

OPTN Compliance Monitoring Plan for Blood Type Determination, Reporting, and Verification policy changes:

Staff will continue reviewing all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements, and will continue investigating potential policy violations. Based upon the proposed language, monitoring will either be changed or continue as follows:

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
Policy 2.6 Deceased Donor Blood Type Determination and Reporting		At OPOs, site surveyors will review the OPO's internal policies, procedures and/or protocols to verify that they include a description of the process for: <ul style="list-style-type: none"> • Verification that the two individuals performing blood type reporting each consulted source documents from two blood type tests • If sub-type of non-A₁ or non-A₁B is reported: <ul style="list-style-type: none"> • Verification that two individuals separately reported the donor's blood type to the OPTN Contractor • Verification that both individuals consulted source documents from two blood type tests
Policy 2.6.A Deceased Donor Blood Type Determination	<i>At OPOs, site surveyors will no longer routinely review a sample of deceased donor records, and any material incorporated into the medical record by reference, to verify that:</i> <ul style="list-style-type: none"> • <i>There are identical results for two separate blood typing tests</i> • <i>Tests were completed on two separate blood samples</i> • <i>The draw times for the samples used for the two tests are at different times</i> 	
Policy 2.6.B Deceased Donor Blood Subtype Determination	<i>If two tests were completed on blood drawn at the same date and time, then documentation showing that the tests were</i>	At OPOs, site surveyors will review a sample of deceased donor records

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
	<p><i>run by two different laboratories will no longer be permitted.</i></p> <p><i>Additionally, at OPOs, site surveyors will review the OPO's internal policies, procedures and/or protocols and interview staff to verify that they have and follow processes for:</i></p> <ul style="list-style-type: none"> • Reporting subtype only when: <ul style="list-style-type: none"> ○ There are identical results for two separate blood subtyping tests ○ Tests were completed on two separate blood samples ○ The draw times for the samples used for the two tests are at different times ○ Samples used were pre-red blood cell transfusion • Documenting the reason when subtyping cannot be completed on A donors 	<p>when subtype is reported, to verify that:</p> <ul style="list-style-type: none"> • There are identical results for two separate blood subtyping tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times • Samples used were pre-red blood cell transfusion
<p>Policy 2.6.C Reporting of Deceased Donor Blood Type and Subtype</p>		<p>Monitored as part of 2.6</p>
<p>Policy 2.15.B Pre-Recovery Verification</p>	<p>At OPOs, site surveyors will review a sample of deceased donor records, and any material incorporated into the medical record by reference, for documentation of a verification for each organ containing:</p> <ul style="list-style-type: none"> • Donor ID • Organ • Organ laterality (if applicable) • Donor blood type <p>At OPOs, site surveyors will review the OPO's internal policies, procedures and/or protocols and interview staff to verify that they have and follow a process that includes:</p> <ul style="list-style-type: none"> • Definition of qualified healthcare professionals to perform the pre-recovery verification • Verification of: <ul style="list-style-type: none"> ○ Donor ID 	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
	<ul style="list-style-type: none"> ○ Organ ○ Organ laterality (if applicable) ○ Donor blood type ○ Donor blood subtype (if used for allocation) ● Verification of the following when the recipient is known prior to recovery: <ul style="list-style-type: none"> ○ Intended recipient unique ID ○ Intended recipient blood type ○ Donor and intended recipient are blood type compatible or intended incompatible ● Documenting that the verification was completed according to OPTN and OPO policies. 	
<p>Policy 3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration</p>	<p>At transplant hospitals, site surveyors will review the hospital's internal policies, procedures and/or protocols and interview staff to verify that they have and follow written protocols for:</p> <ul style="list-style-type: none"> ● Testing two donor blood samples before waiting list registration that: <ul style="list-style-type: none"> ○ Are drawn on separate occasions ○ Have separate collection times ○ Are submitted as separate samples ○ Indicate the same blood type ● Reporting candidate blood type: <ul style="list-style-type: none"> ○ By two qualified healthcare professionals ○ Using all blood type determination source documents 	
<p>Policy 3.3.A Candidates Blood Type Determination Before Waiting List Registration</p>	<p><i>At transplant hospitals, site surveyors will no longer routinely review a sample of medical records, and any material incorporated into the medical record by reference, to verify that:</i></p> <ul style="list-style-type: none"> ● <i>There are identical results for two separate blood typing tests</i> ● <i>Tests were completed on two separate blood samples</i> 	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
	<ul style="list-style-type: none"> • <i>The draw times for the samples used for the two tests are at different times</i> • <i>Test results were available before the patient's registration on the waiting list</i> 	
Policy 3.3.B Reporting of Candidate Blood Type	At transplant hospitals, site surveyors will no longer routinely review a sample of medical records to verify the accuracy of the reported blood type.	
Policy 5.4.B Order of Allocation		OPTN Contractor staff will continue reviewing deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements.
Policy 5.7 Organ Check-In	<p>At transplant hospitals, site surveyors will review the hospital's internal policies, procedures and/or protocols and interview staff to verify that they include written protocols for organ check-in that includes:</p> <ul style="list-style-type: none"> • Timing: <ul style="list-style-type: none"> ○ Upon arrival ○ Before opening external container • Checking: <ul style="list-style-type: none"> ○ Donor ID ○ Organ type ○ Organ laterality • Notifying OPO within 1 hour if it is not an expected organ 	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
<p>5.8 Pre-Transplant Verification</p>	<p>At transplant hospitals, site surveyors will review the hospital's internal policies, procedures and/or protocols and interview staff to verify that they have and follow a process that includes:</p> <ul style="list-style-type: none"> • Pre-transplant verification prior to organ receipt that includes: <ul style="list-style-type: none"> ○ Participation by two licensed healthcare professionals ○ Timing of the pre-transplant verification <ul style="list-style-type: none"> ▪ Recipient in OR ▪ Either before induction of general anesthesia or before incision if the donor is already under continuous sedation ○ Verification of expected donor: <ul style="list-style-type: none"> ▪ Donor ID ▪ Organ ▪ Organ laterality (if applicable) ▪ Blood type ▪ Blood subtype (if used for allocation) ○ Verification of recipient <ul style="list-style-type: none"> ▪ Unique ID ▪ Blood type ○ Verification that the donor and intended recipient are blood type compatible or intended incompatible ○ Sources used for verification ○ Documenting that the verifications were completed according to OPTN and hospital policies. • Pre-transplant verification upon organ receipt that includes: <ul style="list-style-type: none"> ○ Participation by the transplant surgeon and another licensed health care professional 	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
	<ul style="list-style-type: none"> ○ Timing of the pre-transplant verification <ul style="list-style-type: none"> ▪ Organ and recipient are in OR ▪ Before anastomosis of the first organ ○ Verification of donor: <ul style="list-style-type: none"> ▪ Donor ID ▪ Organ ▪ Organ laterality (if applicable) ▪ Blood type ▪ Blood subtype (if used for allocation) ○ Verification of recipient <ul style="list-style-type: none"> ▪ Unique ID ▪ Blood type ○ Verification that the donor and intended recipient are blood type compatible or intended incompatible ○ Verification that the correct donor organ has been identified for the correct recipient ○ Sources used for verification ○ Documenting that the verifications were completed according to OPTN and hospital policies. 	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
Policy 5.8.B Pre-Transplant Verification Upon Organ Receipt	surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the following were verified: <ul style="list-style-type: none"> • Organ • Laterality (if applicable) • Recipient unique identifier 	At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that: <ul style="list-style-type: none"> • The following were verified between organ arrival and implantation: <ul style="list-style-type: none"> • Donor blood type • Recipient blood type • Donor ID • The following are documented: <ul style="list-style-type: none"> • Organ arrival time or documentation showing organ present at time of verification • Verification time • Anastomosis time or documentation showing verification occurred prior to implant
Policy 13.6.A Requirements for Match Run Eligibility for Candidates	Monitored as part of referenced policies.	
Policy 13.6.B Requirements for Match Run Eligibility for Potential KPD Donors	Monitored as part of Policy 14.5.	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
14.5 Living Donor Blood Type Determination	<p>At recovery hospitals, site surveyors will review the hospital's internal policies, procedures and/or protocols and interview staff to verify that they have and follow written protocols for:</p> <ul style="list-style-type: none"> • Testing two donor blood samples before generating the donor ID that: <ul style="list-style-type: none"> ○ Are drawn on separate occasions ○ Have separate collection times ○ Are submitted as separate samples ○ Indicate the same blood type • Reporting subtype only when: <ul style="list-style-type: none"> ○ There are identical results for two separate blood subtyping tests ○ Tests were completed on two separate blood samples ○ The draw times for the samples used for the two tests are at different times ○ Samples used were pre-red blood cell transfusion • Documenting the reason when subtyping cannot be completed on A donors • Reporting candidate blood type: <ul style="list-style-type: none"> ○ By two qualified healthcare professionals • Using all blood type determination source documents 	
Policy 14.5.A Living Donor Blood Type Determination and Reporting	<p>At recovery hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that:</p> <ul style="list-style-type: none"> • There are identical results for two separate blood typing tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times 	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
Policy 14.5.B Living Donor Blood Subtype Determination	<p>At recovery hospitals, site surveyors will review a sample of living donor records, and any material incorporated into the medical record by reference, when subtype is reported, to verify that:</p> <ul style="list-style-type: none"> • There are identical results for two separate blood typing tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times 	
Policy 14.5.C Reporting of Living Donor Blood Type and Subtype	<p>At recovery hospitals, site surveyors will review a sample of medical records to verify the accuracy of the reported blood type (and subtype, if applicable).</p>	
Policy 14.7 Living Donor Pre-Recovery Verification	<p>At recovery hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that:</p> <ul style="list-style-type: none"> • The following were verified: <ul style="list-style-type: none"> ○ Donor ID ○ Organ ○ Laterality ○ Donor blood type ○ Intended recipient blood type ○ Intended recipient unique identifier • The verification took place: <ul style="list-style-type: none"> ○ Before the induction of general anesthesia ○ On the same date as the living donor recovery <p>At recovery hospitals, site surveyors will review the hospital's internal policies, procedures and/or protocols and interview staff to verify that they have and follow a process that includes:</p> <ul style="list-style-type: none"> • Participation by the recovery surgeon and another licensed health care professional • Timing of verification 	

For this policy:	Monitoring will <u>change</u> as follows:	Monitoring will continue as follows:
	<ul style="list-style-type: none"> ○ Before induction of general anesthesia ○ On the day of the organ recovery ● Verification of the donor: <ul style="list-style-type: none"> ○ Donor ID ○ Organ ○ Organ laterality (if applicable) ○ Donor blood type ○ Donor blood subtype (if used for allocation) ● Verification of the intended recipient: <ul style="list-style-type: none"> ○ Unique ID ○ Blood type ● Verification that the donor and intended recipient are blood type compatible or intended incompatible ● Verification that the correct donor organ has been identified for the correct intended recipient <p>Documenting that the verifications were completed according to OPTN and hospital policies.</p>	
Policy 14.9 Living Donor Organ Check-In	Monitored as part of Policy 5.6.	
Policy 14.10 Living Donor Pre-Transplant Verification	Monitored as part of Policy 5.8.B.	