

# ***Proposal to Modify ABO Determination, Reporting, and Verification Requirements***

**Sponsoring Committee:** Operations and Safety  
**Distributed for Public Comment:** Yes; January 2015  
**Effective Date:** Pending programming and notice to OPTN members

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## **This is an updated Policy Notice to Members**

The purpose of this policy notice is to notify members of a change in the effective date of this proposal originally approved by the OPTN/UNOS Board of Directors in June 2015. The effective date for this policy has been changed from February 1, 2016 to effective pending programming and notice to OPTN membership by the OPTN/UNOS Executive Committee.

Programming is now scheduled for the 2<sup>nd</sup> quarter in 2016. The programming will be completed and released *no sooner than* June 1, 2016. Members need to be ready to implement this policy by **June 1, 2016**. A formal system notice will be published 30 days prior to the actual programming release date.

This change will provide members with some additional time to prepare and will provide members with programming tools to help with compliance for a complex set of policy changes.

## **The unchanged text from the original policy notice begins here: Problem Statement**

The transplant community has had many questions regarding ABO policies and their interpretation. The rules have been misunderstood or unclear resulting in compliance issues. In some areas, OPTN and CMS rules differ creating further confusion and requests to align the two where possible. ABO policies have been one of the most frequently cited issues from both the OPTN and CMS.

Accidental ABO incompatible transplants have occurred as well as surgeries where the wrong organ was given to the wrong person, or the organ laterality was confused. Also, there are reports of organ discards due to wrong ABO blood type or discovery of the wrong organ upon arrival.

## **Summary of Changes**

### Definitions:

Definitions for *intended incompatible*, *qualified health care professional*, and *source document* have been added to policies.

### Determination of ABO blood type and subtype:

- The option for OPOs to draw blood samples at one time and send to two different labs has been removed.
- Living donor blood type determination must be completed prior to generation of the living donor ID. This is earlier in the process than prior to incision.
- OPOs, recovery hospitals, and transplant hospitals must have a process included in their written protocols for how to handle conflicting primary blood type results.

### Reporting of ABO blood type and subtype:

Reporting of blood type must be based on both blood type determinations. The initial report and second user verification must be completed prior to the match run for deceased donors. This is earlier in the process than prior to incision.

For living donors, the above changes apply and the timing must be completed prior to registration UNOS using the Living Donor Feedback Form.

Reporting of all blood types and subtypes must be conducted by a qualified health care professional. A qualified health care professional must be defined by the organization (OPO, recovery hospital, or transplant hospital) in their individual protocol.

Match Run:

Policy has been changed to require re-execution of the match run versus the option to re-execute the match run when an organ has not been accepted on a match run and the transplant hospital updates data following notification by the OPO.

Verification (Pre-Surgical):

Adjustments and additions to pre-surgical verifications (some previously referred to as time-outs) in policies have been made. These include:

- Verification of donor ID, donor blood type and subtype (if used for allocation), and organ type (with laterality if applicable), for all deceased donors prior to incision completed by a qualified health care professional who is an OPO employee and the recovering surgeon.
- When the intended recipient is known, verification of the unique intended recipient identifier, intended recipient blood type, and donor and intended recipient are blood type compatible or intended incompatible by two qualified health care professionals, one of which must be an OPO staff member.
- Verification of specified data elements on all living donors, not just those within the same facility. The verification timing has been moved up to prior to administration of general anesthesia on the day of the recovery versus prior to leaving the OR. The elements to be verified are the living donor ID, organ type and laterality (if applicable), donor blood type and subtype (if used for ensuring transplant compatibility or allocation), intended recipient unique identifier, intended recipient blood type, that the donor and intended recipient are blood type compatible or intended incompatible, and that the correct donor organ has been identified for the correct intended recipient. The verification will be completed by the recovery surgeon and another licensed health care provider.
- An organ check-in process has been added for all organs received from outside facilities.
- An additional pre-transplant verification has been added if surgery starts prior to organ arrival. The elements to be verified include the expected donor ID, expected organ (and laterality if applicable), expected donor blood type and subtype (if used for allocation), recipient unique identifier, recipient blood type, and that the expected donor and recipient are blood type compatible (or intended incompatible).
- For all verifications, the policy specifies acceptable sources that can be used to verify each required data element.

Miscellaneous:

Policy has been modified to allow ABO to be labeled on additional red top blood tubes sent with the organ. This is not a requirement. The ABO blood type result may or may not be labeled on the tube.

## **What Members Need to Do**

Definitions:

OPOs, recovery hospitals, and transplant hospitals need to familiarize themselves with definitions for *intended incompatible*, *qualified health care professional*, and *source document*.

Determination of ABO blood type and subtype:

OPOs need to ensure that two separate draws have been completed to determine deceased donor blood type. The option to draw blood at one time and send to two different labs has been removed. Historical blood type results can be used for one of the typings if source documentation of these results is available.

Recovery hospitals must complete living donor blood type determination prior to generation of the living donor ID.

OPOs, recovery hospitals, and transplant hospitals must develop and include a process in their written protocols for how they will handle conflicting primary blood type results.

Reporting of ABO blood type and subtype:

OPOs, recovery hospitals, and transplant hospitals must complete blood type reporting to UNOS based on at least two blood type determinations. The initial report and second user verification must be completed prior to the match run for deceased donors. For living donors, the above changes apply and the timing must be completed prior to registration with UNOS using the Living Donor Feedback Form.

A qualified health care professional must be used to report all blood types and subtypes. A qualified health care professional is defined by the OPO, recovery hospital, or transplant hospital in their individual protocol.

Match Run:

If an organ has not been accepted on a match run and the transplant hospital updates data following notification by the OPO, then the OPO must re-execute the match run prior to allocation.

Verification (Pre-Surgical):

OPOs must perform a verification of the donor ID; donor blood type and subtype (if used for allocation), and organ type (with laterality if applicable) to be recovered on all deceased donors prior to incision. This must be completed by an OPO staff person that is a qualified health care professional and the recovering surgeon.

When the intended recipient is known, the OPO must verify the intended recipient's unique identifier, intended recipient's blood type, and that the donor and intended recipient are blood type compatible or intended incompatible. This must be done using two qualified health care professionals, and one must be an OPO staff member.

Recovery hospitals must conduct a pre-recovery verification on all living donors prior to administration of general anesthesia on the day of the recovery. The verification must include the living donor ID, organ type and laterality (if applicable), donor blood type and subtype (if used for ensuring transplant compatibility or allocation), intended recipient unique identifier, intended recipient blood type, that the donor and intended recipient are blood type compatible or intended incompatible, and that the correct donor organ has been identified for the correct intended recipient. This must be done by the recovery surgeon and another licensed health care provider.

Transplant hospitals must check-in all organs received from outside facilities. The check-in must include confirmation that the external package donor ID and organ type (including laterality if applicable) were as expected.

Transplant hospitals must conduct an additional pre-transplant verification if surgery starts prior to organ arrival. This verification must include the expected donor ID, expected organ (and laterality if applicable), expected donor blood type and subtype (if used for allocation), recipient unique identifier, recipient blood type, and that the expected donor and recipient are blood type compatible (or intended incompatible).

OPOs, recovery hospitals, and transplant hospitals must use acceptable sources, as defined in the policies, to verify each data element.

Miscellaneous:

OPOs may or may not label additional red top blood tubes sent with the organ with the ABO blood type.

### **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

## **1.2 Definitions**

The definitions that follow are used to define terms specific to the OPTN Policies.

**Intended incompatible**

Donor and candidate primary blood types that are biologically incompatible, but transplantation is permissible according to OPTN policy.

**Qualified health care professional**

A person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or recovery hospital written protocol.

**Source document**

An original record of results, or a photocopy or digital copy of the original record.

**2.6 Deceased Donor Blood Type Determination and Reporting**

~~The host OPOs must ensure that each deceased donor's blood type is accurately determined, report the blood type to the OPTN Contractor, and then verify that the correct blood type was reported.~~ develop and comply with a written protocol for blood type determination and reporting that includes *all* of the requirements below.

**2.6.A Deceased Donor Blood Type Determination**

~~The host OPO must ensure that each deceased donor's blood type is accurately determined by testing at least two donor blood samples prior to incision the match run. The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results. If the two samples are from the same blood draw, then the samples must be tested by two different laboratories.~~

Deceased donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples
4. Have results indicating the same blood type

~~The host OPO must document that two separate tests to determine the deceased donor's blood type were performed.~~

The host OPO must document that blood type determination was conducted according to the OPO's protocol and the above requirements.

**2.6.B Deceased Donor Blood Subtype Determination**

~~When a deceased donor is determined to be blood type A, then subtype testing must be completed. Subtype testing must be performed only on pre-transfusion blood samples. The host OPO may choose whether to perform subtype testing on deceased donors with blood type AB.~~

~~When deceased donor blood type A or AB is sub-typed and found to be non-A1 or non-A1B, the host OPO must complete a second subtype test. If the sample used for the second subtype test is from the same blood draw as the sample used for the first subtype test, the second sample must be tested by a different laboratory.~~

Deceased donor blood subtyping must be completed according to the *Table 2-1* and the requirements below.

**Table 2-1: Subtyping Requirements by Primary Blood Type and First Subtype Result**

<u>If the donor's primary blood type is:</u>	<u>Then subtyping is:</u>	<u>A second subtyping must be completed if the first subtype result is:</u>
<u>A</u>	<u>Required</u>	<u>Blood type A, non-A<sub>1</sub></u>
<u>AB</u>	<u>Optional</u>	<u>Blood type AB, non-A<sub>1</sub>B</u>

Deceased donor blood samples for subtyping must:

1. Be tested using pre-red blood cell transfusion samples
2. Be drawn on two separate occasions
3. Have different collection times
4. Be submitted as separate samples

All subtype results reported to the OPTN Contractor must be from two separate tests indicating the same result. If there are conflicting subtype results, the subtype results must not be reported to the OPTN Contractor and the deceased donor must be allocated based on the primary blood type.

For all blood type A donors, The the host OPO must document *either* that blood subtype determination tests have been completed to determine the deceased donor's blood subtype subtyping was completed or the reason it could not be completed.

### **2.6.C Primary Reporting of Deceased Donor Blood Type and Subtype**

~~The host OPO must report the deceased donor's blood type to the OPTN Contractor. The OPO must only report the deceased donor's blood subtype to the OPTN Contractor if two pre-transfusion samples were tested and the test results agree. If there are conflicting subtype test results, the deceased donor must be allocated based on the primary blood type.~~

~~All blood types and subtypes reported to the OPTN Contractor must be entered by a person consulting the source documents from the blood samples used for testing.~~

### **2.6.D Secondary Reporting of Deceased Donor Blood Type and Subtype**

~~In order to verify that the correct blood type and subtype is reported to the OPTN Contractor, each OPO must establish and then implement a protocol for secondary reporting of blood type that is completed by someone:~~

- ~~1. Other than the individual who completed the primary reporting of the donor's blood type to the OPTN Contractor.~~
- ~~2. Consulting source documents from the blood samples used for blood type testing.~~

~~If sub-typing of A or AB blood types is reported and used for allocation, the subtype determination must also be verified. Each OPO must establish and then implement a protocol for secondary reporting of blood subtype that is completed by someone:~~

- ~~1. Other than the individual who completed the primary reporting of the blood subtype determination to the OPTN Contractor.~~
- ~~2. Consulting both source documents from the two samples used for the blood subtype testing~~

The deceased donor is not eligible for a match run until the host OPO completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the host OPO's protocol, must each make an independent report of the donor's blood type to the OPTN Contractor.
2. If the donor's blood subtype will be used for allocation, a qualified health care professional must report the subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the OPO's protocol.
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
  - a. Contain blood type and subtype (if used for allocation) results for the donor
  - b. Indicate the same blood type and subtype (if used for allocation) on the two test results
  - c. Match the result reported to the OPTN Contractor

The OPO must ~~maintain documentation~~ document that ~~secondary~~ reporting was completed using ~~both sub-typing~~ according to the OPO's protocol and the above requirements.

If donation must be accelerated to avoid organ waste, the host OPO may instead complete these requirements after the match run, but prior to organ release to a transplant hospital. The host OPO must document all of the following:

1. The reason that both blood type tests (and subtype tests, if used for allocation) could not be completed, verified, and reported prior to the match run.
2. If there are conflicting primary blood type test results, the host OPO must follow its protocol for resolving the discrepancy and must re-execute the match run if the final ABO result is different from the initial ABO on the original match run.
3. That all required blood type and subtype determinations, verification, and reporting were completed prior to organ release to a transplant hospital.

## **2.15 Organ Procurement**

### **2.15.A Conflicts of Interest**

The organ recovery procedure and the transplantation of organs must *not* be performed by *either* of the following:

- The potential deceased donor's attending physician at the time of death
- The physician who declares the time of the potential deceased donor's death

### **2.15.B ~~Organ Procurement Procedures~~ Pre-Recovery Verification**

Host OPOs must develop and comply with a written protocol to perform a pre-recovery verification for each organ recovered as required below. Qualified health care professionals, as defined in the host OPO's protocol, must perform all verifications. At least one of the individuals performing a verification must be an OPO staff member.

The host OPO must conduct a verification prior to organ recovery according to *Table 2.1* below. Assistance using an OPTN-approved electronic method is permitted.

**Table 2.1: Pre-Recovery Verification Requirements**

<u>The host OPO must verify all of the following information:</u>	<u>Using at least one of these sources:</u>	<u>By the following individuals:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> <li><u>Donor's identification band</u></li> <li><u>OPTN computer system</u></li> </ul>	<ol style="list-style-type: none"> <li><u>On-site recovering surgeon</u></li> <li><u>Qualified health care professional</u></li> </ol>
<u>Organ (and laterality, if applicable)</u>	<ul style="list-style-type: none"> <li><u>Donor medical record</u></li> <li><u>OPTN computer system</u></li> </ul>	<ol style="list-style-type: none"> <li><u>On-site recovering surgeon</u></li> <li><u>Qualified health care professional</u></li> </ol>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> <li><u>Donor blood type and subtype source documents</u></li> </ul>	<ol style="list-style-type: none"> <li><u>On-site recovering surgeon</u></li> <li><u>Qualified health care professional</u></li> </ol>

When the intended recipient is known prior to organ recovery, the host OPO must verify *all* of the additional information according to *Table 2.2* below.

**Table 2.2: Additional Pre-Recovery Verification Requirements When the Intended Recipient is Known Prior to Organ Recovery**

<u>The host OPO must verify all of the following information:</u>	<u>Using at least one of these sources:</u>	<u>By the following individuals:</u>
<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> <li><u>OPTN computer system</u></li> </ul>	<u>Two qualified health care professionals</u>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> <li><u>OPTN computer system</u></li> </ul>	<u>Two qualified health care professionals</u>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> <li><u>OPTN computer system</u></li> </ul>	<u>Two qualified health care professionals</u>

The host OPO must document that the verifications were completed according to the OPO's protocol and the above requirements.

## **2.15.BC Organ Procurement Procedures**

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

### **3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration**

Transplant programs must ~~determine and report each transplant candidate's actual blood type before registering them on the waiting list~~ develop and comply with a written protocol for blood type determination and reporting that includes *all* of the requirements below.

#### **3.3.A Candidate Blood Type Determination before Registration on the Waiting List**

The ~~Transplant~~ transplant programs must ~~determine~~ ensure that each candidate's blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list. The transplant program must develop and comply with a written protocol to resolve conflicting primary blood type results. ~~Transplant programs must test at least two blood samples from two separate blood draws taken at two different times.~~



Candidate blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples
4. Have results indicating the same blood type

The transplant program must document that blood type determination was conducted according to the program's protocol and the above requirements.

### **3.3.B Secondary Reporting of Candidate Blood Type**

~~After the candidate's blood type data are reported to the OPTN Contractor, the candidate will be added to the waiting list but will not be registered as an active candidate until secondary reporting and verification of the candidate's blood type has been completed.~~

~~Each transplant program must develop and comply with a written protocol for secondary reporting of blood type that is completed by someone:~~

1. ~~Other than the individual who reported the candidate's blood type determination at registration on the waiting list.~~
2. ~~Using source documents from the two blood samples used for the blood type testing.~~

The candidate is not eligible to appear on a match run until the transplant program completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the transplant program's protocol, must each make an independent report of the candidate's blood type to the OPTN Contractor
2. Both qualified health care professionals must use all blood type determination source documents to verify they:
  - a. Contain blood type results for the candidate
  - b. Indicate the same blood type on the two test results
  - c. Match the result reported to the OPTN Contractor

~~The transplant program must maintain documentation of this verification document that reporting was completed according to the program's protocol and the above requirements.~~

### **5.4.B Order of Allocation**

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The host OPO may must run an updated re-execute the match run and to allocate the organ according to the updated candidate data.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate

thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.

6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

This policy does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.

## **5.5 Receiving and Accepting Organ Offers**

### **5.5.A Receiving and Reviewing Organ Offers**

Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to VCA transplants.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether compatibility of deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

## **5.6 ~~Blood Type Verification upon Receipt~~ Organ Check-In**

~~When the organ arrives at the transplant hospital and prior to transplant, the transplant hospital must verify the accuracy of the donor ID and blood type against the potential recipient's blood type. Blood subtype accuracy for a deceased or living donor and potential recipient must also be verified if used for allocation. The transplant hospital must document that these verifications occurred.~~

Transplant hospitals must develop and comply with a written protocol to perform organ check-ins as required below.

The transplant hospital must complete an organ check-in any time an organ is recovered outside the facility where the transplant will take place. The organ check-in must be completed upon arrival at the transplant hospital prior to opening the organ's external transport container.

The transplant hospital must use the OPTN external organ label to confirm that the label contains the expected:

1. Donor ID
2. Organ type and laterality (if applicable)

Assistance using an OPTN-approved electronic method is permitted. If the transplant hospital determines that the donor ID, organ type or laterality label information conflicts with the expected information, then the transplant hospital must notify the host OPO as soon as possible, but within one hour, of the determination.

The transplant hospital must document that the organ check-in was completed.

## **5.7 ~~Released Organs~~ Pre-Transplant Verification**

Transplant hospitals must develop and comply with a written protocol to perform pre-transplant verifications as required below.

### **5.7.A Pre-Transplant Verification Prior to Organ Receipt**

If the recipient surgery will begin prior to organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification that meets *all* of the following requirements:

1. Two licensed health care professionals must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur *either*:
  - a. Prior to induction of general anesthesia
  - b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information in *Table 5.1* below. Assistance using an OPTN-approved electronic method is permitted.

**Table 5.1: Pre-Transplant Verification Prior to Organ Receipt Requirements**

<u>The transplant hospital must verify all of the following information:</u>	<u>Using at least <i>one</i> of these sources:</u>
<u>Expected donor ID</u>	<ul style="list-style-type: none"> <li>• <u>OPTN computer system</u></li> <li>• <u>Recipient medical record</u></li> </ul>
<u>Expected organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> <li>• <u>OPTN computer system</u></li> <li>• <u>Recipient medical record</u></li> </ul>
<u>Expected donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> <li>• <u>Donor blood type and subtype source documents</u></li> <li>• <u>OPTN computer system</u></li> </ul>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> <li>• <u>Recipient identification band</u></li> </ul>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> <li>• <u>Recipient blood type and subtype source documents</u></li> <li>• <u>Recipient medical record</u></li> </ul>
<u>Expected donor and recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> <li>• <u>OPTN computer system</u></li> <li>• <u>Recipient medical record</u></li> <li>• <u>Attestation following verification of donor and recipient blood types</u></li> </ul>

If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

### **5.7.B Pre-Transplant Verification Upon Organ Receipt**

At the time of organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification with the following requirements:

1. The transplant surgeon and another licensed health care professional must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information in *Table 5.2* below. Assistance using an OPTN-approved electronic method is permitted

**Table 5.2: Pre-Transplant Verification Upon Organ Receipt Requirements**

<u>The transplant hospital must verify all of the following information:</u>	<u>Using at least one of these sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> <li>• <u>External and internal organ package labels</u></li> <li>• <u>Documentation with organ</u></li> </ul>
<u>Organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> <li>• <u>Organ received</u></li> </ul>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> <li>• <u>Donor blood type and subtype source documents</u></li> </ul>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> <li>• <u>Recipient identification band</u></li> </ul>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> <li>• <u>Recipient blood type source documents</u></li> <li>• <u>Recipient medical record</u></li> </ul>
<u>Donor and recipient are blood type compatible (or intended incompatible)</u>	<ul style="list-style-type: none"> <li>• <u>OPTN computer system</u></li> <li>• <u>Recipient medical record</u></li> <li>• <u>Attestation following verification of donor and recipient blood types</u></li> </ul>
<u>Correct donor organ has been identified for the correct recipient</u>	<ul style="list-style-type: none"> <li>• <u>Recipient medical record</u></li> <li>• <u>OPTN computer system</u></li> </ul>

The transplant hospital must document that the pre-transplant verification upon organ receipt was completed according to the hospital's protocol and the above requirements.

## **5.78 Released Organs**

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

### **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, 5.6: Organ Check-In, and 5.7: Pre-Transplant Verification.*
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
    - 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: active, inactive or removed
- 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
  - 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 44.4.A 14.5: Living Donor Blood ~~type~~ Type Determination and Reporting* 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~~ A qualified health care professional, other than the qualified health care professional who initially 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
    - 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 or be a non-directed donor
  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

## 14.4 Medical Evaluation Requirements for Living Donors

### 14.4.A ~~Living Donor Blood type Determination~~

~~The recovery hospital must ensure that blood typing of each living donor is performed on two separate occasions before the recovery. Two separate occasions are defined as two blood samples taken at different times, and sent to the same or different laboratories.~~

#### 14.4.A.i ~~Living Donor Blood Subtype Determination~~

~~The recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A<sub>1</sub> (negative for A<sub>1</sub>) or non-A<sub>1</sub>B (negative for A<sub>1</sub>B), must ensure a second determination test is performed prior to living donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient. If the initial and second determination subtyping results are not the same, the donor must be allocated based on the primary blood type, A or AB.~~

### 14.4.BA Living Donor Medical Evaluation Requirements

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

**Table 14-6: Requirements for Living Kidney Donor Medical Evaluations**

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>A general living donor history</b>	<ol style="list-style-type: none"> <li>1. A personal history of significant medical conditions which include but are not limited to:                             <ol style="list-style-type: none"> <li>a. Hypertension</li> <li>b. Diabetes</li> <li>c. Lung disease</li> <li>d. Heart disease</li> <li>e. Gastrointestinal disease</li> <li>f. Autoimmune disease</li> <li>g. Neurologic disease</li> <li>h. Genitourinary disease</li> <li>i. Hematologic disorders</li> <li>j. Bleeding or clotting disorders</li> <li>k. History of cancer including melanoma</li> </ol> </li> <li>2. History of infections</li> <li>3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication</li> <li>4. Allergies</li> <li>5. An evaluation for coronary artery disease</li> </ol>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>General family history</b>	<ul style="list-style-type: none"> <li>• Coronary artery disease</li> <li>• Cancer</li> </ul>
<b>Social history</b>	<ul style="list-style-type: none"> <li>• Occupation, employment status, health insurance status, living arrangements, and social support</li> <li>• Smoking, alcohol and drug use and abuse</li> <li>• Psychiatric illness, depression, suicide attempts</li> <li>• Increased risk behavior as defined by the <i>U.S. Public Health Services (PHS) Guideline</i></li> </ul>
<b>Physical Exam</b>	<ul style="list-style-type: none"> <li>• Height</li> <li>• Weight</li> <li>• BMI</li> <li>• Vital signs</li> <li>• Examination of all major organ systems</li> </ul>
<b>General laboratory and imaging tests</b>	<ul style="list-style-type: none"> <li>• Complete blood count (CBC) with platelet count</li> <li>• Blood type and subtype as specified in <i>Policy 14.4.A5: Living Donor Blood Type Determination and Reporting</i> and its subsections</li> <li>• Prothrombin Time (PT) or International Normalized Ratio (INR)</li> <li>• Partial Thromboplastin Time (PTT)</li> <li>• Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)</li> <li>• HCG quantitative pregnancy test for premenopausal women without surgical sterilization</li> <li>• Chest X-Ray</li> <li>• Electrocardiogram (ECG)</li> </ul>



This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Transmissible disease screening</b>	<p>Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> <li>1. CMV (Cytomegalovirus) antibody</li> <li>2. EBV (Epstein Barr Virus) antibody</li> <li>3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery</li> <li>4. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery</li> <li>5. Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery</li> <li>6. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery</li> <li>7. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery</li> <li>8. Syphilis testing</li> </ol> <p>If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to <i>the U.S. Public Health Services (PHS) Guideline</i>, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to <i>the U.S. Public Health Services (PHS) Guideline</i>.</p> <p>For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using <i>either</i>:</p> <ul style="list-style-type: none"> <li>• Intradermal PPD</li> <li>• Interferon Gamma Release Assay (IGRA)</li> </ul>
<b>Endemic transmissible diseases</b>	<p>Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.</p>
<b>Cancer screening</b>	<p>Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for:</p> <ul style="list-style-type: none"> <li>• Cervical cancer</li> <li>• Breast cancer</li> <li>• Prostate cancer</li> <li>• Colon cancer</li> <li>• Lung cancer</li> </ul>

## **14.5 Registration and Blood Type Verification of Living Donors before Donation** **Living Donor Blood Type Determination and Reporting**

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the *Living Donor Feedback Form*. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on *the Living Donor Feedback Form* with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

This policy does not apply to VCA transplants.

Recovery hospitals must develop and comply with a written protocol for blood type determination and reporting that includes all of the requirements below.

### **14.5.A Living Donor Blood Type Determination**

The recovery hospital must ensure that each living donor's blood type is determined by testing at least two donor blood samples prior to generation of the living donor ID. The recovery hospital must develop and comply with a written protocol to resolve conflicting primary blood type results.

Living donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples
4. Have results indicating the same blood type

The recovery hospital must document that blood type determination was conducted according to the hospital's protocol and the above requirements.

### **14.5.B Living Donor Blood Subtype Determination**

Subtyping is optional for living donors.

If the recovery hospital chooses to subtype and pre-red blood cell transfusion samples are available, then subtyping must be completed according to Table 14-2.

**Table 14-2: Subtyping Requirements by First Subtype Result**

<u>If the donor's primary blood type is:</u>	<u>A second subtyping must be completed if the first subtype result is:</u>
<u>A</u>	<u>Blood type A, non-A<sub>1</sub></u>
<u>AB</u>	<u>Blood type AB, non-A<sub>1</sub>B</u>

Living donor blood samples for subtyping must:

1. Be tested using pre-red blood transfusion samples
2. Be drawn on two separate occasions
3. Have different collection times
4. Be submitted as separate samples

All subtype results reported to the OPTN Contractor must be from two separate tests indicating the same result. If there are conflicting subtype results, the subtype results must not be reported to the OPTN Contractor and living donor transplant compatibility or allocation must be based on the primary blood type.

If subtype is determined and reported, the recovery hospital must document that subtyping was conducted according to the above requirements.

**14.5.C Reporting of Living Donor Blood Type and Subtype**

The recovery hospital must report and verify the living donor blood type prior to registration with the OPTN Contractor using the *Living Donor Feedback Form* as required below:

1. Two different qualified health care professionals, as defined in the recovery hospital’s protocol, must each make an independent report to the OPTN Contractor for blood type. For VCA recoveries, the blood type verification and reporting must be recorded in the living donor’s medical record.
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the recovery hospital’s protocol. For VCA recoveries, the blood subtype verification and reporting must be recorded in the living donor’s medical record.
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
  - a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
  - b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the two test results
  - c. Match the result reported to the OPTN Contractor or VCA donor medical record

The recovery hospital must document that reporting was completed according to the hospital’s protocol and the above requirements.

**14.7 Living Donor Pre-Recovery Verification**

Recovery hospitals must develop and comply with a written protocol to perform pre-recovery verifications as required below.

The recovery hospital must conduct a pre-recovery verification that meets *all* of the following requirements:

1. The recovery surgeon and another licensed health care professional must participate in the verification.
2. The verification must occur prior to the induction of general anesthesia on the day of the living donor recovery.
3. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in *Table 14.3* below. Assistance using an OPTN approved electronic method is permitted.

**Table 14.3: Pre-Recovery Verification Requirements**

<u>The recovery hospital must verify <i>all</i> of the following information:</u>	<u>Using at least <i>one</i> of these sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> <li>• <u>Donor identification band</u></li> </ul>
<u>Organ type and laterality (if applicable)</u>	<ul style="list-style-type: none"> <li>• <u>OPTN computer system</u></li> </ul>

<u>The recovery hospital must verify <i>all</i> of the following information:</u>	<u>Using at least <i>one</i> of these sources:</u>
<u>Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)</u>	<ul style="list-style-type: none"> <li>• <u>Donor blood type and subtype source documents</u></li> </ul>
<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> <li>• <u>Recipient medical record</u></li> <li>• <u>OPTN computer system</u></li> </ul>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> <li>• <u>Recipient medical record</u></li> <li>• <u>OPTN computer system</u></li> </ul>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> <li>• <u>OPTN computer system</u></li> <li>• <u>Recipient medical record</u></li> <li>• <u>Attestation following verification of donor and recipient blood types</u></li> </ul>
<u>Correct donor organ has been identified for the correct intended recipient</u>	<ul style="list-style-type: none"> <li>• <u>Donor medical record</u></li> <li>• <u>OPTN computer system</u></li> </ul>

The recovery hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

## **14.78 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials**

### **14.9 Living Donor Organ Check-In**

Transplant hospitals must perform organ check-ins as required by *Policy 5.6: Organ Check-In*.

### **14.10 Living Donor Pre-Transplant Verification**

Transplant hospitals must perform pre-transplant verifications as required by *Policy 5.7: Pre-Transplant Verification*.

## **14.8-11 Reporting Requirements**

### **16.1 Organs Not Requiring Transport**

The transplant hospital and host OPO (if applicable) must develop and follow a protocol to ensure that the correct living or deceased donor organ is transplanted into the correct recipient when *either* of the following occurs:

- ~~Organs are recovered from a deceased donor and remain in the same operating suite as the intended recipient~~
- ~~Organs are recovered from a living donor and remain in the same facility as the intended recipient~~

Time outs must occur:

- ~~1. Before the organ leaves the deceased or living donor operating room~~
- ~~2. Again when the organ arrives at the potential recipient's operating room~~

During these time outs and before the transplant occurs, the transplant hospital must confirm and document that a member of the transplant team identified the correct organ for the correct potential recipient prior to transplant according to *Policy 5.6: Blood Type Verification upon Receipt*.

### **16.4.C Internal Labeling of Blood and Tissue Typing Materials**

Each separate specimen container of blood or tissue typing material must have a label that will

remain secured to the container under normal conditions of transport. The label must include the donor ID and at least *one* of the following identifiers:

- Locally assigned unique ID
- Donor date of birth
- Donor initials

Additionally each specimen should be labeled with *both* of the following:

1. The date and time the sample was procured
2. The type of tissue

The donor blood type and subtype, if used for allocation, should be included on tissue typing material ~~but must not be included on~~ and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.