OPTN

Public Comment Proposal

Modify Living Donor Exclusion Criteria

OPTN Living Donor Committee

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Contents

Modify Living Donor Exclusion Criteria

Affected Policies: *14.4.E: Living Donor Exclusion Criteria*
Sponsoring Committee: *Living Donor*
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Executive Summary

The OPTN Living Donor Committee (the Committee) is proposing to modify *OPTN Policy 14.4.E: Living Donor Exclusion Criteria*. This policy lists fourteen exclusion criteria to living donation. The majority are applicable for all living donors, while some are specific to living kidney and liver donors. The purpose of the proposed modifications are to align exclusion criteria for living donation with current research. The request to evaluate living donor exclusion criteria originally came from transplant community members who identified that modifications to certain living donor exclusion criteria may be warranted. The member requests were specific to the malignancy and diabetes exclusion criteria, but to ensure the relevancy of the entire policy, the Committee found it appropriate to evaluate each exclusion criterion for living donation. The Committee concludes that the majority of living donor exclusion criteria remain current and relevant in order to protect living organ donors. The Committee proposes four modifications to reduce barriers to living donation, while maintaining the protection of living donors.

Purpose

The purpose of the Committee's review of *OPTN Policy 14.4.E: Living Donor Exclusion Criteria* is to ensure the relevancy of living donor exclusion criteria, propose modifications supported by current research, and broaden individuals' opportunities to become living organ donors from a perspective of maintaining living donor and transplant recipient safety. A holistic review and assessment of *OPTN Policy 14.4.E* was completed as the living donor exclusion criteria have not been evaluated since its implementation in 2014. The Committee strives to protect the safety of living donors and transplant recipients, while also ensuring barriers to living donation are limited.

Background

In 2012, the OPTN Board of Directors approved the *Establish Requirements for the Medical Evaluation of Living Kidney Donors* proposal*,* which improved and standardized the psychosocial and medical evaluations for all living kidney donors.[1] Additionally, this policy proposal established living donor exclusion criteria applicable for living kidney donors.[2] Instead of implementing additional living liver donor evaluation requirements, the Committee concluded to expand policy to encompass all living donors.[3] In 2014, the OPTN Board of Directors approved *Modify Existing or Establish Requirements for the Psychosocial and Medical Evaluation of all Living Donors,* developed by the Committee. The proposal expanded the living donor exclusion criteria to include all living donors as well as added exclusion criteria specific to living kidney and living liver donors (**Table 1**).

A modification to the human immunodeficiency virus (HIV) exclusion criterion was approved by the OPTN Board of Directors in 2015.[4] The exclusion criterion was modified to add that transplant programs with an approved variance, according to *OPTN Policy 15.7: Open Variance for the Recovery and Transplantation of Organ from HIV Positive Donors*, may transplant an organ from an HIV positive individual to an HIV positive transplant candidate.[5]

Additional OPTN policy references to living donor exclusion criteria are found in OPTN policy for domino donors and non-domino therapeutic donors as well as kidney paired donation (KPD). Domino and non-domino therapeutic donors are not subject to living donor exclusion criteria as OPTN policy specifies that transplant programs may incorporate *OPTN Policy 14.4.E: Living Donor Exclusion Criteria* as appropriate.[6] In contrast, living donor exclusion criteria applies to living kidney donors who enter into the OPTN Kidney Paired Donation Pilot Program (KPDPP) per *OPTN Policy 13.6.B: Requirement for Match Run Eligibility for Potential KPD Donors*.[7]

[1] OPTN Living Donor Committee, *Briefing Paper*, Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors. Public Comment Period September 16, 2011 – December 23, 2011. https://optn.transplant.hrsa.gov/media/4772/continuous_distribution_of_lungs-public_comment.pdf.
[2] Ibid.
[3] OPTN Living Donor Committee, *Public Comment Proposal*, Proposal to Modify Existing or Establish Requirements for the Psychosocial and Medical Evaluation of all Living Donors. Public Comment Period, March 14, 2014 – June 13, 2014. https://optn.transplant.hrsa.gov/media/1451/pubcommentpropsub_337.pdf.
[4] OPTN Organ Procurement Organization Committee*, Public Comment Proposal,* Proposal to Address the Requirements in the HIV Organ Policy Equity Act. Public Comment Period January 27, 2015 – March 27, 2015. https://optn.transplant.hrsa.gov/media/1147/0115_04_opo_hope_act.pdf.
[5] OPTN Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors
[6] OPTN Policy 14.9.B: Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors
[7] OPTN Policy 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors

Table 1: Living Donor Exclusion Criteria in OPTN Policy[8]

Exclusion criteria for all Living Donors	Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation. Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria: • Is both less than 18 years old and mentally incapable of making an informed decision • HIV, unless the requirements for a variance are met, according *to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
Additional Exclusion Criteria for Living Kidney Donors	Kidney recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • Uncontrollable hypertension or history of hypertension with evidence of end organ damage • Diabetes
Additional Exclusion Criteria for Living Liver Donors	Liver recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor

Transplant community members have contacted the Committee stating that certain sections of living donor exclusion criteria are outdated. Requests to re-evaluate this policy were specific to the living donor exclusion criteria that exclude individuals with active malignancies, or incompletely treated malignancies, and individuals with diabetes. Member feedback cited that these two exclusion criteria are too restrictive based on recent research and updated published guidelines. One inquiry explained that current policy language restricts transplant programs from evaluating potential living donors with low grade malignancies, such as low grade prostate cancer citing that the management of prostate cancer has advanced significantly over the past decade. An additional inquiry stated that type 2 diabetes is no longer an absolute contraindication for living kidney donation, and the current exclusion criterion is too restrictive as it exempts these individuals as suitable living kidney donors.

The Committee formed an Exclusion Criteria Subcommittee (the Subcommittee) to review these member requests, analyze recent research and data, and discuss clinical expertise. Additionally, the Subcommittee reviewed updated guidelines from British Transplantation Society, European Renal Best

[8] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021

Practices Transplantation, and Kidney Disease: Improving Global Outcomes (KDIGO).[9,10,11] While these guidelines provide variations in recommendations, there is consensus that diabetes and malignancy as absolute contraindications for living donation are outdated. The Subcommittee concluded that changes may be warranted and recommended that the Committee continue forward with a project to evaluate *OPTN Policy 14.4.E: Living Donor Exclusion Criteria* in its entirety to ensure protection of living donors and transplant recipients.[12]

Overview of Proposal

Proposed Modifications to Living Donor Exclusion Criteria

"Active malignancy, or incompletely treated malignancy"[13]

The Committee proposes to modify this exclusion criterion for all living donors to allow transplant programs more autonomy in evaluating potential living donors who have active malignancies or incompletely treated malignancies. The Committee acknowledges that there is a broad spectrum of malignancies, and that individuals with low-grade malignancies may be acceptable living donors, as current literature shows the safety for both living donors and transplant recipients.[14]

KDIGO guidelines state that potential living donors may be considered in some cases of "active malignancy with low transmission risk, clear management plan, and minimal risk to the donor".[15] A review of a major living liver donor transplant program in Korea reported that the decision to donate for potential living liver donors who have minimal risk malignancies should be based on individualized clinical judgement and comprehensive informed consent.[16] The British Transplantation Society's guidelines recommend active malignant disease as a contraindication to living donation, but recognizes that consideration for potential living donors with certain types of successfully treated low-grade tumors may be acceptable after careful evaluation and discussion.[17]

The Committee seeks to avoid creating lists of malignancies that are absolute contraindications as well as mandating specific risk thresholds, and prefers to allow transplant programs to have autonomy in their living donor evaluation and acceptance practices. The Committee also recognizes that potential living donors need to be involved in decision-making, and transplant medical professionals should engage these individuals in shared decision-making.[18]

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[9] British Transplantation Society & The Renal Association, Guidelines for Living Donor Kidney Transplantation. (March 2018). https://bts.org.uk/wp-content/uploads/2018/07/FINAL_LDKT-guidelines_June-2018.pdf.
[10] European Renal Best Practice Transplantation guideline development group, Guideline on the Management and Evaluation of the Kidney Donor and Recipient (August 2013). https://www.era-online.org/en/erbp/guidance/transplantation/transplantation/.
[11] KDIGO, Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors. (August 2017). https://kdigo.org/wp-content/uploads/2017/07/2017-KDIGO-LD-GL.pdf.
[12] OPTN Living Donor Committee, *Meeting Summary*, April 19, 2021. https://optn.transplant.hrsa.gov/media/4607/20210419_ldc_summary.pdf.
[13] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021.
[14] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021. https://optn.transplant.hrsa.gov/media/xwzhj1si/20210913_ldc_summary_final.pdf.
[15] KDIGO, Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors. (August 2017).
[16] Nugroho, A., et al. "Evaluation of donor workups and exclusions in a single-center experience of living donor liver transplantation", *Liver Transplantation.* (2017); 23(5):614-624. doi: 10.1002/lt.24762.
[17] British Transplantation Society & The Renal Association, Guidelines for Living Donor Kidney Transplantation. (March 2018).
[18] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021.

The proposed modifications allow transplant programs to evaluate individuals who have low-grade malignancies that do not require current or future treatment, other than surveillance, or have a minimal risk of transmission to the transplant recipient, for living donation. Below are summaries detailing specific considerations the Committee made regarding transmission of risk, low-grade malignancies, and treatment of malignancies, in order to lend further context to the intent of this modification.

Risk of transmission
The proposed modifications to this exclusion criterion allows transplant programs to evaluate individuals whose malignancy has a minimal risk (i.e. less than 0.1 percent) of transmission to the recipient for living donation.

The Committee referenced a framework developed by a subcommittee of the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC), which reviewed literature to develop an approach to risk evaluation in malignancy.[19] While this framework was not specific to living donor malignancies, the Committee found it to be appropriate to apply these risk categorizations to living donors with malignancies. Literature on living donation and malignancy also apply this framework developed by DTAC.[20, 21, 22] The article specifies that minimal risk is equal to, or less than, 0.1 percent.[23] The Committee concluded that individuals with malignancies that have a minimal risk of transmission could be acceptable for living donation based on clinical judgement and informed consent.[24] The Committee does not seek to mandate specific risk thresholds in policy, and prefers to have transplant programs, potential living donors, transplant candidates, and families participate in shared decision making.

For additional context, the risk category of transmission above minimal risk is low risk, defined as a range greater than 0.1 percent to less than, or equal, to 1 percent.[25] The proposed modifications to this exclusion criterion does not intend for potential living donors with malignancies that have a low risk of transmission to the transplant recipient to become living donors. Several articles cite that living donors with low risk malignancies should only be utilized when a transplant candidate has a significant risk of mortality.[26, 27]

Low-grade malignancies
The proposed modifications to this exclusion criterion allows transplant programs to evaluate individuals who have low-grade malignancies for living donation. For an example of an allowable low-grade

[19] Nalesnik, M., et al. "Donor-transmitted malignancies in organ transplantation: Assessment of clinical risk", *American Journal of Transplantation.* (2011);11(6):1140-1147. doi: 10.1111/j.1600-6143.2011.03565.x.
[20] Claisse, G., Gaillard, F., Mariat, C. "Living kidney donor evaluation", *Transplantation.* (2020);104(12):1487-1496. doi: 10.1097/TP.0000000000003242.
[21] Nugroho, A., et al. "Evaluation of donor workups and exclusions in a single-center experience of living donor liver transplantation", *Liver Transplantation.* (2017);23(5):614-624. doi: 10.1002/lt.24762.
[22] British Transplantation Society & The Renal Association, Guidelines for Living Donor Kidney Transplantation. (March 2018). https://bts.org.uk/wp-content/uploads/2018/07/FINAL_LDKT-guidelines_June-2018.pdf.
[23] Nalesnik, M., et al. "Donor-transmitted malignancies in organ transplantation: Assessment of clinical risk", *American Journal of Transplantation.* (2011);11(6):1140-1147. doi: 10.1111/j.1600-6143.2011.03565.x.
[24] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021.
[25] Nalesnik, M., et al. "Donor-transmitted malignancies in organ transplantation: Assessment of clinical risk", *American Journal of Transplantation.* (2011);11(6):1140-1147. doi: 10.1111/j.1600-6143.2011.03565.x.
[26] Kirchner, V., Liu, P., & Pruett, T. "Infection and cancer screening in potential living donors: Best practices to protect the donor and recipient", *Current Transplant Reports.* (2015);2, 35-43. doi: 10.1007/s40472-014-0049-y.
[27] Nugroho, A., et al. "Evaluation of donor workups and exclusions in a single-center experience of living donor liver transplantation", *Liver Transplantation.* (2017);23(5):614-624. doi: 10.1002/lt.24762.

malignancy, the Committee notes that individuals with low-grade prostate cancer may be acceptable living donors.

Prostate cancer is a highly diverse disease, ranging from remarkably slow progression or inactivity to highly aggressive and fatal.[28] Therapeutic decision-making and outcome greatly depend on the appropriate stratification of patients to risk groups which help differentiate between benign versus more aggressive states, and significant progress has been made in this area.[29] Literature reports that in over 100 kidney transplants from deceased donors with prostate cancer, there were no reported malignancy transmissions.[30] Additionally, 10-year patient survival for an individual with low-grade prostate cancer is 99 percent.[31] The proposed modifications to this exclusion criterion removes the current barriers for individuals such as this so they have the opportunity to become living donors.

Treatment of malignancies
The proposed modifications to this exclusion criterion allows transplant programs to evaluate individuals who do not require current or future treatment of their malignancy for living donation. Individuals whose malignancy requires surveillance may be acceptable living donors.

Due to the mention of treatment in the proposed modifications, an individual with a known, non-melanoma skin cancer should be excluded due to the knowledge that future treatment of the potential living donor would be required. While basal cell carcinoma and squamous cell carcinoma are categorized as minimal risk of transmission within the malignancy risk categorizations, the proposed modifications do not intend to allow individuals with these types of malignancies to donate before appropriate treatment.[32] The Committee reasons that individuals with these types of malignancies should undergo treatment and resection before proceeding with living organ donation surgery.[33] Basal cell carcinoma and squamous cell carcinoma can be treated in a short time frame, and it is in the best interest of the donor to seek treatment before participating in an elective surgery.

Regarding individuals with malignancies under surveillance, the U.S. Preventive Services Taskforce, as well as other organizations, have found active surveillance of low grade prostate cancer to be an acceptable treatment.[34] Active surveillance of low-grade prostate cancer may limit the harms of active treatment by forgoing surgery or radiation in favor of ongoing monitoring.[35]

The Committee proposes modifying this exclusion criterion with the following language: “Active or incompletely treated malignancy that requires treatment, other than surveillance, or more than minimal risk of transmission”.

[28] Adamaki, M. & Zoumpourlis, V. “Prostate cancer biomarkers: From diagnosis to prognosis and precision – guided therapeutics”, *Pharmacology & Therapeutics.* (2021);228, 107932. doi: .org/10.1016/j.pharmthera.2021.107932.
[29] Ibid.
[30] Dholakia, S., et al. “Renal donors with prostate cancer, no longer a reason to decline”, *Transplantation Reviews.* (2016);30(1):48-50. doi: 10.1016/j.trre.2015.06.001.
[31] Institute for Quality and Efficiency in Health Care. “Localized prostate cancer: Low-risk prostate cancer: Active surveillance or treatment?”. (2020). https://www.ncbi.nlm.nih.gov/books/NBK487255/.
[32] Nalesnik, M., et al. “Donor-transmitted malignancies in organ transplantation: Assessment of clinical risk”, *American Journal of Transplantation.* (2011);11(6):1140-1147. doi: 10.1111/j.1600-6143.2011.03565.x.
[33] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021.
[34] U.S. Preventive Services Task Force. “Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement”, *JAMA.* (2018);319(18):1901-1913. doi: 10.1001/jama.2018.3710.
[35] Ibid.

"High suspicion of donor coercion"[36]

The Committee proposes to modify this exclusion criterion for all living donors to better align with other OPTN policy references. *OPTN Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements* states that the living donor must be assessed by a psychiatrist, psychologist, or social worker whether their "decision to donate is free of inducement, coercion, and other undue pressure".[37] Additionally, *OPTN Policy 14.3: Informed Consent Requirements* states that the living donor's signature confirms that the donor "is free from inducement and coercion".[38] Due to these additional references to coercion in other OPTN living donor policy, the Committee concluded modifications are necessary for consistency.[39]

An exclusion criterion to address potential living donors who are thought to be induced, coerced, or otherwise pressured into their decision is essential to the ethical basis of living organ donation. The Committee emphasizes that as stewards of the potential living donor's well-being and safety, especially in the context of a surgery with no medical benefit, transplant teams must regard coercive factors as absolute contraindications to living donation. Potential living donors who are influenced by coercive factors are unable to make autonomous and informed choices to donate. The Committee affirms that this exclusion criterion is relevant in ensuring the protection of living donors.

The Committee proposes modifying this exclusion criterion with the following language: "High suspicion of donor inducement, coercion, or other undue pressure".

"High suspicion of illegal financial exchange between donor and recipient"[40]

The Committee proposes to modify this exclusion criterion for all living donors to better align with other OPTN policy references. *OPTN Policy 14.3: Informed Consent* states that living donor recovery hospitals must disclose to living donors that "it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value".[41] Modification to this exclusion criterion will allow for a broader scope as well as consistency within OPTN policy language. The proposed modification specifies that high suspicion of exchange of anything valuable is an absolute contraindication, not solely illegal financial exchanges. The Committee also reviewed NOTA Sec. 274e. Prohibition of organ purchases.[42] The Committee considered adding the term "valuable consideration" into the exclusion criterion but concluded that it may be difficult for living donors and living donor families to understand.[43]

Similar to the aforementioned exclusion criterion for high suspicion of donor coercion, this exclusion criterion is crucial for the ethical basis of living organ donation. The Committee emphasizes that exchange of anything of value interferes directly and substantially with donor autonomy and decision-making. It is prudent for living donor exclusion criteria to uphold standards set in federal law and informed consent policy. The Committee affirms that this exclusion criterion is relevant to protect all living donors.

[36] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[37] OPTN Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements.
[38] OPTN Policy 14.3: Informed Consent Requirements.
[39] OPTN Living Donor Committee, *Meeting Summary,* September 8, 2021.
[40] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[41] OPTN Policy 14.3: Informed Consent Requirements
[42] NOTA 42 U.S.C. §274e.
[43] OPTN Living Donor Committee, *Meeting Summary,* September 8, 2021.

The Committee proposes modifying this exclusion criterion with the following language: "High suspicion of knowingly acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ".

"Diabetes"[44]

The Committee proposes to modify this exclusion criterion for living kidney donors to remove current barriers for select individuals with type 2 diabetes. The Committee proposes for type 1 diabetes to remain an absolute contraindication to living kidney donation.

Type 1 Diabetes
While type 1 and type 2 diabetes may lead to diabetic nephropathy, type 1 diabetes is more likely to lead to end stage renal disease (ESRD).[45] Additionally, type 1 diabetes generally is more common in young adulthood, a critical period of risk for those with type 1 diabetes, and who have many more life years of risk ahead.[46] Due to the vast differences between type 1 diabetes and type 2 diabetes, the Committee concluded retaining type 1 diabetes as an absolute contraindication to living kidney donation is necessary for living kidney donor safety.[47] This is in agreement with the British Transplantation Society, European Best Renal Practices, and KDIGO guidelines.[48, 49, 50]

Type 2 Diabetes
KDIGO and British Transplantation Society guidelines for living kidney donation recommend that the decision to approve potential living kidney donors should be individualized based on demographics, health profiles, and lifetime risk assessments.[51] These guidelines recommend that optimally managed individuals with type 2 diabetes can be considered for living kidney donation after thorough individualized assessments, and in the absence of end organ damage.[52] Although the European Renal Best Practices guidelines recommend diabetes as a contraindication to living kidney donation, it does recognize that donation is allowable in exceptional circumstances.[53]

Much like the current hypertension exclusion criterion, the Committee seeks to allow transplant programs more autonomy in the decision to evaluate select type 2 diabetic individuals as living kidney donors. While the Committee proposes to open the opportunity of becoming a living kidney donor to individuals with type 2 diabetes, they are not comfortable removing type 2 diabetes from living kidney donor exclusion criteria entirely, due to limited long-term outcome data.[54] The proposed modification allows transplant programs to evaluate older individuals with type 2 diabetes, where the time to ESRD or time to chronic kidney disease (CKD) from the diagnosis of type 2 diabetes is longer than their

[44] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[45] Johns Hopkins Medicine. "Diabetic nephropathy (kidney disease)", *Health*. (2021). https://hopkinsmedicine.org/health/conditions-and-diseases/diabetes/diabetic-nephropathy-kidney-disease.
[46] Monaghan, M., Helgeson, V., & Wiebe, D. "Type 1 diabetes in young adulthood", *Current Diabetes Reports.* (2016);11(4)239-250. doi: 10.2174/1573399811666150421114957.
[47] OPTN Living Donor Committee, *Meeting Summary,* October 29, 2021.
[48] British Transplantation Society & The Renal Association, Guidelines for Living Donor Kidney Transplantation. (March 2018).
[49] European Renal Best Practice Transplantation guideline development group, Guideline on the Management and Evaluation of the Kidney Donor and Recipient (August 2013).
[50] KDIGO, Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors. (August 2017).
[51] Ibid.
[52] European Renal Best Practice Transplantation guideline development group, Guideline on the Management and Evaluation of the Kidney Donor and Recipient (August 2013).
[53] Ibid.
[54] OPTN Living Donor Committee, *Meeting Summary,* October 13, 2021.

expected life expectancy, for living kidney donation.[55] Additionally, the individual should have optimally managed type 2 diabetes with no evidence of end organ damage.[56] An individualized assessment of a potential living kidney donor's demographics, comorbidities, and lifetime risk of complications intend to reveal those individuals that should remain excluded from living kidney donation.

The Committee proposes modifying this exclusion criterion with the following language: "Type 1 diabetes" and "Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals evidence of end organ damage or lifetime risk of complications".

Additional Evaluated Living Donor Exclusion Criteria

"Is both less than 18 years old and mentally incapable of making an informed decision"[57]

The Committee considered several modifications but ultimately affirmed to keep this exclusion criterion for all living donors as is in OPTN policy. The Committee discussed the exclusion criterion in two separate categories; 1) age, and 2) informed decision-making. The Committee considered proposing to separate this exclusion criterion into two exclusion criteria, but concluded that would alter the intent.[58]

In regards to age, the Committee acknowledges that there are legal variations in age of maturity among U.S. states and international communities. The Committee discussed modifying the policy language to remove the 18 years old language and replace it with the term "legal age" to allow for the variations in state practices. Additionally, the Committee questioned whether to remove language addressing age restrictions entirely, but concluded that age limits are often included due to the assumption that age connects with the ability to understand, internalize, and repeat back information.[59] Furthermore, NOTA defines children as individuals under the age of 18, and requires the OPTN to "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[60] Therefore, it is important for living donor exclusion criteria to specify certain requirements that consider the safety of children and the future of their health.

In regards to informed decision making, the Committee discussed modifying policy language to specify those who have "superior capacity" or demonstrate to be "mature minors" are able to become living donors. However, the Committee concluded to avoid proposing modifications that are subjective in nature when there was not an identified problem to solve.[61] Additionally, the Committee discussed whether the term "mentally incapable" was too subjective for policy language, but agreed that determining mental capability for informed consent is a part of the evaluation process that potential living donors undergo, therefore it is an acceptable term to maintain.[62]

The Committee acknowledged that the genesis for this living donor exclusion criterion was to express that, in general, living organ donors should be adults but to allow for special circumstances, such as a

[55] Ibid.
[56] Ibid.
[57] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[58] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021.
[59] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021.
[60] NOTA, 42 U.S.C. §274 (b)(2)(M)
[61] OPTN Living Donor Committee, *Meeting Summary,* September 9, 2021.
[62] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021.

parent under the age of 18 donating an organ to their child.[63] The intent of this exclusion criterion is that if a potential living donor is under the age of 18 then they must have the mental capacity to make an informed decision. The Committee reviewed OPTN data of living donors under the age of 18 years and their relationship to the recipient (**Table 2**). Since 2014, there have been eleven living organ donors under the age of 18, all of which were domino donors.[64] A domino donor is an individual who has an organ removed as a component of medical treatment and receives a replacement organ. The organ that was removed is transplanted into another person. [65] It is important to note that domino donors are not required to be evaluated based on living donor exclusion criteria.[66] Review of an expanded timeframe of data prior to 2014 shows that donation to a full, biological sibling is the most common relationship to recipient category for living donors under the age of 18, followed by domino donors.[67]

Table 2: Age of Living Donor and Relationship to Recipient, 2014 - 2021[68]

Age of Living Donor	Total Donations, 2014 - 2021	Relationship to Recipient
<1 Year	0	N/A (n=0)
1-5 Years	0	N/A (n=0)
6-10 Years	1	Non-Biological, Unrelated: Domino (n=1)
11-17 Years	10	Non-Biological, Unrelated: Domino (n=10)

Due to the small number of previous living donors less than 18 years old, as well as transplant programs' determination of informed consent, the Committee did not find just cause to modify this exclusion criterion for living donation, and was cautious in proposing a policy modification that would create unintended consequences. There are rare circumstances in which a team of medical professionals deem a potential living donor less than 18 years old appropriate to be a living donor, and the Committee seeks to balance protecting living donors while not creating barriers to living donation. The Committee affirms that this exclusion criterion is relevant, and plans to continually review data on living donors under the age of 18 to ensure the safety of living donors.[69]

"HIV, unless the requirements for a variance are met, according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors"[70]

The Committee affirms to keep this exclusion criterion for all living donors as is in OPTN policy. The Committee cites that this exclusion criterion protects living donors due to several medical considerations. Individuals with HIV have an increased risk for kidney disease.[71] It is an important future consideration for the potential living donor in the instance of having a singular kidney with ongoing

[63] OPTN Living Donor Committee, *Meeting Summary,* September 9, 2021.
[64] Based on OPTN data as of October 30, 2021.
[65] OPTN Policy 1.2: Definitions
[66] OPTN Policy 14.9.B: Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors
[67] Based on OPTN data as of October 30, 2021.
[68] Based on OPTN data as of October 30, 2021.
[69] OPTN Living Donor Committee, *Meeting Summary,* September 13, 2021.
[70] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[71] Swanepoel, C., et al. "Kidney disease in the setting of HIV infection: Conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) controversies conference", *Kidney International*. (2018); 83:545-559. doi: 10.1016/j.kint.2017.11.007.

exposure to nephrotoxins from medications, taken for HIV management, and the possible progression to CKD.[72]

The Committee acknowledges that, upon appropriate evaluation, an HIV-positive potential living donor may be acceptable for donation to an HIV-positive transplant candidate.[73] This is permitted at transplant programs with an approved variance outlined in *OPTN Policy 15.7: Open Variance for the Recovery and Transplantation of Organ from HIV Positive Donors,* as required by the HIV Organ Policy Equity (HOPE) Act.[74] The Committee affirms this exclusion criterion remains relevant to protect patient safety.

"Evidence of acute symptomatic infection (until resolved)"[75]

The Committee affirms to keep this exclusion criterion for all living donors as is in OPTN policy. An elective surgery that has no direct physical benefit to the living donor can be postponed until an acute symptomatic infection is resolved. Most infections are treatable, usually with short term antibiotics, therefore living donor candidacy can be revisited after resolution of the acute symptomatic infection.[76] Additionally, taking a living donor to the operating room for an elective surgery, while infected, can increase the risk of complications or transmit disease to the recipient who will be immunosuppressed, which could lead to graft loss or death.[77] The Committee affirms this exclusion criterion continues to be relevant to protect live organ donors.

"Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality"[78]

The Committee affirms to keep this exclusion criterion for all living donors as is in OPTN policy. The Committee considered modification to include "substance abuse", but recognized that substance use disorder is in the Diagnostic and Statistical Manual of Mental Disorders (DSM) as a psychiatric diagnosis.[79] Therefore, the Committee concluded it would be unnecessary to include specific mention of substance abuse in this exclusion criterion.[80] Additionally, the Committee considered specifying "chronic" or "active" psychiatric conditions but decided that addition of such language would change the intent of the exclusion criterion and add unintended barriers to living donation.[81]

Research suggests outcomes are similar for donors without psychiatric conditions and with psychiatric conditions if they are controlled.[82] For individuals with a known history of certain types of mental health concerns, undergoing surgery and the additional relational and emotional complexities of the living donation situation can trigger psychiatric decompensation and symptomology.[83] While an individual with mental health diagnoses can indeed become a suitable living donor, the severity, time frame, and

[72] Alsauskas, Z., et al. "Expert opinion on pharmacotherapy of kidney disease in HIV-infected patients", *Expert Opinion on Pharmacotherapy.* (2011); 12(4):691-704. doi: 10.1517/14656566.2011.535518.
[73] OPTN Living Donor Committee, *Meeting Summary*, September 13, 2021.
[74] OPTN Policy 15.7: Open Variance for the Recovery and Transplantation of Organ from HIV Positive Donors
[75] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[76] OPTN Living Donor Committee, *Meeting Summary*, September 13, 2021.
[77] Ibid.
[78] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[79] American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorder* (5th ed.). https://doi.org/10.1176/appi.books.9780890425596.
[80] OPTN Living Donor Committee, *Meeting Summary*, September 8, 2021.
[81] Ibid.
[82] Rowley, A., et al. "Psychiatric disorders: Are they an absolute contraindication to living donation?", *Progress in Transplantation.* (2009);19(2):128-131. doi: 10.1177/152692480901900206
[83] OPTN Living Donor Committee, *Meeting Summary*, September 8, 2021.

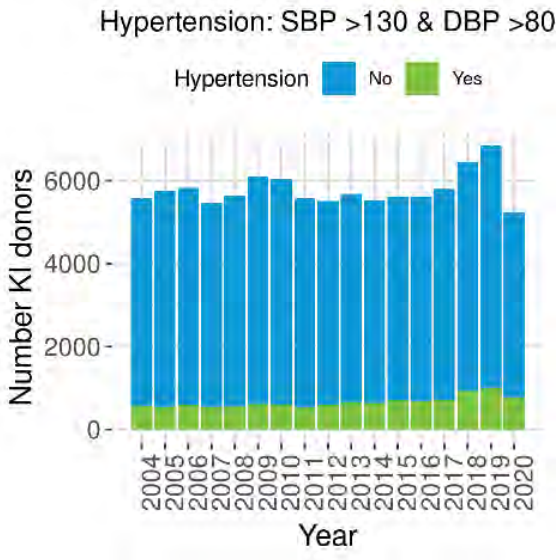
responsiveness to intervention must be considered, along with comprehensive clinical assessment. In any instance where an individual suffers from active psychiatric symptoms that are not responsive to treatment, or if history is deemed to present too high a risk for decompensation, including suicidality, a donor must not proceed to surgery to assure their psychiatric safety.[84] While psychiatric symptomology might be weighted more heavily in a living donor patient population than in other patient populations where there is a need for curative or palliative medical treatment, the Committee concluded this is indeed appropriate – remembering that the living donation event is entirely elective and offers no medical benefit to the live donor. The Committee affirms that this exclusion criterion is relevant in ensuring the protection of living donors.

"Uncontrollable hypertension or history of hypertension with evidence of end organ damage"[85]

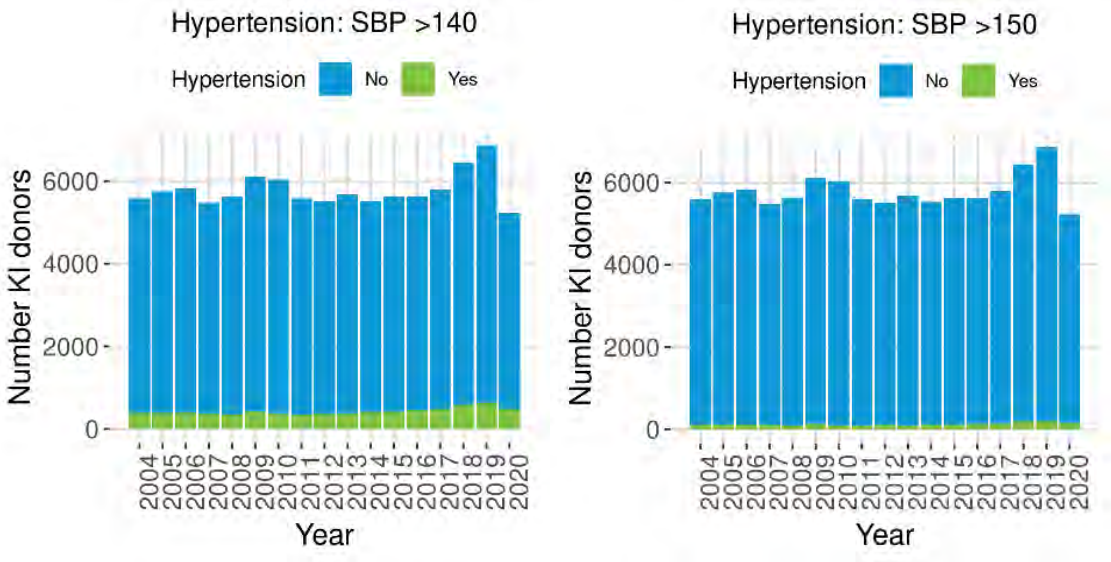
The Committee affirms to keep this exclusion criterion for living kidney donors as is in OPTN policy. High blood pressure is one of the leading causes of kidney failure.[86] It is unknown whether the natural increase in blood pressure seen in living kidney donors post-donation will be further compounded in those individuals with uncontrolled hypertension. Furthermore, a review of existing living kidney donor guidelines agree that patients with uncontrolled hypertension are not suitable for live organ donation.[87]

The Committee recognizes that this exclusion criterion is subjective, but supports the intent of the exclusion criterion in order to allow room for variation of practice among transplant programs.[88] Additionally, OPTN data (**Figure 1**), reviewed by the Committee, confirms that transplant programs are not accepting living kidney donors with high blood pressure (i.e. uncontrolled hypertension). The Committee affirms that this exclusion criterion is relevant to protect live kidney donors.

Figure 1: Number of living kidney donors by hypertension and year of donation for each hypertension definition[89]



[84] OPTN Living Donor Committee, *Meeting Summary*, September 8, 2021.
[85] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[86] Centers for Disease Control and Prevention. "Chronic Kidney Disease Basics", (2021). https://cdc.gov/kidneydisease/basics.html.
[87] Claisse, G., Gaillard, F., Mariat, C. "Living kidney donor evaluation", *Transplantation.* (2020);104(12):1487-1496. doi: 10.1097/TP.0000000000003242.
[88] OPTN Living Donor Committee, *Meeting Summary*, September 29, 2021.
[89] Based on OPTN data as of August 20, 2021.



"HCV RNA positive"[90]

The Committee affirms to keep this exclusion criterion for living liver donors as is in OPTN policy. While hepatitis C virus (HCV) is treatable, the Committee focused their decision on what is in the best interest of live liver donors. Literature reports decreased regenerative capacity of the liver in the setting of chronic viral infection with HCV.[91]

HCV treatment length is between eight to twelve weeks, making it reasonable for transplant candidates to wait for eradication of HCV in the living liver donor before undergoing organ transplantation. In medically urgent cases, OPTN deceased donor liver allocation policy prioritizes for medical urgency, making it unnecessary for living liver donors who test positive for HCV via a ribonucleic acid (RNA) test to donate in these specific cases.[92] In order to protect the living liver donor, the Committee affirmed that it is in the potential living liver donor's best interest to eradicate the HCV and allow for recovery of normal liver function.[93] Additionally, the Committee consulted with OPTN Liver & Intestinal Transplantation Committee (the Liver Committee) leadership regarding the exclusion criteria for living liver donors. The Liver Committee leadership agreed that HCV RNA positive, as well as the four other living liver donor exclusion criteria (further detailed below), remain relevant and appropriate absolute contraindications to living liver donation.

"HBsAg positive"[94]

The Committee affirms to keep this exclusion criterion for living liver donors as is in OPTN policy. Literature for hepatitis B virus (HBV) and liver regenerative capacity is similar to the aforementioned literature regarding HCV and liver regenerative capacity.[95] However, unlike HCV, HBV is not curable.

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[90] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[91] Karidis, N., Delladetsima, I., Theocharis, S. "Hepatocyte turnover in chronic HCV-induced liver injury and cirrhosis", *Gastroenterology Research and Practice.* (2015);654105. doi: 10.1155/2015/654105.
[92] OPTN Policy 9: Allocation of Livers and Liver-Intestines
[93] OPTN Living Donor Committee, *Meeting Summary,* August 11, 2021.
[94] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[95] Oark, E., et al. "Hepatitis B virus inhibits liver regeneration via epigenetic regulation of urokinase-type plasminogen activator", *Hepatology.* (2013);58(2):762-776. doi: 10.1002/hep.26379.

Individuals with HBV have an increased risk of developing hepatocellular carcinoma (HCC) which would make future treatment for HCC more difficult if the individual had undergone liver resection for living donation.[96] In order to protect the living donor, the Committee confirms those who test positive for HBV via a hepatitis B surface antigen (HBsAg) test should be excluded from living liver donation.[97]

"Donors with ZZ, Z-null, null-null and S-null alpha 1-antitrypsinphenotypes and untype-able phenotypes"[98]

The Committee affirms to keep this exclusion criterion for living liver donors as is in OPTN policy. Alpha-1 antitrypsin deficiency defines the disease states with the highest risk of chronic liver disease and pulmonary disease, and has no cure.[99] Individuals develop chronic liver disease because they accumulate abnormal protein within the liver, which leads to cirrhosis and liver failure. The phenotypes addressed in this exclusion criterion are the ones that are associated with the highest risk of chronic disease.[100] The Committee asserts that individuals with one of these phenotypes should remain excluded from becoming live liver donors in order to protect their survival and future health outcomes.[101]

"Expected donor remnant volume less than 30% of native liver volume"[102]

The Committee affirms to keep this exclusion criterion for living liver donors as is in OPTN policy. It is well established that the limit for safe hepatic resection has a range up to 30 percent future liver volume.[103] A lower remnant volume would be unsafe for the live liver donor and could result in post-hepatectomy liver failure.[104] The Committee confirms that this exclusion criterion is relevant in ensuring the protection of living liver donors.

"Prior living liver donor"[105]

The Committee affirms to keep this exclusion criterion for living liver donors as is in OPTN policy. An individual who proceeds with living liver donation is undertaking a substantial risk, and taking that risk on an additional time is excessive for an otherwise healthy individual.[106] Some surgical risks that living liver donors may incur include acute liver failure with the need for future liver transplant, transient liver dysfunction, risk of red cell transfusions, or biliary complications.[107] For the protection of live liver donors, the Committee agrees this exclusion criterion remains relevant.

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[96] Zhang, X., et al. "Risk factors and prevention of viral hepatitis-related hepatocellular carcinoma", *Frontiers in Oncology.* (2021). doi: 10.3389/fonc.2021.686962.
[97] OPTN Living Donor Committee, *Meeting Summary,* August 11, 2021.
[98] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[99] Alpha-1 Foundation. "What is Alpha-1?". https://alpha1.org.
[100] Ibid.
[101] OPTN Living Donor Committee, *Meeting Summary,* August 11, 2021.
[102] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[103] Soin, A., et al. "A worldwide survey of live liver donor selection policies at 24 centers with a combined experience of 19009 adult living donor liver transplant", *Transplantation.* (2019);103(2):39-47. doi: 10.1097/TP.0000000000002475.
[104] Kauffman, R. & Fong, Y. "Post-hepatectomy liver failure", *Hepatobiliary Surgery & Nutrition.* (2014);3(5):238-246. doi: 10.3978/j.issn.2304-3881.2014.09.01.
[105] OPTN Policy 14.4.E: Living Donor Exclusion Criteria as of November 2021
[106] OPTN Living Donor Committee, *Meeting Summary,* August 11, 2021.
[107] OPTN Policy 14.3 Informed Consent Requirements, Table 14-3: Additional Requirements for the Informed Consent of Living Liver Donors

Other Considerations for Living Donor Exclusion Criteria

The Committee considered establishing a criterion to exclude actively incarcerated individuals from living donation. Actively incarcerated individuals are a vulnerable population, which require unique considerations when undergoing evaluation for living donation. The intent of excluding actively incarcerated individuals from living donation was to protect a population that may be more susceptible to inducement, coercion, or other undue pressure.

The Committee does not propose the addition of this exclusion criterion, but seeks to inform the community on their deliberations. The Committee recognized that it may be more difficult to obtain a thorough evaluation of donor coercion, informed decision-making, and informed consent for actively incarcerated individuals. Ultimately, the Committee concluded that transplant programs should have discretion and give due consideration to every eligible potential living donor, regardless of specific circumstances.[108] While there are unique considerations for evaluating an actively incarcerated potential living donor, it does not justify the establishment of an absolute contraindication. Singular cases of living donation can be of great impact, and the Committee supports transplant program's autonomy to make these decisions, in conjunction with their Ethics teams.[109] The Committee intends to further discuss the unique considerations of actively incarcerated living donors.

NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) stated that oversight over living donation of all types falls under the authority of the OPTN.[110] "Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN 'to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule."[111] This project addresses living organ donors by reviewing existing living donor exclusion criteria in OPTN policy in order to increase opportunities for living donation while maintaining the safety of living donors and the potential recipients of organs donated by living donors.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

All transplant programs that perform living donor evaluations will need to become familiar with the modifications to living donor exclusion criteria, especially the new language surrounding malignancy and diabetes. This proposal does not require transplant programs to change their living donor evaluation and acceptance practices. However, should a transplant program choose to expand their living donor evaluation and acceptance practices based on the proposed modifications, there may be additional administrative burden for programs to adapt evaluation protocols.

[108] OPTN Living Donor Committee, *Meeting Summary*, September 13, 2021.
[109] Ibid.
[110] Department of Health and Human Services, Health Resources and Services Administration, "Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines," 71 Fed. Reg. 34946 No. 116 (June 16, 2006). https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-andtransplantation-network-optn-living-donor.
[111] Ibid.

Operations affecting the OPTN

This proposal will not require information technology (IT) effort. Communication and education will be necessary and determined following public comment.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Potential Impact on Select Patient Populations

Modifications to living donor exclusion criteria may impact potential living donors. The intent of the modifications is to broaden the scope of transplant program practice on living donor evaluation and acceptance, and expand opportunities for individuals to become living organ donors while maintaining living donor safety. Transplant program autonomy will also allow for an increase in shared decision making among potential living donors, transplant candidates, families, and medical professionals. This expanded opportunity is specific to individuals with low-grade malignancies, and select type 2 diabetic individuals, as previously detailed. As a result, the impact on the potential living donor population is anticipated to be small; nevertheless, a small increase in living donors will have a remarkable impact.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

There is no projected fiscal impact on histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

There is no projected fiscal impact on organ procurement organizations.

Projected Impact on Transplant Hospitals

There is no projected fiscal impact on transplant hospitals. This proposal does not require transplant programs to change their living donor evaluation and acceptance practices. Should a transplant hospital expand based upon the proposed modifications to living donor exclusion criteria, then the transplant hospital may incur additional costs. These additional costs may be related to staff training, and increased living donor evaluations and acceptances.

Projected Impact on the OPTN

The projected fiscal impact for the OPTN includes standard communication and education efforts for implementation of policy changes.

Post-implementation Monitoring

Member Compliance

This proposal will not change current routine monitoring of OPTN members. The OPTN will continue to verify that living donor recovery hospitals are evaluating living donors according to the requirements in OPTN policy.

Policy Evaluation

Monitoring reports using pre vs. post comparisons will be presented to the Committee after approximately 6 months, 1 year, and 2 years. Metrics included:

- Overall volume of living donors by organ (Kidney and Liver)
- Number and percent of living donors with diabetes indicated on the Living Donor Registration Form
- Short-term outcomes (as reported on the Living Donor Follow up form) by indication of diabetes on the Living Donor Registration Form
- Number and percent of living donors with malignancy indicated on the Living Donor Registration Form (overall and by type of malignancy)
- Volume of tumors transmitted from the donor reported on Post Transplant Malignancy forms

The OPTN and SRTR contractors will work with the Committee on any additional data requests related to the policy change.

Conclusion

The Committee proposes OPTN policy modifications to four living donor exclusion criteria and offers justifications for maintaining other living donor exclusion criteria. Modifications to exclusion criteria related to donor coercion and illegal financial exchange aligns language with other areas of OPTN living donor policy for consistency. The proposed modifications to the malignancy exclusion criterion allows transplant programs more autonomy in evaluating potential living donors with low-grade malignancies and minimal risk of transmission. The proposed modifications to the diabetes exclusion criterion allows transplant programs to evaluate select type 2 diabetic individuals for living kidney donation while maintaining type 1 diabetes as an absolute contraindication to living kidney donation. The Committee proposes these modifications to reduce barriers to living donation, while maintaining the protection of living donor and transplant recipient safety.

Community Feedback

The Committee is requesting feedback on the following:

Living Donor Exclusion Criteria

- Do you agree with the living donor exclusion criteria modifications as proposed? If not, why?
- Do the proposed modifications need to be more or less restrictive? If so, in what way and what are the suggested modifications?
- Are there additional modifications to exclusion criteria that are needed?

Malignancy Exclusion Criterion Modifications

- Are the proposed modifications to the malignancy exclusion criterion clear? If it is not clear, what needs to be clarified?
- How would your transplant program interpret minimal risk of transmission?
- What type of potential living donors would be allowable based on the proposed modifications?

Diabetes Exclusion Criterion Modifications

- Are the proposed modifications to the diabetes exclusion criterion clear? If it is not clear, what needs to be clarified?
- How would your transplant program interpret lifetime risk of complications?
- What type of potential living donors would be allowable based on the proposed modifications?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

14.4.E Living Donor Exclusion Criteria

Table 14-10: Living Donor Exclusion Criteria

Exclusion criteria for all Living Donors	Living donor recovery hospitals may exclude a door with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation. Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria: • Is both less than 18 years old and mentally incapable of making an informed decision • HIV, unless the requirements for a variance are met, according *to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* • Active ~~malignancy,~~ or incompletely treated malignancy that requires treatment, other than surveillance, or more than minimal risk of transmission • High suspicion of donor inducement, coercion, or other undue pressure • High suspicion of knowingly acquiring, receiving, or otherwise transferring anything of value in~~illegal financial~~ exchange for any human organ~~between donor and recipient~~ • Evidence of acute symptomatic infection (until resolved) • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
Additional Exclusion Criteria for Living Kidney Donors	Kidney recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • Uncontrollable hypertension or history of hypertension with evidence of end organ damage • ~~Diabetes~~ • Type 1 diabetes • Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals evidence of end organ damage or lifetime risk of complications
Additional Exclusion Criteria for Living Liver Donors	Liver recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor