OPTN Member Evaluation Plan Preview

The OPTN Member Evaluation Plan will be updated on June 1, 2021, when OPTN policy changes are implemented as part of the alignment of OPTN policies with the 2020 *U.S. Public Health Service Guideline* for assessing solid organ donors and monitoring transplant recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus infection. This preview of Evaluation Plan changes is provided as a planning resource until the Evaluation Plan is updated. All information contained in this document may be subject to future changes.

Policy 14.3: Informed Consent Requirements

Effective Date: 6/1/2021

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 a document signed by the living donor confirming that the donor:

- Is willing to donate
- Is free from inducement or coercion
- Has been informed that he/she may decline to donate at any time

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

- The living donor was offered an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential
- An ILDA was available to assist the living donor during the consent process

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- To provide information to living donors in a language in which the donor is able to engage in a meaningful dialogue with the recovery program staff

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

- It is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations
- That the hospital must (or will) provide an ILDA
- Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation
- A deceased donor organ might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs
- Transplant hospitals determine candidacy for transplantation based on existing hospital-specific guidelines or practices and clinical judgment
- The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and the recipient

- Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that:
    - Exceed local or national averages
    - Do not necessarily prohibit transplantation
    - Are not disclosed to the living donor
- The recovery hospital can disclose to the living donor certain information about candidates only with the permission of the candidate, including:
    - The reasons for a transplant candidate's increased likelihood of adverse outcomes
    - Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law
- Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state or federal public health authorities
- The recovery hospital is required to report living donor follow-up information at six months, one year, and two years post-donation
- The recovery hospital is required to obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease
- Any infectious disease or malignancy pertinent to acute recipient care discovered during the first two years of the donor's post-operative follow-up care:
    - May need to be reported to local, state or federal public health authorities
    - Will be disclosed to their recipient's transplant hospital
    - Will be reported through the OPTN Improving Patient Safety Portal
- The living donor will receive a medical evaluation
- The living donor will receive a psychosocial evaluation
- The hospital may refuse the living donor
- The following are inherent risks associated with evaluation for living donation:
    - Allergic reactions to contrast
    - Discovery of reportable infections
    - Discovery of serious medical conditions
    - Discovery of adverse genetic findings
    - Discovery of abnormalities that may require additional testing at the donor's expense or create the need for unexpected decisions by the transplant team

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided information or disclosure to the donor addressing the risk of the following:

- Death
- Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
- Abdominal symptoms such as bloating, nausea, and bowel obstruction
- The morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions
- Problems with body image
- Post-surgery depression or anxiety
- Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the recipient dies
- Changes to the living donor's lifestyle from donation
- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed
- Need for life-long follow-up at the living donor's expense

- Loss of employment or income
- Negative impact on the ability to obtain future employment
- Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance
- Risks may be temporary or permanent
- Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided the following information to the living donor regarding recipient outcome and survival data:

- When the recipient transplant hospital is known or is the same as the recovery hospital:
    - SRTR's national 1-year patient and transplanted organ survival rates for the organ being donated
    - SRTR's most recent hospital-specific 1-year patient and transplanted organ survival rates for the recipient's transplant hospital for the organ being donated
- When the recipient transplant hospital is not known:
    - SRTR’s national 1-year patient and transplanted organ survival rates for the organ being donated

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living kidney donor regarding:

- Education about expected post-donation kidney function and the potential impact on chronic kidney disease (CKD) and end-stage renal disease (ESRD) on the living kidney donor in the future, including:
    - On average, donors will have a 25-35% permanent loss of kidney function after donation
    - Although risk of ESRD for living kidney donors does not exceed that of members of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors
    - Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young donor cannot predict lifetime risk of CKD or ESRD
    - Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney
    - The development of CKD and subsequent progression to ESRD may be faster with only one kidney
    - Dialysis is required if the living donor develops ESRD
    - Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN policy
- Potential surgical risks:
    - Decreased kidney function
    - Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
    - Risks may be temporary or permanent
    - Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional disclosure to female living kidney donors that:

- Risks of preeclampsia or gestational hypertension may be increased in pregnancies after donation

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living liver donor regarding:

- Potential surgical risks:
    - Acute liver failure with need for liver transplant
    - Transient liver dysfunction with recovery
    - Risk of red cell transfusions or other blood product transfusions
    - Biliary complications, including leak or stricture, that may require additional intervention
    - Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks
    - Risks may be temporary or permanent
    - Risks may include those listed, but are not limited to those listed

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

Evidence as needed to verify compliance

Access to relevant staff who can answer interview questions

What is changing?

Surveyors will begin verifying that living donor recovery hospitals are disclosing to living donors that the hospital is required to obtain and store a living donor blood sample for ten years, only to be used for investigation of potential donor-derived disease.

Policy 14.8.B Living Donor Specimen Collection and Storage

Effective Date: 6/1/2021

At living donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records for the following documentation:

- Blood specimen collection and storage noted in the medical record
- A collection date for stored blood specimens that is no earlier than 1 day before the donor recovery date

Recovery hospitals will provide:

The requested sample of living donor records

What is changing?

Surveyors will begin monitoring this policy as described above.