sensitive as the crossmatch method. If antibodies are detected, then the transplant hospital must identify unacceptable antigens using a solid-phase single phenotype or solid-phase

- single-antigen test. Transplant hospitals must report candidates with no detectable anti-HLA antibodies or unacceptable antigens as unsensitized.
2. The candidate's transplant hospital must report donor antigens that are considered absolute contraindications to transplant with the candidate as unacceptable antigens.
 3. Two separate individuals must review and verify entry of a candidate's unacceptable antigens, one of whom must be the histocompatibility laboratory director or the director's designee. This review must be documented in the candidate's medical record.
 4. Transplant hospitals must retest all active candidates at all of the following times:
 - Every 90 days beginning with the first test
 - When any potentially sensitizing event occurs
 - When a patient who has been inactive for more than three months has been reactivated
 - When an unexpected positive crossmatch that precludes transplantation at the recipient transplant hospital occurs

If any new unacceptable antigens are identified, then the transplant hospital must report these antigens using the process outlined in steps 2 and 3 above. If no new unacceptable antigens are identified, the transplant hospital must document that the antibody screening results in the candidate's medical record.

5. If an unacceptable positive crossmatch occurs between a candidate and the candidate's matched KPD donor, then the candidate's transplant hospital must place the candidate on inactive status prior to the next scheduled match run. The candidate must remain inactive until unacceptable antigens are reviewed and updated as outlined in steps 3 and 4.

13.5.C HLA Typing Requirements for OPTN KPD Donors:

Before a KPD donor can appear on a OPTN KPD match run, the transplant hospital entering the potential KPD donor is responsible for reporting molecular typing results (at the level of serological splits) for all of the following to the OPTN Contractor:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-C
- HLA-DR
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DQA
- HLA-DQB
- HLA-DPB

13.5.D Responding to KPD Match Offers

1. Before declining a KPD match offer due to unacceptable antigens, the KPD candidate's physician or surgeon or their designee must review the matched donor's antigens and their matched candidate's unacceptable antigens with the histocompatibility laboratory director or the director's designee. This joint review must be documented in the candidate's medical record.
2. When a KPD match offer is declined due to either a positive crossmatch or unacceptable antigens prior to crossmatch, the transplant hospital declining the offer must submit a written explanation to the OPTN Contractor within 7 days after declining the offer.

3. The matched candidate's transplant hospital is responsible for performing HLA typing on the matched donor and verifying the HLA information reported prior to transplant.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with Policies *5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt*
2. The candidate's transplant hospital must complete the informed consent process according to KPD Operational Guidelines
3. The candidate's transplant hospital must submit all the information for these required fields to the OPTN Contractor:
 - a. Candidate details, including all of the following:
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Whether the candidate has signed an agreement to participate in the OPTN KPD program
 - Whether the candidate has signed a release of protected health information
 - Whether the candidate is a prior living donor
 - KPD status
 - b. Candidate choices, including all of the following:
 - Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel
 - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
 - Minimum and maximum acceptable donor age
 - Minimum acceptable donor creatinine clearance or GFR
 - Maximum acceptable donor BMI
 - Maximum acceptable systolic and diastolic blood pressure
 - Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
 - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
 - c. Candidate HLA as defined in *Policy 13.5.A: Histocompatibility Requirements for KPD Candidates*
4. The candidate must have current active status in the OPTN KPD program
5. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
6. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program
7. The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with all of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by Policy 14.4.A: Living Donor Blood type Determination with the following modifications:
 - a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
 - b. Someone, other than the person who reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
 - c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types
2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to KPD Operational Guidelines
3. The transplant hospital registering the potential KPD donor must complete the medical evaluation process according to *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:
 - a. Donor details, including all of the following:
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Height and weight
 - Whether the potential KPD donor is a non-directed donor or a paired donor
 - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
 - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
 - Whether the potential KPD donor has signed a release of protected health information
 - Whether the potential KPD donor has signed an informed consent as required in policy
 - Whether the potential KPD donor has undergone a medical evaluation as required in Policy 14: Living Donation
 - Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society
 - KPD status: active, inactive or removed
 - b. Clinical information, including all of the following:
 - The number of anti-hypertensive medications the potential KPD donor is currently taking
 - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
 - Creatinine clearance, date, and method

- Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
- c. Donor choices, including all of the following:
 - Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel
 - Whether the potential KPD donor is willing to ship a kidney
 - Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
 - Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
 - Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor
 - d. Donor HLA as defined in *Policy 13.5.C: Histocompatibility Requirements for KPD Donors*
5. The potential KPD donor must have current active status in the OPTN KPD program
 6. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program
 7. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program
 8. The potential KPD donor must not be in a pending exchange in the OPTN KPD program.

13.7 KPD Screening Criteria

13.7.C Unacceptable Antigens

A transplant hospital ~~may~~ must specify any unacceptable antigens it will not accept for its candidates using the process outlined in *Policy 13.5.B: Antibody Screening Requirements for OPTN KPD Candidates*. The OPTN Contractor will not match the candidate with any potential KPD donor who has one of the candidate's unacceptable antigens entered as a human leukocyte antigen (HLA) value.

13.10 Crossmatching Protocol

The OPTN KPD candidate's transplant hospital must do all of the following:

1. Perform a physical crossmatch between the OPTN candidate and the matched donor before the donor's nephrectomy is scheduled.
2. Perform a final crossmatch prior to transplant.
3. Report all crossmatching results to the OPTN Contractor and the matched donor's transplant hospital.

~~The KPD candidate's transplant hospital must perform a preliminary crossmatch for candidates in the OPTN KPD program before the matched KPD donor's recovery procedure.~~

The transplant hospital registering the potential KPD donor is responsible for arranging shipment of the potential KPD donor's blood sample to the matched candidate's transplant hospital or the laboratory specified by the matched candidate's transplant hospital.

~~The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the results to the OPTN Contractor and the matched KPD donor's transplant hospital.~~