

OPTN Evaluation Plan Pending Updates for September 1, 2016

This document outlines updates to the OPTN Evaluation Plan effective September 1, 2016, and is provided for planning purposes only. All information is subject to change.

Policy 2.13: Post Procurement Follow Up 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:

- 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

OPOs will provide:

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

Policy 3.4.D: Candidate Human Leukocyte Antigen (HLA) 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 UNetSM is consistent with source documentation, including:

- HLA information for candidates registered for a kidney

Transplant hospitals will provide:

The requested sample of medical records

Policy 5.3.C: Informed Consent for Kidneys Based on KDPI Greater than 85%

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-alone transplant recipients who received a kidney with a KDPI score greater than 85% gave written informed consent to receive offers for kidneys with a KDPI score greater than 85%
- Multi-organ transplant recipients whose transplant included a kidney with a KDPI score greater than 85% gave written informed consent to receive the kidney before it was transplanted

Transplant hospitals will provide:

The requested sample of medical records

(Note: Upon implementation, monitoring of *Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%* will replace monitoring of current *Policy 8.5.C Informed Consent for Kidneys Based on KDPI Greater than 85%*.)

Policy 8.5.E: 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-A₁ or blood type AB, non-A₁B provided written informed consent to accept a kidney from a donor with these blood types

Review a sample of medical records, and any material incorporated into the medical record by reference, and the transplant program's written policy regarding its titer threshold for transplanting blood type A, non-A₁ and blood type AB, non-A₁B kidneys into candidates with blood type B to verify that:

- When the program confirmed a candidate's eligibility in UNetSM, the candidate's most recent titer results met the threshold established in the transplant program's internal policy

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 15.4.A: Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

At OPOs, site surveyors will:

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

- Evidence of follow-up on deceased donor test results post-procurement
- Evidence that positive test results and other required relevant information received post-procurement are reported to each recipient hospital via phone call or email within 24 hours of the OPO's receipt, including:
 - The date and time the OPO received the results
 - The name of the individual at the recipient hospital who received the OPO's report
 - The mode or method of the report (by either telephone or email)
- Evidence that any results received post-procurement indicating malignancy or the presence of a Pathogen of Special Interest are reported through the OPTN Improving Patient Safety Portal within 24 hours of the OPO's receipt of the results

OPOs will provide:

The requested sample of deceased donor medical records