OPTN

Public Comment Proposal

OPTN Directive to Reduce the Risk of Donor Derived Rabies Transmission

OPTN Ad Hoc Disease Transmission Advisory Committee

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Contents

OPTN Directive to Reduce the Risk of Donor Derived Rabies Transmission

Affected Policies:	*2.4: Deceased Donor Medical and Behavioral History* *14.4.A: Living Donor Medical Evaluation Requirements* *15.3.B: Donors with Risk Identified Pre-Transplant*
Sponsoring Committee:	*Ad Hoc Disease Transmission Advisory*
Public Comment Period:	*TBD*

Executive Summary

Rabies is a rare but severe disease in humans, and nearly 100% fatal once symptoms are detected.[1] Rabies is most frequently transmitted via the bite or scratch of an infected mammal, but transmission through blood transfusion and solid organ transplant has also occurred.[2] In 2024, a transplant-transmitted rabies case occurred, resulting in the death of one recipient and the explantation and administration of post-exposure prophylaxis to three other recipients.[3] In April of 2025, the Health Resources and Services Administration (HRSA) directed the OPTN to further reduce the risk of donor-derived rabies transmission by considering updates to OPTN Policy and data collection.[4]

After review and consultation with multiple OPTN stakeholder Committees, HRSA, and CDC, the OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) proposes to:

- Establish screening criteria for high-risk rabies exposures in deceased and living donor populations, and standardize data collection of the criteria
- Require organ procurement organizations (OPOs) and Living Donor transplant programs to contact the CDC for additional risk assessment and evaluation when screening criteria are identified in a donor, and
- Require transplant programs to inform potential recipients when screening criteria are identified, and provide appropriate clinical monitoring after transplant, including monitoring specific to the receipt of rabies post-exposure prophylaxis (PEP).

The Committee does not propose to exclude potential donors from consideration for organ donation if screening criteria for high-risk rabies exposure are present. Due to testing limitations, rabies prevention is accomplished solely through risk assessment and administration of PEP. The intention of the proposal is to reduce the risk of future transmission events by enabling educated risk assessment and clinical

[1] "Rabies," World Health Organization, June 5, 2024, https://www.who.int/news-room/fact-sheets/detail/rabies (accessed September 25, 2025)
[2] "Clinical Overview of Rabies," Centers for Disease Control, July 15, 2025, https://www.cdc.gov/rabies/hcp/clinical-overview/index.html (accessed September 25, 2025)
[3] Meeting summary for August 12, 2025 OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/boshddnf/20250812_dtac_open_summary.pdf (accessed September 25, 2025)
[4] HRSA (email directive to the OPTN, April 2, 2025)

decision making by transplant programs and patients.

Purpose

This project seeks to improve patient safety by reducing the risk of rabies transmission via solid organ transplantation. The Committee proposes new screening criteria, standardized data collection, and new protocols for transplant programs to identify and assess rabies risk in deceased and living donors.

Background

Rabies is a rare but severe disease in humans affecting the central nervous system. There is no effective treatment or cure for rabies once symptoms begin.[5] Transmission most frequently occurs through the bite or scratch of an infected mammal but has also occurred through blood transfusion and solid organ transplant.[6] Only mammals transmit and carry the rabies virus; non-mammals such as snakes, birds, and reptiles are not carriers of the disease.[7]

Once a human has been exposed to rabies, prompt medical evaluation and the administration of post-exposure prophylaxis (PEP) is critical to prevent disease development. Symptoms of rabies in humans do not manifest until the virus has reached the brain, after which point the disease is nearly 100% fatal with no approved treatment options.[8] PEP is nearly 100% effective in preventing rabies if it is received after exposure and prior to symptoms developing.[9] PEP includes wound care, administration of human rabies immune globulin (HRIG), and a series of four to five rabies vaccines.[10]

No testing exists to diagnose rabies in humans prior to the onset of symptoms and clinical disease.[11] After clinical onset, multiple antemortem tests are required and postmortem testing of the brainstem and cerebellum tissues is often recommended or required to confirm a human rabies diagnosis.[12] These testing limitations necessitate the need to prevent rabies transmission solely through risk assessment of potential exposures and prompt administration of post-exposure prophylaxis.

From 2015 to 2024, there have been 17 cases of human rabies confirmed in the United States, two of

[5] "About Rabies," Centers for Disease Control, June 24, 2025. https://www.cdc.gov/rabies/about/index.html (accessed September 25, 2025)
[6] "Clinical Overview of Rabies," Centers for Disease Control, July 15, 2025, https://www.cdc.gov/rabies/hcp/clinical-overview/index.html (accessed September 25, 2025)
[7] "Rabies Fact Sheet," District of Columbia Department of Health, https://dchealth.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Rabies%20Fact%20sheet.pdf (accessed September 25, 2025).
[8] "Clinical Overview of Rabies," Centers for Disease Control, July 15, 2025, https://www.cdc.gov/rabies/hcp/clinical-overview/index.html (accessed September 25, 2025)
[9] "About Rabies," Centers for Disease Control, June 24, 2025. https://www.cdc.gov/rabies/about/index.html (accessed September 25, 2025)
[10] "Rabies Post-exposure Prophylaxis Guidance," Centers for Disease Control, July 15, 2025, https://www.cdc.gov/rabies/hcp/clinical-care/post-exposure-prophylaxis.html (accessed September 25, 2025).
[11] "Control of Neglected Tropical Diseases," World Health Organization, https://www.who.int/teams/control-of-neglected-tropical-diseases/rabies/diagnosis (accessed September 25, 2025)
[12] "Laboratory Methods for Rabies Testing," Centers for Disease Control, August 4, 2025, https://www.cdc.gov/rabies/php/labs-specimens/testing.html (accessed September 25, 2025).

which were contracted outside of the United States.[13] While confirmed transmission of rabies to humans is rare, potential human exposure to rabies is broader. The CDC reports 1.6 million Americans seek medical attention for animal bites each year and around 100,000 receive Rabies PEP.[14] In addition, more than 1,000 persons die annually of unexplained encephalitis, presenting the possibility rabies is undiagnosed in certain cases due to the rarity and lack of clinical recognition of the disease.[15]

Transmission of rabies through blood transfusion and solid organ transplantation has also occurred. There have been four instances of documented transplant-transmitted rabies involving deceased donors in the United States since 1979, resulting in seven recipient deaths.

Table 1

Event year	Recipient(s) outcome	Likely source of donor exposure	Donor History
1979	• Corneal graft recipient: *Died*	Unknown animal exposure	Donor described as forester-rancher; no known history of animal bite[16]
2003	• Liver recipient: *Died* • Right kidney recipient: *Died* • Left kidney recipient: *Died* • Arterial graft: *Died*	Bat	No evidence of exposure at time of donation; post-mortem investigation revealed donor had described receiving a bat bite to friends, donor presented to hospital with altered mental state requiring intubation.[17]
2013	• Left kidney recipient: *Died* • Right kidney recipient: *PEP, survived* • Liver recipient: *PEP, survived* • Heart recipient: *PEP, survived*	Raccoon	No evidence of exposure reported at time of donation; post-mortem epidemiologic investigation revealed donor had sustained at least two raccoon bites without seeking medical care, exhibited signs of dysphagia to liquids and altered mental status while hospitalized[18]
2024	• Left kidney recipient: *Died* • Corneal graft recipient 1: *PEP, explantation, survived*	Skunk	Donor risk assessment interview indicated a scratch from a skunk. Post-mortem investigation revealed donor

[13] "Rabies in the United States: Protecting Public Health," Centers for Disease Control, August 4, 2025, https://www.cdc.gov/rabies/php/protecting-public-health/ (accessed September 25, 2025).
[14] Ibid.
[15] Vora, Neil M et al. "Raccoon rabies virus variant transmission through solid organ transplantation." *JAMA* vol. 310,4 (2013): 398-407. https://pmc.ncbi.nlm.nih.gov/articles/PMC7552820/
[16] Houff, S.A., et al. "Human-To-Human Transmission of Rabies Virus By Corneal Transplant." *NEJM* vol. 300, 11 (1979): 603-604.
[17] Srinivasan, Arjun, et al. "Transmission of Rabies Virus from an Organ Donor to Four Transplant Recipients," *NEJM* vol. 352,11 (2005): 1103-11. https://www.nejm.org/doi/full/10.1056/NEJMoa043018
[18] Vora, Neil M et al. "Raccoon rabies virus variant transmission through solid organ transplantation." *JAMA* vol. 310,4 (2013): 398-407. https://pmc.ncbi.nlm.nih.gov/articles/PMC7552820/

	• Corneal graft recipient 2: *PEP, explantation, survived* • Corneal graft recipient 3: *PEP, explantation, survived*		was attacked in daylight by the skunk and had reported hallucinations in the days prior to death.[19]

As summarized above, while rabies risk was not always identified at the time of donation, the post-mortem investigations of the above transplant transmissions sometimes revealed evidence of animal exposures and clinical symptoms associated with the rabies virus. This suggests that improved donor screening and consideration of PEP in transplant recipients may prevent future instances of transplant transmitted rabies.

OPTN Directive and CDC Recommendations

In April of 2025, the OPTN received a directive to further reduce the risk of donor-derived rabies transmission.[20] The Committee was tasked with recommending updates to OPTN Policy.[21] As part of the directive, the OPTN also facilitated data collection from seven OPOs to ascertain the frequency and nature of animal exposures in the deceased donor population. The CDC analyzed this data and presented its findings and recommendations to the DTAC in August of 2025.[22]

The frequency of animal exposures in the deceased donor population has not been estimated prior to the CDC's analysis. The CDC estimated mammal exposure to be present in approximately 913 deceased donors per year and wild mammal exposure to be present in approximately 9 deceased donors per year.[23] The CDC recommended the DTAC consider the establishment of high-risk criteria for rabies exposures in the donor population and standardization of the donor risk assessment for rabies. The CDC also recommended the DTAC consider guidance for OPOs and transplant programs to consult with a rabies public health authority when high risk exposures are identified in a potential donor and consider post-exposure prophylaxis for potential transplant recipients.[24]

Overview of Proposal

Establishment of high-risk rabies criteria and standard data collection

The Committee proposes establishing the following screening criteria for high-risk rabies exposures in the deceased and living donor populations. The Committee proposes standardizing data collection of these criteria for deceased and living donors in the OPTN Computer System. The incubation period of

[19] Meeting summary for August 12, 2025 OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/boshddnf/20250812_dtac_open_summary.pdf (accessed September 25, 2025)
[20] HRSA (email directive to the OPTN, April 2, 2025)
[21] Meeting summary for May 6, 2025 OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/xfogfuwj/20250506_dtac_open_summary.pdf (accessed September 25, 2025)
[22] Meeting summary for August 12, 2025 OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/boshddnf/20250812_dtac_open_summary.pdf (accessed September 25, 2025)
[23] CDC (presentation to OPTN Ad Hoc Disease Transmission Advisory Committee, August 12, 2025)
[24] Ibid.

the rabies virus may last from weeks to months, however, longer incubation periods have been observed and the CDC recommends a time period of 12 months for all criteria.[25],[26]

- Deceased and living donor screening criteria:
    - Direct contact with bats within the last 12 months
    - Bite or scratch within the last 12 months from a wild mammal in the United States (including but not limited to bats, raccoons, skunks, mongoose, or foxes)
    - Bite or scratch from any stray or feral cat within the last 12 months
    - Bite or scratch within the last 12 months from any wild or domesticated mammal (including dogs, cats, or other domesticated mammals) outside of the United States

The Committee proposes these criteria after making the following considerations:

1) The criteria are limited to the highest risk exposures for rabies based on available evidence and seek to avoid overly broad screening of donors
2) The criteria rely on information that is generally available to OPOs through the current Donor Risk Assessment Interview (DRAI) and donor social history[27]
3) The language of the criteria is simple to understand and interpret for OPOs, transplant programs, living donors, and deceased donor family members.

The rationale for each criterion is further discussed below.

Direct contact with bats within the last 12 months

Bats have been responsible for the majority of documented human rabies cases since 2000 and constitute the most widely distributed reservoir of rabies in the United States.[28] A bite from a bat is the suspected source of exposure for the 2003 donor which resulted in four recipient deaths.[29] Not all bat bites result in visible marks and it is possible for an individual to be bitten by a bat without knowing it. Therefore, it is important to identify bat exposure as its own distinct screening criteria, as any direct contact with a bat (to include touching, holding, or sleeping in the same room or area as a bat) is considered high risk for transmission of rabies.[30]

Bite or scratch within the last 12 months from a wild mammal in the United States (including but not limited to bats, raccoons, skunks, mongoose, or foxes)

A bite or scratch from a wild mammal is widely recognized as high risk factor for rabies. Rabies surveillance data indicates that wild mammals account for nearly 92% of positive rabies animal samples.

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[25] "Clinical Features of Rabies," Centers for Disease Control, July 15, 2025, https://www.cdc.gov/rabies/hcp/clinical-care/post-exposure-prophylaxis.html (accessed September 25, 2025).
[26] CDC (presentation to OPTN Ad Hoc Disease Transmission Advisory Committee, August 12, 2025)
[27] "Uniform Donor Risk Assessment Interview (Donor > 12 years old)," American Association of Tissue Banks, https://www.aatb.org/sites/default/files/guidance-docs/2024-12-17%20UDRAI%20-%20Donor%20greater%20than%2012%20-%20final.pdf (accessed September 25, 2025).
[28] Boutelle, Cassandra, et al. "Rabies surveillance in the United States during 2023," *AVMA* vol 263, 10 (2025): 1310-17. https://avmajournals.avma.org/view/journals/javma/aop/javma.25.05.0344/
[29] Srinivasan, Arjun, et al. "Transmission of Rabies Virus from an Organ Donor to Four Transplant Recipients," *NEJM* vol. 352,11 (2005): 1103-11. https://www.nejm.org/doi/full/10.1056/NEJMoa043018
[30] Kunkel A, Minhaj FS, Whitehill F, et al. "*Notes from the Field:* Three Human Rabies Deaths Attributed to Bat Exposures — United States, August 2021." *MMWR* 71 (2022):31–32. http://dx.doi.org/10.15585/mmwr.mm7101a5

Bats, followed by raccoons, are the most commonly reported rabid wildlife.[31] Bites or scratches from rabid wildlife (raccoon and skunk) are the likely sources of donor exposure in the 2013 and 2024 transplant transmission events, which resulted in two recipient deaths and six recipients receiving PEP and/or explantation.[32,33]

Bite or scratch from any stray or feral cat within the last 12 months

Outside of wild animal exposures, cats are the most frequently reported rabid domestic animal. Nearly 200-300 cats are reported to have rabies in the United States each year.[34] While cats account for only 6% of positive rabies animal samples, they pose a higher risk for human exposure than wildlife because humans are more likely to approach cats.[35,36] The CDC estimates that 8,800 individuals receive PEP treatment associated with exposure to rabid or potentially rabid cats each year.[37] Household cats and other domesticated mammals, such as dogs, are largely vaccinated and account for a very small percentage of positive rabies samples.[38] Accordingly, the Committee does not intend to include bites or scratches from a pet or household cat in the donor screening criteria. Instead, this criterion is limited specifically to bites or scratches from stray or feral cats, given the known presence of rabies in the U.S. cat population and that the vaccination status of a stray or feral cat is likely to be unknown.[39]

Bite or scratch within the last 12 months from any wild or domesticated mammal (including dogs, cats, or other domesticated mammals) outside of the United States

Outside of the United States, rabies vaccination rates and national surveillance programs are variable. Dogs are the most common source of rabies transmission to humans outside of the United States, and wild mammals, to include bats, foxes, jackals, monkeys, mongooses, and other wildlife also carry and transmit the rabies virus.[40,41] A bite or scratch from any mammal outside the US requires medical evaluation and is considered a high-risk exposure.

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[31] Boutelle, Cassandra, et al. "Rabies surveillance in the United States during 2023," *AVMA* vol 263, 10 (2025): 1310-17. https://avmajournals.avma.org/view/journals/javma/aop/javma.25.05.0344/

[32] Vora, Neil M et al. "Raccoon rabies virus variant transmission through solid organ transplantation." *JAMA* vol. 310,4 (2013): 398-407. https://pmc.ncbi.nlm.nih.gov/articles/PMC7552820/

[33] Meeting summary for August 12, 2025 OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/boshddnf/20250812_dtac_open_summary.pdf (accessed September 25, 2025)

[34] Ludmer, Sarah et al. "Rabies Outbreak in an Urban, Unmanaged Cat Colony — Maryland, August 2024," *MMWR* 74,31 (2025):480-483. http://dx.doi.org/10.15585/mmwr.mm7431a2

[35] Boutelle, Cassandra, et al. "Rabies surveillance in the United States during 2023," *AVMA* vol 263, 10 (2025): 1310-17. https://avmajournals.avma.org/view/journals/javma/aop/javma.25.05.0344/

[36] Ludmer, Sarah et al. "Rabies Outbreak in an Urban, Unmanaged Cat Colony — Maryland, August 2024," *MMWR* 74,31 (2025):480-483. http://dx.doi.org/10.15585/mmwr.mm7431a2

[37] Brunt, Scott, Heather Solomon, Kathleen Brown, and April Davis. 2021. "Feline and Canine Rabies in New York State, USA" *Viruses* 13, no. 3: 450. https://doi.org/10.3390/v13030450

[38] Boutelle, Cassandra, et al. "Rabies surveillance in the United States during 2023," *AVMA* vol 263, 10 (2025): 1310-17. https://avmajournals.avma.org/view/journals/javma/aop/javma.25.05.0344/

[39] OPTN Ad Hoc Disease Transmission Advisory Committee Meeting, September 22, 2025. https://optn.transplant.hrsa.gov/media/1h1lqlor/20250922_dtac_summary-1.pdf.

[40] "Rabies," World Health Organization, June 5, 2024, https://www.who.int/news-room/fact-sheets/detail/rabies (accessed September 25, 2025)

[41] "Global Rabies: What You Should Know," Centers for Disease Control, July 1, 2025, https://www.cdc.gov/rabies/around-world/index.html (accessed September 25, 2025).

Other screening criteria considered

The Committee considered, and ultimately declined to propose, additional donor screening criteria:

- The Committee discussed whether certain occupations and recreational activities, such as animal rehabilitation and wildlife rescue workers, recreational hunters, and veterinary professionals, carry greater risk of animal exposure and should be factors in donor screening.[42] While these activities may be correlated with frequent mammal exposure, the Committee determined that the engagement in the activity alone is not sufficient to assess a donor's risk for rabies exposure and inclusion of this criteria would result in overly broad donor screening.[43]

- The Committee also discussed whether to include a bite or scratch from all domesticated mammals in the United States, to include dogs and household cats. The Committee considered conditioning this criterion on the animal's vaccination status and the nature of the event, such as if the bite was unprovoked or if the animal was exhibiting behavioral changes. The Committee received feedback from cross-committee discussions that terms such as "unprovoked" or "behavioral changes" are difficult to interpret and that their inclusion may lead to overly broad donor screening.[44,45] Committee members also raised concerns that vaccination status of an animal is unlikely to be known by a deceased donor's next of kin. Additionally, CDC surveillance data indicate that while rabies has been detected in rare instances in domesticated dogs, cats, and livestock, the virus is most commonly detected in the unvaccinated, non-household cat population.[46] Other domesticated mammals, such as dogs, pose a significantly lower risk of rabies in the United States when compared with cats. Notably, the canine rabies virus variant has been eliminated in the United States and CDC surveillance data indicate dogs accounted for only 1% of all confirmed rabid mammals in the United States.[47,48] For these reasons, the Committee determined to limit screening related to domesticated mammal exposures in the United States to a bite or scratch from a stray or feral cat.

- The Committee discussed if a donor's clinical symptoms, such as meningoencephalitis of unknown origin, should be incorporated into the screening criteria.[49] The Committee noted that this type of clinical information is currently available in the donor history, and DTAC has provided guidance for OPOs and Transplant Programs to assist with recognizing Central Nervous System (CNS) Infections in potential deceased donors.[50] Clinical presentation of

[42] Meeting summary for September 2, 2025, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/2a5pxtbh/20250902_dtac_open_summary.pdf.
[43] OPTN Ad Hoc Disease Transmission Advisory Committee Meeting, September 22, 2025, https://optn.transplant.hrsa.gov/media/1h1lqlor/20250922_dtac_summary-1.pdf
[44] Meeting summary for September 2, 2025, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/2a5pxtbh/20250902_dtac_open_summary.pdf.
[45] Briefing to the OPTN Data Advisory Committee, September 8, 2025.
[46] Boutelle, Cassandra, et al. "Rabies surveillance in the United States during 2023," *AVMA* vol 263, 10 (2025): 1310-17. https://avmajournals.avma.org/view/journals/javma/aop/javma.25.05.0344.xml
[47] Ibid.
[48] Ma, Xiaoyue, et al. "Rabies surveillance in the United States during 2021," *AVMA* vol 261, 7 (2023): 1045-1053. https://avmajournals.avma.org/view/journals/javma/261/7/javma.23.02.0081
[49] Meeting summary for August 12, 2025 OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/boshddnf/20250812_dtac_open_summary.pdf (accessed September 25, 2025)
[50] "Guidance for Recognizing Central Nervous System Infections in Potential Deceased Organ Donors," Organ Procurement & Transplantation Network, February 1, 2014, https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/guidance-for-recognizing-central-nervous-system-infections-in-potential-deceased-organ-donors/ (accessed September 25, 2025)

meningoencephalitis may be caused a variety of infections, to include rabies, and if evidence suggests unsuspected or untreated CNS infection, caution should be considered in proceeding with allocation and acceptance of the organs for transplantation.[51] The Committee proposes OPOs and transplant programs remain familiar with the Committee's previous guidance relating to CNS Infections and, if a donor meets an established screening criteria for rabies, include relevant clinical details relating to possible CNS infections in discussions with the CDC and transplant programs.

Estimated number of donors impacted by proposed screening criteria

The Committee reviewed HRSA and CDC's analysis of OPO data to consider how many deceased donors per year may meet the proposed rabies screening criteria. CDC estimated that approximately 9 deceased donors would report wild mammal exposure, including known bites or scratches from bats, each year.[52] This analysis cannot estimate unrecognized donor exposures to bats or exposures occurring outside of the US, and did not differentiate exposure to feral cats from other household mammal exposure. However, CDC notes that review of the data provided by 7 OPOs suggests that most reported non-wild mammal exposure in deceased donors occurred from household pets and would not meet the Committees proposed screening criteria.[53] The Committee notes these limitations in estimating the number of deceased donors per year that will meet the proposed screening criteria (median 9 donors annually, 95% uncertainty interval: 1-31 donors annually), but expects that overall numbers referred to CDC for further evaluation will be low.

Data on living donor animal exposures was not collected or analyzed by HRSA and CDC. As such the Committee is unable to provide an estimate of the number of living donors expected to meet the proposed screening criteria. However, it is reasonable to assume that high risk exposure events do not vary significantly between living and deceased donors, and the Committee does not anticipate a disproportionate impact on living donors.

Policy requirement if a potential donor meets a Rabies screening criteria

Potential donors who meet one of the screening criteria are not excluded from donation. When a screening criterion is met, the proposal requires OPOs and Living Donor transplant programs to contact the CDC for additional risk assessment and evaluation of the exposure prior to organ procurement or recovery. This information must be communicated to the potential recipient's transplant program.

CDC is well-positioned to advise transplant programs regarding the overall risk for rabies and benefit of administering PEP to any potential organ recipient, taking individual details of a potential donor's exposure into account. CDC considers several factors when assessing the risk of a potential exposure. These factors may be available in the donor history but are not practical to include in the standardized screening criteria for all potential donors. Examples include whether or not the animal was quarantined, whether or not the potential donor received medical treatment after exposure, the nature of the

[51] Ibid.
[52] CDC (presentation to OPTN Ad Hoc Disease Transmission Advisory Committee, August 12, 2025).
[53] OPTN Ad Hoc Disease Transmission Advisory Committee Leadership call, September 12, 2025.

animal's behavior, location of animal exposure, and clinical symptoms present in a deceased donor prior to death.

The Committee discussed if state and local health departments could also be consulted to assess a potential donor's risk for rabies, and received concerns from stakeholder Committees regarding availability of a public health authorities to assist an OPO outside of regular working hours.[54,55] The Committee determined that limiting the policy requirement to refer only to the CDC would clarify processes for OPOs and allow for the most reliable pathway to obtain further evaluation of risk in a potential donor.[56] CDC has established a hotline for the transplant community to ensure that OPOs are able to reach a subject matter expert at any time.[57] This service will operate 24 hours a day, 7 days a week, including federal holidays. The Committee's expectation is that this requirement will not cause undue burden on OPOs or CDC, as the number of donors per year that will meet the proposed screening criteria is expected to be fewer than one case per week nationally. The Committee welcomes additional comment on this aspect of the proposal.

Policy when donor history is unknown

The Committee considered that information may not be available to identify if a potential deceased donor meets rabies screening criteria, such as when the potential deceased donor's medical or social history is incomplete or missing.[58] The Committee has provided existing guidance to OPOs and programs that potential donors may pose an increased risk of transmitting multiple infections, to include rabies, when adequate medical and social history is not present.[59] In the context of this proposal, OPOs and Living Donor programs are not required to consult with CDC in the case of an "unknown" rabies risk or missing social history, as there would be no actionable information for the CDC to evaluate. OPOs and transplant programs should broadly consider the elevated risk for disease transmission when evaluating a potential deceased donor with unknown or incomplete medical or social history.

Policy Requirement to Inform Potential Recipients

OPTN policy currently requires transplant programs to provide information and monitoring to potential recipients prior to transplant when certain risk factors are identified in a potential donor.[60] The Committee proposes to expand these requirements to include when a potential donor meets rabies screening criteria. The proposed policy will require transplant programs to inform potential recipients when rabies screening criteria are present in an organ offer and provide appropriate clinical monitoring after transplant.

[54] Briefing to the OPTN Data Advisory Committee, September 8, 2025.
[55] Meeting summary for September 2, 2025, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/2a5pxtbh/20250902_dtac_open_summary.pdf
[56] OPTN Ad Hoc Disease Transmission Advisory Committee Meeting, September 22, 2025. https://optn.transplant.hrsa.gov/media/1h1lqlor/20250922_dtac_summary-1.pdf.
[57] The phone number for this service is 770-488-7100.
[58] Meeting summary for September 2, 2025, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/2a5pxtbh/20250902_dtac_open_summary.pdf
[59] "Guidance for Recognizing Central Nervous System Infections in Potential Deceased Organ Donors," Organ Procurement & Transplantation Network, February 1, 2014, https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/guidance-for-recognizing-central-nervous-system-infections-in-potential-deceased-organ-donors/ (accessed September 25, 2025)
[60] OPTN Policy 15.3.B: *Donors with Risk Identified Pre-Transplant*

The Committee solicited feedback from the Patient Affairs Committee and Transplant Coordinators Committee to better understand the types of information that is most critical in this scenario.[61,62] The Committee received feedback that information around the receipt of rabies PEP is particularly important to potential recipients. It is crucial that potential recipients understand what to expect when receiving PEP, the implications for PEP on their recovery, and any risks or follow up care needed after receiving rabies PEP. Patient Affairs Committee representatives also emphasized the need for this information to be provided to patients' caregivers and at multiple points in their post-transplant journey.[63] The proposed policy includes requirements for clinical monitoring specific to PEP to be provided to recipients, and the Committee welcomes suggestions and feedback from the community on how best to ensure this information is provided to potential recipients.

Considerations for living donors

All four documented cases of transplant-transmitted rabies involved deceased donors. However, due to the variable incubation period of the disease it is biologically possible for rabies to be present and undetected in a living donor. The Committee solicited input from the Living Donor Committee and CDC and determined to seek feedback on the inclusion of parallel rabies screening criteria and requirements for living donors.[64]

The current proposal would add rabies screening criteria to the living donor medical evaluation requirements and standardize data collection through the living donor registration form. If a living donor meets a rabies screening criteria, the proposal requires the Living Donor program to follow the same process as an OPO and contact CDC for further evaluation and risk assessment prior to organ recovery. CDC will consider the same range of factors and may leverage the same quantitative assessment tools in evaluating the living donor exposure as it would for a deceased donor exposure. CDC's evaluation could include recommendations for either the potential living donor or the potential recipient to receive PEP.[65]

The Committee's expectation is that this requirement will not cause undue burden on Living Donor programs or CDC, as the number of donors per year that will meet the proposed screening criteria is expected to be small. The Committee welcomes additional feedback on the inclusion of living donors in this proposal and additional considerations for living donors from the community.

NOTA and Final Rule Analysis

The Committee submits this proposal under the authority of the National Organ Transplantation Act (NOTA), which states that the OPTN shall "adopt and use standards of quality for the acquisition and transportation of donated organs"[66] as well as under the authority of the OPTN Final Rule, which states "[t]he OPTN Board of Directors shall be responsible for developing….policies, consistent with

[61] OPTN Ad Hoc Disease Transmission Advisory Committee Leadership call, August 29, 2025.
[62] Meeting Summary for August 21, 2025, OPTN Transplant Coordinator Committee, https://optn.transplant.hrsa.gov/media/ay1hszte/20250821_tcc-meeting-summary.pdf
[63] Meeting summary for September 2, 2025, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/2a5pxtbh/20250902_dtac_open_summary.pdf
[64] OPTN Ad Hoc Disease Transmission Advisory Committee Leadership call, August 29, 2025.
[65] Meeting summary for September 2, 2025, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov/media/2a5pxtbh/20250902_dtac_open_summary.pdf
[66] 42 USC §274(b)(2)(E)

recommendation of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases."[67,68] This proposal will require all living and deceased donors to be screened for high-risk exposures to prevent the spread of rabies, and for programs to provide recipient monitoring in accordance with clinical guidelines, including monitoring specific to receipt of post-exposure prophylaxis if provided.

This proposal will also require new data collection. This data collection proposal is submitted under the authority of NOTA and OPTN Final Rule. NOTA requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants,"[69] and the Final Rule requires the OPTN to "maintain records of all transplant candidates, all organ donors and all transplant recipients."[70] This proposal would collect data from potential deceased donors and living donors on rabies risk criteria within the timeframe designated by the OPTN.

Implementation Considerations

Member and OPTN Operations

This proposal would impact organ procurement organizations, transplant hospitals, and the OPTN, but would not impact histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

Organ Procurement Organizations will be required to include whether the potential deceased donor meets any criteria, as defined in OPTN policy, that would put the organ recipients at risk for acquiring rabies. This information will be recorded in the deceased donor's medical and behavioral history and entered in the OPTN Computer System. If any criteria are met, the OPO must contact CDC for additional evaluation prior to organ procurement and communicate that information to transplant programs.

Operations affecting Transplant Hospitals

Living donor recovery hospitals are required to include risk criteria for rabies, as defined in OPTN policy, in the Living Donor Medical Evaluation, and report that information to the OPTN on the Living Donor Registration Form. If risk criteria are identified in a potential donor, the transplant program must contact CDC for additional evaluation prior to organ recovery.

If a potential deceased or potential living donor meets any criteria, as defined in OPTN policy, that would put the organ recipients at risk for acquiring rabies, all transplant programs must provide information to

[67] 42 CFR §121.4(a)(2)
[68] In 2006, the Department of Health and Human Services (HHS) directed the OPTN to exercise oversight over living donation. 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 (accessed June 23, 2020). Under 42 CFR 121.4(a)(6), the Secretary directed 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." This direction established the OPTN's authority to make policies regarding living donors and living donor organs to the same extent the OPTN has the authority to make policies regard deceased donors and deceased donor organs.
[69] 42 USC 274(b)(2)(I)
[70] 42 CFR Part 121.11II(a)(i2i)(i).

the recipient or their agent that risk criteria are present in the donor. Programs must document this information was provided in the intended recipient's medical record, and provide recipient monitoring in accordance with clinical guidelines, including monitoring specific to receipt of post-exposure prophylaxis, if provided.

Operations affecting the OPTN

For deceased donors, the OPTN will require data collection of rabies risk criteria in the OPTN Computer System. For living donors, the OPTN will require data collection of rabies risk criteria on the Living Donor Registration Form.

This proposal requires the submission of data that are not presently collected by the OPTN. Data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995, which may impact the implementation timeline.

Potential Impact on Select Patient Populations

This proposal implements screening for high-risk rabies exposures for all potential deceased and potential living donors. The proposal will improve patient safety for recipients by reducing unintended disease transmissions, deaths, and graft explantations due to rabies exposure.

This proposal may result in more recipients receiving rabies PEP after transplantation if accepting an offer from a donor meeting rabies screening criteria. This proposal is not expected to have a disproportionate impact on select patient populations.

Projected Impact on the OPTN[71]

It is estimated that $(**redacted**) - $(**redacted**) will be needed to implement this proposal. Implementation would involve communications, educational materials, updates to OPTN documents, software engineering, IT project management, analysis, and quality assurance. It is estimated that $(**redacted**) - $(**redacted**) would be needed for ongoing support of this proposal. Ongoing support will include member support, Committee discussions, system maintenance, and compliance monitoring. The total cost to support this proposal is estimated to be $(**redacted**) - $(**redacted**).

Post-implementation Monitoring

Member Compliance

The Final Rule requires that policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews."[72] During OPO, living donor recovery hospital, and transplant hospital site surveys, an OPTN Contractor, on behalf of the OPTN, will

[71] Unredacted cost information has been made available to OPTN Board members.
[72] 42 CFR §121.8(a)(7).

review a sample of deceased donor medical records, and any material incorporated into the medical record by reference, for documentation of:

- Evaluation of potential deceased donors for any of the risk criteria for rabies as outlined in OPTN Policy 2.4: Deceased Donor Medical and Behavioral History, as well as contact with CDC if any of the criteria were met.
- Evaluation of potential living donors for any of the risk criteria for rabies as outlined in OPTN Policy 2.4: Deceased Donor Medical and Behavioral History, as well as contact with CDC if any of the criteria were met.
- The intended recipient or recipient's agent was informed after the organ offer but before transplant that risk criteria for rabies are present in the donor, and that recipient monitoring was provided in accordance with clinical guidelines, including monitoring specific to receipt of post-exposure prophylaxis if provided.

Any data entered into the OPTN Computer System may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The policy will be formally evaluated at 1 year and 2 years post-implementation.

The following metrics, and any other subsequently requested by the Committee, will be evaluated as data becomes available and sample size allows.

1. The number and percent of deceased donors with reported risk factors for rabies, overall and by organ type, post-policy implementation
2. The number and percent of living donors with reported risk factors for rabies, overall and by organ type (kidney, liver), post-policy implementation
3. The number and percent of deceased donors with reported risk factors for rabies meeting each individual risk criteria, overall and by organ type, post-policy implementation
4. The number and percent of living donors with reported risk factors for rabies meeting each individual risk criteria, overall and by organ type, post-policy implementation
5. Organ utilization rate for deceased donors by risk factors for rabies status, post-policy implementation
6. Organ non-use rate for deceased donors by risk factors for rabies status, post-policy implementation
7. Volume of rabies virus potential donor-derived disease transmission events (PDDTE) submitted through the OPTN Computer System Improving Patient Safety Portal

Conclusion

The Ad Hoc Disease Transmission Advisory Committee seeks to improve patient safety by reducing the risk of rabies transmission via solid organ transplantation. The Committee proposes new screening criteria and standardized data collection to identify high-risk rabies exposures in deceased and living donors. The Committee further proposes requirements for OPOs and Living Donor transplant programs to consult with CDC when high-risk rabies exposures are identified in a potential donor, and to inform potential recipients when a high-risk rabies exposure is identified in an organ offer and provide appropriate clinical monitoring after transplant.

Considerations for the Community

- Does the community support extending rabies screening requirements to living donors? Are there different considerations for screening living donors for rabies risk that the Committee should contemplate?
- Are the proposed requirements for programs to inform patients when screening criteria are identified in a donor sufficient, or should more explicit informed consent requirements be adopted?
- What educational resources would be beneficial for potential recipients who may accept an offer from a donor meeting rabies screening criteria? How can information around the implications, benefits, and risks of receiving PEP best be provided to potential recipients in a transplant setting?
- What additional information would help OPOs and living donor programs operationalize the requirement to contact CDC when a donor meets one of the rabies screening criteria?
- What experiences have OPO and living donor programs had with evaluating donors with reported animal exposures in their medical and social history? Does your program experience match the Committee's assumptions that donors meeting the proposed screening requirements will be low?
- Are the proposed rabies screening criteria clear and understandable to the community?
- Are there different or additional strategies to prevent rabies transmission in solid organ transplant that should be considered?
- How would OPOs and programs consider operationalizing the new requirements if the OPTN pursues a phased implementation approach? Under this scenario, the policy requirements would take effect prior to rabies screening data collection being standardized in the OPTN Computer System, and OPOs would be required to consult CDC if they observed any of the screening criteria in the donor history.

Policy and/or Bylaws 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.

2.4 Deceased Donor Medical and Behavioral History

The medical and behavioral history for each potential deceased donor must include *all* of the following:

1. Any testing and laboratory results used to identify the presence of transmissible diseases or malignancies, treated and untreated, or any other known condition that may be transmitted by the deceased donor organ and may reasonably impact the recipient.
2. Whether the potential deceased donor has any risk factors associated with disease transmission, including blood-borne pathogens. If the deceased donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Services (PHS) Guideline*, the host OPO must communicate this information to all transplant programs receiving organs from the deceased donor.
3. Whether the potential deceased donor has a history of prior exposure or treatment with non-recombinant Human Pituitary Derived Growth Hormone (HPDGH). If so, the potential deceased donor has an increased risk of prion disease and the host OPO must communicate this information to all transplant programs receiving organs from the donor.
4. Whether the potential deceased donor meets any of the following criteria that would put the organ recipients at risk for acquiring rabies:
   - Direct contact with bats within the last 12 months
   - Bite or scratch within the last 12 months from a wild mammal in the United States (including but not limited to bats, raccoons, skunks, mongoose, or foxes)
   - Bite or scratch from any stray or feral cat within the last 12 months
   - Bite or scratch within the last 12 months from any wild or domesticated mammal (including dogs, cats, or other domesticated mammals) outside of the United States

   If any of the above criteria are met, the OPO must contact the CDC for additional evaluation prior to organ procurement and communicate that information to all transplant programs receiving organs from the donor.

14.4 Medical Evaluation Requirements for Living Donors

14.4.A Living Donor Medical Evaluation Requirements

A medical evaluation of the living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Tables 14-6* through *14-10* below.

Table 14-6: Requirements for Living Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
General donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease
General family history	• Coronary artery disease • Cancer
Social history	• Occupation • Employment status • Health insurance status • Living arrangements • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Risk criteria for acute HIV, HBV, and HCV infection according to the *U.S. Public Health Services (PHS) Guideline* • Risk criteria for rabies, as outlined in OPTN *Policy 2.4: Deceased Donor Medical and Behavioral History*. If risk criteria are identified in a potential donor, the transplant program must contact the CDC for additional evaluation prior to organ recovery.
Physical Exam	• Height • Weight • BMI • Vital signs • Examination of all major organ systems

This evaluation must be completed:	Including evaluation for and assessment of this information:
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in OPTN *Policy 14.5: Living Donor Blood Type Determination and Reporting* and its subsections • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)
Transmissible disease screening	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 5. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 6. Hepatitis B core antibody (total anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 7. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 10. Syphilis testing For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using *either*: • Intradermal PPD • Interferon Gamma Release Assay (IGRA)

This evaluation must be completed:	Including evaluation for and assessment of this information:
Endemic transmissible diseases	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer

15.3.B Donors with Risk Identified Pre-Transplant

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

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

Each time any of the following occurs:	Then transplant programs must do *all* of the following:
• The donor tests positive for *any* of the following: a. Hepatitis B surface antigen (HBsAg) b. Hepatitis B nucleic acid test (NAT) c. Hepatitis C NAT	1. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant 2. Document this consent in the intended recipient's medical record 3. Follow the recipient for the development of potential donor-derived disease after transplant
• The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the organ offered is a kidney, liver, or liver-kidney	1. A transplant physician must confirm that the candidate is living with HIV. 2. A transplant physician must explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 3. Document this consent in the intended recipient's medical record

Each time any of the following occurs:	Then transplant programs must do *all* of the following:
• The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant program participates in an approved variance according to *Policy 15.7.D: Open Variance for the Recovery and Transplantation of Non-Kidney and Non-Liver Organs from Donors with HIV*	1. Confirm that the candidate is living with HIV. 2. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 3. Document this consent in the intended recipient's medical record
• The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*	1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor 2. Document that this information was provided in the intended recipient's medical record

• The donor meets any criteria that would put the organ recipients at risk for acquiring rabies, including:
  • Direct contact with bats within the last 12 months
  • Bite or scratch within the last 12 months from a wild mammal in the United States (including but not limited to bats, raccoons, skunks, mongoose, or foxes)
  • Bite or scratch from any stray or feral cat within the last 12 months
  • Bite or scratch within the last 12 months from any wild or domesticated mammal (including dogs, cats, or other domesticated mammals) outside of the United States
	1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor.
	2. Document this information was provided in the intended recipient's medical record.
	3. Provide recipient monitoring in accordance with clinical guidelines, including monitoring specific to receipt of post-exposure prophylaxis if provided.