

**Briefing Paper**

# 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

<i>Affected Policies:</i>	<i>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</i>
<i>Sponsoring Committee:</i>	<i>Ad Hoc Disease Transmission Advisory</i>
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## 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 Waitlist<sup>sm</sup> 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.

## **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.

EBV, 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 and representatives of the American Society of Transplant Surgeons (ASTS) and American Society of Transplantation (AST).

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*)
- UNet<sup>sm</sup> 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
- PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation<sup>1</sup> (hereafter referred to as PHS increased risk 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 increased risk guideline 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

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<sup>1</sup> Seem DL, Lee I, Umscheid CA, and Kuehnert MJ. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. Public Health Reports. 2013;128(4):247-343.

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 strongly believes 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 CoPs related to 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 the 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 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**

<b>If the donor tests positive for:</b>	<b>Then candidates may choose not to receive offers on the following match runs:</b>
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.

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\*Based on OPTN Data as of May 4, 2018; data subject to change based on future data submission or correction.

### **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.

## Was this proposal changed in response to public comment?

Yes, this proposal was changed in response to public comment. The DTAC met by teleconference on March 13, 2018 and for their in-person meeting on March 29, 2018 in Richmond, Virginia to discuss public comment and consider post public comment revisions.

### Public Comment Summary

During the public comment period (January 23 – March 23, 2018), this policy proposal received 22 comments on the OPTN website. DTAC presented the proposal to nine committees: Ethics, Kidney, Liver and Intestines, MPSC, PAC, Operations and Safety, Pediatrics, Thoracic, and Vascularized Composite Allograft. All Committees were supportive of the proposal. Nine of eleven regions supported the proposal. Regions 2, 9, and 10 had unanimous support. Four professional societies, ASTS, AST, American Society for Histocompatibility and Immunogenetics (ASHI), and North American Transplant Coordinators Organization (NATCO), all submitted comments in support of the proposal.

Region 3 did not support the proposal. Region 8 was split (6-8-8). Two individuals commented on the proposal and expressed concerns. All comments will be detailed below according to themes that emerged through public comment.

The Committee received feedback on the two specific questions posed to the community as part of 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?

The Committee also received feedback on the following additional topics:

1. Support to clarify policy
2. Timing of informed consent
3. Importance of pre-transplant education and best practices
4. Patient centric materials
5. Risk proportion needs balance
6. Frustration with PHS increased risk guideline requirements

#### *Feedback Question 1: Signature and Documentation Requirements*

The DTAC asked for specific feedback on two questions. The first question was whether a signature should be required for informed consent. Current policy requires documentation of the discussion and informed consent. It does not specify that a signature is required. The majority of respondents did not believe that a signature should be required in policy. Obtaining informed consent after organ offer and before transplant is often done in a phone call when the organ offer is made. Obtaining a signature might not be practical due to the timing. Some respondents requested that policy be silent on this issue, however, the DTAC believes that the minimum requirement must be in policy to reduce transplant community confusion and to establish the baseline for monitoring. The ASTS and the PAC favored obtaining a patient signature. After considering these comments, the DTAC decided to leave the policy as is which requires discussion and documentation. Policy is the minimum requirement and transplant programs can obtain signatures if they choose. Table 2 below summarizes responses to the feedback question.

**Table 2: Summary of public comment responses: Is signature needed for informed consent?**

	Patient Signature Required	Documentation Without Patient Signature	Other suggestions
Regions		4 total (3, 7, 8, 10)	<ul style="list-style-type: none"> <li>• Either but do not specify in policy (2)</li> <li>• Let transplant program decide (3)</li> </ul>
Committees	Patient Affairs (except 1 member)	Pediatrics Thoracic	<ul style="list-style-type: none"> <li>• Mirror increased risk process (Kidney)</li> <li>• Do not specify in policy (Liver)</li> <li>• No strong preference (MPSC)</li> </ul>
Professional Organizations	ASTS	NATCO	<ul style="list-style-type: none"> <li>• No consensus do not specify in policy (AST)</li> </ul>
General Public	1 individual		

*Feedback Question 2: Specific Conditions*

The second feedback question DTAC asked was for concerns or comments about the list of conditions in the current candidate screening and re-execute the match OPTN Policies. The issue of whether CMV screening is still clinically relevant for intestine candidates has been anecdotally raised during other projects. In addition, screening for hepatitis B surface antigen (HBsAg) has not been included historically in candidate screening due to small numbers and lack of use. As treatments have emerged and NAT testing helps differentiate past exposure versus active viremia, use of organs with positive results for HCV has been increasing. Between 2013 and 2018, the number of HCV positive deceased donors with at least one organ transplanted rose from 361 to 775 and the proportion rose from 4.4% to 7.5% of all deceased donors<sup>2</sup>. While it has been more common to transplant positive donor organs into positive recipients, there are programs that are now using HCV antibody positive/NAT negative (Ab+/NAT-) organs for negative recipients. Given these changing trends in transplantation since 2007 when programming for candidate screening started, and 2015 when policies were last amended, the DTAC requested feedback on specific conditions used for candidate screening (Policy 5.3.B Infectious Disease Screening Criteria) and re-executing the match (5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results) Policies. Based on public comment, the DTAC decided not to make changes to those policies at this time. The feedback, however, was used to shape the proposed informed consent policy. Table 3 below summarizes public comment on this question.

**Table 3: Summary of public comment responses: Do conditions for candidate screening and re-execute the match need to change?**

	Yes	Yes	No	Other
	Add	Delete		
Regions		CMV 5 total (1,3,8,9,11)  Hepatitis C Ab+/NAT- 1 total (9)	1 total (2)	<ul style="list-style-type: none"> <li>• Living list outside policy (7)</li> <li>• Not enough conditions (8)</li> </ul>

<sup>2</sup> Data obtained from the OPTN database on May 3, 2018; data subject to change based on future data submission or correction.

	Yes	Yes	No	Other
	Add	Delete		
Committees	EBV for Pediatrics CMV for all organs (Patient Affairs)	CMV (Liver and Intestines Operations and Safety Pediatrics)  Hepatitis B Core or Hepatitis C Ab+/NAT- (Thoracic)	Kidney MPSC	<ul style="list-style-type: none"> <li>Living list outside policy (MPSC)</li> </ul>
Professional Organizations	CMV for all organs (AST Kidney Community of Practice)		AST ASTS NATCO	
General Public	CMV for all organs/ (2 individuals)			

Region 11 supported the proposal with an amendment to remove CMV (intestines only) from informed consent requirements. Region 3 felt that the OPTN should not be making policy regarding informed consent and that transplant hospitals should develop their own informed consent policies. Region 8 was split (6-8-8) due to disagreements over what specific conditions should require informed consent and a general sentiment that more conditions should be in informed consent requirements. Both individuals who submitted comments felt that informed consent for CMV should be required for all organs due to serious sequelae that can happen.

Due to scope of the debate and the changes made post public comment, the summary of Committee discussions will be outlined in a separate section below.

*Support to clarify policy*

In general, the transplant community was highly supportive of simplifying and clarifying the policy. The challenge of defining “known medical condition” that can be transmitted according to “medical judgment” was acknowledged. The DTAC, along with multiple audiences, discussed conditions warranting informed consent. The discussions took into account recent data regarding: risk of disease transmission, availability of effective prophylactic and treatment strategies, organ shortage, organ utilization, risk of organ discard, and mortality on the waiting list. These discussions led to better understanding that there were no perfect answers and where to draw the line is not obvious. The Committee intends for this policy to be a minimum standard. Transplant hospitals should obtain informed consent when needed according to their internal policies, state laws, and to be compliant with the CMS CoPs if they are a Medicare or Medicaid provider.

*Timing of informed consent*

Some commenters felt that the timing could be better clarified in policy. There is the general informed consent that applies to all candidates (or potential candidates) that must be completed before transplant. Based on the request, the DTAC proposed to change the timing clause here to read “any time prior to” as opposed to “before”. There are other additional circumstances that require informed consent prior to transplant such as when a donor meets criteria for being PHS increased risk. This additional consent requirement is specific to a potential transplant recipient (defined in OPTN Policy as a candidate appearing on a match run). Because this requirement is based on an identified donor, the timing must be logically after organ offer. Current policy language uses the term “before transplant”. This language will be clarified to state, “after organ offer but before transplant”.

A concern is that the community might still misinterpret policy and for example obtain consent during the evaluation period for using a PHS increased risk donor and believe that they have completed the requirement. The error would be not realizing that consent currently is and will still be required for these type of donors (increased risk) after organ offer yet prior to transplant for both deceased and living donors.

DTAC does plan to develop and provide significant education to the community to help dispel any misperceptions.

*Importance of pre-transplant education and best practices*

The importance of conducting a thorough general informed consent and providing candidate education throughout the process was suggested. The Committee will be working with the UNOS Professional Education department to develop education on this topic. The DTAC moved general consent to the beginning of the policy to emphasize its importance as well as be in chronological order. DTAC believes that prior to listing or during the evaluation process is the best time to have an educated and comprehensible informed consent. The Committee believes this is when the likelihood of being offered an organ positive for CMV or EBV should be discussed as the majority of transplants performed are from donors positive for one or both conditions. Regardless of the proposal outcome, the DTAC will serve as a subject matter expert (SME) to help develop professional education materials on this topic.

*Patient centric materials*

Several members have asked for checklists or standard information that can be given to candidates in order to help with the informed consent process. Commenters identified the need for materials that are patient centric with appropriate health literacy and cultural competency incorporated in their development. The DTAC is checking on an effort started with AST to develop patient materials related to increased risk. The hope is that this effort could help meet this need.

*Risk proportion needs balance*

Several transplant professionals, including the ASTS representative on the informed consent work group, raised the concern that we are overemphasizing certain risks without providing appropriate balance. Some risks are heavily regulated in mandated informed consent (e.g. increased risk) while others such as the “number of sclerosing glomeruli” on a kidney are not. There is concern that too much emphasis on obtaining informed consent for certain risks compared to the risk of dying on the waitlist leads to unnecessary patient fear and organ turn downs. A balanced approach to risk will be included in professional education efforts. The DTAC is aware of this concern. They put some risk perspective in the [guidance document](#) “Understanding the Risk of Transmission of HIV, Hepatitis B, and Hepatitis C from U.S. PHS Increased Risk Donors” published last year addressing use of increased risk organs.

*Frustration with PHS increased risk guideline requirements*

Several commenters raised specific frustration with the PHS increased risk guideline designation and OPTN informed consent requirements suggesting again that they do not balance the risk of refusing a transplant. It is feared that some tenets in the increased risk definition might be causing undue concern for candidates and leading to organ discard. The relevancy of the concern is growing as now one-quarter of all deceased donors fall within the increased risk definition and therefore must be consented to receive the organ. OPTN data from 2017 show that 2,704 out of 10,286 (26%) deceased donors were classified as increased risk.<sup>3</sup>

The DTAC has worked to publish more information about concerns related to organs from donors with intravenous drug use (IVDU). From data available, these donors appear to be most likely to transmit HIV, HBV, or HCV. While this is of continued concern due to the growing opioid epidemic and subsequent increase in donors with this type of history, the converse consideration of relatively good organ quality due to the younger age of most IVDU and availability of treatments for HCV is not heard as often. The risk of using these organs might be perceived as greater than the actual data indicate. Furthermore, other risks, such as the risk of dying on the waitlist, might not be considered in appropriate perspective given the emphasis on PHS increased risk. Member concerns have been shared with the CDC ex-officio DTAC member. The PHS includes CDC who develops and publishes the guideline. The OPTN is not the author of and cannot change the guideline. The OPTN, however, is bound within the Final Rule to be consistent with CDC guidelines for donor testing and recipient follow up and thus parts of the PHS increased risk guideline have been incorporated into OPTN policy.

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<sup>3</sup> United Network for Organ Sharing Research Department. What do the Numbers Say? OPTN/UNOS Descriptive Data Analyses. Prepared for the DTAC Full Committee. March 29, 2018.

## Post Public Comment Changes for Specific Conditions and Other Considerations

### *CMV*

Based on public comment, DTAC leadership proposed eliminating CMV from the requirements. Contradictory responses were raised during public comment period; while a few comments favored consent for CMV, and even extending it to ALL organ types, most responses opposed having consent being part of an OPTN/UNOS policy. The DTAC concluded that a robust discussion about CMV should take place initially at the time of listing for transplant if possible. The proposed policy includes the expectation that discussions about conditions such as CMV will happen during the general informed consent process. An educational initiative is planned to promote these discussions at a time when then the patient can ask questions and receive answers outside of the pressured time of organ offer.

The feedback received from the Liver and Intestines Committee, as well as the Pediatric Committee, weighed heavily in making this recommended change. These groups have the greatest concerns for their constituencies since currently it is only required for intestinal transplants. Accordingly, it was felt that CMV should be removed from the informed consent requirement for intestinal transplants at the time of organ offer. These groups also questioned the necessity of having CMV as part of candidate screening and re-executing the match run; however Region 11 felt strongly that CMV screening was still applicable even if removed from the consent policy.

To determine the impact, current data were reviewed. In 2017, there were 108 intestine donors and 44 of them were CMV positive.

Because of the small number and resources required for IT programming changes, the DTAC did not want to propose changes for candidate screening and re-execute the match policies with this proposed action.

### *HBV and HCV*

The DTAC remained cognizant of the need to be consistent with CDC recommendations as per the Final Rule. The PHS increased risk guideline recommendation 14 states: "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." Accordingly, it was felt that HBV and HCV should be included in the informed consent policy.

Excluding only CMV for intestines would likely be confusing if the policy were tied to candidate screening and re-execute the match policies. Furthermore, the Committee decided that the policy did not need to match as candidate screening might be a larger set of conditions as it exists for both efficiency and safety reasons. It was decided to return to listing the conditions in the policy that would require informed consent.

DTAC members had a lengthy discussion as to whether anti-HBc and anti-HCV (HBV and HCV antibody tests, respectively) should be included in the age of NAT which indicates active infection. The factors that were included in the discussion included: risk of disease transmission, available effective prophylactic and treatment strategies, organ shortage, organ utilization, risk of organ discard, and mortality in the waitlist. Recent single center cohort studies and the 2017 AST HCV Consensus Conference stated that organs from donors who were HCV Ab+/NAT- confer a low risk of transmission as these results indicate past but not active infection. Furthermore, the available new therapies for HCV are highly effective in solid organ transplantation.

When DTAC studied several cases where unexpected transmission occurred in HCV Ab+/NAT – donors it turned out that all of these donors were PHS increased risk due to IVDU with a cause of death related to active drug use and overdose. The risk of disease transmission is likely to be related to their risk for acquisition of a new HCV infection. These cases likely represent donor HCV re-infection during the eclipse period of NAT testing. Although NAT is highly sensitive, it does not detect HCV until 3-5 days after infection. Candidates electing to accept these organs would be consenting for increased risk due to being increased risk (IVDU). To date, all cases of HCV transmission from HCV Ab+/NAT- donors have been from PHS increased risk donors with IVDU and other risk factors.

The Committee also debated whether to include anti-HBc as a positive test indicative of HBV infection. In some cases, HBV can remain dormant in the liver and become reactivated. The Committee discussed the availability of vaccination and prophylaxis as the strategy to mitigate this low risk. DTAC believes that the HBV results should be considered as part of an individual recipient/organ donor quality discussion, given that the majority of transplants pose essentially no recipient risk. In addition, as with CMV, recipients can be given prophylaxis to prevent disease. The proposed general informed consent requirement addresses this issue by adding the clause that centers need to inform candidates that test results can impact post-transplant management (e.g. need to give prophylaxis). Enforcing consent on centers using HBVcAb+ (yet HBsAg and NAT negative) donors particularly for non-liver recipients, when the documented risk of transmission under those circumstances is very low, may actually result in more discards. After much debate and based on the above considerations, the Committee decided on not including the antibody tests for HBV and HCV in the informed consent requirements. The proposal will include positive tests for HBsAg, HBV NAT, and HCV NAT as these represent active viremia.

The DTAC did consider the PHS increased risk guideline definition of what positive tests define infection in the donor. The PHS guideline uses the term “presumed infected” and includes any donor with a positive test for antibody and/or NAT results. For HBV, this includes anti-HBc, HBsAg, and/or NAT. For HCV, this includes anti-HCV and/or NAT. OPTN Policy must be consistent with but not necessarily identical to the recommendations according to the Final Rule. For example, in current policies, the OPTN requires post-transplant testing for HIV, HBV, and HCV after use of an increased risk donor organ. These policies do not specify timing or test type while the PHS increased risk guideline is more specific. After the DTAC had agreed upon the concept for the policy, the UNOS/OPTN general legal counsel and Chief Medical Officer were consulted. They agreed that the DTAC definition using HBV and HCV NAT results, as well as HBsAg, but not including antibody tests would be sufficiently consistent with the PHS increased risk guideline and therefore meet the OPTN obligation in the Final Rule.

#### *Informed Consent Cross-Reference in Re-Executing the Match Policy*

Once the DTAC agreed upon the concept to limit informed consent requirements to test that equate to active viremia, the Committee discussed an existing cross reference in *Policy 5.5.B: Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results to Policy 15.3.A: Donors with Additional Risk Identified Pre-transplant*. When a candidate has accepted an organ with a pending result that then is found to be positive, the candidate who has accepted the organ has the right to continue with the acceptance and transplant once informed and consented about the positive result. The proposed conditions in informed consent policy would not be an exact match to those that trigger a new match run if certain positive results become available.

Data were reviewed. In 2017, there were 69 donors who met the potential re-execute the match criteria where a match was run prior to having results but subsequent positive results became available and at least one organ was still transplanted. Of the 69 donors, 14 donors had at least one organ accepted at the time the positive results became known. Only three recipients had indicated on candidate screening that they did not want that type of positive organ (1= HBcAb, 2 = HCV Ab)<sup>4</sup>. In these cases, the positive results did not change the outcome. These three recipients continued with acceptance and transplantation of these organs. The other recipients had indicated that they would accept positive organs on the candidate screening.

The revised proposed policy would not require result disclosure or informed consent to those undergoing a match re-run, although transplant centers could have internal policies to do this. The revised proposed policy would not require result disclosure or informed consent although transplant centers could have internal policies to do so. The number of recipients for whom this cross-reference might apply is small (n =20) and the DTAC believes that most users will primarily use Policy 15.3 as their reference. This positive CMV or antibody results should be handled similarly to how EBV and CMV will be handled. It is not known at the time of listing if patients had the discussion with their providers about what type of organ would be accepted. In addition, a significant amount of time may have passed (e.g. 6 years for one of the three who received a kidney) and therefore the medical rationale might have changed (e.g. patient’s health worsening

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<sup>4</sup> Data obtained from the OPTN database on April 16, 2018; data subject to change based on future data submission or correction.

and cannot wait for other offers). Transplant hospitals will be required to obtain informed consent from candidates accepting actively infected HBV or HCV NAT positive donor organs.

The post public comment changes in summation include:

- Requiring informed consent for a smaller subset of positive tests that indicate active disease outlined in Table 4 below.
- Clarifying timing language for both the general informed consent and the informed consent required for certain conditions after organ offer
- Other minor edits for clarity and brevity

**Table 4: Post Public Comment Changes for Informed Consent of Transmittable Disease**

<b>If donor is positive for (test name below), then informed consent is required after organ offer and prior to transplant</b>	<b>Public Comment Tie to candidate screening and re-execute the match policy conditions</b>	<b>Final Post PC Proposal Delete anti-HBc and anti-HCV. Tests do not indicate active viremia.</b>
Anti-HBc (HBV core antibody)	Yes	No
HBsAg	No	Yes
HBV NAT	Yes	Yes
Anti-HCV (HCV antibody)	Yes	No
HCV NAT	Yes	Yes
CMV Intestines (INT) only	Yes	No

The DTAC voted unanimously (15-0) at their April 24, 2018 teleconference to send the proposed policy to the OPTN/UNOS Board of Directors for consideration at their June 2018 meeting.

## 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 regards to 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 for conditions as specified.

An analysis of 2017 data would mean that recipients taking an organ from the numbers of donors shown below in Tables 5 and 6 would have to provide informed consent after being offered an organ from that donor yet prior to transplant.

**Table 5: Estimated numbers of deceased donors whose organs would require informed consent in proposed Policy 15.3.B Donors with Risk Identified Pre-Transplant**

<b>Informed Consent Condition or Test</b>	<b>Number with Test Result Reported</b>	<b>Number with Condition or Positive Test</b>	<b>Positive Test Result but not Increased Risk</b>
HBsAg +	10,280	11	8
HBV NAT +	10,284	16	7
HCV NAT +	10,285	503	80

Informed Consent Condition or Test	Number with Test Result Reported	Number with Condition or Positive Test	Positive Test Result but <i>not</i> Increased Risk
Increased Risk	N/A	2,704	N/A
Hemodiluted Specimen	N/A	181*	N/A
HOPE Act (HIV + for any test)	See below	9**	See below
Anti-HIV (HIV Ab)	10,218	13	7
HIV Ab/Ag Combo	106	0	0
HIV NAT	10,285	6	4
Total Donors	10,286	2,814	

Based on OPTN Data as of May 4, 2018; data subject to change based on future data submission or correction.

+ = positive

\* = depends on test. Low (172) = HIV Ab; High (181) = HBV & HIV NAT

\*\* = 9 donors resulting in 19 transplants in 2017. 25 deceased donors since HOPE Act Implementation (11/2015). 51 transplants (31 kidney, 19 liver, 1 en-bloc kidney)

**Table 6: Estimated numbers of living donors whose organs would require informed consent in proposed *Policy 15.3.B Donors with Risk Identified Pre-Transplant***

Informed Consent Condition or Test	Number with Test Result Reported	Number with Condition or Positive Test
HBsAg +	6,161	29
HBV NAT +	6,161	9
HCV NAT +	6,161	3
Increased Risk	Not collected	Not collected
Hemodiluted Specimen	Not applicable	Not applicable
HOPE Act (HIV status reported to OPTN)	6,161	0
Total Donors	6,188	41

Based on OPTN Data as of May 4, 2018; data subject to change based on future data submission or correction.

## 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 UNetSM.

There will not be any additional research needs or changes for Organ Center operations. Professional Education will provide an educational program prior to the implementation of the policy that will focus on the policy changes and effective practices for discussing and obtaining informed consent.

## **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 (HBsAg and NAT) and HCV (NAT), 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 HBV and HCV viremic 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 recipient or the 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 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

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 will 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 recipient or the recipient's agent gave consent before transplant when:

- An organ was accepted from a donor who tested positive for:
  - Hepatitis B surface antigen (HBsAg)
  - Hepatitis B nucleic acid test (NAT)
  - Hepatitis C NAT

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

## **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~~).

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**RESOLVED, that changes to Policies 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**

### **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:~~

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

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### 54 **15.3.A General Risks of Potential Malignancy or Disease Transmission**

55 Transplant programs must ~~also~~ inform ~~potential~~ candidates of the general risks of potential

56 transmission of malignancies and diseases from organ donors, including *all* of the following

57 information:

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- 59 1. Deceased donors are evaluated and screened according to as outlined in Policy 2.3:
- 60 Evaluating and Screening Potential Deceased Donors.
- 61 2. Living ~~Donors~~ are required to undergo screening for ~~the~~ diseases listed in according to
- 62 Policy 14.4: Medical Evaluation Requirements for Living Donors.
- 63 3. ~~That~~ There is no comprehensive way to screen deceased and living donors for all
- 64 transmissible diseases.
- 65 4. ~~That transmissible~~ Malignancies and diseases ~~and malignancies~~ may be identified and
- 66 transmitted after transplant.
- 67 5. Donor evaluation and screening results may impact post-transplant evaluation, screening,
- 68 and management of the candidate.

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

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

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### 76 **15.3.AB Donors with Additional Risk Identified Pre-Ttransplant**

77 If ~~additional donor disease or malignancy transmission risk is identified pre-transplant, the~~

78 ~~transplant program must do all of the following:~~

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

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86 Transplant programs must meet the requirements according to Table 15-1 below when the

87 deceased or living donor has risk of disease transmission identified pre-transplant.

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**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"> <li>• <u>The donor tests positive for <i>any</i> of the following:</u> <ul style="list-style-type: none"> <li>a. <u>Hepatitis B surface antigen (HBsAg)</u></li> <li>b. <u>Hepatitis B nucleic acid test (NAT)</u></li> <li>c. <u>Hepatitis C NAT</u></li> </ul> </li> <li>• <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></li> <li>• <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></li> <li>• <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></li> </ul>	<ol style="list-style-type: none"> <li>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></li> <li>2. <u>Document this consent in the intended recipient's medical record</u></li> <li>3. <u>Follow the recipient for the development of potential donor-derived disease after transplant</u></li> </ol>

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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 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 ~~a#~~ both of the following in addition to routine post-transplant care:

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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

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*[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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