OPTN Evaluation Plan Pending Updates for September 1, 2018

This document outlines sections of the OPTN Evaluation Plan that will be updated on September 1, 2018. It is provided for planning purposes only, and all information is subject to change.

This document includes three types of updates:

- Entries for Policies 15.3.B and 15.3.C are tied to implementation of the policy proposal "Clarify Informed Consent Policies for Transmittable Diseases" that was approved by the OPTN Board of Directors in June 2018.
- Entries for Policies 16.6.A, 16.6.B, and 16.6.C are tied to implementation of the policy proposal "Reduce Reporting Burdens and Clarify Policies on Extra Vessels" that was approved by the OPTN Board of Directors in June 2018.
- The remaining entries below have been modified to more thoroughly describe the methods used to routinely review certain policies, or to remove certain elements that are no longer being routinely monitored. In addition to the changes below, the entries for *Policy 3.4.D: Candidate Human Leukocyte Antigen (HLA) Requirements* and *Policy 15.1: Patient Safety Contact* will be deleted in their entirety in the September 1 publication.

Contents

Policy 2.2: OPO Responsibilities

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- An authorization to donate
- Reasons for excluding any donors from the eligible death definition
- Declaration of death note, including
    - Date and time of pronouncement of death
    - Signature(s) of the person(s) required under the relevant state's laws
- Serum archival noted in the donor chart

Review a sample of deceased donors in UNet℠ to verify that the following source documents were uploaded to UNet℠:

- ABO typing
- ABO subtyping (if applicable)
- Results for infectious disease tests that are required by *Policy 2.9: Required Deceased Donor Infectious Disease Testing*
- Death pronouncement
- Authorization for donation

Review a sample of deceased donor records to verify that data reported through UNet℠ is consistent with source documentation, including:

- Infectious disease test results

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.3: Evaluating and Screening Potential Deceased Donors

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- That the OPO attempted to obtain the donor's medical and behavioral history

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.5: Hemodilution Assessment

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- The calculations used to determine hemodilution
- The date and time of the blood draw for the blood used for the serological screening tests
- The date and time of the blood draw used to determine hemodilution
- If the donor samples are hemodiluted:
    - That the donor was designated as increased risk in UNet℠
    - That the following were communicated to the accepting transplant programs:
        - Any screening results from the hemodiluted specimens
        - The tests completed on the hemodiluted specimens
        - The hemodilution calculation used for the hemodiluted specimens, if requested

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.6: Deceased Donor Blood Type Determination and Reporting

At OPOs, site surveyors will:

Review the OPO's internal policies, procedures, and protocols to verify that they have a written protocol(s) that includes:

- Determining blood type by testing two separate blood samples with different collection times
- A process for resolving conflicting primary blood types
- A definition of the qualified health care professionals who can participate in blood type verification and reporting
- That blood type verification and reporting occurs prior to the match run
- That the two individuals performing blood type reporting each consult source documents from all blood type tests

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for blood type determination and reporting.

OPOs will provide:

The OPO's internal policies, procedures and protocols for the management of deceased donors

Access to relevant staff who can answer interview questions

Additional Guidance:

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 2.6.B: Deceased Donor Blood Subtype Determination

At OPOs, site surveyors will:

Review the OPO's internal policies, procedures, and protocols to verify that they have a written protocol(s) that includes:

- Determining blood subtype by testing two separate blood samples with different collection times
- Only using pre-red blood cell transfusion samples for subtyping
- Not reporting subtype when there are conflicting subtyping results

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for blood subtype determination and reporting.

Review a sample of deceased donor records when subtype is reported, to verify that:

- 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

OPOs will provide:

The requested sample of deceased donor medical records

The OPO's internal policies, procedures and protocols for the management of deceased donors

Access to relevant staff who can answer interview questions

Policy 2.8: Required Deceased Donor General Risk Assessment

At OPOs, site surveyors will:

Review a sample of deceased donor records for documentation that there are results or other evidence that the following were performed:

- Urinalysis within 24 hours before cross clamp

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.12: Post Procurement Follow Up and Reporting

At OPOs, site surveyors will:

Review the OPO's internal policies, procedures, and protocols to verify that they have a written protocol(s) for:

- Obtaining deceased donor test results and reporting them to the OPTN Contractor
- Reporting positive test results and relevant information to receiving transplant programs and, when required, to the OPTN Improving Patient Safety Portal

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for post-procurement follow-up and reporting of deceased donor test results.

OPOs will provide:

The OPO's internal policies, procedures, and protocols for the management of deceased donors

Access to relevant staff who can answer interview questions

Policy 2.14.B: Pre-Recovery Verification

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- A verification for each organ containing:
    - Donor ID
    - Organ
    - Organ laterality (if applicable)
    - Donor blood type

Review the OPO's internal policies, procedures, and protocols to verify that they have a written protocol(s) that includes:

- Definition of qualified healthcare professionals to perform the pre-recovery verification
- Verification of the following by the on-site recovering surgeon and a qualified health care professional:
    - Donor ID
    - Organ
    - Organ laterality (if applicable)
    - Donor blood type
    - Donor blood subtype (if used for allocation)
- Verification of the following by two qualified health care professionals when the intended recipient is known prior to recovery:
    - Intended recipient unique identifier
    - Intended recipient blood type
    - Donor and intended recipient are blood type compatible or intended incompatible
- Sources used for verification

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for pre-recovery verifications.

OPOs will provide:

The requested sample of deceased donor medical records

The OPO's internal policies, procedures and protocols for the management of deceased donors

Access to relevant staff who can answer interview questions

Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration

At transplant hospitals, site surveyors will:

Review the hospital's internal policies, procedures, and protocols to verify that they have a written protocol(s) that includes:

- Testing two candidate blood samples before waiting list registration that:
    - Are drawn on separate occasions
    - Have different collection times
    - Are submitted as separate samples
    - Indicate the same blood type
- Reporting candidate blood type:
    - By two qualified healthcare professionals
    - Using all blood type determination source documents
- Definition of qualified health care professionals who can participate in blood type verification and reporting
- A process for resolving conflicting primary blood type results

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for blood type determination and reporting.

Transplant hospitals will provide:

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Access to relevant staff who can answer interview questions

Additional Guidance:

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 5.7: Organ Check-In

At transplant hospitals, site surveyors will:

Review the hospital's internal policies, procedures, and protocols to verify that they have a written protocol for:

- Organ check-in including the following elements:
    - Timing:
        - Upon arrival at the transplant hospital
        - Before opening external container
    - Verification using OPTN external label of:
        - Donor ID
        - Organ type
        - Organ laterality (if applicable)
    - Notifying OPO within 1 hour if it is not an expected organ

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for organ check-in.

Transplant hospitals will provide:

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Access to relevant staff who can answer interview questions

Policy 5.8: Pre-Transplant Verification

At transplant hospitals, site surveyors will:

Review the hospital's internal policies, procedures, and protocols to verify that they have a written protocol(s) that includes:

- Pre-transplant verification prior to organ receipt that includes:
    - Participation by two licensed healthcare professionals
    - Timing of the pre-transplant verification
        - Recipient in O.R.
        - Either before induction of general anesthesia or before incision if the recipient is already under continuous sedation before arriving in the O.R.
    - Verification of expected donor:
        - Donor ID
        - Organ
        - Lung laterality (if applicable)
        - Blood type
        - Blood subtype (if used for allocation)
    - Verification of recipient
        - Unique identifier
        - Blood type
    - Verification that the expected donor and intended recipient are blood type compatible or intended incompatible
    - Sources used for verification
- Pre-transplant verification upon organ receipt that includes:
    - Participation by the transplant surgeon and another licensed health care professional
    - Timing of the pre-transplant verification
        - Organ and recipient are in O.R.
        - Before anastomosis of the first organ
    - Verification of donor:
        - Donor ID
        - Organ
        - Organ laterality (if applicable)
        - Blood type
        - Blood subtype (if used for allocation)
    - Verification of recipient
        - Unique identifier
        - 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

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital’s policies and procedures for pre-transplant verifications.

Transplant hospitals will provide:

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Access to relevant staff who can answer interview questions

Additional Guidance:

For purposes of this policy, a living donor organ is not considered "received" until it has been recovered.

Policy 5.8.B: Pre-Transplant Verification upon Organ Receipt

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:

- The following were verified between organ arrival and anastomosis:
    - Donor ID
    - Organ
    - Laterality (if applicable)
    - Donor blood type
    - Recipient unique identifier
    - Recipient blood type
    - Donor and recipient are blood type compatible or intended incompatible
    - Correct donor organ has been identified for the correct recipient
- The following are documented:
    - Intended recipient arrival time in O.R. or documentation showing intended recipient present at time of verification
    - Organ arrival time in O.R. or documentation showing organ present at time of verification
    - Verification time
    - Anastomosis time or documentation showing verification occurred prior to anastomosis

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

For purposes of this policy, a living donor organ is not considered "received" until it has been recovered.

Policy 6.1.A: Adult Heart Status 1A Requirements

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 data reported through UNet℠ is consistent with source documentation, including:

- Any of the criteria selected on the adult status 1A justification form:
    - Evidence of admission to the hospital that registered the candidate on each day registered at status 1A, plus at least one of the following:
        - Assistance of a total artificial heart (TAH), intra-aortic balloon pump (IABP), or extracorporeal membrane oxygenation (ECMO) on each day registered at status 1A
        - Assistance of continuous mechanical ventilation on each day registered at status 1A
        - Continuous hemodynamic monitoring and a continuous infusion of one or more intravenous inotropes that meets minimum dosages for:
            - Dobutamine
            - Dopamine
            - Milrinone
            - Epinephrine
            - Norepinephrine
    - Assistance of a left ventricular assist device (LVAD), right ventricular assist device (RVAD), or left and right ventricular assist devices (BiVAD) on each day registered at status 1A
    - Assistance with mechanical circulatory support with device-related complications

Transplant hospitals will provide:

The requested sample of medical records

Policy 6.1.D: Pediatric Heart Status 1A Requirements

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 data reported through UNet℠ is consistent with source documentation, including:

- Any of the criteria selected on the pediatric status 1A justification form:
    - Evidence of admission to the hospital that registered the candidate on each day registered at status 1A, plus at least one of the following:
        - Administration of continuous mechanical ventilation on each day registered at status 1A
        - Assistance of an intra-aortic balloon pump on each day registered at status 1A
        - Ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion
        - Infusion of a qualifying high-dose IV inotrope or multiple qualifying IV inotropes on each day registered at status 1A, plus a qualifying congenital heart disease diagnosis
    - Assistance of a mechanical circulatory support device

Transplant hospitals will provide:

The requested sample of medical records

Policy 6.3: Status Exceptions

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 data reported through UNet℠ is consistent with source documentation, including:

- Evidence of admission to the hospital that registered the candidate on each day registered at status 1A
- All information reported in the narrative field of the status 1A justification form

Transplant hospitals will provide:

The requested sample of medical records

Policy 8.5.D: Allocation of Kidneys by Blood Type

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:

- Kidney transplant recipients with blood type B who received a kidney from a donor with blood type A, non-A_1 or blood type AB, non-A_1B provided written informed consent to accept a kidney from a donor with these blood types

Verify that the transplant program has a written policy regarding its titer threshold for transplanting blood type A, non-A_1 and blood type B, non-A_1B kidneys into candidates with blood type B

Transplant hospitals will provide:

The requested sample of medical records

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Policy 14.5: Living Donor Blood Type Determination and Reporting

At living donor recovery hospitals, site surveyors will:

Review the hospital's internal policies, procedures, and protocols and interview staff to verify that they have a written protocol(s) that includes:

- Testing two donor blood samples before generating the donor ID that:
    - Are drawn on separate occasions
    - Have different collection times
    - Are submitted as separate samples
    - Have results indicating the same blood type
- Reporting subtype only when:
    - Tests are completed on two separate blood samples
    - The draw times for the samples used for the two tests are at different times
    - Samples used are pre-red blood cell transfusion
    - There are no conflicting subtype results
- Reporting candidate blood type:
    - By two qualified healthcare professionals
    - Using all blood type determination source documents
- Definition of qualified health care professionals who can participate in blood type verification and reporting
- A process for resolving conflicting primary blood type results

Interview recovery hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for living donor blood type determination and reporting

Recovery hospitals will provide:

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Access to relevant staff who can answer interview questions

Additional Guidance:

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 14.7: Living Donor Pre-Recovery Verification

At living donor recovery hospitals, site surveyors will:

Review the hospital's internal policies, procedures, and protocols to verify that they have a written protocol that includes:

- Participation by the recovery surgeon and another licensed health care professional
- Timing of verification:
    - Before induction of general anesthesia
    - On the day of the organ recovery
- Verification of the donor:
    - Donor ID
    - Organ
    - Organ laterality (if applicable)
    - Blood type
    - Blood subtype (if used for allocation)
- Verification of the intended recipient:
    - Unique identifier
    - 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
- Sources used for verification

Interview recovery hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for living donor pre-recovery verification.

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The following were verified:
    - Donor ID
    - Organ
    - Organ laterality (if applicable)
    - Donor blood type
    - Intended recipient unique identifier
    - Intended recipient blood type
    - Donor and intended recipient are blood type compatible or intended incompatible
    - Correct donor organ has been identified for the correct intended recipient
- The verification took place:
    - Before the induction of general anesthesia
    - On the same date as the living donor recovery

Recovery hospitals will provide:

The requested sample of living donor records

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Access to relevant staff who can answer interview questions

Policy 15.3.B: Donors with Risk Identified Pre-Transplant

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:

- The potential recipient or recipient's agent gave consent after the organ offer but before transplant when:
    - The accepted organ was from a donor who tested positive for:
        - Hepatitis B surface antigen (HBsAg)
        - Hepatitis B nucleic acid test (NAT)
        - Hepatitis C NAT
    - The accepted organ was from a donor meeting PHS increased risk criteria
    - The accepted organ was from a donor whose HIV, hepatitis B, or hepatitis C screening was performed using a hemodiluted specimen
    - The accepted kidney or liver was from an HIV positive donor, and the transplant hospital participates in an approved variance according to *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*

Transplant hospitals will provide:

The requested sample of medical records

Policy 15.3.C: Recipients of Organs from Donors with Increased Risk of Disease Transmission

At transplant hospitals, site surveyors will:

Review the hospital's internal policies, procedures, and protocols to verify that they have a written protocol for:

- Post-transplant HIV, hepatitis B, and hepatitis C testing of recipients who have received an organ from a donor meeting PHS increased risk criteria

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for post-transplant testing of recipients who have received an organ from a donor meeting PHS increased risk criteria.

Transplant hospitals will provide:

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Access to relevant staff who can answer interview questions

Policy 16.6.A: Extra Vessels Use and Sharing

At transplant hospitals, site surveyors will:

Interview staff members who have been designated to oversee the storage and use of vessels, to verify knowledge that:

- Extra vessels can only be used in implantation or modifications of organ transplants

Transplant hospitals will provide:

Access to relevant staff who can answer interview questions

Policy 16.6.B: Extra Vessels Storage

At transplant hospitals, site surveyors will:

Interview relevant staff and substantiate the information obtained in the interview through review of internal policies, procedures, and protocols to obtain evidence that the hospital's standard practice is:

- That extra vessels from a donor are not stored for later use if the donor has tested positive for:
    - HIV by antibody, antigen or nucleic acid test (NAT)
    - Hepatitis B surface antigen (HBsAg)
    - Hepatitis B (HBV) NAT
    - Hepatitis C (HCV) antibody or NAT
- That stored extra vessels are used only for organ transplantation
- That at least one person has been designated to monitor the storage, use, destruction, and reporting of extra vessels
- To package, label, and store extra vessels according to OPTN policy requirements
- To maintain a log of stored extra vessels, as well as all records relating to the monitoring and use of extra vessels
- To monitor extra vessels daily and log security and refrigerator temperature checks
- To destroy unused extra vessels within 14 days after the recovery date

Review compliance rates for:

- Destruction of vessels within 14 days after recovery

Transplant hospitals will provide:

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Evidence as needed to verify compliance

Access to relevant staff who can answer interview questions

Policy 16.6.C: Reporting Requirements for Extra Vessels

At transplant hospitals, site surveyors will:

Review compliance rates for:

- Reporting extra vessel disposition within 7 days after use, sharing, or destruction

Transplant hospitals will provide:

Evidence as needed to verify compliance

Additional Guidance:

All vessels shared between hospitals must be reported, even if they are not used.

The receiving transplant hospital is not required to report vessels as shared when it receives vessels directly from the recovering OPO.

Policy 18.1: Data Submission Requirements

At OPOs, site surveyors will:

Review rates of compliance with submission dates for the following forms submitted to the OPTN within the review timeframe:

- Deceased Donor Registration (DDR)
- Deceased Donor Feedback
- Potential Transplant Recipient (PTR) refusal codes

Review a sample of deceased donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet℠ on the DDR is consistent with source documentation.

OPOs will provide:

The requested sample of deceased donor medical records

Evidence as needed to verify compliance

At living donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The date and time of the registration of the donor via UNet℠ occurred before the date and time of the start of the recovery

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet℠ is consistent with source documentation, including:

- The following donor information is reported on the LDR:
    - ABO
    - Serologies
    - Height
    - Weight
    - Conversion from laparoscopic
    - Organ recovery date
    - Organ recovered
    - Recovery facility
    - Workup facility
    - Discharge date

Review rates of compliance with submission dates for LDRs submitted to the OPTN within the review timeframe.

Recovery hospitals will provide:

The requested sample of living donor records

Evidence as needed to verify compliance

Additional Guidance:

When calculating the due date for deceased donor feedback forms, the procurement date is defined as the date the donor entered the operating room for purposes of organ recovery