

Public Comment Proposal

Clarify Informed Consent Policy for Transmittable Conditions

OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee

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Clarify Informed Consent Policy for Transmittable Conditions

Affected Policies: 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

Sponsoring Committee: Ad Hoc Disease Transmission Advisory

Public Comment Period: January 22, 2018 – March 23, 2018

Executive Summary

Current policy states that specific pre-transplant informed 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, including HIV.” The phrase “known medical condition” has led to questions and varying applications in practice. The Membership and Professional Standards Committee (MPSC) notes in a memo to the Ad Hoc Disease Transmission Advisory Committee (DTAC) that broad interpretation of this policy would require specific informed consent for any positive serology, culture, or other donor test result and that this would be cumbersome without adding patient benefit. For example, Epstein-Barr virus (EBV) and cytomegalovirus (CMV) are common conditions and typically do not impact organ use except under unusual circumstances. Requiring specific informed consent prior to surgery for those serologies or other donor culture results may not be reasonable and leads to undue burden on the program.

The DTAC consistently has maintained that the policy was not meant to include transmissions that are common in organ transplantation. The DTAC expects that these would be included as part of routine pre-transplant education. Due to the interpretation concerns, the DTAC proposes changes to this policy.

This proposal specifies conditions requiring informed consent prior to transplant. The Committee proposes linking conditions that would require specific consent to those that exist in *Policy 5.3.B Infectious Disease Screening Criteria*. This policy specifies organ specific preferences that can be made in Waitlistsm for individual candidates on whether organ offers will be received from donors who have tested positive for certain transmittable conditions. Currently, this policy includes CMV for intestines only, as well as hepatitis B (HBV) core antibody and Nucleic Acid Test (NAT), hepatitis C (HCV) antibody and NAT for heart, intestine, kidney, liver, lung, pancreas, heart-lung, and kidney-pancreas listings. Organs from HIV positive donors may only be recovered and transplanted according to Final Rule requirements. Currently, use is only permissible for kidney and liver transplantation. Consent requirements for these organs, outlined in *Policy 15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*, would not change.

Linking pre-transplant informed consent requirements to existing candidate screening conditions will provide consistency and specificity. It establishes the principle that if organ offers are screened based on a specific positive infectious disease result, then positive results for those conditions will require pre-transplant informed consent. Future changes to the screening policy would cascade to the informed consent policy. These changes also address the growing use of positive organs for conditions such as HCV.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

1. Should informed consent policy include an actual patient signature or is discussion and medical record documentation sufficient?
2. Do you have any concerns or comments about the list of conditions in the current candidate screening (*Policy 5.3.B Infectious Disease Screening Criteria*) and re-execute the match (*5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results*) policies?

What problem will this proposal address?

Policy 15.3 requiring that specific informed consent (due to potential disease transmission) be obtained pre-transplant is vague and leads to varying interpretations. The MPSC sent a memo to the DTAC in April 2017 requesting further clarifications. They shared concerns that the term “known medical condition” is vague, and potentially confusing. In both living and deceased donor transplants, donors may have a positive serology or culture found prior to recovery of which the transplant program is aware but would not impact the decision to accept or reject a specific organ donation. A broad interpretation of the current policy would include requiring a specific informed consent for any positive serology, culture, or other donor test result.

Epstein-Barr virus (EBV), cytomegalovirus (CMV), and culture results were mentioned as examples. The MPSC did not believe that many, if any; adult programs would complete a specific informed consent for an EBV or CMV mismatch, as these are common. Applying this policy to require specific informed consent prior to surgery for those serologies or other donor culture results may not be reasonable.

The DTAC has consistently maintained that the policy intent was not to include CMV and EBV mismatches when questions have arisen, as they are considered part of the regular business of transplant and are quite frequent. In the 2010 proposal resulting in the current language, one commenter asked specifically that CMV be specified as an informed consent requirement. The response was “both current and proposed policies require CMV screening in potential organ donors. Transplant programs are responsible for developing their own practices for sharing potential risks related to donor derived disease transmission with potential candidates before listing and also when organ offers are received.” Accordingly, when reviewed in 2010 it was not felt that a general policy should include informed consent for CMV. The DTAC believes that the possibility of a CMV or EBV mismatch would be better discussed as part of routine pre-transplant education. The DTAC leadership shared these thoughts with MPSC leadership. The DTAC leadership formally responded to the MPSC inquiry with a memo indicating that positive donor EBV and CMV results were not recommended conditions for specific informed consent.

The current proposal was developed by the DTAC to attempt to address these questions and other potential language interpretation issues. To remove the current ambiguity this policy provides specific criteria when pre-transplant organ-offer specific informed consent is required.

Why should you support this proposal?

The proposal provides specificity that will assist transplant programs and candidates in knowing what general and organ-offer consents are required by OPTN/UNOS policies.

Policy requires discussion of potential disease transmissions takes place when a transplant program is discussing with a potential candidate the possibility of being placed on the Waiting List. The DTAC proposes adding a clause to the general consent requirements that post-transplant management might be impacted by testing results. Not every possible situation can be discussed or anticipated. The discussion when considering being placed on the Waiting List, however, can be done in a more calm and measured environment than at the time of organ offer. For this reason, it is a better time to discuss the concept of potential donor disease transmission issues such as EBV and CMV mismatch possibilities as well as unknown infections or malignancies that were not recognized in a donor. The transplant program can take the opportunity to explain their specific practices about how they typically evaluate and handle common situations (e.g. increased risk donors, donors who are positive for EBV or CMV, donors who might have other transmissible conditions such as renal cell carcinoma). Informed consent policy at the time of organ offer is proposed to be for the same infectious disease conditions that are currently used for screening when adding a candidate to the Waiting List.

How was this proposal developed?

This proposal was developed by forming a work group of the DTAC members. The Joint Societies considered this project under their normal process and elected to name representatives to the existing DTAC work group. The American Society of Transplant Surgeons (ASTS) and American Society of Transplantation (AST) both named representatives.

The work group met monthly following project approval in July 2017. They surveyed members about current informed consent practices. They reviewed the policy development history from its origins in 1992 when only human T-lymphotropic (HTLV) and human-derived pituitary growth hormone were required informed consent conditions. The work group considered various policy options to address the current identified problem including:

1. Eliminating the vague language referencing known medical conditions that might be transmittable in the transplant program's medical judgment
2. Limiting conditions to positive tests for HCV and HBV
3. Using the Pathogens of Special Interest list referenced in current OPTN policy as a proxy for conditions

Work group members and other DTAC members identified and discussed many issues that should be considered when developing the proposal, including:

- Policy should be the minimum acceptable standard
- Policy needs to be enforceable
- Whether or not the informed consent discussion that occurs prior to transplant of organ should have documentation in the recipient chart versus have a signed consent document
- Variability may exist in state informed consent laws
- Informed consent is also required by Centers for Medicaid and Medicare Services (CMS) Conditions of Participation (CoPs)
- Other related and relevant OPTN policies (*Policy 5.5 Re-Execution of the Match Run and Bylaw Appendix L. 15: OPTN Determinations and Actions*)
- UNetsm product liability
- Concerns for patient safety must be a priority even if obtaining informed consent is challenging
- Concerns that it is impossible to consent for all potential conditions
- Specific conditions may not be appropriate to be part of policy
- US Public Health Service (PHS) Guideline Recommendation 14

The work group and full DTAC agree that the emphasis and bulk of discussion needs to occur at registration when a rational, calm, and extensive discussion can take place. The proposed policy reflects this by moving the existing general risk section to the beginning of the policy. The rationale for the re-organization is two-fold. First, the discussion of general risks occurs earlier chronologically in the transplant process. Second, placing the general consent language first emphasizes that the importance of having the potential transmission risk when the patient is considering being registered versus a conversation when a specific organ offer becomes available.

The work group and full DTAC discussed which illnesses should require consent at the time of organ offer. HIV transplantation is addressed in separate OPTN policies in accordance with the HIV Organ Policy Equity (HOPE) Act and this circumstance should not be included in this policy. PHS recommendation 14 states that "When organs from HBV- or HCV-infected donors will be used, the transplant center team primarily responsible for the patient's care should have an informed consent discussion with the transplant candidate, or medical decision maker, prior to transplantation regarding the risks related to disease transmission." They discussed what does HCV and HBV infection mean in the age of serology and NAT. This is an evolving scientific discussion.

The work group and full DTAC discussed whether informed consent might be interpreted as a separate document. There was a lack of consensus with some on the group believing informed consent to be a documented discussion and others interpreting the need for an actual patient (or their surrogate) signature. Discussion included that from the legal standpoint a signed form is the best case for informed consent because there is no question about what was communicated. When discussed and documented in a

medical note there can be a question about how much the patient understood. Electronic health record (EHR) documentation might be the next best thing commented one member. It was noted that informed consent is an area already heavily regulated by states. The Committee was advised to be more specific and not to duplicate state efforts. The DTAC decided to seek public comment feedback regarding whether consent needs to include a patient signature or if discussion and documentation, as currently required as a minimum, is sufficient.

The work group and full DTAC grappled with the issue of how hard it is to determine which conditions need consent. In addition, they noted that the “transmittable” part is also difficult to enforce. Members did comment that, regardless of policy, the standard of care is to discuss all potential concerns with patients. It was noted that hospital policies or OPTN/UNOS policies could be used to determine the standard of care. In addition, it was recognized that policy language vagueness creates potential for unintended consequences and guidance is needed.

The ASTS perspective was considered. They strongly believe that guiding principle should be proportional to patient risk. HBV and HCV are reasonable risks because they affect listing decisions and affect access to transplant. Other conditions can be rare events and impossible to cover in policy language. The policy language does need to be appropriately broad to provide education and stress that there is uncertainty in transplant. More specific policy language would be a huge burden on transplant hospitals and could discourage people from accepting organs that could save their lives.

It was noted that the revised PHS increased risk guideline was published in 2013. Since that time some of the high-risk conditions addressed in the guidelines are now curable or manageable and do not cause death. It was also noted the need to obtain consent prior to use of PHS increased risk organs is currently in policy and will not change in the future.

The work group was made aware of the informed consent provision under the CMS Conditions of Participation (CoPs) 42 CFR 482.102. It requires transplant centers to implement written protocols related to informed consent regarding organ risk on several fronts. OPTN/UNOS policy might be viewed as a redundant provision. It was also mentioned that HCV and HIV are rapidly changing fields and therefore if policy or regulations become outdated it still takes significant time to change them.

Significant discussion revolved around the inherent challenges of enforcing policy, a major reason that MPSC referred the policy to the DTAC, and the challenges of appropriately informing patients of potential risk. Although some expressed concern about vague language creating enforcement challenges, there might be a counter argument to have something in policy to say we expect informed consent. Even if not easily enforceable, there could be a problem if a transplant program were to not act properly then this would reflect poorly on the OPTN. The Committee discussed whether it would be onerous to obtain consent as one participant expressed concern that although the issue is challenging it is one to be solved not silenced. A counterpoint discussion revolved around the extremely low risk of transmission compared to greater risks from quality of the organ that have never been mandated under consent policies and that information overload may inadvertently lead to greater patient death on the wait list due to organ decline.

To deal with these issues the DTAC leadership met with the Patient Affairs Committee (PAC) leadership during the policy development. The PAC leadership emphasized the need to distinguish between PHS increased risk and actually positive or infected with the related conditions. The PAC leadership did not express concerns with the direction of the proposal. The DTAC leadership will also meet with the Ethics Committee leadership to make sure their opinions are considered.

The work group and its members expressed that patients should be fully informed and that disease is an inherent risk of transplant but that explaining or consenting all individual risk is not likely achievable in a comprehensive way, particularly at the time of actual transplant. It was suggested that emphasis should be on educating potential transplant candidates about these risks at listing for transplant. Some members questioned whether too much information would lead to organ turndowns that ultimately put a patient at greater risk of poor outcomes.

Ultimately, the DTAC decided that clarity needed to be a priority and put forward a proposal that will tie pre-transplant specific organ informed consent to existing *Policy 5.3.B Infectious Disease Screening Criteria*. This policy outlines organ-specific preferences that can be made in Waitlist for individual candidates on whether organ offers will be received from donors who have tested positive for certain transmittable

conditions. Currently, this policy includes CMV for intestines only, as well as hepatitis B core antibody and Nucleic Acid Test (NAT), hepatitis C antibody and NAT for heart, intestine, kidney, liver, lung, pancreas, heart-lung, and kidney-pancreas listings. Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the Final Rule and currently use is only permissible for kidney and liver transplantation. Current infectious disease screening options available for candidates in *Policy 5.3.B Infectious Disease Screening Criteria* is shown below in Table 1.

Table 1: Donor Infectious Disease Screening Options from Policy 5.3.B Infectious Disease Screening Criteria

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human Immunodeficiency Virus (HIV); Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	Kidney, Liver; Use of HIV positive donor organs is only permissible for kidney and liver transplantation at this time.

Policy 15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs also outlines informed consent requirements for HIV positive organs. This proposal would not change any of these requirements.

Linking pre-transplant organ offer informed consent to candidate screening establishes a principle and is specific. It will also incorporate changes that might occur over time to the screening policy that would be consistent from listing through transplant. These changes also address the growing use of positive organs for conditions such as HCV as effective treatments have become available. The proposal does not change required informed consent for PHS increased risk organs or for organs where HIV, HBV, or HCV testing was performed on a hemodiluted specimen.

In addition, the proposal still emphasizes the need to educate about potential disease transmission early in the process of listing a person for transplantation.

How well does this proposal address the problem statement?

The proposal addressed the problem statement by removing policy ambiguity. *OPTN Bylaw Appendix L.15: OPTN Determinations and Actions* would allow pursuing member action in a situation where a member action does not follow a widely accepted standard of medical care.

Current UNet data indicates the following:

Candidates

As of September 30 2017, 116,350 patients were waiting for an organ on the Waiting List*. Of these:

- 71,318 (61.3%) indicated that they would accept an organ from a Hepatitis B core positive donor
- 8,021 (6.9%) indicated they would accept an organ from a Hepatitis B NAT positive donor
- 8,083 (6.9%) indicated they would accept an organ from a Hepatitis C antibody positive donor
- 1,931 (1.7%) indicated they would accept an organ from a Hepatitis C NAT positive donor
- 272 patients were registered as waiting for an intestine. Of these, 159 (58.5%) indicated that they would accept an intestine from a CMV antibody positive donor.

Donors

Between October 1, 2016 and September 30, 2017, 10,326 deceased donors from whom at least one organ was recovered for transplant in the U.S., of which:

- 9,205 (89.1%) tested positive for EBV (IgG or IgM)
- 6,283 (60.8%) tested positive for CMV
- 744 (7.2%) tested positive for HCV Antibody
- 495 (4.8%) tested positive for HCV NAT
- 478 (4.6%) tested positive for HBV core antibody
- 15 (0.1%) tested positive for HBV NAT

Transplants

From those donors, 31,662 recovered organs were transplanted into 27,396 recipients. Of these recipients,

- *CMV Mismatches*: 5,755 CMV-negative recipients received an organ from a CMV-positive donor (among 10,109 CMV-negative recipients)
- *EBV Mismatches*: 2,322 EBV-negative recipients received an organ from an EBV-positive donor (among 2,726 EBV-negative recipients)
- *HBV Mismatches*: 746 HBV-negative recipients received an organ from a HBV-positive donor (among 23,717 HBV-negative recipients)
- *HCV Mismatches*: 346 HCV-negative recipients received an organ from a HCV-positive donor (among 24,079 HCV-negative recipients)
- *CMV Mismatches (Intestines only)*: 21 CMV-negative recipients received donated intestines from a CMV-positive donor (among 57 CMV-negative intestine recipients and 110 intestine recipients)

These data show both the large number and high percentage of CMV and EBV mismatch transplants. Over half of all CMV negative recipients receive a CMV positive donor organ and 85 percent of all EBV negative recipients receive an EBV positive organ. These data support the principle of discussing this possibility as part of the general consent process at listing rather than requiring specific consent at organ offer due to the common nature of these types of transplants.

The data also illustrate the number of recipients that would be at greatest risk of becoming infected due to a HBV, HCV, or CMV-intestines only mismatch. These recipients would require organ-specific informed consent prior to transplant.

The strength of this principle is that it will provide clearer instruction and help assure that all candidates receive the same type of organ-specific informed consent if needed as required by policy.

The weakness or unintended consequence might be that a donor organ transmits a condition that had not been consented for specifically prior to transplant and the recipient has a bad outcome (e.g. organ loss) because they had assumed that a specific informed consent would have been obtained prior to transplant.

The DTAC reviews reported potential donor-derived transmissions. The data do not support that there are many donor-derived transmissions detected prior to transplant. Between 2008 and 2017, there have been 312 proven or probable transmissions from data available to date. Only 11 or 3.5% were detected prior to transplant. This would suggest that detectable unexpected transmissions are rare events and that most transmissions are not detected until after transplant.

Which populations are impacted by this proposal?

All potential candidates would be impacted by this proposal, as it will require transplant programs review their method for broaching consent with potential recipients ahead of transplant, in particular with regard donor screening results that may affect post-transplant evaluation. In addition, candidates will be required to provide informed consent specific to organ offers from donors that test positive conditions as specified in the proposal.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is potentially some impact here as reducing the ambiguity will help ensure consistent and safer practice among the specific agents named in policy. It is also possible that in some programs there will be fewer informed consents.
5. *Promote the efficient management of the OPTN:* Reducing policy ambiguity will help avoid unnecessary member investigations and actions. It might also reduce member work in determining and obtaining specific informed consent.

How will the OPTN implement this proposal?

This proposal will not require programming in UNet.

There will not be any additional research needs or changes for Organ Center operations. Instructional Innovations will monitor the development of this proposal and determine what the best course of action is for education.

How will members implement this proposal?

Transplant hospitals will need to examine their current informed consent practices at organ offer as well as practices at time of adding candidates to the Waiting List. If they do not currently obtain informed consent from intended recipients prior to transplant when transplanting donors with positive results for HBV (core antibody and NAT), HCV (antibody and NAT), and CMV intestine donors only), then they will need to implement changes to meet the new requirements.

Transplant Hospitals

Transplant hospitals will need to review their education and consent practices performed at the time of listing. The policy will require that potential candidates be informed that donor evaluation and screening results may impact post-transplant evaluation, screening, and management of the candidate.

Transplant hospitals might need to adjust their practices for obtaining specific informed consent although it is believed that most programs do already apply this policy to positive hepatitis B and hepatitis C donors. In these cases, there would not be additional effort required to comply with the changes. A small number of transplant hospitals may reduce the number of specific informed consents they complete. This will be largely an impact on transplant hospital practices but without significant fiscal implications.

OPOs

No impact is expected for OPOs.

Histocompatibility Laboratories

No impact is expected for histocompatibility laboratories.

Will this proposal require members to submit additional data?

No, this proposal will not require members to submit additional data.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all policy requirements may be subject to OPTN review, and members must provide documentation as requested.

During routine site surveys, surveyors will continue to review a sample of medical records for documentation that a potential recipient or recipient's agent gave consent before transplant when:

- An organ was accepted from a donor meeting PHS increased risk criteria
- An organ was accepted from a donor whose HIV, hepatitis B, or hepatitis C screening was performed on a hemodiluted specimen
- A kidney or liver was accepted from an HIV positive donor

This review currently occurs under *Policy 15.3 Informed Consent of Transmissible Disease Risk*. Based on the proposed policy changes, this monitoring would occur under revised *Policy 15.3.B Donors with Risk Identified Pre-Transplant*, along with additional new monitoring for Policy 15.3.B outlined below.

The following new monitoring would be added to routine site surveys:

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 a potential recipient or recipient's agent gave consent before transplant when:

- An organ was accepted from a donor who tested positive for:
 - Hepatitis B core antibody (HBcAb)
 - Hepatitis B nucleic acid test (NAT)
 - Hepatitis C (HCV) antibody
 - Hepatitis C nucleic acid test (NAT)
- An intestine was accepted from a donor who tested positive for cytomegalovirus (CMV)

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/or protocols and interview staff to verify that they have and follow a written protocol for post-transplant testing of recipients for HIV, hepatitis B, and hepatitis C.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The committee will continue to request feedback from UNOS site surveyors regarding whether members understand and are compliant with informed consent requirements.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

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. That 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 transplant.~~
- ~~2. Document consent in the potential candidate's medical record.~~

15.3.AB Donors with Additional Risk Identified Pre-Transplant

~~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 donors have risk of disease transmission identified pre-transplant.

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

<u>If any of the following occurs:</u>	<u>Then transplant programs must do all of the following:</u>
<ul style="list-style-type: none"> • <u>A donor tests positive for any of the infectious diseases used for match run screening according to <i>Policy 5.3.B: Infectious Disease Screening Criteria</i></u> • <u>A 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 donor HIV, hepatitis B, or hepatitis C screening, according to <i>Policy 2.5: Hemodilution Assessment</i></u> 	<ol style="list-style-type: none"> 1. <u>Explain the risks and obtain informed consent from the potential transplant recipient or the potential recipient's agent before transplant.</u> 2. <u>Document this consent in the potential recipient's medical record.</u> 3. <u>Follow any recipient of the organs for the development of potential donor-derived disease after transplantation.</u>

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

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

1. ~~Additional post-transplant testing for HIV, hepatitis B, and hepatitis C, and hepatitis B as 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.~~ Additional post-transplant testing for HIV, ~~hepatitis B, and~~ hepatitis C, ~~and hepatitis B~~ as 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.~~ Treatment of or prophylaxis for the transmissible disease, when available.

[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.]

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