

OPTN/UNOS Policy Notice

Clarify Informed Consent Policy for Transmittable Conditions

Sponsoring Committee:	Ad Hoc Disease Transmission Advisory
Policy/Bylaws Affected:	5.5.B (Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results), 15.3 (Informed Consent of Transmissible Disease Risk), 15.3.A (Donors with Additional Risk Identified Pre-transplant), and 15.3.B (Donors at Increased Risk for Transmission of Blood-borne Pathogens)
Public Comment:	January 22, 2018 – March 23, 2018
Board Approval Date:	June 12, 2018
Effective Date:	September 1, 2018

Problem Statement

Current policy for informed consent of transmissible disease risk is vague. It states that consent is required “when the donor has a known medical condition that may, in the transplant hospital’s medical judgment, be transmissible to the recipient”. It may imply the need for individual consent for every positive test result and which would not be reasonable and might cause undue burden on transplant programs.

Summary of Changes

These changes establish the principle that if organ offers are screened based on a specific positive infectious disease result, and then positive results for those conditions will require the transplant program to obtain pre-transplant informed consent from the intended recipient. These changes also address the growing use of positive organs for conditions such as HCV.

The following will change to policy for informed consent of transmissible diseases:

Action	Current Policy Requirement	Approved Policy Requirement in effect 9/1/2018
<p>Clarify conditions for which intended recipients must provide informed consent due to a donor condition</p>	<ul style="list-style-type: none"> • Known medical condition that may, in the transplant hospital's medical judgment, be transmissible • Donor meets criteria for US Public Health Service (PHS) increased risk, including hemodiluted blood sample used for HIV, hepatitis C, or hepatitis B testing 	<ul style="list-style-type: none"> • Adds positive test results for: <ul style="list-style-type: none"> ○ Hepatitis C Nucleic Acid Test (NAT) ○ Hepatitis B Surface Antigen (HBsAg) ○ Hepatitis B NAT ○ HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital is an approved HOPE Act program (HIV positive test consent already in effect under HOPE Act, however language further specified here) • Deletes "known medical condition"
<p>Provide further clarification of timing for informed consent</p>	<p>All candidates or potential recipients must provide informed consent regarding potential transmission risks.</p> <p>This is referred to as general informed consent. It covers what all donors are screened for and that it is impossible to test for all potential conditions.</p> <p><i>General</i> informed consent must be obtained <i>before</i> transplant.</p> <p><i>Specific</i> informed consent must be obtained <i>before</i> transplant of any organ when the donor has a known medical condition or meets US PHS increased risk criteria.</p>	<ul style="list-style-type: none"> • Moved general informed consent requirements to first section of policy • Clarified that consent can be obtained "<i>any time prior to transplant</i>". This means that the consent timing is variable as long as it is completed before transplant (for example, before registering a patient or during candidate medical evaluation) • Clarified that when a donor tests positive for certain conditions or meets US PHS increased risk criteria, informed consent must be obtained "<i>after organ offer but before transplant</i>". This means that it is not acceptable to get a "blanket" informed consent at candidate registration that covers consent for these situations. The consent applies when an organ offer is made.

Action	Current Policy Requirement	Approved Policy Requirement in effect 9/1/2018
Added required discussion point in general informed consent	General informed consent currently requires that candidates be informed about: <ul style="list-style-type: none"> • Required screening performed on deceased and living donors • That it is impossible to test for all potential conditions • That some conditions might be discovered post-transplant 	The following clause is added to the existing list of requirements: <ul style="list-style-type: none"> • Donor evaluation and screening results may impact post-transplant evaluation, screening, and management of the candidate.
Deleted informed consent requirement when the match run must be re-executed	When a potential transplant recipient has accepted an organ, then the donor has a positive test that triggers a match re-run per policy, the potential recipient can still accept the organ but must provide informed consent	Whenever a donor tests positive for hepatitis C NAT, hepatitis B NAT, or HBsAg, then informed consent must be obtained whether or not the match was re-executed. Programs no longer have to obtain informed consent when donors test positive for hepatitis B core antibody (anti-HBc), hepatitis C antibody (anti-HCV), or cytomegalovirus (CMV) and the recipient had accepted the organ before the positive result.

What Members Need to Do

Transplant hospitals will need to:

- Examine and possibly revise their consent protocols and practices to comply with the revised policies
- Examine their practices at both the time before transplant, as well as at the time of organ offer

If not doing so already, transplant hospitals will need to:

- Inform candidates that donor evaluation and screening results may impact post-transplant evaluation, screening, and management of the candidate at any time before transplant
- Obtain informed consent from intended recipients after organ offer, yet prior to transplant, when transplanting donor organs with positive results for HBV (HBsAg and NAT) and HCV (NAT)

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results

If a host OPO executes a match run with negative or pending results for any of the infectious diseases listed in *Table 5-1: Donor Infectious Disease Screening Options* and subsequently receives a positive result for any of these tests, then it must report the updated information to the OPTN Contractor and do the following:

1. When a deceased donor organ has *not* been accepted for a potential transplant recipient, then the OPO must do *all* of the following for each organ being allocated:
 - a. Stop allocation on the original match run for this donor
 - b. Re-execute the match run according to the infectious disease screening options as follows:
 - i. A new positive Cytomegalovirus (CMV) result will apply to re-execution of the intestine match run
 - ii. A new positive hepatitis B (HBcAb or HBV NAT) or hepatitis C (HCV Ab or HCV NAT) result will apply to re-execution of *all* organ types
 - c. Allocate the organ using this updated match run
2. When a deceased donor organ has already been accepted for a potential transplant recipient, the host OPO must do *all* of the following for each organ being allocated:
 - a. Report this new infectious disease test result to the first transplant hospital on the match run that accepted the organ as soon as possible, but within one hour, of receipt of the new test result
 - b. Re-execute the match run for use as follows:
 - i. For re-allocation of the organ *if* the offer to the primary potential transplant recipient is declined after receipt of the positive infectious disease test
 - ii. For back-up organ offers based upon the new positive test result

When the transplant hospital is notified by the host OPO of these new positive infectious disease results, it must ~~do both of the following~~:

- ~~1. Notify the host OPO whether the organ will be accepted or declined, within one hour of receipt of the new test result.~~
- ~~2. Meet the requirements according to *Policy 15.3.C: Informed Consent Requirements after Re-Execution of the Match Run Due to New Information*~~

15.3 Informed Consent of Transmissible Disease Risk

~~Transplant programs must obtain specific informed consent before transplant of any organ when any of the following occurs:~~

- ~~• The donor has a known medical condition that may, in the transplant hospital's medical judgment, be transmissible to the recipient, including HIV.~~
- ~~• The donor meets any of the criteria for increased risk of transmitting HIV, hepatitis B, and hepatitis C as specified in the *U.S. Public Health Services (PHS) Guideline*.~~
- ~~• When a hemodiluted specimen is used for donor HIV, hepatitis B, or hepatitis C screening, according to *Policy 2.5: Hemodilution Assessment*.~~

15.3.A General Risks of Potential Malignancy or Disease Transmission

Transplant programs must ~~also~~ inform ~~potential~~ candidates of the general risks of potential transmission of malignancies and diseases from organ donors, including *all* of the following information:

1. Deceased donors are evaluated and screened according to ~~as outlined in~~ *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living ~~donors~~ are required to undergo screening for ~~the diseases listed in~~ according to *Policy 14.4: Medical Evaluation Requirements for Living Donors*.

3. ~~That~~ There is no comprehensive way to screen deceased and living donors for all transmissible diseases.
4. ~~That transmissible~~ Malignancies and diseases and malignancies may be identified and transmitted after transplant.
5. Donor evaluation and screening results may impact post-transplant evaluation, screening, and management of the candidate.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the ~~potential~~ candidate or candidate's agent ~~before~~ any time prior to transplant.
2. Document consent in the ~~potential~~ candidate's medical record.

15.3.AB Donors with Additional Risk Identified Pre-~~T~~ransplant

If ~~additional donor disease or malignancy transmission risk is identified pre-transplant,~~ the transplant program must do all of the following:

1. ~~Explain the risks and obtain informed consent from the potential transplant recipient or the potential recipient's agent before transplant.~~
2. ~~Document this consent in the potential recipient's medical record.~~
3. ~~Follow any recipient of the deceased or living donor organs for the development of potential donor-derived disease after transplantation.~~

Transplant programs must meet the requirements according to *Table 15-1* below when the deceased or living donor has risk of disease transmission identified pre-transplant.

Table 15-1: Requirements for Donors with Risk Identified Pre-Transplant

<u>Each time any of the following occurs:</u>	<u>Then transplant programs must do <i>all</i> of the following:</u>
<ul style="list-style-type: none"> • <u>The donor tests positive for <i>any</i> of the following:</u> <ol style="list-style-type: none"> a. <u>Hepatitis B surface antigen (HBsAg)</u> b. <u>Hepatitis B nucleic acid test (NAT)</u> c. <u>Hepatitis C NAT</u> • <u>The donor meets any of the criteria for increased risk of transmitting HIV, hepatitis B, or hepatitis C, as specified in the <i>U.S. Public Health Services (PHS) Guideline</i></u> • <u>A hemodiluted specimen is used for the donor HIV, hepatitis B, or hepatitis C testing, according to <i>Policy 2.5: Hemodilution Assessment</i></u> • <u>The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to <i>Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors</i></u> 	<ol style="list-style-type: none"> 1. <u>Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant</u> 2. <u>Document this consent in the intended recipient's medical record</u> 3. <u>Follow the recipient for the development of potential donor-derived disease after transplant</u>

15.3.B-C Recipients of Organs from Donors at with Increased Risk of Disease Transmission for Transmission of Blood-borne Pathogens

Transplant programs must develop and comply with a written protocol for post-transplant testing for HIV, hepatitis B, or hepatitis C, for recipients who receive an organ from a donor who meets any of the criteria for increased risk of transmitting HIV, hepatitis B, or hepatitis C, as specified in the U.S. Public Health Services (PHS) Guideline. If a donor is found to have an increased risk for transmitting blood borne pathogens, †The transplant program must offer recipients of these donor organs ~~at both~~ of the following in addition to routine post-transplant care:

1. Additional post-transplant testing for HIV, hepatitis B, and hepatitis C, and hepatitis B according to the transplant program's protocols appropriate based on the recipient's pre-transplant status. Every transplant hospital must develop and implement a written protocol for post-transplant testing for these diseases.
2. Treatment of or prophylaxis for the transmissible disease, when available medically appropriate

[Subsequent heading numbers, and any table captions and cross-references, affected by the re-numbering of this policy will also be changed as necessary.]

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