

Kidney Paired Donation

Pilot Program

Operational Guidelines

*Interim Implementation*

**Version 10.0**

**Effective: January 21, 2016**

# KPD 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.

a. Transplants centers:

i. 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.

ii. **KIDNEY PAIRED DONATION PROGRAM INFORMATION DISCLOSURE AND CONFIDENTIALITY AGREEMENT**

**WHEREAS**, the OPTN operates a national kidney paired donation (KPD) program to aid participants in the system with identifying optimal matches for potential living donor kidney transplants.

**WHEREAS**, participants in the KPD system have agreed to abide by certain KPD Program Operating Guidelines as a condition of participation in the OPTN KPD Program, in addition to obligations of OPTN membership.

**WHEREAS**, participants in the KPD Program must share Protected Health Information with and among other participants in the KPD Program to facilitate safe, effective, and efficient transplantation of living donor organs. Participants must also ensure that Protected Health Information shared as part of the KPD Program is treated with the same degree of care and protections provided by Business Associates of Covered Entities under the Health Insurance Portability and Accountability Act ("HIPAA").

**NOW THEREFORE**, the parties agree to abide by the provisions of this Agreement with respect to any Protected Health Information or Electronic Protected Health Information (as defined below) disclosed to other participants in the OPTN KPD Program.

1. Definitions. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule and Security Rule.

a. KPD Program. The OPTN KPD Program ("KPD Program") matches living donor/ candidate pairs with other living donor candidate pairs or non-directed donors (donors who do not require that a specific candidate be matched in order for the donor to be matched through KPD) to create transplant opportunities for candidates entered in KPD. The KPD Program accepts all pairs except those that would not require immunosuppression drugs as a result of transplantation. It is an opt-in program available to any transplant hospital with an OPTN/UNOS approved kidney and living donor kidney program.

b. KPD Program Participant or Participant. A "Participant" is an OPTN/UNOS approved transplant hospital who is participating in the OPTN KPD Program.

c. Disclosing KPD Program Participant. "Disclosing KPD Program Participant" shall

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mean a participant in the OPTN KPD Program who is sharing Protected Health Information with other participants of the OPTN KPD Program.

- d. Protected Health Information. "Protected Health Information" or PHI shall have the same meaning as the term "protected health information" in 45 C.F.R.164.501, limited to the information created or received by Participant from or on behalf of Disclosing KPD Program Participant. "Protected Health Information" shall also include "electronic protected health information" as defined in 45 C.F.R.160.103, limited to the information created or received by Participant from or on behalf of Disclosing KPD Program Participant.
- e. Individual. "Individual" means a living donor/ candidate pair or non- directed donor in the KPD Program.
- f. Breach. "Breach" shall have the meaning given to such terms under Health Information Technology for Economic and Clinical Health (HITECH) Act (42 U.S.C. Section 17921).

### 2. Obligations of Participant

- a. Participant agrees not to use or disclose Protected Health Information under this Agreement other than as permitted or required by this Agreement or as required by law.
- b. Participant agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement. Participant agrees to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of EPHI that Participant creates, receives, maintains, or transmits on behalf of Disclosing KPD Program Participant.
- c. In the event of any use or disclosure of PHI in violation of this Agreement, the Participant agrees to, in consultation with the Disclosing KPD Program Participant, mitigate, to the extent practicable, any harmful effect that is known to Participant of a use or disclosure of Protected Health Information by Participant of such improper use or disclosure.
- d. Participant agrees to, as soon as practicable, but in no event later than within five (5) days of becoming aware of any use or disclosure of PHI in violation of this Agreement report any such disclosure to the Disclosing KPD Program Participant. Participant shall promptly report to Disclosing KPD Program Participant any security incident of which it becomes aware in the following time and manner: (i) any security incident will be reported to Disclosing KPD Program Participant in writing, within five (5) business days of the date on which Participant first becomes aware of such security incident; and (ii) any Breach of Protected Health Information (whether electronic, oral or in any other medium and whether secure or unsecured) shall be reported to Disclosing KPD Program Participant within five (5) days of such Breach. For purposes of this paragraph, "security incident" shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with systems operation in an information system.
- e. Participant agrees to ensure that any agent, including a subcontractor, to whom

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it provides Protected Health Information received from, or created or received by Participant on behalf of Disclosing KPD Program Participant agrees to the same restrictions and conditions that apply through this Agreement to Participant with respect to such information. Participant agrees to ensure that any agent to whom it provides EPHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such EPHI.

- f. Participant agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Disclosing KPD Program Participant to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R.164.528.
        - g. Participant agrees to provide to Disclosing KPD Program Participant or an Individual, in a reasonable time and manner, information collected in accordance with this Agreement, to permit Disclosing KPD Program Participant to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. 164.528.
3. Obligations of UNOS. Upon request, UNOS shall make available to all Participants in the KPD Program a list of all Participants who have executed this Information Disclosure and Confidentiality Agreement, to facilitate the sharing of essential information by and among KPD Program Participants.
4. Permitted Uses and Disclosures by Participant
  - a. General Use and Disclosure Provisions. Except as otherwise limited in this Agreement, Participant may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Disclosing KPD Program Participant as specified in this Agreement
  - b. Specific Use and Disclosure Provisions
    - i. Except as otherwise limited in this Agreement, Participant may use Protected Health Information for the proper management and administration of the Participant or to carry out the legal responsibilities of the Participant.
    - ii. Except as otherwise limited in this Agreement, Participant may disclose Protected Health Information for the proper management and administration of the Participant or to carry out the legal responsibilities of the Participant, provided that disclosures are Required By Law, or Participant obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Participant of any instances of which it is aware in which the confidentiality of the information has been breached.
    - iii. Participant may use Protected Health Information to report violations of law to appropriate Federal and State authorities.
5. Obligations of Disclosing KPD Program Participant- Provisions for Disclosing KPD Program Participant To Inform Participant of Privacy Practices and Restrictions

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- a. Disclosing KPD Program Participant shall notify Participant of any limitation(s) in its notice of privacy practices of Disclosing KPD Program Participant in accordance with 45 C.F.R. 164.520, to the extent that such limitation may affect Participant's use or disclosure of Protected Health Information.
- b. Disclosing KPD Program Participant shall notify Participant of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Participant's use or disclosure of Protected Health Information.
- c. Disclosing KPD Program Participant shall notify Participant of any restriction to the user disclosure of Protected Health Information that Disclosing KPD Program Participant has agreed to in accordance with 45 C.F.R. 164.522, to the extent that such restriction may affect Participant's use or disclosure of Protected Health Information.
- d. Disclosing KPD Program Participant shall obtain any consent, authorization or permission that may be required by the Privacy Rule or applicable state laws and/or regulations prior to furnishing Participant the Protected Health Information pertaining to an individual.

### 6. Term and Termination

- a. Term. This Agreement shall be effective as of the Effective Date set forth above, and shall terminate when all of the Protected Health Information provided by Disclosing KPD Program Participant to UNOS or provided to another Disclosing KPD Program Participant, is destroyed or returned to Disclosing KPD Program Participant, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.
- b. Termination for Cause. Upon a material breach of these obligations of confidentiality by Participant, UNOS or Disclosing KPD Program Participant shall provide an opportunity for Participant to cure the breach. If Participant has breached a material term of this Agreement and cure is not possible, then UNOS may immediately terminate this

Agreement and remove Participant from further participation in the KPD Program.

- c. Effect of Termination. Upon termination of this Agreement, for any reason, Participant shall return or destroy all Protected Health Information received from any and all Disclosing KPD Program Participants. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Participant. Participant shall retain no copies of the Protected Health Information. In the event that Participant determines that returning or destroying the Protected Health Information is infeasible, Participant shall provide to Disclosing KPD Program Participant notification of the conditions that make infeasible. If Disclosing KPD Program Participant agrees that such return is infeasible, Participant shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Participant

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maintains such Protected Health Information.

- d. Removal from List. Upon termination of this Agreement, for any reason, UNOS shall remove Participant from the list of all Participants who have executed this Information Disclosure and Confidentiality Agreement, which is maintained by UNOS and provided to KPD Program participants.

### 7. Miscellaneous

- a. Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for either Party or both Parties to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.
- b. Survival. The respective rights and obligations of Participant of this Agreement shall survive the termination of this Agreement.
- c. Third Party Beneficiaries. This Agreement between Participant and UNOS is intended to confer assurances of confidentiality and protections only to other participants in the OPTN KPD Program who have also executed this Information Disclosure and Confidentiality Agreement. It is acknowledged and agreed that Disclosing KPD Program Participants are intended beneficiaries of the protections of this Agreement in order to facilitate the safe, effective, and efficient transplantation of human organs.

#### b. Candidates:

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

#### c. Potential Living Donors:

- i. Must meet the evaluation requirements set forth in *OPTN/UNOS Policy 14.5: Registration and Blood Type Verification of Living Donors before Donation*
- ii. Must be consented according to the consent process outlined in *OPTN/UNOS Policy 14.1: Psychosocial Evaluation Requirements for Living Donors* and in the Informed Consent for Candidates and Informed Consent for KPD Donors Section of *OPTN/UNOS Policy 13: Kidney Paired Donation*.
- iii. Must be evaluated according to the medical evaluation outlined in *OPTN/UNOS Policy 14.4: Medical Evaluation Requirements for Living Donors*.
- iv. Must consent in writing to participate in the Kidney Paired Donation Pilot Program.

### 2. Records Required:

- All records below must be maintained and submitted to the OPTN contractor upon request:
  - o Record of candidate's informed consent in writing to participate in the Kidney Paired Donation Pilot Program in the candidate's medical record
  - o 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 medical record
  - o Record of the potential living donor requirements according to *OPTN/UNOS Policy 14: Living Donation* in the potential living donor's medical record.

## Receiving and Accepting Match Offers

1. Purpose: To provide deadlines for KPD match offers
2. Procedures:
  - a. Each OPTN KPD program must designate a KPD contact to receive notification of match offers.
  - b. Each OPTN KPD program must meet the following deadlines upon receiving a KPD match offer:

<b>The following members:</b>	<b>Must:</b>	<b>Within:</b>
Each transplant hospital receiving a match offer	Report to the OPTN Contractor a preliminary response	2 business days of receiving the match offer.
The matched candidate's transplant hospital and the matched donor's transplant hospital	Agree in writing upon all of the following: <ul style="list-style-type: none"> <li>• contents required in the crossmatch kit</li> <li>• instructions for the donor</li> <li>• address at which to send the completed blood samples</li> </ul>	4 business days of receiving the match offer.
The matched donor's transplant hospital	Report to the OPTN Contractor the agreed upon date of the crossmatch	4 business days of receiving the match offer.
The matched donor's transplant hospital	Make all of the following matched donor's records accessible to the matched candidate's transplant hospital: <ul style="list-style-type: none"> <li>• any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital</li> <li>• whether the matched donor is increased risk according to the <i>U.S Public Health Services (PHS) Guideline</i></li> <li>• additional records requested by the matched candidate's transplant hospital</li> </ul>	4 business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN Contractor the results of the crossmatch	15 business days of receiving the match offer.
The matched candidate's transplant hospital	Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN Contractor	15 business days of the match offer.

- c. If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.
- d. The transplant hospital may request an extension for any of the deadlines above by submitting a request in writing to the OPTN Contractor. This written request must include the reason for the request and the new requested deadline date. Upon receipt of the request for extension, the OPTN Contractor will notify all of the transplant hospitals in the exchange. Upon notification, the transplant hospitals in the exchange must respond to the request for extension within 2 business days. If all other transplant



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hospitals in the exchange agree to the extension, it will be granted. If any of the transplant hospitals in the exchange refuse the extension request, the extension will not be granted.

The transplant hospitals will have two business days to respond to the extension request. At the end of the first business day, the OPTN Contractor will send a second notification to any transplant hospital that has not yet responded. If any of the transplant hospitals fail to respond to the extension request at the end of the second business day, the extension will not be granted and the exchange will be terminated.

### 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. Prior to matching, no information about candidates or potential living donors will be shared with other centers by the system.
  - b. 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.
  - c. After the match, the system will allow the potential living donor's center to see the center of the matched candidate.

### 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.

## **Donor Pre-Select**

1. Purpose: The purpose of the donor pre-select tool is to decrease the number of match offers that are declined prior to crossmatch, increasing the efficiency of the KPD system.
2. Procedures:
  - a. The Donor Pre-Select allows transplant centers to preview potential matched donors and indicate whether they would possibly accept or refuse the donor if their candidate matched in a KPD Match Run. It allows the system to screen out offers you would not accept based on the basic information provided in the tool.
  - b. Entering a pre-acceptance will allow your candidate to potentially match with this donor in future KPD match runs, you are not committing to accepting any future match offer you may receive.
  - c. Entering a refusal will prevent your candidate from matching with this donor in future match runs.