

Notice of OPTN Policy and Data Collection Changes

Modify Lung Donor Data Collection

Sponsoring Committee:	Lung Transplantation
Policy Affected:	<i>2.11.D: Required Information for Deceased Lung Donors</i>
Data Collection Affected:	OPTN Donor Data and Matching System Deceased Donor Registration (DDR) OPTN Waiting List Lung Offer Filters
Public Comment:	January 21, 2025 - March 19, 2025
Board Approved:	June 10, 2025
Effective Date:	Pending implementation and notice to OPTN members

Purpose of Policy and Data Collection Changes

The purpose of this proposal is to promote efficiency of lung allocation by changing 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.

Proposal History

Since the implementation of continuous distribution for lungs in March 2023, the Committee has advanced policy and other initiatives to enhance the efficiency of lung allocation. These efforts include the development of Lung Offer Filters, improved data collection to support offer evaluation, and system enhancements to streamline processes for OPOs and transplant programs. In December 2024, the OPTN Board of Directors approved the *Promote Efficiency of Lung Donor Testing* proposal, which aimed to standardize lung offers by requiring timely and relevant donor information to support organ offer decisions. This proposal included revisions to *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and corresponding guidance. While that initiative focused on policy and guidance updates, the *Modify Lung Donor Data Collection* proposal focuses on refining data collection practices to further improve efficiency in the lung offer and allocation process.

Summary of Changes

OPTN Donor Data and Matching System	Deceased Donor Registration (DDR)	OPTN Waiting List	Lung Offer Filters
Add			
<ul style="list-style-type: none"> History of Smoking <ul style="list-style-type: none"> Cigarette Smoking History <ul style="list-style-type: none"> Calculation of pack years based on data inputs Vape Use History Marijuana Smoking History Peak Inspiratory Pressure (PIP) 	<ul style="list-style-type: none"> Cigarette Smoking History 	<ul style="list-style-type: none"> Acceptable donor Predicted Total Lung Capacity (pTLC) range 	<ul style="list-style-type: none"> Donor cigarette use exceeds
Remove			
<ul style="list-style-type: none"> Cigarette use (>20 pack years) ever <ul style="list-style-type: none"> And continued in the last six months 	<ul style="list-style-type: none"> Cigarette use (>20 pack years) ever <ul style="list-style-type: none"> And continued in the last six months 	<ul style="list-style-type: none"> Accept a donor with cigarette use > 20 pack years ever? 	
Modify			
<ul style="list-style-type: none"> Diagnostic Test Status <ul style="list-style-type: none"> Diagnostic Test Type 			

To further enhance clarity regarding Peak Inspiratory Pressure (PIP) reporting requirements, *OPTN Policy 2.11.D: Required Information for Lung Donors* was modified to include a requirement to report PIP.

Implementation

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. This proposal is expected to have low fiscal impact on OPOs.

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. There were no significant fiscal impacts indicated with this proposal.

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.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

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.~~ 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.~~ 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.~~ 4. Sputum gram stain

~~4-5.~~ 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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Affected Data Collection Changes

New language is underlined (example) and language that is deleted is struck through (~~example~~).

Changes to OPTN Donor Data and Matching System

Action	Data Field	Child Field	Response Option/ Data Entry Description
Add	History of Smoking		<ul style="list-style-type: none"> • Yes • No • Unknown <p>If Yes-</p> <ul style="list-style-type: none"> • Cigarette Smoking History • Vape Use History • Marijuana Smoking History
Add		Cigarette Smoking History	<ul style="list-style-type: none"> • Current cigarette smoker • Former cigarette smoker • Never smoked cigarettes • Cigarette smoking history unknown <p>If Current cigarette smoker, or if Former cigarette smoker-</p> <p>Frequency of cigarette smoking:</p> <ul style="list-style-type: none"> • Packs per day • Cigarettes per day • Unknown <p>How many years did the donor smoke?:</p> <ul style="list-style-type: none"> • Enter years in open text field • Unknown <p>Cigarette pack years calculated and displayed.</p>

Add		Vape Use History	<ul style="list-style-type: none"> • Current vape user • Former vape user • Never vaped • Vape history unknown <p>If Current vape user or Former vape user-</p> <p>Frequency of vape use</p> <ul style="list-style-type: none"> • Every day • Every week • Less than weekly • Unknown <p>How many years did the donor vape?:</p> <ul style="list-style-type: none"> • Enter years in open text field • Unknown
Add		Marijuana Smoking History	<ul style="list-style-type: none"> • Current marijuana smoker • Former marijuana smoker • Never smoked marijuana • Marijuana smoking history unknown <p>If Current marijuana smoker or Former marijuana smoker-</p> <p>Frequency of marijuana smoking:</p> <ul style="list-style-type: none"> • Every day • Every week • Less than weekly • Unknown <p>How many years did the donor smoke?:</p> <ul style="list-style-type: none"> • 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 ₂ O).
Modify	Diagnostic Test Type ¹		Add Right Heart Catheterization to dropdown list of tests

¹ 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		<p>Select test status:</p> <ul style="list-style-type: none"> • Complete • Pending (awaiting result) • Unable to complete <p>If status is Unable to complete, select all reasons that apply:</p> <ul style="list-style-type: none"> • Capacity/workflow issue • Proxy refusal • Expertise issue • Equipment issue • Donor instability • Other, specify - free text
Remove	Cigarette Use (>20 Pack Years) Ever		<ul style="list-style-type: none"> • Yes • No • Unknown <p>If yes- And Continued in the Last Six Months?:</p> <ul style="list-style-type: none"> • Yes • No • Unknown

Changes to the Deceased Donor Registration (DDR)

Action	Data field	Response Option/ Data Entry Description
Add	Cigarette Smoking History	<ul style="list-style-type: none"> • Current cigarette smoker • Former cigarette smoker • Never smoked cigarettes • Cigarette smoking history unknown <p>If Current cigarette smoker, or if Former cigarette smoker-</p> <p>Frequency of cigarette smoking:</p> <ul style="list-style-type: none"> • Packs per day • Cigarettes per day • Unknown <p>How many years did the donor smoke?:</p> <ul style="list-style-type: none"> • Enter years in open text field • Unknown

Remove	Cigarette Use (>20 Pack Years) Ever	<ul style="list-style-type: none"> • Yes • No • Unknown <p>If yes- And Continued in the Last Six Months?:</p> <ul style="list-style-type: none"> • Yes • No • Unknown
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Proposed changes to the OPTN Waiting List

Action	Data field	Response Option/Data Entry Description
Add	<u>Acceptable donor predicted Total Lung Capacity (pTLC) range</u>	<u>Enter minimum and maximum acceptable donor pTLC range in Liters (L)</u>
Remove	<u>Accept a donor with cigarette use > 20 pack years ever?</u>	<ul style="list-style-type: none"> • Yes • No

Proposed changes to lung Offer Filters

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

Affected 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.² 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.

² Cleveland Clinic, Smoking, <https://my.clevelandclinic.org/health/articles/17488-smoking>. Accessed October 23, 2024.

- 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 donor 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.
 - 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**³: 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.

³ 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.

- 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** ⁴: 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.
 - **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.

⁴ National Institute on Drug Abuse, Cannabis, <https://nida.nih.gov/research-topics/cannabis#use-cannabis>. Accessed October 23, 2024.

Peak Inspiratory Pressure (PIP) ⁵: 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 H₂O). 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.⁶ These formulas were developed on an all-European cohort. Variability between donors' actual TLC and their 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.

⁵ 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.

⁶ 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 J 2021; 57: 2000289 [https://doi.org/10.1183/13993003.00289-2020].