OPTN

Briefing to the OPTN Board of Directors on

Modify Lung Donor Data Collection

OPTN Lung Transplantation Committee

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OPTN

Modify Lung Donor Data Collection

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Sponsoring Committee: *Lung Transplantation*
Public Comment Period: *January 21, 2025- March 19, 2025*
Board of Directors Meeting: *June 9, 2025- June 10, 2025*

Executive Summary

The purpose of this proposal is to promote efficiency of lung allocation by considering changes to OPTN data collection to make it easier for lung programs to respond to lung offers. This proposal aims to streamline communication and information sharing between Organ Procurement Organizations (OPOs) and lung transplant programs as lung transplant programs consider organ offers. **Table 1** shows a summary of the Lung Committee's (the Committee) proposed data changes.[1]

Table 1. Overview of proposed data changes

OPTN Donor Data and Matching System	Deceased Donor Registration (DDR)	OPTN Waiting List	Lung Offer Filters
Add			
• History of Smoking o Cigarette Smoking History ▪ Calculation of pack years based on data inputs o Vape Use History o Marijuana Smoking History • Peak Inspiratory Pressure (PIP)	• Cigarette Smoking History	• Acceptable donor Predicted Total Lung Capacity (pTLC) range	• Donor cigarette use exceeds
Remove			
• Cigarette use (>20 pack years) ever o And continued in the last six months	• Cigarette use (>20 pack years) ever o And continued in the last six months	• Accept a donor with cigarette use > 20 pack years ever?	
Modify			
• Diagnostic Test Status o Diagnostic Test Type			

[1] *Modify Lung Donor Data Collection,* OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).

In response to public comment feedback, the Committee made a post–public comment revision to include "donor instability" as a selectable reason for OPOs when reporting if a donor diagnostic test could not be completed.[2] To streamline data collection on diagnostic testing "right heart catheterization" will be added to the diagnostic test type drop down list. To further enhance clarity regarding Peak Inspiratory Pressure (PIP) reporting requirements, the Committee also proposes adding a requirement to report PIP in *OPTN Policy 2.11.D: Required Information for Lung Donors.*[3]

Purpose

The purpose of this proposal is to promote efficiency of lung allocation by considering changes to OPTN data collection to include the information necessary for transplant programs to respond to lung offers. This proposal aims to streamline communication and information sharing between OPOs and lung transplant programs as lung transplant programs consider organ offers.[4]

Background

Since the implementation of Continuous Distribution of lungs in March 2023,[5] the Committee has engaged in policy efforts that aim to increase efficiency in lung allocation.[6] These efforts include the introduction of Lung Offer Filters, new data collection for evaluating offers, and system enhancements to help streamline the allocation process for OPOs and transplant programs. In December 2024, the OPTN Board of Directors approved *Promote Efficiency of Lung Donor Testing*, which will change requirements in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and *Guidance on Requested Deceased Lung Donor Information* once implemented.[7] The development of *Promote Efficiency of Lung Donor Testing* was the Committee's response to the community after hearing transplant programs' concerns about the currency and completeness of information in the organ offers they receive. Most often members stated that the donor data available at the time they are expected to review and respond to lung offers is outdated or incomplete. *Promote Efficiency of Lung Donor Testing* aimed to bring more standardization to lung offers by proposing policy updates that require relevant and timely donor information that make it easier for lung transplant programs to make decisions about organ offers.

While the *Promote Efficiency of Lung Donor Testing* proposal addressed policy requirements and guidance, *Modify Lung Donor Data Collection* addresses data collection aimed to improve efficiency during the lung offer and allocation processes. The Committee proposes additional and updated data collection that would provide lung programs with crucial information for making decisions on lung offers. Additionally, the Committee proposes innovative new features to the OPTN Computer System to filter and screen lung donors, in addition to streamlining communication between OPOs and programs.

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[2] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[3] Ibid.
[4] *Modify Lung Donor Data Collection,* OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[5] *Establish Continuous Distribution of Lungs*, OPTN Lung Transplantation Committee, December 2021, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[6] *Promote Efficiency of Lung Allocation*, OPTN Lung Transplantation Committee, June 2024, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[7] Ibid.

Proposal for Board Consideration

The Committee proposes the addition of new data collection to include History of Smoking (Cigarette Smoking History, Vape Use History, Marijuana Smoking History), Peak Inspiratory Pressure (PIP), and Acceptable Donor Predicted Total Lung Capacity (pTLC) range. The Committee proposes modifying current Diagnostic Testing data collection by adding Diagnostic Test Status. Additionally, the Committee proposes an addition to Lung Offer Filters, which would allow programs to bypass offers for donors whose cigarette smoking history exceeds a cigarette pack year threshold of their choosing. Lastly, the Committee proposes removing the data fields that indicate if a donor smoked greater than 20 pack years and if the program would accept a donor with greater than 20 pack years smoking history.[8] This existing cigarette smoking data collection is proposed for removal because it is being replaced with the proposed cigarette smoking data collection which aims to be more comprehensive and provide additional utility for filtering offers.

In response to public comment feedback, the Committee made a post–public comment revision to include "donor instability" as a selectable reason for OPOs when reporting if a donor diagnostic test could not be completed.[9] To streamline data collection on diagnostic testing “right heart catheterization” will be added to the diagnostic test type drop down list. To further enhance clarity regarding PIP reporting requirements, the Committee also proposes adding a requirement to report PIP in *OPTN Policy 2.11.D: Required Information for Lung Donors.*[10]

OPTN Donor Data and Matching System

The OPTN Donor data and Matching System focuses on the registration of deceased donors, organ matching, organ offers, and placement. **Table 2** displays the proposed data collection changes to the OPTN Donor Data and Matching System, including History of Smoking (Cigarette Smoking History, Vape Use History, Marijuana Smoking History) in addition to PIP, Diagnostic Test Status, and Diagnostic Test Type.

[8] Meeting Summary for November 14, 2024, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[9] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[10] Ibid.

Table 2. Proposed changes to OPTN Donor Data and Matching System

Action	Data Field	Child Field	Response Option/ Data Entry Description
Add	History of Smoking		• Yes • No • Unknown If Yes- • Cigarette Smoking History • Vape Use History • Marijuana Smoking History
Add		Cigarette Smoking History	• Current cigarette smoker • Former cigarette smoker • Never smoked cigarettes • Cigarette smoking history unknown If Current cigarette smoker, or if Former cigarette smoker- Frequency of cigarette smoking: • Packs per day • Cigarettes per day • Unknown How many years did the donor smoke?: • Enter years in open text field • Unknown Cigarette pack years calculated and displayed.

Add		Vape Use History	• Current vape user • Former vape user • Never vaped • Vape history unknown If Current vape user or Former vape user- Frequency of vape use • Every day • Every week • Less than weekly • Unknown How many years did the donor vape?: • Enter years in open text field • Unknown
Add		Marijuana Smoking History	• Current marijuana smoker • Former marijuana smoker • Never smoked marijuana • Marijuana smoking history unknown If Current marijuana smoker or Former marijuana smoker- Frequency of marijuana smoking: • Every day • Every week • Less than weekly • Unknown How many years did the donor smoke?: • Enter years in open text field • Unknown
Add	Peak Inspiratory Pressure (PIP)		Enter PIP in open text field in centimeters of water pressure (cm H_2O).
Modify	Diagnostic Test Type [11]		Add Right Heart Catheterization to dropdown list of tests

[11] Other Diagnostic test types in dropdown include Angiography; Bronchoscopy; Cardiac catheterization; Chest x-ray; CT/MRI; Echocardiograms; EKGs; Ultrasounds; Other specify.

Modify	Diagnostic Test Status		Select test status: • Complete • Pending (awaiting result) • Unable to complete If status is Unable to complete, select all reasons that apply: • Capacity/workflow issue • Proxy refusal • Expertise issue • Equipment issue • Donor instability • Other, specify - free text
Remove	Cigarette Use (>20 Pack Years) Ever		• Yes • No • Unknown If yes- And Continued in the Last Six Months?: • Yes • No • Unknown

Add

History of Smoking

The Committee proposes more detailed data collection on Cigarette Smoking History and the addition of new fields for Vape Use History and Marijuana Smoking History. Although challenging to quantify, vape and marijuana use are clinically relevant for evaluating offers and may inform research on their impact on post-transplant outcomes. [12, 13] Current data collection lacks discrete fields for donor Vape Use History and Marijuana Smoking History, which may result in donors being reported as non-smokers despite significant vape or marijuana use. Capturing this information would give transplant programs a more complete view of a donor's history and support better-informed offer evaluations.

If "Yes" is selected for the History of Smoking field, users will be prompted to provide information on cigarette, vape, and marijuana use.

Cigarette Smoking History

The Committee proposes data collection on Cigarette Smoking History to include donor smoking status (current, former, never, unknown). If the donor is a current or former cigarette smoker, the OPO will be

[12] Workgroup Meeting Summary for June 11, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[13] JM Rappaport, HU Siddiqui, et. al, Cleveland Clinic Lung Transplantation Center, "Effect of donor smoking and substance use on post-lung transplant outcomes," *J Thorac Cardiovasc Surg*, 2023 Aug: 166(2):383-393.e13. doi: 10.1016/j.jtcvs.2023.01.028. Epub 2023 Feb 7. PMID: 36967372.

required to enter frequency of cigarette smoking (entered as packs per day, cigarettes per day, or unknown) and years the donor smoked (enter years in open text field or enter unknown). The Committee proposes that if both the frequency and years fields are completed with responses that are not unknown, the OPTN Donor Data and Matching System will automatically calculate the number of pack years the donor smoked.[14]

Currently, the OPTN Donor Data and Matching System captures whether a donor smoked for greater than 20 pack years and if cigarette smoking had continued in the last six months. Promote Efficiency in Lung Allocation Workgroup (Workgroup) members from lung transplant programs reported that this information is unhelpful in evaluating offers. To be more clinically valuable, lung transplant program representatives expressed the need for additional detail on the number of pack years a donor smoked.[15] Initially, the Workgroup discussed capturing donor cigarette smoking history in smaller pack year categories with data collection that would allow an OPO to indicate if the donor had a cigarette smoking history of less than 5 pack years, 5-10 pack years, 10-20 pack years, 20-30 pack years, 30-40 pack years, or greater than 40 pack years.[16] Ultimately the Committee recommends collection of the raw data to calculate pack years (packs per day or cigarettes per day and number of years smoked). This option is even more granular than categorical collection because it allows OPOs to more accurately report the information they receive from donor historians, as opposed to selection from pack year ranges. The Workgroup discussed that collection of the raw data and the automatic calculation of pack years would accommodate OPOs and reduce potential errors resulting from miscalculation during unit conversion.[17] The Committee proposes that the system allows either packs per day or cigarettes per day be entered into the frequency field.[18] This aims to allow for more flexible data entry, especially when a donor smokes only a few cigarettes a day or week. For example, if a donor smoked 3 cigarettes a week (3 cigarettes per 7 days), the user would enter 0.4 cigarettes per day.[19]

The calculations for pack years are as follows:

Packs per day:

$$Number\ of\ packs\ smoked\ per\ day \times Number\ of\ years\ the\ person\ smoked$$

Cigarettes per day:

$$\frac{Number\ of\ cigarettes\ smoked\ per\ day}{20} \times Number\ of\ years\ the\ person\ smoked$$

The Committee considered including data on how long ago a donor quit smoking, but members agreed that this was less clinically relevant to the offer evaluation, especially when compared to data regarding pack years.[20]

[14] Meeting Summary for November 14, 2024, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[15] Workgroup Meeting Summary for June 11, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[16] Ibid.
[17] Workgroup Meeting Summary for July 9, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[18] Ibid.
[19] Workgroup Meeting Summary for October 15, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[20] Workgroup Meeting Summary for August 20, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

Vape Use History

Although the long-term effects of vaping on pulmonary health are not yet fully understood, the Workgroup acknowledged the community's concern regarding its potential impact on lung function.[21] The Workgroup agreed that access to donor vape use history could prompt transplant programs to conduct a more thorough evaluation of donor chest imaging in cases where vaping is reported.[22, 23]

Vape use refers to the inhalation of vapor through the mouth, usually from a battery-operated electronic device (such as an electronic cigarette) that heats up and vaporizes a liquid or solid.[24] The Committee proposes data collection on Vape Use History to include donor use status (current, former, never, unknown). If the donor is a current or former vape user, the OPO will be required to enter frequency of vape use (every day, every week, less than weekly, unknown) and years the donor vaped (enter years in open text field or enter unknown).

Before deciding on the frequency of vape use data field, the Workgroup investigated available methods for quantifying vape use. The Workgroup found that current research methods for quantifying vape use include number of cartridges per day and number of uses per day. Members agreed that this level of detail would be too granular to collect accurately from donor historians. When determining response options for frequency of vape use, the Workgroup discussed the inclusion of "multiple times daily" and "less than monthly" but agreed these should be removed because such granularity is not clinically meaningful and could be overly burdensome to OPOs and the donor historians.

The Workgroup considered adding vape type, such as with marijuana and with or without nicotine. Though such granularity in data collection would be useful to future research, members agreed that information on vape type would not impact efficiency of offer evaluation.[25] However, the Committee proposes that if a donor vaped marijuana or Tetrahydrocannabinol (THC), it should be entered under Vape Use History instead of Marijuana Smoking History.

Marijuana Smoking History

The Workgroup proposes data collection on Marijuana Smoking History, as current literature demonstrates that marijuana use negatively impacts lung function and is detrimental to respiratory health.[26] Given the increasing legalization of marijuana, the Workgroup agreed that obtaining a donor's marijuana smoking history is an important consideration when evaluating lung offers.[27]

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[21] John Erhabor, Zhiqi Yao, et al., "E-cigarette Use and Incident Cardiometabolic Conditions in the All of Us Research Program", *Nicotine & Tobacco Research*, 2025: ntaf067, https://doi.org/10.1093/ntr/ntaf067.
[22] Workgroup Meeting Summary for August 13, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[23] L. Honeycutt, K. Huerne, et al., "A systematic review of the effects of e-cigarette use on lung function," *NPJ Prim Care Respir Med*, 2022 Oct 22;32(1):45. doi: 10.1038/s41533-022-00311-w. PMID: 36273009; PMCID: PMC9588082.
[24] American Cancer Society, "What Do We Know About E-cigarettes?", https://www.cancer.org/cancer/risk-prevention/tobacco/e-cigarettes-vaping/what-do-we-know-about-e-cigarettes.html. Accessed October 23, 2024.
[25] Workgroup Meeting Summary for August 13, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[26] J. Vásconez-González, K. Delgado-Moreira, et al., "Effects of Smoking Marijuana on the Respiratory System: A Systematic Review," *Subst Abus,* 2023 Jul;44(3):249-260. doi: 10.1177/08897077231186228. Epub 2023 Sep 20. PMID: 37728136.
[27] Workgroup Meeting Summary for June 11, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

Similar to proposed data collection for Vape Use History, the Committee proposes data collection on marijuana smoking history to include donor smoking status (current, former, never, unknown). If the donor is a current or former marijuana smoker, the OPO will be required to enter frequency of marijuana smoking (every day, every week, less than weekly, unknown) and years the donor smoked (enter years in open text field or enter unknown).

The Workgroup was also interested in methods for quantifying marijuana use. After discussing this idea with OPO representation on the Workgroup, members agreed that current research methods for quantifying marijuana use which involve joint-years, gram-years, and other estimates of usage, are either not applicable to all forms of marijuana smoking or too granular to collect accurately from donor historians.[28] The Workgroup also discussed collecting marijuana smoking methods (e.g. joint, bong, etc.), but ultimately decided against it after agreeing that currently there is no demonstrated clinical significance, and it would not impact efficiency of offer evaluation.[29] Additionally, the Workgroup discussed the inclusion of "multiple times daily" and "less than monthly" in the response options for frequency of marijuana smoking history, but agreed these should be removed because such granularity is not clinically meaningful and could be overly burdensome to OPOs and the donor historians.[30]

Public comment feedback on the addition of History of Smoking data collection

Feedback indicated broad consensus across professional societies, regions, transplant programs, and OPOs that more granular and structured smoking history data is clinically valuable.[31] Stakeholders agreed that the updated data collection, including the automated calculation of cigarette pack years and the addition of data on vaping and marijuana use will provide transplant programs with more valuable information for evaluating lung offers. Some concerns highlighted that family members may not have detailed knowledge of donor smoking habits. The Committee proceeded with no post-public comment changes to this part of the proposal. The Committee reaffirmed its proposal for the History of Smoking, Cigarette Smoking History, Vape Use History, and Marijuana Smoking History data collection and data definitions.

Peak Inspiratory Pressure (PIP)

The Committee proposes the addition of data collection on the Peak Inspiratory Pressure (PIP). PIP would be entered in centimeters of water pressure (cm H_2O). Upon implementation of *Promote Efficiency of Lung Donor Testing, OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* would require the PIP to be reported with the ventilator settings at the same frequency as Arterial Blood Gases (ABGs).[32]

[28] Workgroup Meeting Summary for July 9, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[29] Workgroup Meeting Summary for August 13, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[30] Workgroup Meeting Summary for September 10, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[31] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[32] Meeting Summary for November 14, 2024, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

PIP is an indirect measure of donor lung compliance[33] and a fundamental metric captured on ventilators, making it easy to obtain for reporting purposes.[34, 35] OPO representatives on the Workgroup agreed that the PIP is easily obtainable and many OPOs currently enter this data for offer evaluation.[36] The Workgroup discussed that collecting plateau pressure (Pplat) may be more desirable as PIP is the surrogate value for Pplat; however, data for Pplat is often less reliable due to the variability in how it is measured by clinical staff.[37] The Committee proposes PIP values be reported with ABGs, as PIP values would be inaccurate if they were reported during donor managment.[38]

Public comment feedback on the addition of Peak Inspiratory Pressure (PIP) data collection

While there is general agreement that assessing lung compliance is important, feedback indicated that the community is divided on the collection of PIP.[39] Supporters consider PIP a readily available and operationally feasible metric that could assist with organ offer decisions. In contrast, some community members argue that PIP is an imperfect surrogate for true lung compliance and may mislead decision-making if used in isolation. These stakeholders advocate for the collection of more informative and contextual ventilator data, such as Pplat, positive end-expiratory pressure (PEEP), and tidal volume. Additional concerns include variability when PIP is documented across donor hospitals and the potential burden of mandatory reporting. Stakeholders also requested greater clarity on the ventilator settings and timing associated with the proposed PIP data collection.

During post–public comment discussions, the Committee revisited its rationale for recommending the collection of PIP as opposed to Pplat.[40] The Committee reaffirmed its support for collecting PIP, citing its accessibility and reliability, as it is obtained directly from the ventilator. In contrast, Pplat was considered more subject to variability, as its measurement can be influenced by differences in interpretation and technique among clinical staff.

In response to feedback requesting greater clarity on the timing of PIP collection and concerns that PIP may be collected in isolation without specific ventilator settings, the Committee recommended revising *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* to clearly state when PIP must be collected and what ventilator settings must accompany it.[41] In the public comment proposal, the Committee stated that, "Upon implementation of *Promote Efficiency of Lung Donor Testing*, *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* would require the PIP to be reported with the ventilator settings at the same frequency as ABGs." This means that whenever an ABG is required in the policy, PIP must also be collected and reported, along with the relevant ventilator parameters.

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[33] Z Edwards, P. Annamaraju, *Physiology, Lung Compliance*, [Updated 2023 Mar 13], In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK554517/.
[34] AL Mora Carpio, JI Mora, *Ventilator Management*, [Updated 2023 Mar 27], In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448186/Ventilator Management.
[35] Meeting Summary for August 13, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[36] Ibid.
[37] Ibid.
[38] Meeting Summary for September 10, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[39] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[40] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[41] Ibid.

OPTN Policy 2.11.D: Required Information for Deceased Lung Donors defines a "challenge gas" as an ABG obtained with including specific ventilator settings for PEEP, tidal volume, and fraction of inspiratory oxygen concentration (FiO2). The policy requires that a challenge gas be collected within four hours prior to the initial lung offer made by the host OPO on a match run. This requirement must be fulfilled before the initial lung offer can be sent. Additionally, the policy outlines information the host OPO must make reasonable efforts to obtain for all deceased lung donors. If this information cannot be obtained, the host OPO must document the reason and make the documentation available to the OPTN upon request. Among this information are challenge gases, which must be obtained at least every 6–8 hours between the time of the initial offer and organ recovery. The requirement for PIP collection is aligned with these standards. PIP must be reported at the time the initial challenge gas is collected within four hours prior to the first offer and within the 6–8 hour intervals thereafter. As with other required information, if the host OPO is unable to obtain PIP or related data, it must document the reason and make that documentation available to the OPTN upon request.

Modify

Diagnostic Test Status

The Committee proposes modifying the current data collection on Diagnostic Testing to include Diagnostic Test Status. This modification would allow an OPO to indicate if diagnostic testing collected in the OPTN Donor Data and Matching System is complete, pending or unable to complete.[42] Current diagnostic tests include angiography, bronchoscopy, cardiac catheterization, chest x-ray, computed tomography (CT)/magnetic resonance imaging (MRI), echocardiograms, electrocardiogram (EKGs), ultrasounds, and other specify. A multi-select would allow the OPO to select the reason(s) if the test could not be completed. Proposed reasons include capacity/workflow issue, proxy refusal, expertise issue, equipment issue, and other, specify.[43]

Initially, the Workgroup discussed adding the above diagnostic test status data collection to only bronchoscopy and chest CT scans. Members agreed that this feature aims to increase efficiency by reducing communication between OPOs and transplant centers outside the OPTN Donor Data and Matching System regarding test status and barriers to testing completion.[44] To ensure consistency in reporting requirements for diagnostic tests, members of the Workgroup supported adding diagnostic test status options to all diagnostic tests in the OPTN Donor Data and Matching System. [45] The Workgroup agreed upon the test status options: complete, pending (awaiting test result), and unable to complete. Required reporting of the reason(s) if the test could not be completed ensures OPOs are accountable for meeting policy requirements.[46] The options to report capacity/workflow, expertise, and equipment issues would capture information on the extent of OPO/donor hospital resource limitations. "Proxy refusal" would apply to cases in which the donor's proxy declines testing. The preference to refrain from data fields in the "other, specify" format was acknowledged; however, members reported a need to capture less common scenarios that could not be categorized otherwise.[47] *Promote Efficiency of Lung Donor Testing* requires that OPOs document the reason(s) any of the Lung Donor Testing outlined

[42] Meeting Summary for August 20, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[43] Meeting Summary for August 20, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[44] Ibid.
[45] Ibid.
[46] Ibid.
[47] Ibid.

in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* could not be obtained.[48] This data modification to Diagnostic Testing better enables OPOs to align with this requirement.

Public comment feedback on the modification of Diagnostic Test Status data collection

Overall, stakeholders expressed support for the Committee's intent to streamline communication and minimize unnecessary back-and-forth by including the diagnostic testing status field.[49] One of the most consistently voiced benefits of adding diagnostic test status fields is the potential to improve efficiency and reduce communication delays between OPOs and transplant centers. Stakeholders emphasized that the real-time visibility of whether key diagnostic tests are complete, pending, or unable to be completed would allow transplant teams to make quicker, more confident decisions about organ acceptance.

While many stakeholders support the intention of collecting diagnostic test statuses to improve transparency and decision-making, technical and workflow challenges were raised. Some respondents agreed that without real-time notifications, transplant programs would still rely on manual updates from OPOs (calls, emails, notes). They recommended the addition of such notifications to the policy's implementation. Some OPO stakeholders noted that because the diagnostic test type dropdown does not include RHC, they use angiography to record a RHC result.

During discussions regarding the potential inclusion of automatic electronic notifications for diagnostic testing status updates, the Committee learned of a broader, OPTN-approved project that is expected to address this issue more comprehensively. Led by the OPTN Operations and Safety Committee, this project aims to re-evaluate deceased donor testing requirements for all organs except lung, with the goal of promoting greater efficiency in the organ offer process.[50] As a result, the Committee agreed that the scope of the current project should not be expanded to include electronic notifications and that this issue would be more appropriately addressed in coordination with future notification standards applicable across all organs. [51]

As a post–public comment revision, the Committee proposes adding "donor instability" as a selectable reason for OPOs when reporting that a donor diagnostic test could not be completed.[52] The Committee clarified that this option should be used when a donor is too unstable for diagnostic testing. To ensure accurate data recording, RHC is being proposed as an addition to the diagnostic test type dropdown list.

Remove

Cigarette Use (>20 Pack Years) Ever

The Committee proposes removing data collection from the OPTN Donor Data and Matching System that requires OPOs to indicate if a donor smoked greater than 20 pack years and continued smoking in the last six months.[53] As previously mentioned, the Committee proposes more granular and clinically

[48] *Promote Efficiency of Lung Donor Testing*, OPTN Lung Transplantation Committee, December 2024 https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[49] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[50] Meeting Summary for June 14, 2024, OPTN Executive Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[51] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[52] Ibid.
[53] Meeting Summary for November 14. 2024. OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

significant Cigarette Smoking History data collection and supports that the current cigarette smoking data collection in the OPTN Donor Data and Matching System is no longer necessary and can therefore be removed.[54]

Public comment feedback on the removal of Cigarette Use (>20 Pack Years) Ever data collection

Stakeholders expressed support for removing the Cigarette Use (>20 Pack Years) Ever data field, recognizing that it would be replaced by a more detailed data collection that captures donor smoking status, frequency, duration, and includes an automated pack year calculation.[55] The Committee proceeded with no post-public comment changes to this part of the proposal. The Committee reaffirmed its recommendations for the removal of Cigarette Use (>20 Pack Years) Ever data collection as proposed in public comment.[56]

Deceased Donor Registration (DDR)

The Deceased Donor Registration (DDR) is a record of donor information completed for all deceased donors from whom at least one organ has been recovered for the purposes of transplantation. The Committee proposes updating the DDR collection instrument to mirror the proposed addition of Cigarette Smoking History data and proposed removal of Cigarette Use (>20 Pack Years) Ever and Continued in Last Six Months data collection. **Table 3** shows the proposed changes to the DDR.

Table 3. Proposed changes to the Deceased Donor Registration (DDR)

Action	Data field	Response Option/ Data Entry Description
Add	Cigarette Smoking History	• Current cigarette smoker • Former cigarette smoker • Never smoked cigarettes • Cigarette smoking history unknown If Current cigarette smoker, or if Former cigarette smoker- Frequency of cigarette smoking: • Packs per day • Cigarettes per day • Unknown How many years did the donor smoke?: • Enter years in open text field • Unknown

[54] Ibid.
[55] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[56] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

Action	Data field	Response Option/ Data Entry Description
Remove	Cigarette Use (>20 Pack Years) Ever	• Yes • No • Unknown If yes- And Continued in the Last Six Months?: • Yes • No • Unknown

The proposed Marijuana Smoking History data changes will not be mirrored on the DDR. On September 14, 2023, the OPTN implemented data collection changes to the DDR that captures information on deceased donor drug use history, including any history of marijuana smoking.[57] This data collection is as follows:

Ever use or take drugs, such as steroids, cocaine, heroin, amphetamines, opioids or marijuana?

- Type of drug
- How often and how long was it used?
- When was it last used?
- Route (inhaled, needles, ingested)

The proposed Vape Use History and PIP data changes will also not be mirrored on the DDR. PIP is a lung-specific data point that needs to be collected at multiple points in the donation process alongside ABGs.[58] The Committee felt Vape Use data collection would be more useful to capture at the point of offer evaluation.[59]

Public comment feedback on the proposed changes to the Deceased Donor Registration (DDR)

There was no substantive feedback on proposed data changes to the DDR. The Committee proceeded with no post-public comment changes to this part of the proposal. The Committee reaffirmed its recommendations for the addition of Cigarette Smoking History data collection and data definitions and the removal of Cigarette Use (>20 Pack Years) Ever data collection as proposed in public comment. [60]

[57] *Modifications to the Deceased Donor Registration (DDR)*, OPTN Organ Procurement Organization Committee, June 2021, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[58] Workgroup Meeting Summary for August 13, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[59] Ibid.
[60] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

OPTN Waiting List

The OPTN Waiting List is the list of candidates registered to receive organ transplants. When a donor organ becomes available, the matching system generates a new, more specific list of potential recipients based on the criteria defined in that organ's allocation policy. The Committee proposes the addition of an optional feature that would allow a transplant program to screen donors based on an acceptable donor pTLC range. The Committee proposes the removal of data collection that allows a program to indicate if they would accept a donor with a cigarette use greater than 20 pack years. **Table 4** shows the proposed changes to the OPTN Waiting List.

Table 4. Proposed changes to the OPTN Waiting List

Action	Data field	Response Option/Data Entry Description
Add	Acceptable Donor Predicted Total Lung Capacity (pTLC) Range	Enter minimum and maximum acceptable donor pTLC range in Liters (L)
Remove	Accept a Donor with Cigarette Use > 20 Pack Years Ever?	• Yes • No

Add

Acceptable Donor Predicted Total Lung Capacity (pTLC) Range

Total Lung Capacity (TLC) is the volume of air in the lungs upon the maximum effort of inspiration.[61] TLC can be reported as actual (aTLC) or predicted (pTLC) values. The aTLC refers to the real, measured total lung capacity of an individual, obtained through pulmonary function tests, while pTLC is an estimation of total lung capacity that is calculated based on factors like height, age, and birth sex.[62] The Committee proposes the calculation and display of pTLC for the donor and updating Lung Donor Acceptance Criteria to allow for screening of donors that are outside a range of the transplant program's acceptable pTLC values. Transplant programs may use this optional feature by entering the minimum and maximum range of donor predicted total lung capacity they would accept for their patient in Liters (L).[63] Additionally, the Committee proposes that this screening could be used in addition to donor height screening or in place of donor height screening.[64]

The Committee proposes the use of the Global Lung Initiative's (GLI) formula to calculate the donor's pTLC.[65] The Committee discussed the limitations of the GLI formula, including that it was developed on an all-European cohort and that variability between donors' actual TLC and their pTLC may be greater in a more racially and ethnically diverse American donor population than in the European cohort in which

[61] "Total Lung Capacity", *ScienceDirect*, Accessed December 11, 2024, https://www.sciencedirect.com/topics/medicine-and-dentistry/total-lung-capacity
[62] Workgroup Meeting Summary for June 11, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[63] Ibid.
[64] Workgroup Meeting Summary for August 20, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[65] Meeting Summary for September 27, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

the formula was originally developed.[66] The Committee recommends programs account for this potential increased variability by setting wider acceptable ranges of donor pTLC in the donor acceptance criteria. Additionally, the Committee recommends that if a donor's height or age falls outside of the GLI formula limitations (donors outside 5-80 years of age or 50-230 cm tall), the pTLC will not be calculated or used for screening.

Before recommending the GLI formula for calculating donor pTLC, the Committee considered using the European Respiratory Society (ERS) formula. The Committee consulted with experts in the Pulmonary Function Testing (PFT) field, who recommended the GLI reference equations, as they are the current standard for reporting and interpretation of lung volume measurements.[67, 68] After thoroughly discussing the limitations expressed above, the Committee recommends proceeding with the GLI formula.[69] Given the need to increase efficiency in lung allocation and the formula's utility in size-matching, members agreed it would be justified to use this formula until and unless a calculation is validated against a more diverse cohort in the future, in which case the Committee would revisit this recommendation to make sure that it remains up to date with science and practice in the community. Members suggested displaying a disclaimer in the OPTN system to bring awareness to the limitations of the formula.[70] It is important to note that in alignment with the American Thoracic Society's Official Statement on Race, Ethnicity and Pulmonary Function Test Interpretation, the GLI formula does not include any race-based coefficients.[71] **Figure 1** shows the GLI formula.

Figure 1. Global Lung Initiative formula [72, 73]

TLC	Male	exp(−10.5861+0.1433*log(age)+2.3155*log(height)+Mspline)
	Female	exp(−10.1128+0.1062*log(age)+2.2259*log(height)+Mspline)

In January 2024, the Committee released *Promote Efficiency of Lung Allocation* to public comment.[74] This project proposed new data collection in the OPTN Donor Data and Matching System to aid evaluation of lung offers and provided an overview of planned and potential system enhancements that are intended to make it easier for lung transplant programs to say "yes" to organ offers. One of the feedback questions for the community asked, "How else might the OPTN improve the efficiency of lung

[66] G.L. Hall, N. Filipow, et al., "Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry," *Eur Respir J*, 2021 Mar 11;57(3):2000289. doi: 10.1183/13993003.00289-2020. PMID: 33707167.
[67] Meeting Summary for September 27, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[68] G.L. Hall, N. Filipow, et al., "Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry," *Eur Respir J*, 2021 Mar 11;57(3):2000289. doi: 10.1183/13993003.00289-2020. PMID: 33707167.
[69] Ibid.
[70] Ibid.
[71] *ATS Publishes Official Statement on Race, Ethnicity and Pulmonary Function Test Interpretation,* American Thoracic Society, Accessed November 20, 2024, https://site.thoracic.org/about-us/news/ats-publishes-official-statement-on-race-ethnicity-and-pulmonary-function-test-interpretation.
[72] G.L. Hall, N. Filipow, et al., "Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry," *Eur Respir J*, 2021 Mar 11;57(3):2000289. doi: 10.1183/13993003.00289-2020.
[73] Age represents the donor's age in years and height represents the donor's height in cm. Mspline is an age-and-sex-varying coefficient that is provided by the GLI for use with this equation.
[74] *Promote Efficiency of Lung Allocation*, OPTN Lung Transplantation Committee, June 2024, accessed November 20, 2024, https://optn.transplant.hrsa.gov (accessed November 20, 2024).

allocation for both transplant programs and OPOs?" One of the most common and actionable responses to this question was the addition of pTLC to the OPTN Computer System. During discussions about ways to operationalize this feature, the Committee considered providing a field for the transplant program to report aTLC for lung candidates in the OPTN Waiting List, or that the system would calculate and display the pTLC for lung candidates, based on data that is already required in the system.[75] The Committee did not adopt either of these options, and instead proposes the calculation of pTLC for donors with the transplant program's ability to screen based on the calculated pTLC. Members discussed the variation in size-matching practices and that the use of pTLC is a surgeon-driven decision. The Committee proposes this feature as optional and therefore, it may improve efficiency for some programs but not all.[76]

Public comment feedback on the addition of Acceptable Donor Predicted Total Lung Capacity (pTLC) Range

Stakeholders broadly supported adding Acceptable Donor Predicted Total Lung Capacity (pTLC) Range, recognizing its potential to improve donor-recipient size matching and lung allocation efficiency.[77] Respondents emphasized that pTLC offers a more informed basis for decision-making than donor height alone, provided the limitations of the GLI formula are acknowledged. Transplant programs noted that the automatic calculation of donor pTLC will ensure accurate calculation. The Committee reaffirmed the addition of acceptable donor pTLC range and data definitions as proposed in public comment.[78]

Remove

Accept a Donor with Cigarette Use > 20 Pack Years Ever

The Committee proposes the removal of data collection from the OPTN Waiting List that allows a program to indicate if they would accept a donor with a cigarette use greater than 20 pack years.[79] This proposed change removes the capability to set candidate-level screening on donor smoking history, as often times programs have a standard cutoff of pack years they will accept for all their candidates, as opposed to candidate-specific pack year preferences.[80] The following section describes an addition to Lung Offer Filters, which improves upon the current data collection. Once implemented, the "accept a donor with a cigarette use greater than 20 pack years" field will no longer be necessary.

Public comment feedback on the removal of Accept a Donor with Cigarette Use > 20 Pack years Ever

Stakeholders expressed support for removing the Accept a Donor with Cigarette Use > 20 Pack years Ever data field, acknowledging that it would be replaced by a more flexible lung offer filter.[81] This new

[75] Meeting Summary for June 11, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[76] Ibid.
[77] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[78] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[79] Meeting Summary for November 14, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[80] Meeting Summary for June 11, 2024, OPTN Lung Transplantation Committee Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[81] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).

filter allows transplant programs to set their own threshold for acceptable cigarette pack year history, including retaining the 20 pack year benchmark if desired. While a couple of commenters emphasized the significance of the 20 pack year threshold, the proposed filter accommodates this preference. Based on the overall feedback, the Committee made no post–public comment changes to this portion of the proposal and reaffirmed its proposal to remove the Accept a Donor with Cigarette Use > 20 Pack years Ever data field.[82]

Lung Offer Filters

Organ offer filters allow transplant programs to apply custom-designed, program-specific, multi-factorial filters to bypass donor offers that they do not want to receive. The purpose of offer filters is to get to organ offer acceptance faster by reducing the number of unwanted organ offers that OPOs need to make and transplant programs need to review, thereby decreasing allocation time and increasing organ acceptance. **Table 5** shows the proposed changes to the Lung Offer Filters.

Table 5. Proposed changes to lung Offer Filters

Action	Data field	Response Option/Data Entry Description
Add	Donor Cigarette Use Exceeds	Enter number of pack years an acceptable donor must not exceed

Add

Donor Cigarette Use Exceeds

The Committee proposes the addition of a lung offer filter which allows programs to filter out lung offers that exceed a cigarette pack year quantity of their choosing.[83] For example, if a program indicated they did not want to see any lung offers from donors that have more than 30 cigarette pack years, the program would only receive lung offers from donors that have 30 cigarette pack years or less. This proposed addition to Lung Offer Filters could be used in combination with the existing lung offer filters implemented in January 2024.[84, 85] Programs will still be able to exclude certain candidates from this filter if they want those candidates to receive offers from donors with any cigarette smoking history.[86]

Public comment feedback on the addition of Donor Cigarette Use Exceeds offer filter

Respondents expressed support for the inclusion of a lung offer filter based on donor cigarette use, emphasizing its potential to improve efficiency.[87] Stakeholders endorsed this filter as a practical and impactful tool to align donor offers with center-specific acceptance criteria. The ability to preemptively exclude unsuitable offers based on a clearly defined data point was described as a way to reduce unnecessary communication and expedite lung placement. Feedback was also supportive of extending

[82] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[83] Workgroup Meeting Summary for August 20, 2024, OPTN Lung Transplantation Committee See Promote Efficiency of Lung Allocation Workgroup, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[84] *Offer Filters now available for lung allocation,* https://unos.org/news/offer-filters-now-available-for-lung-allocation/.
[85] Lung Offer Filters include “donor type”, “distance in nautical miles”, “donor age is less than”, and “donor age is more than”.
[86] Meeting Summary for November 14, 2024, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[87] *Modify Lung Donor Data Collection*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).

filter options to marijuana, vape use, and diagnostic testing status at a future date. The Committee made no post–public comment changes to this portion of the proposal.[88]

Feedback regarding the Uniform Donor Risk Assessment Interview (UDRAI)

Many commenters emphasized that the current UDRAI is outdated and in need of modernization, noting that it does not differentiate between cigarette, vaping, or marijuana use and fails to capture the quantity or frequency of use—critical details for evaluating donor lung quality.[89] Stakeholders expressed strong support for updating the UDRAI in tandem with OPTN policy changes, urging the OPTN to collaborate with the governing bodies responsible for the UDRAI to ensure any new data fields added to the Donor Data and Matching System are also reflected in the DRAI. Without such coordination, commenters warned that duplicative data collection across systems would increase documentation time for OPO staff, introduce inconsistencies in donor records, and complicate compliance reviews and chart audits.

The OPTN does not own the UDRAI, and therefore it is outside the scope of this policy to directly update the form. However, the Committee recommends that the OPTN collaborate with the American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations (AOPO), and the Eye Bank Association of America (EBAA) to consider updates to the UDRAI.[90]

Overall Sentiment from Public Comment

The Committee welcomed all input on Modify Lung Donor Data Collection, but asked for the following specific feedback during public comment:

- Will this new and updated data collection provide transplant programs with useful, granular information for making decisions about potential lung donors?
- Do OPOs foresee challenges or burden related to this data collection?
- Could the data fields, response options, or data definition be clearer?
- Does the community support use of the Global Lung Function Initiative (GLI) calculation to predict Total Lung Capacity?
- Will lung transplant programs use the proposed addition to lung offer filters?
- Do OPOs and transplant programs think the proposed Diagnostic Test Status data collection will increase efficiency and decrease back and forth regarding the availability of lung donor testing?
- Do patients and donor family members support proposed data collection changes to streamline communications between transplant programs and OPOs to place organs more efficiently?

The proposal was released for public comment from January 21, 2025 - March 19, 2025. Respondents were able to provide sentiment and comments through regional meetings, committee meetings and a form on the OPTN website. Demographic information was collected from all respondents.

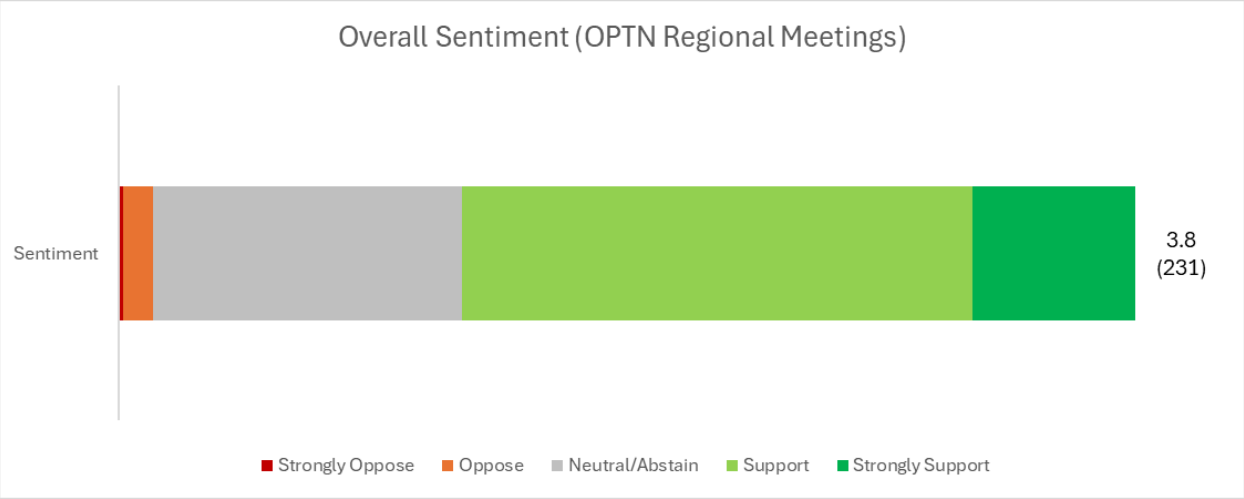
[88] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[89] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[90] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

Sentiment in Public Comment

Sentiment by Region (OPTN Regional Meetings)

Figure 2 shows the overall sentiment captured during OPTN regional meetings, based on a total of 231 responses. Overall, feedback was generally supportive of the proposal, reflected in an average sentiment score of 3.8. However, several regions expressed specific concerns, which are discussed in greater detail throughout this briefing paper.

Figure 2. Overall Sentiment (OPTN Regional Meetings)[91, 92]

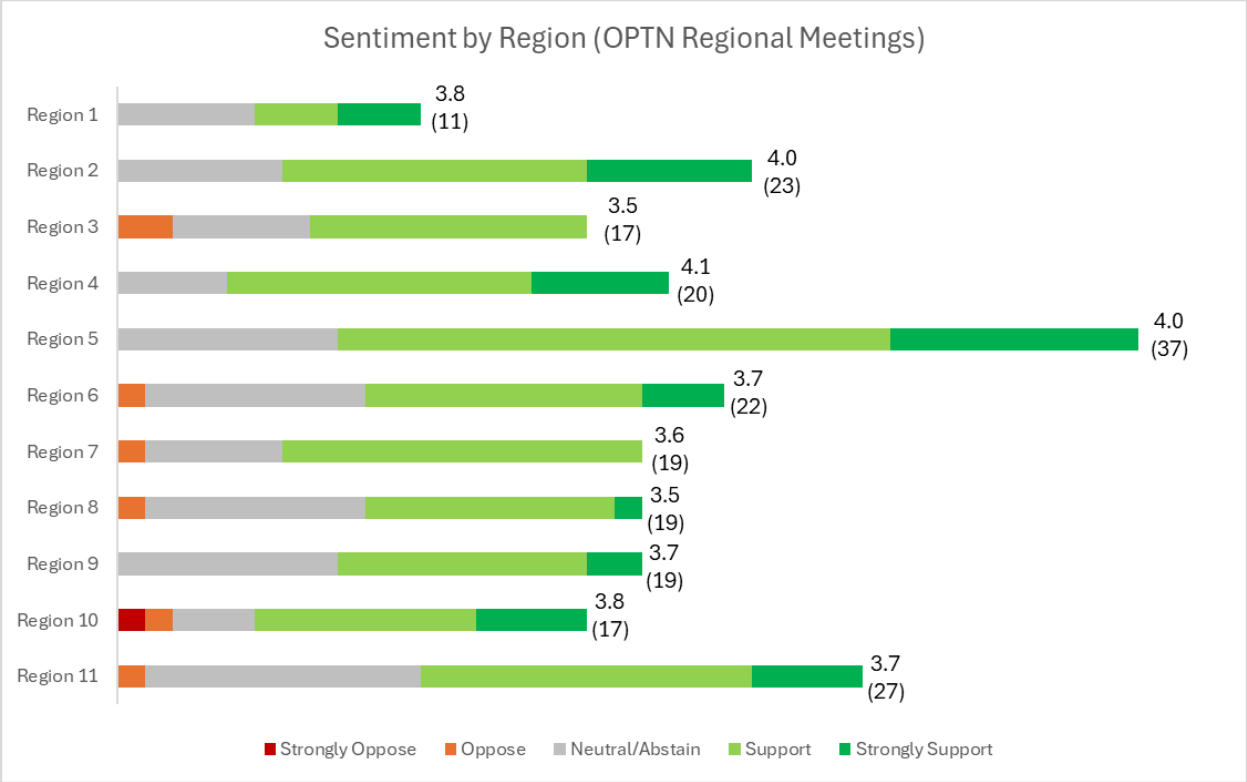


[91] The top number represents the average sentiment score, and the second number in parentheses represents the total number of respondents.

[92] Sentiment is collected on public comment proposals during OPTN regional meetings and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5).

Figure 3 shows sentiment received at OPTN regional meetings by region. Sentiment by region was generally supportive. A few respondents in regions 3, 6, 7, 8, 10, and 11 submitted opposing and/or strongly opposing sentiment.

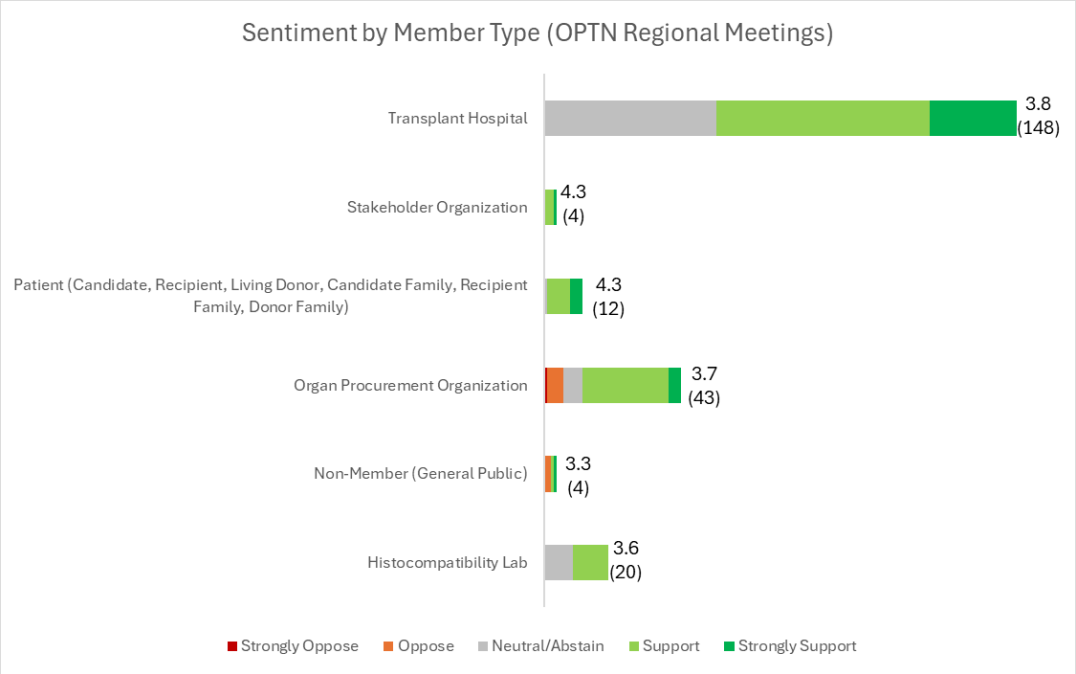
Figure 3. Sentiment by Region (OPTN Regional Meetings)[93, 94]



[93] The top number represents the average sentiment score, and the second number in parentheses represents the total number of respondents. The size of the bar reflects the total number of respondents per region.
[94] Sentiment is collected on public comment proposals during OPTN regional meetings and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5).

Figure 4 shows sentiment received at OPTN regional meetings by member type. Sentiment by member type was generally supportive, with transplant hospitals submitting the most responses. Organ Procurement Organizations and Non-Member (General Public) expressed opposing or strongly opposing sentiment. All other member types submitted supportive, strongly supportive, and/or neutral sentiment.

Figure 4. Sentiment by Member Type (OPTN Regional Meetings)[95, 96]



[95] The top number represents the average sentiment score, and the second number in parentheses represents the total number of respondents. The size of the bar reflects the total number of respondents by member type.
[96] Sentiment is collected on public comment proposals during OPTN regional meetings and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5).

Support on OPTN Website

The public comments submitted on the OPTN website were categorized based on the sentiment expressed in the text submitted. Each comment was analyzed to identify whether it conveyed support, opposition, or neutrality towards the proposal. The following definitions were used to ensure clarity and consistency in the categorization process:

- **Support:** The text of the public comment expressed a positive stance towards the proposal. Supportive comments typically contained language that endorsed, agreed with, or advocated for the proposal.
- **Do Not Support:** The text of the public comment expressed a negative stance towards the proposal. Comments that do not support the proposal contained language that opposed or disagreed with the proposal.
- **Neutral:** The text of the public comment did not clearly express a positive or negative stance towards the proposal. Neutral comments lacked definitive "support" or "not support" language or presented balanced viewpoints on the proposal.

Figure 5 shows the overall support from the OPTN website comments. Overall, 58% (14) of comments were supportive, and 42% (10) of comments were neutral.

Figure 5. Overall Support (OPTN Website Comments)

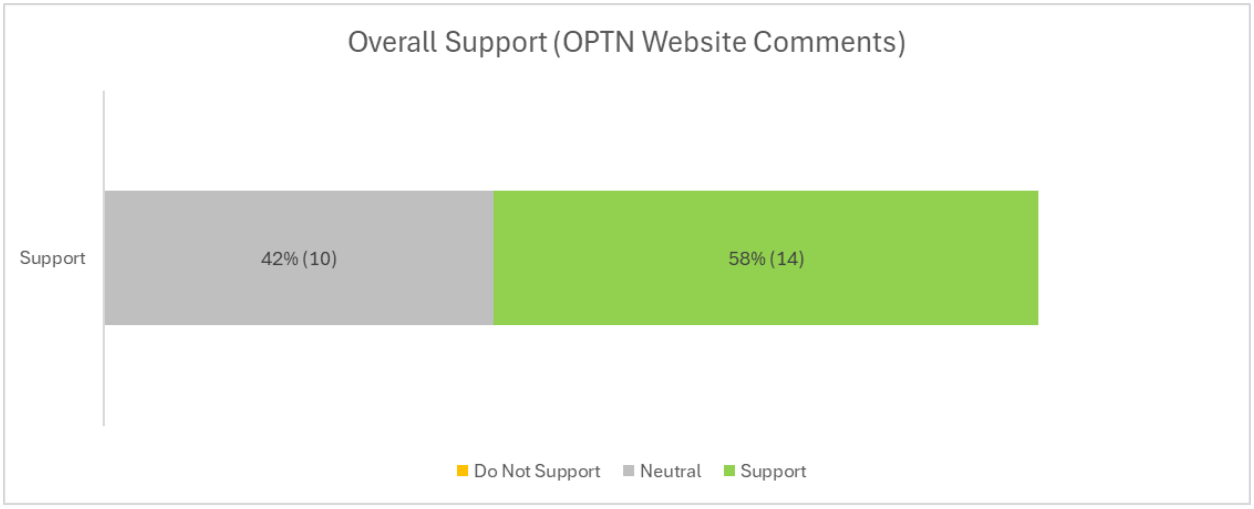
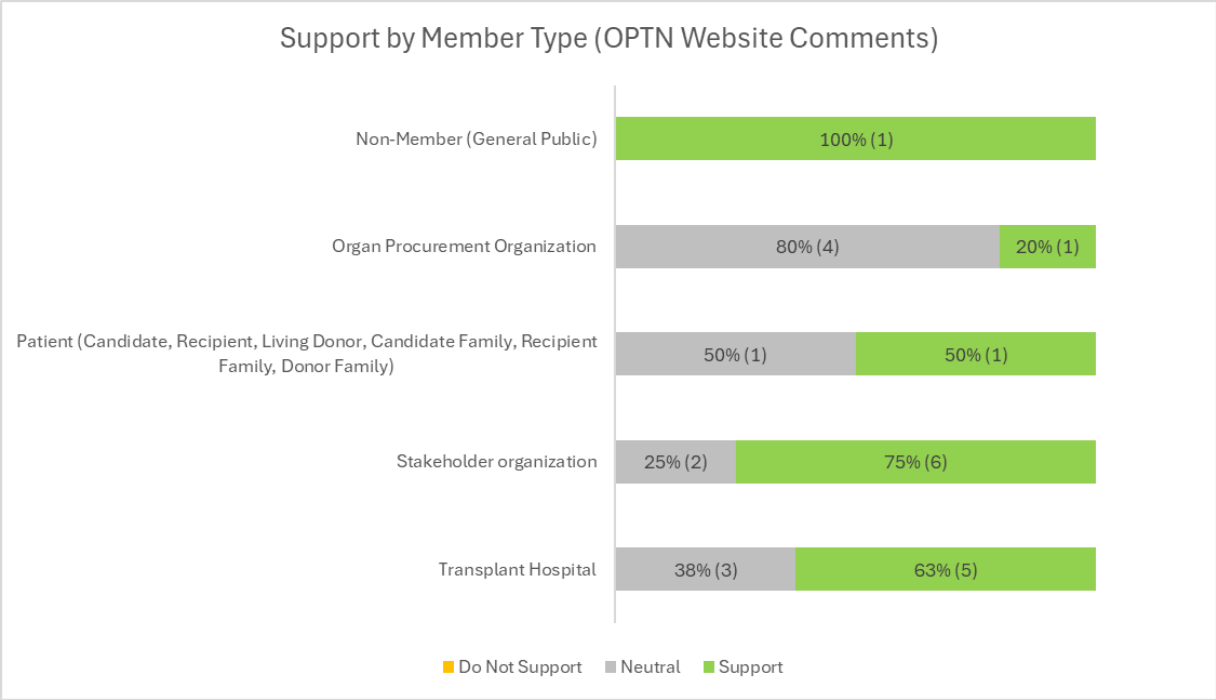


Figure 6 shows the support by member type on the OPTN website comments. Support by member type was generally supportive, with all member type submitting either supportive or neutral comments.

Figure 6. Support by Member Type (OPTN Website Comments)



Overall, public comment sentiment expressed during OPTN regional meetings and on the OPTN website indicated broad support for the proposal. Most regions and member types reported neutral, strong, or strongly supportive sentiment, with minimal opposition. Comments submitted on the OPTN website reflected either supportive or neutral sentiment across all respondents and member types.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall "collect, analyze, and publish data concerning organ donation and transplants,"[97] as well as the OPTN Final Rule, which states that the OPTN shall "maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors."[98] This proposal would manage information about organ donors, as it requires donor data collection in the OPTN Donor Data and Management System and DDR. It would also manage information about transplant candidates by providing tools for screening and filtering donors through new features to the OPTN Waiting List and Lung Offer Filters.

[97] 42 U.S.C. §274(b)(2)(I).
[98] 42 C.F.R. §121.11(a)(1)(i).

OPTN Strategic Plan

Increase the number of transplants: If the completeness of data for organ offers received by lung transplant programs improves, these programs will be able to review/respond to offers more quickly and accept organs earlier in the allocation process.

Implementation Considerations

The OPTN, OPOs, and lung transplant programs would need to take action to implement this proposal. This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Organ Procurement Organizations

Operational Considerations

OPOs would be required to provide additional data on deceased lung donors in the OPTN Donor Data and Matching System. Reporting this additional lung donor data may require staff training, adjustments to existing workflows, and increased staff time spent on each lung donor offer. OPOs should also be aware of the changes to the DDR.

Fiscal Impact

This proposal is expected to have low fiscal impact on OPOs. Extra time will be needed to review additional data points added by the proposal.

Transplant Programs

Operational Considerations

Transplant programs will need to ensure staff are educated on the new features in OPTN Waiting List and Lung Offer Filters and consider modifying how offers are screened at the candidate-level (via donor acceptance criteria) and bypassed at the program-level (via offer filters). Programs should also be aware of changes to changes to the OPTN Donor Data and Matching System.

Fiscal Impact

There were no significant fiscal impacts indicated with this proposal.

Histocompatibility Laboratories

Operational Considerations

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

Fiscal Impact

There were no significant fiscal impacts indicated with this proposal.

OPTN

Operational Considerations

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that 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. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

To implement this proposal, the OPTN would add new data fields in the OPTN Computer System and communicate data and policy changes to the transplant community. The OPTN would provide help documentation for the new data fields to provide additional instruction for submitting these data.

Resource Estimates

It is estimated that $560,690 will be needed to implement this proposal. Implementation would include enhancement of the Offer Filters Explorer database and user interface work, building and updating of appropriate forms in the OPTN Computer System, creation of communications and education, as well as community outreach. It is estimated that $68,687 will be needed for ongoing support. Ongoing support will include continued maintenance of the OPTN Computer System, member support and education, as well as post-implementation monitoring at 6 months, 1 year, and 2 years. The total estimate for both implementation and ongoing support is $629,377.[99]

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[100] This proposal will not change the current routine monitoring of OPTN members. Any data entered in the OPTN Computer System may be reviewed, and members are required to provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[101] The impact of changes to donor testing requirements will be monitored six months post-implementation and then annually for two years, as the Committee sees fit. Each report will evaluate the following metrics, using pre and post comparisons when appropriate:

- Sequence number of the final acceptor
- Number of programs notified before the final acceptor
- Number of programs notified for the first time after the final acceptor
- Allocation time (time from first electronic notification to offer acceptance)
- Utilization rate by donor type
- Non-use rate by donor type

[99] Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.
[100] 42 C.F.R. §121.8(a)(7).
[101] 42 C.F.R. §121.8(a)(6).

Each report will also summarize the reasons that select diagnostic tests were unable to be completed. Additional summaries of new data collection fields will be provided at the request of the Committee.

Conclusion

This proposal, sponsored by the OPTN Lung Transplantation Committee, intends to promote efficiency of lung allocation by considering changes to OPTN data collection to make it easier for lung programs to respond to lung offers.[102] This proposal aims to streamline communication and information sharing between OPOs and lung transplant programs as they consider lung organ offers.

The Committee proposes the addition of new data collection to include History of Smoking (Cigarette Smoking History, Vape Use History, Marijuana Smoking History), Peak Inspiratory Pressure (PIP), and Acceptable Donor Predicted Total Lung Capacity (pTLC) Range.[103] The Committee proposes modifying current Diagnostic Testing data collection by adding Diagnostic Test Status. Additionally, the Committee proposes an addition to Lung Offer Filters, which would allow programs to bypass offers with donors that exceed a cigarette pack year threshold of their choosing. Lastly, the Committee proposes removing the data fields that indicate if a donor smoked greater than 20 pack years and if the program would accept a donor with greater than 20 pack years smoking history.

As a result of post–public comment discussions, the Committee made a post–public comment revision to include "donor instability" as a selectable reason for OPOs when reporting that a donor diagnostic test could not be completed.[104] To streamline data collection on diagnostic testing “right heart catheterization” will be added to the diagnostic test type drop down list. To further enhance clarity regarding PIP reporting requirements, the Committee also proposes adding a requirement to report PIP in *OPTN Policy 2.11.D: Required Information for Lung Donors.*[105]

[102] *Modify Lung Donor Data Collection Public Comment*, OPTN Lung Transplantation Committee, January 2025, https://optn.transplant.hrsa.gov (accessed April 16, 2025).
[103] Ibid.
[104] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).
[105] Meeting Summary for April 14, 2025, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov (accessed May 5, 2025).

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.

2.11.D. Required Information for Deceased Lung Donors

The host OPO must ensure that all the following additional information for all deceased lung donors is obtained and provided with the lung donor offer:

1. Challenge gases as specified below. A challenge gas is defined as an arterial blood gas obtained with *all* of the following:
    - Positive end-expiratory pressure (PEEP) of 5-8 cmH2O
    - Fraction of inspiratory oxygen concentration (FiO2) 100%
    - Tidal volume of 6-8 mL/kg ideal body weight (IBW)
        i. For donors 18 years or older, and 5 feet or taller, IBW must be calculated using the National Heart, Lung, and Blood Institute (NHLBI) formula
        ii. For donors less than 18 years old or shorter than 5 feet, IBW may be calculated using any race-neutral IBW equation.

    A challenge gas must be obtained within 4 hours prior to the initial offer made by the host OPO on a lung match run.

    Any challenge gases drawn after a recruitment maneuver must be drawn at least 30 minutes following that recruitment maneuver. A recruitment maneuver is defined as any procedure done to temporarily reinflate the donor lungs to assist in assessing organ quality.
2. Peak Inspiratory Pressure (PIP) associated with the challenge gas that was obtained within 4 hours prior to the initial offer made by the host OPO on a lung match run.
~~2.~~ 3. Images or interpretation by a radiologist or qualified physician of a chest x-ray performed within 3 hours prior to the initial offer made by the host OPO on a lung match run.
~~3.~~ 4. Sputum gram stain
~~4.~~ 5. Lung laterality

The host OPO must make reasonable efforts to obtain the following information for all deceased lung donors. If the host OPO obtains any of the following information, it must be provided with the lung donor offer. If the host OPO cannot obtain this information, the host OPO must document the reason and make this documentation available to the OPTN on request.

- Challenge gases, including the associated Peak Inspiratory Pressure (PIP), at least every 6-8 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery.
- Updated images or interpretation of a chest x-ray performed at least every 24 hours between the time of the initial offer made by the host OPO on a lung match run and the organ recovery.
- Bronchoscopy, results. If the host OPO cannot perform a bronchoscopy,-lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and time limitations in *Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers* are maintained.

- Chest computed tomography (CT) scan
- HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens prior to final organ acceptance
- Either echocardiogram or right heart catheterization to screen for pulmonary hypertension

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Proposed Changes to Data Collection

Proposed changes to OPTN Donor Data and Matching System

Action	Data field	Child Field	Response Option/ Data Entry Description
Add	History of Smoking		• Yes • No • Unknown If Yes- • Cigarette Smoking History • Vape Use History • Marijuana Smoking History
Add		Cigarette Smoking History	• Current cigarette smoker • Former cigarette smoker • Never smoked cigarettes • Cigarette smoking history unknown If Current cigarette smoker, or if Former cigarette smoker- Frequency of cigarette smoking • Packs per day • Cigarettes per day • Unknown How many years did the donor smoke?: • Enter years in open text field • Unknown Cigarette pack years calculated and displayed.
Add		Vape Use History	• Current vape user • Former vape user • Never vaped • Vape history unknown If Current vape user or Former vape user- Frequency of vape use • Every day • Every week • Less than weekly • Unknown How many years did the donor vape?: • Enter years in open text field • Unknown

Add		**Marijuana Smoking History**	• **Current marijuana smoker** • **Former marijuana smoker** • **Never smoked marijuana** • **Marijuana smoking history unknown** **If Current marijuana smoker or Former marijuana smoker-** **Frequency of marijuana smoking** • **Every day** • **Every week** • **Less than weekly** • **Unknown** **How many years did the donor smoke?:** • **Enter years in open text field** • **Unknown**
Add	Peak Inspiratory Pressure (PIP)		Enter PIP in open text field in centimeters of water pressure (cm H_2O).
Modify	Diagnostic Test Type		Right Heart Catheterization
Modify	Diagnostic Test Status [106]		Select test status • Complete • Pending (awaiting result) • Unable to complete If status is Unable to complete, select all reasons that apply • Capacity/workflow issue • Proxy refusal • Expertise issue • Equipment issue • Donor instability • Other, specify - free text
Remove	~~Cigarette use (>20 pack years) ever~~		• ~~Yes~~ • ~~No~~ • ~~Unknown~~ ~~If yes- And continued in the last six months?:~~ • ~~Yes~~ • ~~No~~ • ~~Unknown~~

[106] Diagnostic tests include Angiography; Bronchoscopy; Cardiac catheterization; Chest x-ray; CT/MRI; Echocardiograms; EKGs; Ultrasounds; Other specify.

46 **Proposed changes to the Deceased Donor Registration (DDR)**

Action	Data field	Response Option/ Data Entry Description
Add	Cigarette Smoking History	• Current cigarette smoker • Former cigarette smoker • Never smoked cigarettes • Cigarette smoking history unknown If Current cigarette smoker, or if Former cigarette smoker- Frequency of cigarette smoking • Packs per day • Cigarettes per day • Unknown How many years did the donor smoke?: • Enter years in open text field • Unknown
Remove	~~Cigarette use (>20 pack years) ever~~	~~• Yes~~ ~~• No~~ ~~• Unknown~~ ~~If yes- And continued in the last six months?:~~ ~~• Yes~~ ~~• No~~ ~~• Unknown~~

47 **Proposed changes to the OPTN Waiting List**

Action	Data field	Response Option/Data Entry Description
Add	Acceptable donor predicted Total Lung Capacity (pTLC) range	Enter minimum and maximum acceptable donor pTLC range in Liters (L)
Remove	~~Accept a donor with cigarette use > 20 pack years ever?~~	~~• Yes~~ ~~• No~~

48 **Proposed changes to lung Offer Filters**

Action	Data field	Response Option/Data Entry Description
Add	Donor cigarette use exceeds	Enter number of pack years an acceptable donor must not exceed

Proposed Changes to Data Definitions

History of Smoking: Select yes if the donor has any history of smoking cigarettes, marijuana, or vapes. Select No if the donor has no history of smoking cigarettes, marijuana, or vapes. Select unknown if donor historian or donor medical records are not available or it is not clear or known if the donor had a history of smoking cigarettes, marijuana, or vapes. Required field.

If **yes** is selected, use the dropdowns to indicate cigarette smoking, marijuana smoking, and vaping history

- **Cigarette smoking history:** Cigarette smoking refers to the inhalation of smoke from a burning cigarette into the lungs.[107] Field required if History of Smoking is yes.
    - **Current cigarette smoker**: Select if donor smoked cigarettes up until time of death.
    - **Former cigarette smoker**: Select if donor had smoked cigarettes in the past, but quit before time of death.
    - **Never smoked cigarettes:** Select if the donor never smoked cigarettes.
    - **Cigarette history unknown:** Select if the donor historian and donor medical records are not available or it is not clear or known if the donor had a history of smoking cigarettes.

    If donor is a **Current cigarette smoker** or **a Former cigarette smoker:**

    - **Frequency of cigarette smoking:** Enter on average, how many packs per day **or** cigarettes per day in respective field. Field required if Cigarette Smoking History is either current cigarette smoker or former cigarette smoker.
        - Packs per day: enter the average number of cigarette packs smoked each day. This can be entered as a whole number (1 pack, 2 packs) or decimals (0.25 pack, 0.5 pack). Absolute range- minimum: 0.1 packs, maximum: 5 packs.
        - Cigarettes per day: enter the average number of cigarettes smoked each day. This can be entered as whole numbers (1 cigarette, 2 cigarettes) or decimals (0.1 cigarette, 0.5 cigarettes).For example, if a donors smoked 3 cigarettes a week (3 cigarettes per 7 days), enter .4 cigarettes. Absolute range- minimum: 0.1 cigarette, maximum: 20 cigarettes. There are 20 cigarettes in each pack.
        - Unknown: Select if the donor historian and donor medical records are not available or it is not clear or known how many packs per day or cigarettes per day the donor smoked. If unknown is entered, cigarette pack years will not be calculated.
    - **How many years did the donor smoke?:** The number of years as a cigarette smoker. Enter years in open text field. Used to calculate donor cigarette pack years. If the donor has smoked less than a year, enter as decimal. Field required if Cigarette Smoking History is either **Current cigarette smoker** or **Former cigarette smoker.** Absolute range: minimum- 0, maximum- donor's age.

[107] Clevland Clinic, Smoking, https://my.clevelandclinic.org/health/articles/17488-smoking. Accessed October 23, 2024.

- Unknown: Select if the donor historian and donor medical records are not available or it is not clear or known how many years the donor smoked. If unknown is entered, cigarette pack years will not be calculated.

- **Vape Use History** [108]**:** Vape use refers to the inhalation of vapor through the mouth from a usually battery-operated electronic device (such as an electronic cigarette) that heats up and vaporizes a liquid or solid. Report if donor has a history of vaping because lung transplant programs may rule out donors with this history in combination with other factors. Field required if History of Smoking is yes. If a donor vaped marijuana or THC, it should be entered under Vape Use History.
  - **Current vape user**: Select if donor vaped up until time of death.
  - **Former vape user**: Select if donor had vaped in the past, but quit before time of death.
  - **Never vaped:** Select if the donor never vaped.
  - **Vape history unknown:** Select if the donor historian and donor medical records are not available or it is not clear or known if the donor had a history of vaping.

  If donor is a **Current vape user** or **a Former vape user**-
    - **Frequency of vaping:** Indicate, on average, how often the donor vapes/vaped. Field required if Vape Use History is either current vape user or former vape user.
      - Every day: Select if the donor vaped every day.
      - Every week: Select if the donor vaped once a week or more but less than once a day.
      - Less than weekly: Select if the donor vaped less than once a week.
      - Unknown: Select if the donor historian and donor medical records are not available or it is not clear or known how often the donor vaped.
    - **How many years did the donor vape?:** Indicate the number of years as a vape user. Enter years in open text field. If the donor has smoked less than a year, enter as decimal. Field required if Vape Use History is either current vape user or former vape user. Absolute range: minimum- 0, maximum- donor's age.
      - Unknown: Select if the donor historian and donor medical records are not available or it is not clear or known how many years the donor vaped.

- **Marijuana Smoking History** [109]**:** Marijuana smoking refers to the inhalation of smoke or vapor released by heating the flowers, leaves, or extracts of cannabis and releasing the main psychoactive chemical, THC, which is absorbed in the bloodstream via the lungs. Report if donor has a history of marijuana smoking. If a donor vaped marijuana or THC, enter that information under Vape Use History. Field required if History of Smoking is yes.
  - **Current marijuana smoker**: Select if donor smoked marijuana up until time of death.

[108] American Cancer Society, What Do We Know About E-cigarettes?, https://www.cancer.org/cancer/risk-prevention/tobacco/e-cigarettes-vaping/what-do-we-know-about-e-cigarettes.html. Accessed October 23, 2024.
[109] National Institute on Drug Abuse, Cannabis, https://nida.nih.gov/research-topics/cannabis#use-cannabis. Accessed October 23, 2024.

- **Former marijuana smoker**: Select if donor had smoked marijuana in the past, but quit before time of death.
- **Never smoked marijuana:** Select if the donor never smoked marijuana.
- **Marijuana smoking history unknown:** Select if the donor historian and donor medical records are not available or it is not clear or known if the donor had a history of smoking marijuana.

If donor is a **Current marijuana smoker** or a **Former marijuana smoker**-

- **Frequency of marijuana smoking:** Indicate, on average, how often the donor smoked marijuana. Field required if Marijuana Smoking History is either current marijuana smoker or former marijuana smoker.
  - Every day: Select if the donor smoked marijuana every day.
  - Every week: Select if the donor smoked marijuana once a week or more but less than once a day.
  - Less than weekly: Select if the donor smoked marijuana less than once a week.
  - Unknown: Select if the donor historian and donor medical records are not available or it is not clear or known how often the donor smoked marijuana.
- **How many years did the donor smoke?:** Indicate the number of years as a marijuana smoker. Enter years in open text field. If the donor has smoked less than a year, enter as decimal Field required if Marijuana Smoking History is either current marijuana smoker or former marijuana smoker. Absolute range: minimum- 0, maximum- donor's age.
  - Unknown: Select if the donor historian and donor medical records are not available or it is not clear or known how many years the donor smoked marijuana.

Peak Inspiratory Pressure (PIP) [110]: The highest pressure delivered by the ventilator at any instant during a single ventilatory cycle. Enter the donor PIP in centimeters of water pressure (cm H_2O). PIP values are reported with the ventilator settings alongside Arterial Blood Gases (ABGs). Absolute range- minimum: 10, maximum: 50.

Acceptable donor predicted Total Lung Capacity (pTLC) range: This field allows for screening lung donors based on the donor's predicted total lung capacity. Enter the minimum and maximum range of donor predicted total lung capacity the program would accept for their patient in Liters (L). Absolute range- minimum: 0.10, maximum: 14.00.

The system calculates the donor's pTLC based on the Global Lung Initiative's (GLI) formulas.[111] These formulas were developed on an all-European cohort. Variability between donors' actual TLC and their

[110] Science Direct, Peak Inspiratory Pressure, https://www.sciencedirect.com/topics/nursing-and-health-professions/peak-inspiratory pressure#:~:text=Peak%20Inspiratory%20Pressure%20is%20the,airway%20resistance%20and%20lung%20compliance. Accessed October 23, 2024.

[111] Hall GL, Filipow N, Ruppel G, et al. Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry. Eur Respir J2021; 57: 2000289 [https://doi.org/10.1183/13993003.00289-2020].

pTLC may be greater in a racially diverse American donor population than in the European cohort in which the formula was originally developed. It is recommended to account for this potential increased variability when setting donor acceptance criteria. If donor age or height are outside of GLI formula limitations (donors outside 5-80 years or 50-230 cm tall) or the GLI calculation is not available, the pTLC will not be calculated or used for screening.

Diagnostic testing

- **Diagnostic test status:** Report if diagnostic testing is Complete, Pending, or Unable to be completed. Field is required for all selected diagnostic testing.
  - **Complete**: Select if test is complete and results are available.
  - **Pending:** Select if awaiting test results.
  - **Unable to be completed:** Select if test is unable to be completed for any reason.

  If Unable to be completed is selected, select all reasons that apply-

    - **Capacity/workflow issue:** Select if unable to complete test due to staffing/personnel resource limitations.
    - **Proxy refusal:** Select if unable to complete test due to donor family timeframe or authorization challenges.
    - **Expertise issue:** Select if unable to complete test due to lack of available trained staff.
    - **Equipment issue:** Select if unable to complete test due to lack of equipment.
    - **Donor instability:** Select if donor is too unstable for test.
    - **Other, specify - free text:** Enter other reason test is unable to be completed.

  Donor cigarette use exceeds: Enter the number of pack years of cigarette use an acceptable donor must not exceed. Absolute range- minimum: 0, maximum: 100.
- Pack year equation: Number of packs of cigarettes smoked per day X Number of years the person smoked.