United States Senate
Committee on Finance

Ron Wyden, Ranking Member
Charles E. Grassley, Member

Operation Transplant:
Examining the Need for Oversight in the Organ Donation System

Staff Report

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I. Introduction

Organ Procurement Organizations (OPOs) are not-for-profit organizations responsible for the procurement of organs for transplant or research.[1] The U.S. transplant system is complex, and OPOs are a vital partner in the "procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients."[2] OPOs are legally permitted to recover organs, as well as provide education and support to donor families.[3] Currently, there are 55 OPOs serving their designated service areas (DSA).[4] In the DSA model, each OPO serves as the exclusive entity authorized to procure donor organs for transplant in the geographic area defined by the Centers for Medicare and Medicaid Services (CMS).[5]

The Senate Committee on Finance has jurisdiction over health programs under the Social Security Act.[6] Under section 1138(b)(1)(A)(i) of the Social Security Act, the Secretary of Health and Human Services (HHS) has the authority to pay and re-certify OPOs if the organization has met the standards to be a qualified OPO.[7] In order to maintain this certification status from HHS, OPOs must meet the requirements of section 1138(b) of the Social Security Act and are required to be in compliance with the Federal Conditions for Coverage (CfCs) set forth in 42 C.F.R. Part 486, Subpart G.[8] CMS oversees this re-certification process for OPOs.

In the entire history of the U.S. transplant system, CMS has never decertified an OPO.[9] Stakeholders have argued that because OPOs face little-to-no consequences for underperformance, CMS's certification metrics need to be reformed.[10] To address this need for additional accountability, CMS released a final rule in 2020 titled, "Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations," which was included in the Federal Register in February 2021.[11] This rule changed the way CMS measures OPO performance metrics by updating the transplantation and donation rate measures monitored every year.[12] At the end of each re-certification cycle, each OPO will be assigned a tier-ranking based on its performance for both donation and transplantation rates, as well as its performance on the re-certification survey.[13] The goal of the new rule is to "revise the outcome measures for assessing OPO performance to ensure they are transparent,

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[1] UNOS, *Organ Procurement Organizations*, https://unos.org/transplant/opos-increasing-organ-donation/.
[2] 42 C.F.R. Part 486 at 7814 (Feb. 2, 2021), https://www.govinfo.gov/content/pkg/FR-2021-02-02/pdf/2021-02180.pdf.42.
[3] *Id.*; Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.
[4] UNOS, *supra* note 1.
[5] Centers for Medicare and Medicaid Services, *The Transplant Eco-System: The Role of Data in CMS Oversight of The Organ Procurement Organizations* (Apr. 28, 2023), https://www.cms.gov/blog/transplant-eco-system-role-data-cms-oversight-organ-procurement-organizations.
[6] Senate Finance Committee, *Jurisdiction*, https://www.finance.senate.gov/about/jurisdiction.
[7] 42 C.F.R. § 121.9-10 (2025), https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121.
[8] Centers for Medicare and Medicaid Services, *State Operations Manual Appendix Y- Organ Procurement Organization* (2018) at 3, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_y_opo.pdf.
[9] OPO DATA, *FAQs*, https://www.opodata.org/faqs/.
[10] 42 C.F.R. Part 486, *supra* note 2.
[11] *Id.*; Centers for Medicare and Medicaid Services, *supra* note 3.
[12] 42 C.F.R. Part 486, *supra* note 2.
[13] *Id.*; Centers for Medicare and Medicaid Services, *supra* note 5 (By law, OPOs must undergo a regular re-certification process – currently a 4-year recertification cycle – to ensure that OPOs continue to meet the requirements CMS has defined in the CfCs.).

reliable, and enforceable; support higher donation rates; help shorten transplant waiting lists; reduce discarded but viable organs; and increase safe, timely transplants that save lives."[14]

This staff report addresses two specific, long-standing concerns the Committee has raised regarding OPO practices and the inadequacy of HHS oversight of OPOs:

1) The loophole allowing pancreata recovered for research to be counted toward recertification without adequate verification that the organs were in fact used to advance research focused on pancreatic islet cell transplantation.

2) Inadequate transparency and oversight of conflicts of interest among OPO leaders and governing board members.

While the Committee continues to have serious concerns about other aspects of the operation and oversight of OPOs, these two issues represent foundational concerns that, if not adequately addressed, undermine public trust in this vital, lifesaving activity.

We have raised these concerns on multiple occasions, including in a letter regarding an April 2022 HHS Request for Information (RFI) titled, "Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities."[15] In that letter we called on CMS to "[r]emove the loophole in the 2020 regulations that enabled OPOs to count pancreata for research in the metrics" and urged CMS to "include the procurement of pancreata islet cells for transplant rather than the much broader inclusion of all pancreata for research."[16] We have repeatedly made clear that including only pancreata islet cells for transplant is consistent with Congressional intent.[17] OPO's abuse of this loophole, CMS's inaction in fully clarifying and addressing the loophole, and the failure to verify every organ counted toward recertification of OPOs undermines HHS oversight and allows underperforming OPOs to inflate their performance at the cost of critically ill patients.

Additionally, in the April 2022 letter, we called on CMS to "require robust, independent oversight by each OPO governing board and medical advisory boards" and require members of these boards to "follow professional guidelines that require them to attest to serve the public interest and oversee OPO leadership, policies, and procedures" and "disclose any conflicts of interest, including any direct or indirect financial arrangements relating to organ donation or transplantation."[18]

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[14] Centers for Medicare and Medicaid Services, *supra* note 3.
[15] Letter from Senators Wyden, Grassley, Young, Cardin, and Moran to the Honorable Xavier Becerra, Secretary, the Department of Health and Human Services, and the Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services (Apr. 7, 2022), https://www.finance.senate.gov/imo/media/doc/040722%20Wyden%20Grassley%20Young%20Transplant%20System%20RFI%20letter.pdf.
[16] *Id.*
[17] *Id.*
[18] *Id.*

A. Investigative History

On March 20, 2023, then-Chairman Wyden and Senators Grassley, Cardin, and Young sent letters to One Legacy, Donor Alliance, LifeQuest Organ Recovery Services, Indiana Donor Network, Kentucky Organ Donor Affiliates, Mid-America Transplant, New Jersey Organ and Tissue Sharing Network, LifeBanc, Lifeline of Ohio, and Texas Organ Sharing Alliance, seeking data on pancreata recovery rates and processes following the updated regulations by CMS.[19] This investigation aimed to shed light on efforts by OPOs to exploit a CMS-created loophole allowing OPOs to falsely inflate their performance metrics by reporting pancreata procurements that did not meet the standard of islet cell transplantation research consistent with regulation and statute.[20]

Additionally, on September 11, 2023, then-Chairman Wyden and Senators Grassley, Cardin, and Young, sent letters to executives and leadership of LifeCenter Organ Donor Network, Midwest Transplant Network, Versiti Wisconsin, Donor Alliance, LifeShare Network, Gift of Life Donor Program, Tennessee Donor Services, and New Mexico Donor Services requesting information about instances in which these executives potentially abused their positions for monetary gain.[21] This investigation focused on potential conflicts of interest and abuse of taxpayer money by these OPOs and their executives.[22]

These investigations build on the work Senator Grassley and Ranking Member Wyden have conducted for nearly two decades to shed light into the organ donation system, and their joint and individual efforts to bring accountability to appropriate stakeholders at each step in the organ donation, procurement, and transplantation process. Since March 2023, investigative staff have reviewed more than one thousand pages of internal research protocols and conflicts of interest documents produced by all seventeen OPOs. Investigative staff have also met with attorneys, lobbyists, representatives, and executives from each OPO to discuss their respective responses and document productions.

This staff report describes how OPOs, with respect to the pancreata investigation, utilized the loophole created by CMS's lack of clarity in defining terms and operationalizing oversight in verifying pancreata islet cell research organs to increase the number of pancreata procured for certification, creating higher CMS performance ratings for themselves. Finally, the report examines the processes by which OPOs verify that pancreata used for research was in fact being used for islet cell research, as required by statute and regulation. The findings of the pancreata investigation are far reaching as it relates to CMS metrics, patients, and donor trust.

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[19] Press Release *Wyden, Grassley, Cardin, Young Raise Alarm Over Dramatic Increase in Pancreata Procurement* (Mar. 21, 2023), https://www.finance.senate.gov/chairmans-news/wyden-grassley-cardin-young-raise-alarm-over-dramatic-increase-in-pancreata-procurement-.

[20] *Id.*

[21] Press Release, *Wyden, Grassley, Cardin, Young Investigate Organ Donation System for Potential Self-Dealing and Financial Conflicts of Interest* (Sep. 11, 2023), https://www.finance.senate.gov/chairmans-news/wyden-grassley-cardin-young-investigate-organ-donation-system-for-potential-self-dealing-and-financial-conflicts-of-interest. (These letters were sent to Barry Massa of LifeCenter Organ Donor Network, Jan Finn of Midwest Transplant Network, Colleen McCarthy of Versiti Wisconsin, Jennifer Prinz of Donor Alliance, Jeff Orlowski of LifeShare Network, Rick Hasz Gift of Life Donor Program, Marty Sellers of Tennessee Donor Services, and Wayne Dunlop of New Mexico Donor Services.)

[22] *Id.*

This staff report also describes how OPOs, with respect to the conflicts of interest investigation, identify, make known, and handle conflicts of interest between executives and employees of the OPO. Additionally, it highlights the varying degrees of definitions of conflicts of interests OPOs utilize and submit to CMS. Further, the report examines the issues related to the conflicts of interest forms and disclosures, specifically that there is currently a lack of clarity as it relates to the definition of conflicts of interest, as well as what should be included when disclosing those conflicts. Finally, this staff report discusses the implications of how OPOs identify and handle conflicts of interest without having clarity from CMS.

II. Key Findings

A. Pancreata

1. OPOs surveyed by the Committee reported an 850% increase in the total number of pancreata recovered for research without reporting a clear corresponding research benefit.

2. The language of the OPO final rule and the subsequent practices at some OPOs has resulted in a framework that is inconsistent with the legislative requirements of 42 U.S.C. 273(c).

3. Differences in this verification process arose between OPOs that worked with researchers vs. biobanks vs. third-party research clearing houses in their ability to verify actual use of pancreata reported to CMS as recovered for research, as well as the details of research protocols. In essence, OPOs are unable to verify that pancreata sent to biobanks and third-party research clearinghouses were used for bona-fide pancreatic islet cell transplantation research.

B. Conflicts of Interest

1. Each OPO independently developed their own policies to define and deal with conflicts of interest, which vary among the OPOs in critical details, generally making the review of conflicts difficult. Despite having regulatory authority and oversight of OPOs, CMS has not required uniform conflicts of interest policies and procedures.

2. There are key differences among the various conflicts of interest policies which the OPOs operate under. Those differences include whether employees are covered or just the directors and officers, whether and how the board of directors may approve a transaction despite a conflict, and whether conflicts of interest include those which arise from ethical or political conflicts or solely financial conflicts.

3. OPO conflicts of interest policies in general are vague on what details must be reported, as well as how those conflicts are recorded, reviewed, and kept for the record. This makes the task of identifying conflicts in future transactions, after they have been reported, difficult.

4. Notably, while OPO conflicts of interest policies varied significantly in application, every conflicts of interest policy focused on corporate conflicts and the interests of the OPO without a focus on conflicts to the national needs of the organ donation system in the public interest.

III. Pancreata: The Loophole

A. Overview

Senators Grassley and Wyden have been sounding the alarm on the pancreata loophole for over three years. In April 2022, the Senators raised this issue to Secretary Becerra and Administrator Brooks-LaSure in a letter regarding CMS's transplant system RFI.[23] In that letter, the Senators requested CMS include only the procurement of pancreata islet cells for transplant for recertification rather than the much broader inclusion of all pancreata for research, because the total number of reported pancreata for research doubled in 2021 after remaining steady for years prior.[24] In July 2022, Secretary Becerra responded stating, "I also appreciate your concern regarding the inclusion of pancreata procured for research…CMS will be monitoring the procurement of pancreata to evaluate for potential gaming of the metrics by OPOs and will take actions as needed."[25] Then, in March 2023, the Senators wrote letters to ten OPOs seeking data on pancreata recovery rates following the updated regulations and raised preliminary findings with senior CMS officials at a July 11, 2023, oversight roundtable on the topic.[26]

Other stakeholders and members of the public have also raised concerns with CMS. In response to the OPO final rule, several commenters opposed the inclusion of pancreata for research "since procuring pancreata for research is not a normal function of OPOs and is highly dependent upon the demands of the local researchers," and that "including the pancreata for research would lead to artificial inflation of the organ transplantation rate; that we should use a third performance metric to assess performance for pancreata procured for research; and that we did not properly define the scope of 'pancreata procured for research.'"[27] Diabetes researchers have raised similar concerns. In a March 2024 Washington Post article, Mark Atkinson, a longtime University of Florida researcher of Type 1 diabetes, who works with organizations that distribute pancreata for

[23] Letter from Senate Finance Committee, *supra* note 15.
[24] *Id*.
[25] Letter from the Honorable Xavier Becerra, Secretary, the Department of Health and Human Services, to Senators Wyden, Grassley, Young, Cardin, and Moran (July 2022), On File with Senate Finance and Judiciary Committee Staff.
[26] Press release, *supra* note 19; Press Release, *Bipartisan Senators Meet With HRSA, CMS Officials To Discuss Organ Transplant Modernization And Reform* (July 11, 2023), https://www.grassley.senate.gov/news/news-releases/bipartisan-senators-meet-with-hrsa-cms-officials-to-discuss-organ-transplant-modernization-and-reform.
[27] 85 F.R. 77898, at 169, https://www.federalregister.gov/d/2020-26329/p-169.

research, said, "[m]y fear is that what was meant for good, in terms of pancreas donation, is being bastardized for self-preservation" by OPOs. He added that he was aware of the increased efforts by some OPOs to collect the organs but had not seen a corresponding increase in researchers' need for them.[28]

The legislative history, statutory requirements, and CMS's statements in the preamble to the 2020 Federal Register Notice (FRN), make clear that the definition of pancreata used for research should be narrowly constructed to include only pancreata utilized in bona fide research focused directly on pancreata islet cell transplantation as a treatment for Type I diabetes.[29] However, as currently written, OPOs have interpreted that the current regulations would allow for recovery of all types of pancreata research, not just islet cell research.[30]

Additionally, CMS noted in the OPO final rule that, "[w]e will continue to monitor the trends of pancreata procured for research and will use the survey process to conduct further investigation into any anomalies that such monitoring reveal."[31] The legislative history pertaining to the inclusion of this requirement makes clear Congress's intent that only pancreata procured to facilitate research to advance pancreatic islet cell transplantation should be counted for the purposes of OPO recertification. In fact, the Pancreatic Islet Cell Transplantation Act of 2004, the bill that created the language in 42 U.S.C. 273(c), requiring that research pancreata be counted for purposes of recertification, states that the intent of the Act is to

> [A]mend the Public Health Service Act to increase the supply of pancreatic **islet cells** for research, and to provide for better coordination of Federal efforts and information on islet cell transplantation.[32]

If this were not clear enough, the House of Representatives report accompanying H.R. 3858, the Pancreatic Islet Cell Transplantation Act of 2004, states the goal of the legislation is to expand "the capabilities of pancreatic islet cell research."[33] Finally, CMS's language in the preamble to the December 2020 FRN states:

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[28] Lenny Bernstein, *Lawmakers probe whether organ procurers are 'gaming the system*, (Mar. 21, 2023), WASH POST https://www.washingtonpost.com/health/2023/03/20/organ-transplant-groups-pancreas-collection/; 85 FR 77898, *supra* note 27.
[29] 85 FR 77898, *supra* note 27.
[30] Donor Alliance to Senators Wyden, Grassley, Cardin, and Young (Apr. 14, 2023) (6400% increase in pancreata place for research between 2021-2022.); Indiana Donor Network to Senators Wyden, Grassley, Cardin, and Young (Apr. 7, 2023) (747% increase in pancreata place for research between 2021-2022.); Lifebanc to Senators Wyden, Grassley, Cardin, and Young (Apr. 7, 2023) (2000% increase in pancreata place for research between 2021-2022.); Lifeline of Ohio to Senators Wyden, Grassley, Cardin, and Young (Apr. 6, 2023) (392% increase in pancreata place for research between 2021-2022.); LifeQuest Organ Recovery Services to Senators Wyden, Grassley, Cardin, and Young (Apr. 21, 2023) (267% increase in pancreata place for research between 2021-2022.); Mid-America Transplant to Senators Wyden, Grassley, Cardin, and Young (Apr. 3, 2023) (56% increase in pancreata place for research between 2021-2022.); OneLegacy to Senators Wyden, Grassley, Cardin, and Young (Apr. 7, 2023) (390% increase in pancreata place for research between 2021-2022.); Texas Organ Sharing Alliance to Senators Wyden, Grassley, Cardin, and Young (Apr. 6, 2023) (216% increase in pancreata place for research between 2021-2022.); NJ Sharing Network to Senators Wyden, Grassley, Cardin, and Young (Apr. 7, 2023) (89% increase in pancreata place for research between 2021-2022.); and Kentucky Organ Donor Affiliates to Senators Wyden, Grassley, Cardin, and Young (Apr. 21, 2023) (10% increase in pancreata place for research between 2021-2022.).
[31] 85 FR 77898, *supra* note 27.
[32] 42 U.S.C. § 273(c).
[33] H.R. Rep. No. 108-726, at 2 (2004).

> **Pancreata procured for islet cell research** are included in the outcome measures of this final rule. We carefully considered other options to address pancreata procured for research, such as creating a process measure for these organs, creating a unique outcome measure, and counting these organs in the outcome measures of this final rule as less than the full value of a transplanted organ. However, these alternative policy approaches did not meet the PHS Act, which states that "Pancreata procured by an organ procurement organization (OPO) and used for islet cell transplantation or research shall be counted for purposes of certification or recertification . . . .[34]

CMS further stated, "[w]e think that the impact of pancreata for research on the overall rankings of OPOs will continue to be minimal" and that "only bona fide research conducted by a qualified researcher using a pancreas from an organ donor would be counted, and it would be counted as a single research project regardless of the number of research activities performed using **that one pancreas and its islets.**"[35] Finally, CMS stated that it intends to "continue to monitor the trends of pancreata procured for research and will use the survey process to conduct further investigation into any anomalies that such monitoring reveal," making clear the need to monitor this requirement for potential abuse and issue clarification as necessary.[36] OPOs continue to take advantage despite the efforts of CMS to clarify their intent.

B. Findings

In order to determine the efficacy of the rule allowing OPOs to use pancreata for research as a recertification performance metric, the Senators asked ten OPOs to provide copies of the research protocols for each study that OPOs provided pancreata for between 2018 and 2022.[37] Despite CMS's belief that this requirement would continue to have minimal impact,[38] the Senators' investigation shows that OPOs are reporting pancreata procured for research at a troubling rate and that many cannot show that reported organs are being used for bona fide research, let alone the bona fide islet cell research, that is consistent with the legislative intent. Since the rule was finalized, OPO reporting of pancreata recovered for research has increased by more than four-fold, with some OPOs recovering hundreds of pancreata and labeling them as "research," not "islet cell research."[39]

Among the ten OPOs Senators Wyden and Grassley contacted regarding procurement of pancreata for research, the total number of pancreata recovered for research increased from 169 in 2018 to 1,606 in 2022, representing an **850% increase**.[40] These ten OPOs reported that in 2018 (before the CMS metric was created) 148 of the 169, or 87.6%, of pancreata recovered for research

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[34] 85 FR 77898, *supra* note 27. (emphasis added).
[35] *Id*. (emphasis added).
[36] *Id*.
[37] Press release, *supra* note 19.
[38] 42 C.F.R Part 486 at 7814, *supra* note 2.
[39] Goldberg DS et al., *Open. Procurement of Pancreatic Tissue for Research From Deceased Donors Before vs After the CMS Final Rule in 2020* (Sep. 6, 2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808963.
[40] Letters from OPOs, *supra* note 30.

were used on research specific to islet cell transplantation.[41] However, in 2022—one year after the final rule was enacted—the same ten OPOs self-reported that only 769 of the 1606, or 47.9%, of the pancreata recovered for research were used on research specific to islet cell transplantation.[42] This alone is a shocking indication that OPOs are abusing the lack of clarity in the regulatory language.

This data may not fully capture the number of pancreata actually used, or not used, for research specific to pancreatic islet cell transplantation. Some OPOs, including those subject to the Senators' investigation, reported that, in many cases, they are unaware of, or barred from knowing, the research protocols of organizations they have provided pancreata to for research.[43]

The Senators' investigation found that OPOs suddenly increased the procurement of pancreata for research and established—or greatly expanded—relationships with researchers with a focus on pancreata.[44] OPOs also provided research protocol documentation, as well as documents regarding the usage of pancreata procured for research. These documents had significant variation, which calls into question whether the research conducted legitimately advanced pancreatic islet cell transplantation—consistent with federal law.[45] These arrangements fell loosely into three categories:

- Third party research, including federally funded studies and other studies conducted under Institutional Review Board protocols at an academic research center, and other research generally seen as bona fide research;

- In-house research conducted by the OPO or a closely affiliated research entity; or

- Research clearinghouses and biobanks.

Based on the OPOs disclosures to the Senators, we found, as it related to third party research:

- Significant variation of due diligence conducted by the OPO to validate that the research protocols were consistent with the CMS

[41] *Id*.
[42] *Id*.
[43] OneLegacy, *supra* note 30 at 8 ("OneLegacy performs due diligence to ensure that it is only supplying research pancreata to reputable, third-party laboratories and institutions with which it has long-standing relationships, OneLegacy does not substantively evaluate or approve the research protocols of those entities. Doing so would exceed its area of expertise as an organ procurement organization."); Lifebanc OHLB, *supra* note 30 at 2 ("Due to confidential contractual obligations with the researchers and the nature of the researchers' proprietary information, we are providing information which is not otherwise protected. These responses are blinded and summarized to protect the active and ongoing research of these scientists"); LifeQuest, *supra* note 30 at 4 ("Neither reviews or approves research studies or accompanying protocols that research entities undertake, nor does it track financial transactions associated with each research study. It is the role of research institutions to communicate with researchers about approved projects.").
[44] Letters from OPOs, *supra* note 30.
[45] Letters from OPOs, *supra* note 30.

requirement that pancreata counted for recertification be used to facilitate bona fide pancreatic islet cell transplantation research;

- Questionable practices to validate whether pancreata were actually used for research; and

- Third party research arrangements provided more robust documentation of research protocols and actual organ usage, though OPOs reported variability in being allowed to review those protocols and determine whether the research was related to pancreatic islet cell transplantation.

In-house research arrangements were less common and allowed for validation of research protocols and usage, but research protocols often did not appear related to pancreatic islet cell transplantation.[46] In fact, some OPOs egregiously benefited from the loophole, inflating their performance metrics without advancing research, which directly contradicts the law's intent.[47]

Finally, as it relates to clearinghouses and biobanks, the investigation found serious concerns as OPOs had little-to-no ability to verify the usage of the pancreata procured or the appropriateness of research conducted.[48] While some of the research facilitated by clearinghouses and biobanks may indeed offer benefits, these arrangements were severely lacking in documentation necessary for adequate oversight of OPO performance and appeared to represent egregious manipulation of the loophole.[49]

In response to the Senators' inquiry, many of the OPOs stated that it is the responsibility of the research facilities or institutions receiving the pancreata to inform the OPOs on the purpose, methods, and efficacy of the research being conducted on the pancreata and other organs that OPOs supply.[50] Therefore, many of the OPOs did not submit research protocols for some or all of the projects for which they supplied pancreata.[51] This failure on the part of some of the OPOs to verify to CMS that the pancreata they procured for research were for "bona fide research"—let alone

[46] Letters from OPOs, *supra* note 30.
[47] Letters from OPOs, *supra* note 30 (Showing that of the 10 OPOs who were asked to provide research protocols for the institutions which they sent organs for research, only 4 could affirm that pancreata went toward islet cell research); *see also* 42 C.F.R. Part 486 at 7814, *supra* note 2.
[48] Letters from OPOs, *supra* note 30; A biobank is a facility that stores and preserves biological samples for potential use in future research while third-party research clearing houses include organizations such as the International Institute for the Advancement of Medicine, which several OPOs reported working with to provide organs for research to qualified medical and scientific professionals without insight into the protocols, qualifications, or even identities of the researchers.
[49] Letters from OPOs, *supra* note 30.
[50] OneLegacy, *supra* note 30 at 7 ("As an OPO, OneLegacy's involvement in research is as a procurement source for pancreata and other organs, including lung, liver, kidney and bladder. While OneLegacy performs due diligence to ensure that it is only supplying research pancreata to reputable, third-party laboratories and institutions with which it has long-standing relationships, OneLegacy does not substantively evaluate or approve the research protocols of those entities. Doing so would exceed its area of expertise as an organ procurement organization."); LifeQuest, *supra* note 30 at 4 ("LifeQuest provides pancreata specimens to the CTSI Biorepository, which provides a number of services, including providing biospecimens; biospecimen processing services; and secure, monitored storage to assist researchers. The storage facility allows researchers to access pancreas tissue for years after it has been received. LifeQuest neither reviews or approves research studies or accompanying protocols that research entities undertake, nor does it track financial transactions associated with each research study. It is the role of research institutions to communicate with researchers about approved projects.").
[51] OneLegacy, *supra* note 30; LifeQuest, *supra* note 30; LifeBanc, *supra* note 30.

toward islet cell research—flies in the face of the spirit of the regulations and the purpose of the national transplant system.[52] It is especially concerning because many of these OPOs have sent pancreata to biobanks and other institutions or facilities that hold pancreata for an unknown period to be used for purposes that may be undefined or nonexistent.[53]

Not all OPOs are similarly situated in this regard. Several included thorough presentations of the criteria which entities must meet prior to a pancreas being sent for research.[54] Additionally, these OPOs included the research protocols and study purposes at the institutions and facilities which received the pancreata.[55] It is thus apparent that OPOs have the ability to provide robust documentation, indicating that the onus can and should be placed upon the OPOs to ensure that the pancreata they provide for research can be traced to a research purpose in line with the law's intent.

C. Current Status

In an August 2024 memorandum regarding OPO CfCs, CMS stated that it expects that, "OPOs will maintain documentation that the pancreas has been accepted for use in bona fide islet cell research conducted by a qualified researcher."[56] However, the findings of this investigation demonstrate that despite CMS's expectations, many OPOs do not maintain documentation showing, or cannot independently verify, that every pancreata procured for research was in fact used for islet cell research.

Prior to the August 2024 memorandum, on January 18, 2024, CMS released a memorandum clarifying that the definition of donor in the OPO CfCs included only pancreata "*used* for *islet cell transplantation or research*."[57] CMS stated that the term "research" within the definition "specifically refers to research for islet cell transplantation," meaning that the intent of Congress and CMS—that "research" in this context referred specifically and exclusively to research for islet cell transplantation—is clearly outlined in both statute and regulation.[58] This memorandum further clarified that OPOs are not to include pancreata procured for research as a procurement if the organ was procured for "potential" research alone.[59] Thus, if an OPO "cannot validate the actual use of the organ for islet cell research," they cannot count it as a procurement in their reporting metric.[60] CMS therefore made clear, since January 2024, that OPOs are required to keep documentation on pancreata submitted for islet cell research so that CMS can verify that data.

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[52] Department of Health and Human Services, *Organ Transplantation Issues and Recommendations*, Report of the Task Force on Organ Transplantation (1986), at 86, https://books.google.com/books?id=_dFeP9DKBNYC&pg=PR23&source=gbs_selected_pages&cad=1#v=onepage&q&f=false.
[53] Letters from OPOs, *supra* note 30.
[54] *Id*.
[55] *Id*.
[56] Centers for Medicare and Medicaid Services, Center for Clinical Standards and Quality, *Organ Procurement Organization (OPO) Conditions for Coverage – Reporting Data Related to Pancreata Procured for Research* (Aug. 29, 2024), https://www.cms.gov/files/document/qso-24-19-opo.pdf.
[57] Centers for Medicare and Medicaid Services, Center for Clinical Standards and Quality, *Organ Procurement Organization (OPO) Conditions for Coverage – Definition Clarification* (January 18, 2024), https://www.cms.gov/files/document/qso-24-04-opo.pdf (emphasis in original).
[58] *Id.*
[59] *Id.*
[60] *Id.*

In the current survey process, the State Operations Manual mentions "islet cells" twice.[61] Both instances require the number of organs used for research per donor, including pancreata used for islet cell research, to be reviewed.[62] However, despite the expectation that OPOs will "maintain documentation that the pancreas has been accepted for use in bona fide islet cell research conducted by a qualified researcher," CMS does not require surveyors to review more than just the number.[63] The current survey guidance is silent on the types of documents that CMS expects OPOs to maintain.[64]

IV. Conflicts of Interest

A. Overview

In order to maintain certification status from CMS, OPOs must meet the requirements of section 1138(b) of the Social Security Act (the Act) and are required to be in compliance with the CfCs set forth in 42 C.F.R. Part 486, Subpart G.[65] CMS surveys OPOs every four years to determine compliance with these requirements.[66] As described by CMS, "[t]he purpose of the survey process is to determine whether the OPO meets all applicable statutory and regulatory requirements."[67] Surveys are unannounced and accomplished through observations, interviews, and document/record reviews.[68] As part of this survey process, OPOs must have bylaws in place to address conflicts of interest.[69] Specifically, the "OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members."[70] Additionally, OPOs must "[e]nsure that the written bylaws for each of the currently operating boards of the OPO address at a minimum:

a) Potential or appearance of conflicts of interest for board members (define conflict and measures to identify and prohibit conflicts);

b) Length of terms for members; and

c) Criteria for selecting and removing members."[71]

Conflicts of interest within the transplant system, including OPOs and the Organ Procurement and Transplantation Network (OPTN) Board and committees, has long been a

[61] Centers for Medicare and Medicaid Services, State Operations Manual, *Appendix Y – Organ Procurement Organization Interpretive Guidance* (2018), at 37, 39, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_y_opo.pdf.
[62] *Id*. at 37 (The number of organs used for research per donor, including pancreata used for islet cell research.).
[63] *Id.*
[64] *Id.*
[65] *Id.* at 3.
[66] *Id.* at 36.
[67] *Id.* at 3.
[68] *Id.*
[69] *Id.* at 5-6.
[70] *Id.* at 51. Z094 (Rev. 115, Issued: 05-23-14, Effective: 05-23-14, Implementation: 05-23-14) (Standard) §486.324(d).
[71] *Id.*

concern of the Senators. Specifically, in 2020, Senators Wyden, Grassley, Cardin, and Young sent a letter to then-HHS Secretary Alex Azar that noted, "OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs."[72] Further, in August 2022, the Senate Committee on Finance held a hearing titled, "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network."[73] The bipartisan staff report associated with this hearing highlighted a 2012 case involving the Alabama Organ Center (AOC) and its Executive Director being charged for his role in a scheme to receive kickbacks from a funeral home.[74] According to a whistleblower complaint, the AOC Executive Director participated in a "money laundering" scheme and other financial improprieties and alleged AOC violated its own "Standard Operating Procedure."[75]

Additionally, in November 2022, Senators Wyden, Grassley, Cardin, and Young sent a letter to Dr. Victor J. Dzau, then-President of the National Academies of Sciences, Engineering, and Medicine (NASEM), raising concerns about potential conflicts of interests that may have had an undue influence on a NASEM report entitled, "Realizing the Promise of Equity in the Organ Transplantation System," which included recommendations for HHS to improve the OPTN.[76] The letter noted that groups in the transplant industry, such as UNOS and the Association of Organ Procurement Organizations (AOPO), were lobbying HHS to implement these recommendations.[77] The letter also highlighted that several NASEM committee members were engaged in consulting agreements with OPOs who could stand to gain financially if HHS implemented the NASEM recommendations.[78]

As a result of these and other apparent financial conflicts between OPOs and outside entities, Senators Grassley and Wyden sent a letter on September 5, 2023, requesting answers about certain OPOs' financial interests and business relationships.[79] Despite clear evidence that OPOs need to address the numerous allegations of conflicting business and financial relationships, the OPTN is currently not required to collect financial information such as details on financial relationships, board member compensation, or affiliated businesses. Further, the Senators' investigation has shown that even when formal complaints are made about financial conflicts of interest, the OPTN, and its current contractor UNOS, have failed to act. In light of these failures

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[72] Letter from Senate Finance Committee to the Honorable Alex M. Azar, Secretary, Department of Health & Human Services, (Oct. 23, 2020), https://www.finance.senate.gov/imo/media/doc/FinalSIGNED%20-%20Grassley%20Wyden%20to%20HHS%2023Oct2020.pdf; *see also* Paul Rosenberg et al., *Transforming Organ Donation In America* (2020), https://www.bridgespan.org/getmedia/4905f7a5-41d7-4240-bd31-0017ec500029/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf.

[73] *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*, Before Sen. Comm. on Finance, 117th Cong. (Aug. 3, 2022), https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE)%20on%20website.pdf.

[74] *Id*.

[75] *Id*. (The Committee found that the United Network for Organ Sharing (UNOS), the OPTN contractor, deemed this whistleblower complaint to fall outside of OPTN policies.).

[76] Letter from Senate Finance Committee to Victor J. Dzau, President, National Academies of Sciences, Engineering, and Medicine (Nov. 17, 2022), https://www.finance.senate.gov/imo/media/doc/111722%20Wyden%20Grassley%20Cardin%20Young%20Letter%20to%20NASEM%20-%20conflicts%20of%20interest%20organ%20procurement.pdf.

[77] *Id*.

[78] *Id*.

[79] Press release, *supra* note 21.

and lack of reporting requirements, additional transparency is needed to ensure these financial and business relationships do not place Americans in need of a lifesaving organ transplant at risk.

B. Findings

a. Basic Conflict Definitions

As previously mentioned, there are concerns regarding the lack of CMS regulations related to how OPOs should define conflicts of interest and administer their conflicts policies. As part of this investigation, Senators Wyden and Grassley asked eight OPOs to disclose their conflicts of interest policies. Based on the responses received, there are ambiguities within the industry as it relates to OPO conflicts of interest policies. This presents an opportunity for CMS to clarify what conflicts of interest are in the context of organ procurement.

As an initial matter, each of the OPOs assert that conflicts of interest can be actual or potential, that is, could be perceived as an actual conflict even if it may not be, and treats both instances alike.[80] Further, all of the OPOs under investigation agreed that conflicts arise when a covered person, or their immediate family member, has an ownership or investment interest in another business with which their OPO is doing, or will do, business and whether covered persons have a "compensation arrangement" with another entity.[81] For seven of the OPOs, "[c]ompensation includes direct and indirect remuneration as well as gifts or favors that are substantial in nature."[82]

The OPOs did, however, differ in what each of their conflicts of interest policies cover. The conflicts of interest policies for LifeShare, TN/NM Donor Services, LifeCenter, and Gift of Life Donor Program do not include non-officers or non-directors (employees) as covered persons.[83] On the other hand, Midwest Transplant Network (MTN), Donor Alliance, and Versiti do extend their conflicts of interest policies to cover all employees, not just officers and directors.[84]

b. How Conflicts Are Reported

All OPOs require covered persons to sign an annual conflicts of interest form asserting they have read and understand each OPOs' conflicts of interest policy.[85] If these covered persons have a conflict, all OPOs, except Gift of Life Donor Program, stipulate that the covered person must disclose the conflict on that annual conflicts of interest form.[86] Aside from these annual forms, Versiti and Donor Alliances' policies mandate that any possible conflict must be reported by covered persons as soon as it is known to them or should be known.[87] All of the OPOs require

[80] MTN 000940; LifeShare 000861; DA-SFC-000808; DCIDS-SFC-000001 (Covers Tennessee Donor Network and New Mexico Donor Services); GLDP-SFC 00196; GLDP-SFC 00199; GLDP SFC 00202; LODN 000676; Versiti Conflicts of Interest Policy (page 4 of 7).
[81] *Id.*
[82] MTN 000941; DCIDS-SFC-000001-2; Versiti Conflict of Interest Policy (page 2 of 7); LODN 000675.
[83] LifeShare_000860; DCIDS-SFC-000001.
[84] MTN 000940; DA-SFC-000808; Versiti Conflicts of Interest Policy, Exhibit B, at 1.
[85] MTN 000941; LifeShare 000861; DA-SFC-000811; DCIDS-SFC-000004-05; Versiti Conflicts of Interest Policy, at 4; LODN000678; GLDP-SFC-00196; GLDP-SFC-00199; GLDP-SFC-00200.
[86] *Id.;* LODN000678.
[87] DA-SFC-000811; Versiti Conflicts of Interest Policy, at 3.

disclosure of actual or potential conflicts when a conflicted transaction or arrangement emerges, that is, before their employer enters into a conflicted, or possibly conflicted, deal.[88] Additionally, five of the eight OPOs specify to whom the conflict is reported, whether it be to human resources, the President/CEO, or board of directors.[89]

c. Allowing Conflicted Transactions

Aside from MTN, each of the OPOs include conflicts of interest policies allowing for the board of directors to approve a conflicted, or potentially conflicted, transaction.[90] For the most part, these policies follow a general pattern: the board can move ahead with a transaction in which there is an actual or potential conflict if 1) there is a full disclosure of the material facts of the conflict by the director or officer who has an interest in the transaction; 2) that interested board member leaves the board meeting; 3) the remaining disinterested board members hold a majority vote approving the transaction; and 4) the transaction is fair to the OPO and is legal.[91]

TN/NM Donor Services, LifeCenter, and Versiti include more robust oversight, tasking the board with exercising due diligence to determine if there is an alternative transaction that the OPO could enter into that would not be conflicted.[92] Upon determining that there is an alternative transaction, there must be a majority vote on whether the conflicted transaction is still more beneficial than the non-conflicted alternative.[93]

d. Types and Numbers of Reported Conflicts

Between 2015 and 2023:

- MTN reported 20 conflicts involving outside employment, 2 outside board membership conflicts, and 1 reported shareholder/investment interest;

- LifeShare reported 22 outside employment conflicts, 8 outside board membership conflicts, and 3 conflicts involving family members of covered persons;

- Donor Alliance reported 7 outside employment conflicts, 8 outside board membership conflicts, 1 family member conflict, and 4 non-profit/foundation membership conflicts;

[88] MTN 000941; LifeShare 000861; DA-SFC-000811; DCIDS-SFC-000004-05; Versiti Conflicts of Interest Policy, at 5-6; LODN000676; GLDP-SFC-00202

[89] LODN000676 (Board of Directors or committee handling a proposed transaction); GLDP-SFC 00196; GLDP-SFC 00199; GLDP-SFC 00202 (Relevant board or President/CEO); Versiti Conflicts of Interest Policy, Exhibit B (Board Chair, President & CEO, Board Committee Chairperson, or Chief Compliance Officer), at 3; MTN 000941 (”Immediate Leader or CEO”); DA-SFC-000811 (President/CEO).

[90] LifeShare 000860; DA-SFC-000809-10; DCIDS-SFC-000002-03; LODN 000676; Versiti Conflicts of Interest Policy, at 5-6; GLDP-SFC-00196; GLDP-SFC-00199; GLDP-SFC-00202.

[91] *See generally Id.* (The policies differ slightly in their language but the above captures the spirit and legal landscape of each policy).

[92] DCIDS-SFC-000002-03; LODN000676; Versiti Conflicts of Interest Policy, at 5-6. .

[93] *Id.*

- TN/NM Donor Services reported 2 outside employment conflicts, 2 outside board membership conflicts, 1 family member conflict, and 1 shareholder conflict;

- LifeCenter reported 53 conflicts involving outside employment, 6 conflicts involving family member employment, 6 ethical conflicts, and 18 financial conflicts;

- Gift of Life Donor Program reported 7 conflicts involving outside board service, 5 financial conflicts, and 8 conflicts involving outside employment, and

- Versiti asserted it did not have any conflicts.

It should be noted that the conflicts reported were often the same people (i.e., one person could have both an outside employment and an outside board membership conflict) over successive years. It is unclear from the disclosure forms whether these are actual or potential conflicts, and there is no indication as to how they were reviewed or handled by the OPOs. Many of the covered persons also included very little information on their forms, simply naming a hospital, for example, without an explanation as to their role at that hospital or how their disclosure conflicted or potentially conflicted with their role at the OPO.[94]

V. Recommendations:

A. Pancreatic Islet Cell Research Recommendations

a. CMS should further clarify the requirements and expectations of OPOs reporting pancreata to be counted toward certification or recertification in a manner consistent with the statutory requirements and legislative intent.

CMS's actions in January 2024 to clarify that reported pancreata must be "*used* for *islet cell transplantation or research*" to be counted toward certification or recertification and their attempt in August 2024 to clarify that OPOs must "maintain documentation that the pancreas has been accepted for use in bona fide islet cell research conducted by a qualified researcher" are steps in the right direction.[95] However, CMS must take further steps to ensure compliance.

CMS should update the State Operations Manual to specify that surveyors must review documentation to validate the ultimate disposition of pancreata for bona fide islet cell research by a qualified researcher. To this end, CMS should define "bona fide pancreatic islet cell transplantation" research to facilitate the adequacy of documentation received and maintained by the OPOs.

[94] On File with Senate Finance and Judiciary Committee Staff.
[95] Centers for Medicare and Medicaid Services, *supra* note 57.

We acknowledge the limited benefits of 42 U.S.C. 273(c), requiring pancreata procured for pancreatic islet cell research be counted for purposes of recertification and recommend that Congress consider revising the statute. The original intent of the legislative provision was to increase researcher access to pancreata to be used in bona fide pancreatic islet cell transplantation research. However, stakeholders have argued that the incentive to procure pancreata for such research by including those organs in the calculations to determine OPO performance is unnecessary.[96] Specifically, as mentioned in this report, procuring pancreata for research is not a normal OPO function and depends highly on the needs of local researchers, which can lead to skewed or inaccurate comparison of OPOs.[97] Including pancreata procured for pancreatic isle cell research as part of the CMS recertification metric has been "bastardized for self-preservation," and despite the increased efforts to procure pancreata for islet cell research, there has not been a corresponding need from researchers for these organs.[98] Finally, we noted that the current provision may create undue burden for CMS, the OPTN, and OPOs to adequately track utilization of pancreata for research in a way not required for other organs recovered for research.

B. Conflicts of Interest Policy Recommendations

a. CMS should further clarify the requirements and expectations of OPOs regarding conflicts of interest to make clear that OPO governing boards and medical advisory boards, as well as CMS surveyors, should monitor actual and potential conflicts of interest.

The Task Force on Organ Transplantation, established by the National Organ Transplant Act of 1984, noted in its 1986 report that donated organs should be considered "a national resource to be used for the public good" and that "the public must participate in the decisions of how this resource can be used to best serve the public interest."[99] This laudable goal cannot be achieved without transparency into actual and potential conflicts of interest of those authorized to make critical decisions, which impacts potential donors, how donors and donor family members are cared for, and how procured organs are handled prior to transplant.

To this end, it is critical that those entrusted with leadership responsibilities at federally certified OPOs disclose conflicts of interest, including direct or indirect financial arrangements, relating to organ donation or transplantation. CMS should clearly define the expectations and requirements to be addressed in OPO conflicts of interest policies and the roles of OPO governing boards, medical advisory boards, and CMS surveyors in reviewing and evaluating those policies and conflicts.

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[96] Association of Organ Procurement Organizations, *AOPO Statement on Senate Finance Committee Letters to OPOs on Pancreata for Research* (Mar. 21, 2023), https://aopo.org/aopo-statement-on-senate-finance-committee-letters-to-opos-on-pancreata-for-research/.
[97] *Id*.
[98] Lenny Bernstein, *supra* note 28.
[99] Department of Health and Human Services, *supra* note 52.

b. OPOs should adopt universal standards clearly defining policy coverage, scope of conflicts, and disclosure procedures.

Every OPO enumerated which levels of staff are covered under its conflicts of interest policy. However, both LifeCenter and Gift of Life Donor Programs' corporate compliance policies appear to capture additional groups of covered employees.[100] In the interest of clarity for employees, OPOs should clearly define who is covered under their official written conflicts of interest policy.

Further, each OPO should clearly define the scope of conflicts covered under its policy. While each OPO recognized that a conflict of interest may be "actual or potential," and framed conflicts around financial interests, LifeCenter and Versiti also acknowledge that conflicts may be personal, ethical, or political in nature.[101] In the interest of clarity for covered employees, and in the interest of the national transplantation system, OPOs should better define the scope of conflicts covered in their official written conflicts of interest policies and ensure consistency across any supplemental materials.

Several OPO conflicts of interest policies, including Life Center and Donor Alliance, incorporate robust provisions defining outside work and what is required of, or prohibited by, persons covered.[102] Because of the potential for outside employment raising actual or potential conflicts of interest, such as outside employment at a transplant center or biobank, each OPO should clarify their policies regarding outside work, including whether and when it is necessary to get approval and what activities are prohibited. This recommendation applies to OPO board members who concurrently sit on the board(s) of other organizations. Outside board membership can have an outsized impact on an organization. Each OPO should clearly define the policies for board members who also sit on other boards. The policy should clearly state that such outside board membership *is* a conflict, and outline how those conflicts are to be reported, reviewed and adjudicated.

Lastly, each OPO should clearly state the procedures for disclosing actual or potential conflicts of interest. Most policies outline the individuals or entities to which employees must make disclosures.[103] Additionally, many policies gave employees multiple options for who they can report to—whether it be to various executives, boards, or committees.[104] Given the importance

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[100] *See* LifeCenter Organ Donor Network By-Laws of Board of Directors, Exhibit A, Conflict of Interest Policy; LODN000675 (Conflicts of interest policy applies to "Directors, principal officers, or members of a committee with governing board delegated powers"); LifeCenter Corporate Compliance Program, at 10; LODN 000485 (Suggesting the conflict of interest policy also applies to "employees, board members, medical directors, and assistant medical directors"); Gift of Life Donor Program Governing Board of Directors Conflict of Interest Agreement, GLDP-SFC 00196; Transplant Foundation Board Member Conflict of Interest Agreement, GLDP-SFC 00199; Gift of Life Family House Board Member Conflict of Interest Agreement, GLDP-SFC 00202 (Conflicts of interest policy applies to all three boards); Gift of Life Donor Program and Its Affiliates, Corporate Compliance Program, Principle 4, GLDP-SFC 00186 (Requiring employees to consult the President and CEO if they have questions about actual or potential conflicts).

[101] *See* LifeCenter Corporate Compliance Program, at 10; LODN 000485; Versiti Conflicts of Interest Policy, Exhibit B, at 2.

[102] LifeCenter Corporate Compliance Program, LODN000485, at 10; Donor Alliance COI at DA-SFC-000810.

[103] LODN000676 (Board of Directors or committee handling a proposed transaction); GLDP-SFC 00196; GLDP-SFC 00199; GLDP-SFC 00202 (Relevant board member or President/CEO); Versiti Conflicts of Interest Policy, Exhibit B (Board Chair, President & CEO, Board Committee Chairperson, or Chief Compliance Officer), at 3; MTN 000941 ("Immediate Leader or CEO"); DA-SFC-000811 (President/CEO).

[104] *Id.*

of establishing a clear chain of command for disclosures, each policy should clearly (1) identify to whom employees must make conflicts of interest disclosures and (2) state what information must be included in the disclosure.

c. OPOs Should Ensure Board Involvement, Oversight, and Recording.

Most OPOs allow for their board of directors to approve a transaction or contract where one or more of its members have an actual or potential conflict but some do not have written procedures. For example, MTN does not address this issue within their conflicts of interest policy, making it unclear what the board's procedure is when confronted by an actual or potentially conflicted transaction.[105] Without written policies and procedures in place, it is difficult to assess the board's approval after the fact. OPO policies should clearly describe the process to disclose and confront actual or potential conflicts.

On the subject of oversight, each OPO should include in their conflicts of interest policies a provision detailing which conflicts are to be reported, when they are to be reported, and how they are reviewed. It is unclear where conflicts are reported and what the internal decision-making process is when a conflict occurs. This provision should also describe how these conflicts are recorded and the records are to be maintained to allow for future audits.

Each OPO submitted conflicts of interest disclosure forms but they didn't require details with respect to the transactions at issue. In order to ensure appropriate and meaningful oversight of those reported conflicts, OPO conflicts of interest disclosure forms should include the material facts related to the reported conflicts of interest. Each policy should ensure that when conflicts are reported the details of that actual or potential conflict, such as where the person has outside employment, their duties, where their spouse holds employment, among other issues, should be disclosed.

VI. Conclusion

While the Senators continue to assess the information each OPO provided, this investigation has revealed that additional consistency, transparency, and clarity is needed to strengthen the integrity of the organ procurement network. Making these improvements will help ensure the health and safety of organ donors and recipients. By providing further clarity with respect to pancreata being recovered strictly for bona fide research on pancreatic islet cell transplantation, CMS can close the pancreata loophole, which has allowed OPOs to inflate their recertification numbers. Additionally, policies and procedures that require consistent and transparent information regarding conflicts of interest will assist CMS and OPOs to ensure improper financial relationships are exposed early.

To date, since 1988, there have been over 500,000 organ donors, with nearly 1.1 million transplants occurring during that same time period.[106] Additionally, as of 2024, there were 170

[105] *See generally* MTN Conflict of Interest Policy, MTN 000940.
[106] Organ Procurement and Transplantation Network, *National Data*, https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.

million people in the United States registered as organ donors.[107] The Senators' decades-long oversight of the OPTN, including this investigation into select OPOs, shows there is significant room for improvement. We believe the recommendations to modernize and clarify the pancreata for islet cell research rule and conflicts of interest policies are key steps in ensuring that the 170 million registered organ donors can trust the system and the system works for them and organ recipients. Congress stands ready to work with OPOs, CMS, HRSA, the OPTN, and other stakeholders to improve the United States organ procurement and transplant industry. We urge OPOs and CMS to implement the recommendations from this staff report.

[107] Donor Alliance Organ & Tissue Donation, *How Many People are Organ Donors?* (Apr. 2, 2024), https://www.donoralliance.org/newsroom/donation-essentials/how-many-people-are-organ-donors/#:~:text=As%20of%202024%2C%20170%20million%20people%20in%20the,donation.%20That%E2%80%99s%20why%20more%20willing%20donors%20are%20needed.

Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T [redacted]
F [redacted]
www.hoganlovells.com

April 14, 2023

The Honorable Ron Wyden
Chairman
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510-6200

The Honorable Charles E. Grassley
Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510-6200

The Honorable Benjamin L. Cardin
Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510-6200

The Honorable Todd Young
Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Re: Response to March 20, 2023 Letter

Dear Chairman Wyden and Senators Grassley, Cardin, and Young:

On behalf of our client, Donor Alliance ("Donor Alliance" or the "OPO"), we are responding to your letter dated March 20, 2023 (the "March 20 Letter"), which was addressed to CEO Jennifer Prinz. Donor Alliance appreciates the opportunity to assist the Finance Committee with this important inquiry. Attached to this letter is Donor Alliance's response to the March 20 Letter.

The submission of this information does not waive, nor is it intended to waive, any rights, privileges, or immunities of Donor Alliance with respect to this matter, including any applicable attorney-client, work product, or other privilege or immunity. Moreover, to the extent that non-responsive information has inadvertently been disclosed, Donor Alliance does not agree to any expansion in the scope of the Committee's Letter. Donor Alliance expressly reserves any applicable rights, privileges and immunities to which it is entitled under applicable law.

The responses in this letter may include confidential business information and sensitive details regarding Donor Alliance's internal business practices and should therefore be kept confidential. Because of the sensitive nature of this information, in the event that the Committee intends, during its inquiry into this matter, to disclose any Donor Alliance information contained in this letter to any other person, Donor Alliance requests that it be given one week advance notice in order to permit it to address the issue with the Committee. Similarly, in the event that the Committee intends to disclose any of this information in any public forum or to a third party who does not expressly agree to maintain the confidentiality of the information, Donor Alliance requests that it be given one week advance notice in order to permit it to address the issue with the Committee.

* * *

If you have any questions regarding the contents of this letter, please do not hesitate to contact me at [redacted]

Sincerely,

Aaron Cutler
Counsel for Donor Alliance
Partner
[redacted]
D [redacted]

Attachment

Donor Alliance's Response to the Letter of March 20, 2023

Before turning to the Requests in the March 20 Letter, we would first like to offer some context about Donor Alliance. By way of introduction, Donor Alliance is the federally designated, non-profit OPO serving Colorado and most of Wyoming. Our community depends on us during some of the most vulnerable times in their lives. Those waiting for a transplant rely on us for a second chance at life, while the families of donors depend on us to honor their loved ones' heroic decisions to give the gift of life.

Donor Alliance is a Malcolm Baldrige National Quality Award-winning organization. The Baldrige Award, which is designed and managed by the National Institute of Standards and Technology ("NIST") of the U.S. Department of Commerce, is the nation's only Presidential award for performance excellence. According to NIST, it is the highest level of national recognition for performance excellence that a U.S. organization can receive. Donor Alliance is one of only three OPOs to have ever received this prestigious award; however, our work is not done.

Donor Alliance is committed to our mission of saving and healing lives through donation and transplantation. Every year from 2015 to the present, Donor Alliance has increased the number of organs procured for transplantation. Even during the pandemic, we were able to maintain continuity and continue Donor Alliance's trend of year over year growth.

Due to Donor Alliance's efforts, Colorado and Wyoming maintain some of the highest percentages of individuals joining the state donor registries in the country. Colorado led the country in 2022 with a 66% registration rate, Wyoming was in the top five with a 61% registration rate, and both states consistently surpass the national average of 51%. These high registration rates have helped fuel Donor Alliance's growth. In 2022, for example, Donor Alliance facilitated 829 organ transplants (excluding pancreata for research), which is a Donor Alliance record and a 29% increase over 2021 performance.

Donor Alliance also recognizes the importance of advancing medical research through procuring all suitable research organs. Beginning in November 2021, Donor Alliance partnered with the University of Colorado to supply pancreata for research. In 2022, the first full year of our partnership with the University, Donor Alliance successfully placed 130 pancreata for research. As you will see in our responses to Requests 1, 3, and 4, the data show a significant increase in the number of pancreata recovered by Donor Alliance and accepted for research by the University of Colorado. Within the University of Colorado system, the pancreata are specifically being utilized by the University of Colorado Anschutz Medical Campus Biobank for its ongoing research projects. As a result of this successful effort, Donor Alliance and the University of Colorado are exploring opportunities to expand our partnership.

Despite our improvements in performance, we never rest in our commitment to honor all donors and donor families through donation and transplantation. We continue to invest in tools and technology to maximize all donation opportunities in our quest to maintain Tier 1 status for donation rate under the CMS performance metrics and reach Tier 1 status for transplant rate.

Donor Alliance is committed to continuous improvement and remains steadfast in its goal of ensuring that the United States remains the leader in organ donation and transplantation.

* * *

Request 1: The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.

Response to Request 1: Donor Alliance presents the following table showing, in the first row, the total number of pancreata recovered by the OPO, per year, from 2018 to 2022. In the interest of completeness, Donor Alliance is also providing data on pancreata recovered with intent to place for transplant or research, but that were subsequently discarded due to concerns about organ suitability. This data is reflected in the second row. Although these pancreata were recovered, but not ultimately used, they are not reflected in Donor Alliance's performance metrics, as reported to CMS. Nor are these pancreata included in Donor Alliance's response to Request 4.

Jan 1-Dec 31	2018	2019	2020	2021	2022
Pancreata Recovered	13	20	11	25	161
Pancreata Recovered and Discarded (unable to place for transplant or research)	0	4	2	6	6

Donor Alliance recognizes the importance of increasing both transplantation and the utilization of pancreata for research. Of note, the 161 pancreata recovered by Donor Alliance in 2022 includes the 130 pancreata successfully placed for research referenced above. Donor Alliance's research partnership with the University of Colorado is the single-most important factor responsible for the increase in pancreata recovered in 2022.

Request 2: The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2022.

Response to Request 2: Donor Alliance presents the following table showing the total number of pancreata successfully placed for transplant by the OPO, per year, from 2018 to 2022.

Jan 1-Dec 31	2018	2019	2020	2021	2022
Pancreata Successfully Placed for Transplant	11	15	7	17	25

Request 3: The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.

Response to Request 3: Donor Alliance presents the following table, which shows the total number of pancreata accepted for research, per year, from 2018 to 2022.

Jan 1-Dec 31	2018	2019	2020	2021	2022
Pancreata Accepted for Research	2	1	2	2	130

Request 4: The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Response to Request 4: Donor Alliance presents the following table, which shows the total number of pancreata recovered for research and transplant reported by the OPO as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Jan 1-Dec 31	2018	2019	2020	2021	2022
Pancreata Recovered for Research and Transplant Combined	13	16	9	19	155

Request 5: The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.

Response to Request 5: Donor Alliance presents the following table, which shows the total number of pancreata recovered by the OPO for research specifically focused on islet cell transplantation, per year, from 2018 to 2022. The data in the table reflects partnerships maintained between Donor Alliance and the University of Colorado's Barbara Davis Center for Childhood Diabetes and the International Institute for the Advancement of Medicine ("IIAM"), respectively. The Barbara Davis Center's research mission entails identifying preventive therapies, treatments, and a cure for Type 1 Diabetes.[1] IIAM is a highly specialized non-profit organization that partners with OPOs and global research institutes to provide "non-transplantable organs to the medical research community for purposes of combatting and curing disease."[2]

Jan 1-Dec 31	2018	2019	2020	2021	2022
Pancreata Recovered for Research Focused on Islet Cell Transplantation	2	1	2	2	1

[1] https://medschool.cuanschutz.edu/barbara-davis-center-for-diabetes.
[2] https://iiam.org/about-iiam/.

For context, Donor Alliance is aware of only one islet cell research program within its donor service area (DSA), which is the University of Colorado's Barbara Davis Center for Childhood Diabetes. In 2017, Donor Alliance entered into an agreement with the Barbara Davis Center for islet cell research. In an effort to supply more recovered pancreata for research generally, and islet cell research in particular, Donor Alliance entered into the aforementioned research agreement with the University of Colorado's Biobank in November 2021. As part of this collaboration, the Barbara Davis Center will have increased access to functional pancreata islet cells for ongoing research projects. As a result, Donor Alliance expects to see an increase in pancreata islet cell research within its DSA in the coming years.

Request 6: How many total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Response to Request 6: Donor Alliance presents the following table, which shows the total number of donors the OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Jan 1-Dec 31	2018	2019	2020	2021	2022
Donors Reported as Part of CMS Performance Metric Calculations	160	191	215	232	272

This table, with a 70% increase in donations from 2018 to 2022, illustrates the strong basis upon which Donor Alliance has achieved and maintained its Tier 1 status for donation rate.

Request 7: How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022. Any guidance documents on protocol for pancreas recovery produced by the OPO staff from 2018 to 2022.

Response to Request 7: Donor Alliance presents the following table, showing the total number of donors the OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022.

Jan 1-Dec 31	2018	2019	2020	2021	2022
Donors Who Only Had a Pancreas Removed for Research	0	0	0	0	0

As a matter of practice, Donor Alliance only facilitates an organ recovery with intent to transplant one or more organs. Donor Alliance does not facilitate cases to only recover pancreata for

research. Nevertheless, there are instances in which Donor Alliance facilitates an organ recovery with intent to transplant an organ that is later not accepted by a transplant center. In these cases, Donor Alliance may be able to facilitate a pancreas for research. In 2022, for example, of the 272 organ donor cases facilitated by Donor Alliance, 15 of these cases resulted in a total of 44 organs with intent to transplant being rejected by transplant centers. Of these 44 organs, 15 pancreata were successfully accepted for research by the OPO's partners.

Finally, Donor Alliance is providing two standard operating procedures related to protocols for pancreas recovery produced by the OPO staff from 2018 to 2022. First, Donor Alliance is also providing the OPO's standard operating procedure entitled, "Organs for Research (OP-540.01)," at DA-SFC-000001 – DA-SFC-000002. This document outlines the procedure utilized to ensure that organs are recovered for research if they cannot be placed for transplantation and where authorization for research has been obtained. Second, the OPO's standard operating procedure entitled, "Organ and Tissue Research Sample Request Approval Process," at DA-SFC-000003 – DA-SFC-000007. This document outlines Donor Alliance's process for reviewing and approving outside requests for organ and/or tissue to be used for research and/or education.

Request 8: Finally, we request copies of the research protocols, along with documentation of review and approval of these protocols for each study the OPO is providing pancreata for research and the number of pancreata procured for each study, per year, from 2018 to 2022. Please include any financial transactions between your OPO and the associated researchers or their institutions related to this research.

Response to Request 8: Donor Alliance is producing copies of the associated research protocols for pancreata procured for each study, per year, from 2018 to 2022, as well as supporting documents. *See* DA-SFC-000008-000102.

- The University of Colorado Research Protocol 21-4748 (attached at DA-SFC-000027 – DA-SFC-000027; DA-SFC-000028 – DA-SFC-000028) functions as an umbrella protocol for specimens provided by the Donor Alliance to the University of Colorado Biobank Pathology Shared Resource ("PSR"), an institutional wide facility that provides research and clinical trial services to the research community at the University of Colorado Anschutz Medical Campus and beyond. The specimens provided under the following studies were used for research projects at the University of Colorado Anschutz Medical Campus.
    - Studies under the umbrella of the University of Colorado 21-4748 Protocol include:
        - ***University of Colorado Cancer Center:*** Organoid and Tissue Modeling Shared Resource ("OTMSR").

          There is no separate research (IRB) protocol for this study as it is covered under umbrella protocol 21-4748; HHS Grant P30CA046934 (award abstract from the HHS.Gov website attached at DA-SFC-000102) Cancer Center Support Grant, PI: Richard Schulick, MD.

Pancreatic specimens are used to develop methods to be able to establish pancreatic organoids both for the establishment of normal organoids from donor specimens as well as to develop and finetune methods to be able to develop organoids from pre-malignant and malignant lesions of pancreatic specimen from patients. Established normal organoids are available to investigators and research programs investigating pancreatic diseases.

- ***University of Colorado Department of Immunology:*** Control of Cytotoxic Lymphocytes by Polymorphic KIR3SL3.

  There is no separate research (IRB) protocol for this study as it is covered under umbrella protocol 21-4748. This study utilizes pancreatic specimens in support of ongoing funded research: 1R56AI155729-01; PI: Paul Norman PhD. and Liyen Loh PhD.

  Major Goals: KIR are among the most polymorphic human genes, and in addition to differential control of infections and cancers, their diversity is associated with susceptibility to reproductive disorders and autoimmunity. In this project, the researchers describe the biological function and immunotherapeutic potential of KIR3DL3, a putative inbibitory receptor of undetermined function and tissue distribution. *Manuscript under review:* Journal: Science Immunology, Manuscript Number: ade5343, Title: Polymorphic KIR3DL3 expression modulates tissue-resident and innate-like T cells (draft attached at DA-SFC-000066 – DA-SFC-000101).

- Studies not under the umbrella of 21-4748 with separate attached protocols:

  - Protocol 17-1933; Dynamics of Human Pancreas Function and COMIRB Approval, PI: Richard Benninger PhD. Barbara Davis Center for Diabetes, at DA-SFC-000008 – DA-SFC-000009; DA-SFC-000010 – DA-SFC-000014.

  - Protocol 21-2599; IPMN tissue analysis and establishment of CAM assay, PI: Sana Karam, MD, PhD-Associate Professor Radiation Oncology – Anschutz, at DA-SFC-000015 – DA-SFC-000026.

  - Protocol 17-2159; Human Immune Tissue Network Protocol, PI: Roberta Pelanda PhD. Professor of Immunology and Microbiology Anschutz School of Medicine, at DA-SFC-000031 – DA-SFC-000040.

- The IIAM Islet Cell research protocol is also attached at DA-SFC-000029 – DA-SFC-000030.

Also attached are certain supporting documents helpful for understanding the research protocols: 1) the University of Colorado Materials Use Agreement (DA-SFC-000041 – DA-SFC-000047) and 2) the IIAM recovery agreement (DA-SFC-000050 – DA-SFC-000065).

Additionally, Donor Alliance presents the following table, which shows, in the first and second rows, the total number of pancreata procured by the OPO for research, per year, from 2018 to 2022, in partnership with the IIAM and the University of Colorado, respectively.

Jan 1-Dec 31	2018	2019	2020	2021	2022
IIAM: Pancreas for Research Accepted	2	1	2	1	1
University of Colorado: Pancreas for Research Accepted	0	0	0	1	129

With respect to financial transactions between Donor Alliance and the associated researchers or their institutions related to research involving the recovery of pancreata, Donor Alliance presents the following table. This table shows, in the first row, fees paid to Donor Alliance from research organizations to cover the costs associated with the recovery of each pancreata for research. In the second row, the table shows the dollar amount of research grants funded by the Donor Alliance Foundation for medical research specific to pancreata. The Foundation was created by Donor Alliance in December 1993 as a nonprofit 501(c)(3) and re-established in August 2017. The Foundation operates exclusively for charitable, scientific and educational purposes. Among other areas, the Foundation provides financial support to social and clinical research grantees. The goal of the grants shown in the second row is to seed larger scale research efforts with respect to pancreata within the OPO's DSA.[3]

Jan 1-Dec 31	2018	2019	2020	2021	2022
Fees Paid to Donor Alliance on Reimbursement Basis from Research Organizations for Pancreata	$4,000	0	$4,000	$2,000	$2,000
Donor Alliance Foundation-Funded Research Grants for Medical Research Specific to Pancreata	0	0	0	$15,000	$20,000

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[3] https://www.donoralliance.org/who-we-are/foundation/.

JONES DAY

51 LOUISIANA AVENUE, N.W. • WASHINGTON, D.C. 20001-2113
TELEPHONE [redacted] • FACSIMILE: [redacted]

DIRECT NUMBER: [redacted]

CONFIDENTIAL

April 7, 2023

VIA ELECTRONIC MAIL TO COMMITTEE ON FINANCE STAFF

The Honorable Ron Wyden
United States Senate
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles E. Grassley
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

The Honorable Ben Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

The Honorable Todd Young
United States Senate
185 Dirksen Senate Office Building
Washington, DC 20510

RE: March 20, 2023 Letter to Indiana Donor Network

Dear Chairman Wyden, Senator Grassley, Senator Cardin, and Senator Young:

We submit this letter on behalf of Indiana Donor Network in response to your letter of March 20, 2023. Your letter sets forth requests for certain information concerning Indiana Donor Network's recovery of pancreata for research purposes—particularly after CMS chose to include such pancreata in its transplant performance metric under the 2021 OPO Final Rule. Indiana Donor Network appreciates the Committee on Finance's continued work to improve the U.S. organ donation and transplantation system and is happy to accommodate your requests.

Information responsive to your requests is set forth below. Documents containing responsive information have also been collected from Indiana Donor Network and will be sent to your staff via separate FTP. The password for the 7-zip file containing those documents will be: [redacted]. Indiana Donor Network requests confidential treatment of all documents and information produced to the Committee.

BACKGROUND

Indiana Donor Network in no way relies on the recovery of research pancreata to drive performance. In fact, removing pancreata for research entirely from the equation, Indiana Donor Network's records reflect that transplanted organs have *increased* by 53%—more than 330 organs per year—since 2018, as a result of Indiana Donor Network's transplant recovery efforts.

Pancreata are used by Indiana Donor Network in connection with research *only if rejected for transplant*, and Indiana Donor Network staff have never entered an operating room with the intention solely to recover a pancreas for research. As detailed below and reflected in documents being produced in response to Request No. 7 in your March 20 letter, there were only six cases from 2018 to 2022 where the sole organ recovered was a pancreas used in research—*and all involved situations where other organs intended to be recovered for transplant were deemed not viable*. During that same time, Indiana Donor Network cared for 1,206 organ donors in total, as calculated by the CMS performance metric, meaning that less than 0.5% of the total had only a pancreas recovered for research. Indiana Donor Network allocated 133 pancreata for transplant during that same period.

Although increasing the total number of organs transplanted is and always will be Indiana Donor Network's overriding focus, Indiana Donor Network also believes in the importance of organ research. The OPO thus takes pride in the fact that it has built a robust, multi-organ research program over the past several years. Its extensive research partnerships include collaborations with internationally renowned academic centers on subject matter as varied as liver perfusion and xenotransplantation. Indiana Donor Network also operates its own organ and tissue recovery center in Indianapolis, which compared to recovering in a hospital, yields better outcomes, reduced healthcare costs, and a better experience for donors' families, while freeing up resources for Indiana Donor Network's partner hospitals. To make this system work, Indiana Donor Network must continually educate recovery center staff on clinical operations; research organs—including pancreata—are a necessary element in this education and development. Indiana Donor Network documents all pancreata and other organs placed for such research purposes. And pancreata represent a small part of these research efforts, comprising only 22% of research organs recovered by Indiana Donor Network since the start of 2018, according to Indiana Donor Network's records.

Notwithstanding the virtues of encouraging such organ research, Indiana Donor Network has never supported CMS's decision to include research pancreata in the transplant performance metric under the 2021 OPO Final Rule. A standalone metric for research organ recovery might make good policy, but CMS's decision to include research organs among transplanted organs for purposes of the metric has made little sense. Indiana Donor Network, in fact, does not even track pancreata placed for research when internally assessing its recovery performance.

Yet the reality is, CMS *did* choose to assess the performance of Indiana Donor Network, and all other OPOs, based in part on the number of pancreata placed for research. In doing so, the regulator grading Indiana Donor Network's performance has signaled the importance of such research recovery efforts, and Indiana Donor Network has sought to comply. Although a minimal part of the OPO's overall organ recovery operation, Indiana Donor Network has made recovery of research pancreata, consistent with its understanding of CMS's OPO Final Rule, a greater focus since 2021, as reflected in Indiana Donor Network's internal data presented below.

RESPONSES TO REQUESTS IN MARCH 20 LETTER

REQUEST NO. 1

The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.

The following table provides the total number of pancreata recovered by Indiana Donor Network yearly from 2018 to 2022, according to Indiana Donor Network's records.

Year	Pancreata Recovered
2018	36
2019	30
2020	39
2021	51
2022	177
TOTAL	333

REQUEST NO. 2

The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2022.

We were uncertain whether Request No. 2, in requesting data on pancreata "placed for transplant," seeks annual information on the total number of pancreata successfully *transplanted* or the total number of pancreata successfully *allocated* to a transplant center. To accommodate the Committee, the tables below provide both sets of data from 2018 to 2022, according to Indiana Donor Network's records.

Year	Pancreata Transplanted
2018	28
2019	18
2020	29
2021	28
2022	30
TOTAL	133

Year	Pancreata Allocated
2018	35
2019	22
2020	35
2021	35
2022	34
TOTAL	161

REQUEST NO. 3

The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.

The table below sets out the total number of pancreata Indiana Donor Network placed annually for research from 2018 to 2022, according to Indiana Donor Network's records. As noted above, since 2021, Indiana Donor Network has placed a greater emphasis on placing research pancreata in light of the CMS 2021 OPO Final Rule.

Year	Research Pancreata
2018	2
2019	9
2020	5
2021	17
2022	144
TOTAL	177

REQUEST NO. 4

The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

The following table presents the total number of pancreata Indiana Donor Network recovered for research and transplant and reported to CMS as part of CMS's performance metric calculations from 2018 through 2022, according to Indiana Donor Network's records.

Year	CMS Research & Transplant Pancreata
2018	30
2019	27
2020	34
2021	45
2022	174
TOTAL	310

REQUEST NO. 5

The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.

The table below sets forth the annual total number of pancreata Indiana Donor Network recovered for research focused on islet cell transplantation yearly from 2018 to 2022, according to Indiana Donor Network's records.

Year	Islet Cell Research Pancreata
2018	0
2019	3
2020	1
2021	5
2022	2
TOTAL	11

REQUEST NO. 6

How many total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

The following table presents the total number of donors Indiana Donor Network reported to CMS as part of CMS's performance metric calculations annually from 2018 to 2022, according to Indiana Donor Network's records.

Year	Total CMS Organ Donors
2018	170
2019	188
2020	238
2021	276
2022	334
TOTAL	1206

REQUEST NO. 7

How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022. Any guidance documents on protocol for pancreas recovery produced by the OPO staff from 2018 to 2022.

The following table reflects the total number of donors Indiana Donor Network reported to CMS yearly from 2018 to 2022 where the donor only had a pancreas recovered for research (with no other organs recovered from the donor for any other purpose), according to Indiana Donor Network's records.

Year	Only Pancreas Removed for Research
2018	0
2019	0
2020	0
2021	1
2022	5
TOTAL	6

Additional support for the foregoing figures, as well as documentation and data identified as responsive to Request Nos. 7 and 8 in your March 20 letter, will be included among the documents being sent separately to your staff by FTP. Some of the documents bear redactions of UNOS ID numbers pursuant to health privacy laws. No documents identified as responsive to the requests have been withheld or redacted on the basis of any privilege.

If you have any questions, please contact me.

Respectfully,

E. Stewart Crosland

Enclosure (via separate FTP)

DONATE LIFE Lifebanc

Saving and Healing Lives through Organ, Eye, and Tissue Donation

April 7, 2023

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Charles E. Grassley
Member
Committte of Finance
United States Senate
Washington, DC 20510

The Honorable Benjamin L. Cardin
Member
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Todd Young
Member
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Wyden, Ranking Member Crapo and Committee Members:

We are pleased to provide the U.S. Senate, Committee on Finance (the Committee) the information requested regarding Lifebanc's (OHLB or Lifebanc) recovery practices specifically related to pancreata recovered for both research and transplantation from 2018 to 2022. We applaud this Committee's efforts in ensuring the integrity and usage of the precious gifts that thousands of Americans donate upon their death each year.

Lifebanc has proudly served Northeast Ohio's communities with the opportunity for organ and tissue donation since 1986 when established as one of the original seven independent organ procurement organizations (OPO) in the U.S. We have been committed to upholding the standards of not only the regulatory bodies that regulate our daily practices including the Centers for Medicare and Medicaid Services (CMS), but most importantly the individuals and their families who make the generous decision to donate organs, tissues and corneas. Their donations provide those waiting with not only their only option to live in some cases, but also the ability to impact thousands of others through research and education.

Lifebanc has ensured that the precious gifts on which donors and their families authorize us to conduct research are matched only with bona fide research endeavors. Some of these notable

studies over the years include, but are not limited to, the National Institutes of Health's (NIH) APOLLO research study to improve outcomes after kidney donation and kidney transplantation[1], research in the advancement of Vascular Composite Allografts, including, face, limbs, and uterus transplants, SUID Tissue Consortium (Sudden Unexpected Infant Death), as well as advancement in organ perfusion technologies to further the ability of organs for transplantation.

In response to the core matter raised in your inquiry in question #8, we provide to you our approach to research project selection which demonstrates our strict adherence to bona fide research. For Lifebanc, this process includes a formal internal procedure by which a designated committee reviews and analyzes various research programs and chooses the most appropriate programs to ensure the legitimacy and compliance of the researcher(s). Lifebanc holds the research programs and projects in which we participate to the highest standards. We provide organs for research and education to projects or studies available through established scientific institutions or organizations that follow guidelines ensuring the organ is being utilized for bona fide research. In addition and to develop the surgical skill competency to support the approved research projects limited pancreata were recovered in 2022 by internal and external staff to ensure proper technique and preservation were utilized to meet the researcher requirements.

In Northeast Ohio, we are uniquely positioned to have world renowned health systems and research hubs with whom we can partner. Part of this quality assurance process for ongoing research projects includes entering into contractual agreements with the researchers which provides Lifebanc with a measure of accountability. Those agreements require the researcher to represent and warrant their duties to compliance with the law as well as provide information to share with donor families about the nature of their research. Due to confidential contractual obligations with the researchers and the nature of the researchers' proprietary information, we are providing information which is not otherwise protected. These responses are blinded and summarized to protect the active and ongoing research of these scientists. **In response to your question #8, we provide the following summary of the projects in which pancreata were supplied for research in the years 2018 through 2022, including any financial transactions:**

- The researcher facilitates in-depth analyses of neonatal to adult pancreata and other tissues from organ donors. This research helps scientists better understand the tissue and cellular organization of the pancreata as well as the pathophysiology of diseases and disorders that are common to the organ. A key focus of the research is devoted to studying Type 1 Diabetes (T1D) to develop a comprehensive view of how T1D develops at the different physiological levels.

[1] Available at: https://www.niaid.nih.gov/clinical-trials/apollo-study.

- The researcher facilitates in-depth analyses of neonatal to adult pancreata and other tissues from organ donors who have T1D or the autoantibodies that make them susceptible to the disease, Type 2 Diabetes (T2D), as well as from healthy donors, to develop a comprehensive view of how T1D and T2D develops at the different physiological levels.

- The researcher will utilize the pancreata to isolate cells that are involved in maintaining blood glucose in our body. They will study processes that can prevent people from developing diabetes and chronic pancreatitis. Their goal is to improve their process of islet cell isolation from the pancreata and perform cutting edge biomedical research that will develop new therapeutics for pancreatic diseases.

- The researcher is examining the pancreatic islet cells to evaluate all types of diabetes including T1D and T2D to evaluate and study the changes in endothelial cell morphology and function.

- The researcher is looking to find the ultimate diabetic cure by identifying early diabetes marker(s) and designing an effective prevention plan through her examination of the human pancreatic islet cells.

With respect to the use of pancreata for research, it is the practice of Lifebanc to count the pancreata and/or islet cells supplied for research based on CMS's metrics in effect. In other words, we have not counted them as a transplant before August 1, 2022 based on the prior CMS regulations. Lifebanc has not attached a cost to research organs, outside of additional supplies or equipment necessary for any independent research studies. When appropriate, Lifebanc has received a nominal fee from the International Institute for the Advancement of Medicine (IIAM) to cover resource and/or expenses. The total financial transactions between Lifebanc and the IIAM related to pancreata-specific recoveries in the years of 2018 to 2022 has totaled $7,500. All other research studies to which pancreata and/or islet cells have been provided involved no financial transactions during this time frame. Lifebanc provides board approved sponsorships through our independent foundation to support research, community outreach, and innovation pertaining to organ and tissue studies. However, it is important to note that these funds have come from third party donation sources and are not related to any funding from the acquisition and placement of organs.

We will address the remainder of the Committee's requests in the order in which you requested them.

Lifebanc takes pride in not only our research compliance, but also on our overall compliance with the complex CMS regulations involving organ procurement generally. As the Committee is likely well aware, healthcare regulations and specifically OPO regulations, involve a complex

interplay between past regulations, certification and reporting cycles, and a delayed publication of OPO performance metrics. Therefore, before providing additional responsive material, we find it necessary to note that the timeframe in which the Committee requests information referencing 42 CFR Part 486[2] falls under two separate governing guidelines. During years 2018-July 2022, the former version of the CMS guidelines and metrics were applicable. For the timeframe on and after August 1, 2022, the new and now current metrics and accreditation guidelines are in effect (the Updated Regulations). The Updated Regulations will be used to assess OPO performance and subsequently determine an OPO's re-certification eligibility in 2026 based on the performance years 2022-2026 which will be measured based on the Updated Regulations.

Congress through the Updated Regulations created a 3-tiered performance structure such that OPOs whose performance falls into the Tier 1 category, the highest category, will be automatically recertified beginning in 2026. OPOs whose performance falls in Tier 2 will need to re-bid and show improvement action plans to be re-certified. OPOs in Tier 3 will be ineligible for recertification. ***But the key change in the Updated Regulations and the most on point to your inquiry is the calculation of organs donated.*** As you point out in your letter, '"only bona fide research conducted by a qualified researcher using a pancreas from an organ donor" will be counted in CMS's performance measures' [referencing the Updated Regulations]. Note that in the prior regulations, pancreata used for research were not counted as transplanted organs and were not otherwise part of the CMS measurement system. By Congress's addition of this very specific inclusion[3], it intended to target such additional efforts by measuring OPOs in this fashion.

Although Lifebanc contributed to organ research prior to these Updated Regulations, it is clear that all OPOs instituted a renewed focus on pancreata donation for research with the recent Updated Regulations. **In response to your question #1, "Total number of pancreata recovered by Lifebanc per year from 2018 to 2022", we report as follows:**
2018: 12; 2019: 19; 2020: 13; 2021: 21; 2022: 81.
Similarly, based on the CMS interim performance reports provided in March 2022, 90% of OPO Tier 1 performers participated and received credit for pancreata research. Deemed top

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[2] Published at 85 FR 77898, available at: https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to.
[3] 85 FR 77902, Available at: https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26329.pdf ; *"We carefully considered other options to address pancreata procured for research, such as creating a process measure for these organs, creating a unique outcome measure, and counting these organs in the outcome measures of this final rule as less than the full value of a transplanted organ. However, these alternative policy approaches did not meet the PHS Act, which states that "Pancreata procured by an organ procurement organization (OPO) and used for islet cell transplantation or research shall be counted for purposes of certification or recertification . . . ." To meet this statutory requirement, we have chosen to include pancreata for research in the outcome measures in the same way that organs procured for transplantation are included."*

performers by the CMS standards, these Tier 1 OPOs show similar results with the implementation of the Updated Regulations and collectively increased pancreata for research by 43% between the 2021 and 2022 interim reports. Thus, it is reasonable to suggest that when CMS established new guidelines, that we would see this increased trend in pancreata data. As a practical matter and as mentioned above, pancreata and islet cell research provides substantial insight into specifically the causes of diabetes since the pancreas is responsible for the production of insulin. As one of the costliest chronic diseases plaguing Americans, "with a disproportionate burden among our minority population"[4] OPOs are well-poised to provide researchers with additional opportunities to find the cause and potentially eradicate this terrible disease with these Updated Regulations and ultimately decrease the need for transplant in this underserved population.

2. While the overall trend in pancreata recovery has increased over the requested time period, another important factor the Committee should consider in its review are factors affecting donation outside of the Updated Regulations. For example, it is important to note that pancreata transplants across the nation suffered a dramatic decrease over the years of 2020 and 2021 due COVID related concerns. Lifebanc's transplanted pancreas trend shows marginal annual growth between 2018 and 2022.
The total number of pancreata successfully placed for transplant by Lifebanc is as follows: 2018: 5; 2019: 12; 2020: 11; 2021: 14; 2022: 16.

3. Another of these outside factors to consider is the availability of research projects—an institution's ability to take new pancreata. It is important to note that during the years of 2020 and 2021, there were a limited number of research opportunities due to the COVID pandemic and we have since seen an increase in requests and opportunities to place non-transplantable organs for active research projects. Our opportunities to pair non-transplantable pancreata and/or islet cells have increased since more public attention has been brought to the availability of this precious gift, not only as a result of the Updated Regulations, but also by the public opinion on the importance of research since the pandemic and advances in scientific research and epidemiology. Lifebanc's research partnerships are based on the need of the scientific community and the variation of inquiries and opportunities will fluctuate from year to year. In other words, Lifebanc works to ensure that no organ donation is unusable.. **By year, the total number of Pancreata placed for research by Lifebanc is as follows: 2018: 3; 2019: 3, 2020: 1; 2021: 3 and 2022: 63.**

4. As with the prior outside factors, public awareness also plays a key role in our performance. Donation success strongly hinges on donors' and their families' understanding of what donation can do to save a life. This includes not only transplant to recipient, but also research which can prevent and cure disease. As part of our mission to educate, Lifebanc shares

[4] "Fighting Diabetes' Deadly Impact on Minorities." FDA, 10 Apr. 2020, www.fda.gov/consumers/consumer-updates/fighting-diabetes-deadly-impact-minorities. Accessed 3 Apr. 2023.

all donor outcomes with the donor's family, including research impact. Donor families have shared that knowing their loved ones' donations to research can ultimately impact thousands of lives through new discoveries and innovation has been the motivation to continue this practice and spurned potential donors to make this important decision. **Our data for this question is as follows:**

Total organs provided by year and specific to pancreata research and transplant:

2018: Pancreata for research and transplant: 8, Total number of ALL research organs recovered: 104
2019: Pancreata for research and transplant: 13, Total number of ALL research organs recovered: 72
2020: Pancreata for research and transplant: 12, Total number of ALL research organs recovered: 40
2021: Pancreata for research and transplant: 16, Total number of ALL research organs recovered: 78
2022: Pancreata for research and transplant: 79, Total number of ALL research organs recovered: 92

5. With the recent publicity surrounding the Updated Regulations, researchers have a new heightened awareness and are looking to develop islet-specific research programs now that there are potentially more pancreata available primarily from donors whose pancreata are unusable for transplant but still useful in research. Because the specifics of some studies, like those completed through IIAM, are blinded we are unable to give a complete number for each of the pancreas provided specifically for islet research. We can however comment on the research projects reviewed by our committee, all of which are focused exclusively on islet cell viability and related Type 1 and Type 2 diabetes-based research to determine genetic patterns related to the islet, islet response to alternative perfusion technologies, and islet yield determination studies. In addition, Lifebanc has been able to provide one pancreas for the purposes of islet cell transplantation in the year of 2022[5].

6. Lifebanc is proud of the growth it achieved in the five-year period for which the Committee has requested data. With each subsequent year, Lifebanc has implemented continuous improvement measures to further increase the number of organ donors willing to save the lives of others. Our key mission is to help save and heal lives. That includes educating and sharing the power of organ donation. Since there are always more candidates waiting than matchable organs available, we must work tirelessly to help increase donation awareness and support advancement of medicine efforts to reduce disease burden on our communities. **In consideration of the overlapping regulations on the time period of data requested, the**

[5] Witkowski P, Philipson LH, Kaufman DB, Ratner LE, Abouljoud MS, Bellin MD, Buse JB, Kandeel F, Stock PG, Mulligan DC, Markmann JF, Kozlowski T, Andreoni KA, Alejandro R, Baidal DA, Hardy MA, Wickrema A, Mirmira RG, Fung J, Becker YT, Josephson MA, Bachul PJ, Pyda JS, Charlton M, Millis JM, Gaglia JL, Stratta RJ, Fridell JA, Niederhaus SV, Forbes RC, Jayant K, Robertson RP, Odorico JS, Levy MF, Harland RC, Abrams PL, Olaitan OK, Kandaswamy R, Wellen JR, Japour AJ, Desai CS, Naziruddin B, Balamurugan AN, Barth RN, Ricordi C; "Islets for US" Collaborative. The demise of islet allotransplantation in the United States: A call for an urgent regulatory update. Am J Transplant. 2021 Apr;21(4):1365-1375. doi: 10.1111/ajt.16397. Epub 2021 Feb 10. PMID: 33251712; PMCID: PMC8016716.

following numbers are reflected based on the CMS performance metrics applicable to each year along with the Updated Regulations calculation and represents the total donors we reported as part of CMS's performance metric calculations, per year, from 2018 to 2022:
2018, Prior to Aug. 1, 2022 Regulations: 162 CMS donors, Updated Regulations: 153 CMS donors
2019, Prior to Aug. 1, 2022 Regulations: 151 CMS donors, Updated Regulations: 137 CMS donors
2020, Prior to Aug. 1, 2022 Regulations: 170 CMS donors, Updated Regulations: 154 CMS donors
2021, Prior to Aug. 1, 2022 Regulations: 182 CMS donors, Updated Regulations: 163 CMS donors
2022, Prior to Aug. 1, 2022 Regulations: 231 CMS donors, Updated Regulations: 205 CMS donors

7. Lifebanc has only had one single pancreas "recovered for research purposes only" in the year 2022 and none for the prior years requested. Even in this specific case, Lifebanc was actively placing transplantable organs up until the time of recovery when all transplant centers declined for transplantation. At that time, the donor family authorized research recovery for their loved one as well as tissue and cornea recovery which took place and was successfully recovered. It is important to note that Lifebanc offers and exhausts all efforts to place organs for transplant. *Unfortunately of ALL the organ offers made in the last three (3) years, 2020-2022, approximately 50% were declined for transplant by all U.S. transplant centers.*[6] Transplantation opportunities are always the primary intention and research to advance medicine is a consideration when all offers have been declined by all U.S. Transplant Centers the donor has authorized, we shift focus to research opportunities to honor each donor's gift to the fullest potential possible.

We realize that our responses to these questions are highly summarizing in nature to be responsive yet respectful of the Committee's time. As you can see, OPO regulation is a complex framework which requires an in-depth understanding of the legal and practical factors involved. We re-iterate Lifebanc's commitment to operating with integrity as the recipient of federal funding. It is unfortunate to think that some would game the system and operate outside the rules. Lifebanc has and will continue to surround itself with information, education and compliance advisors who assist us in our endeavor to remain compliant. Our goal is to keep saving and healing lives and to do that we need an organ procurement system that operates with integrity.

To that end and for that reason, we would like to extend an invitation to any Committee member or member(s) of your staff to visit our OPO to gain a better knowledge and understanding of our day-to-day practice and commitment to saving and healing lives in the great state of Ohio and beyond. We continue to stand true in our commitment to honor each donation opportunity and will continue to advocate for each donor, their families and the many individuals waiting on the U.S. transplant list.

---

[6] OPTN Data Files, 'Three Years of Organ Offers", available at: https://optn.transplant.hrsa.gov/data/; accessed on 04/03/2023.

In closing, and most importantly, our growth and lives saved through donation continue to reflect our daily mission and are aligned to meet the goals of the Updated Regulations. Lifebanc is on pace to be Tier 1 by the end of 2023 whether pancreata for research are included in the certification process or not.

Not including pancreata for research donors, Lifebanc increased our transplanted donor rate by 12.9% from 2021 to 2022 and through our best performing first quarter ever we are on pace for an additional 30% increase for 2023, meaning significantly more lives will be saved by the incredible gifts entrusted to us from our donors and their loved ones.

Respectfully,

Gordon Bowen, Lifebanc CEO

April 6, 2023

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles E. Grassley
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin Cardin
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Todd Young
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Chairman Wyden and Senators Grassley, Cardin and Young,

The purpose of this letter is to provide responses to the request on March 20, 2023, from the U.S. Senate Finance Committee for data from Lifeline of Ohio on pancreas procured for research. Lifeline of Ohio welcomes the opportunity to share the information requested and is grateful to the Committee for ensuring the highest level of performance among stakeholders in the donation and transplantation system.

As the organ procurement organization serving Central and Southeastern Ohio and two counties in West Virginia, Lifeline of Ohio's mission is to save and heal lives through the gift of donation. We acknowledge our role as described in the Centers for Medicare and Medicaid Services' (CMS) Final Rule, "Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" as "critical to ensuring that the maximum possible number of transplantable human organs is available to individuals with organ failure who are on a waiting list for an organ transplant."

To that end, we exhaust every opportunity to recover organs for transplant first and then for research and honor the generous decision of heroic donors and their families to help others through the gift of donation. Since 2018, Lifeline of Ohio has increased the total number of all donated research organs, excluding pancreas, by 170%, with lungs being the most recovered organ for research year over year.

Lifeline of Ohio follows the regulations set forth by our regulatory bodies, including CMS and the OPO Final Rule. The following narrative provides responses to the inquiries by the U.S. Senate Finance Committee regarding pancreata recovered for transplant and research by Lifeline of Ohio from 2018 to 2022.

Be assured that our commitment to our donors, their families, those suffering from organ disease is steadfast, and we are dedicated to collaboration with the greater organ donation and transplantation community to increase the opportunity to save and heal lives through donation.

Regards,

Andrew S. Mullins
Chief Executive Officer

770 Kinnear Road, Suite 200 Columbus, Ohio 43212 www.lifelineohio.org

Lifeline of Ohio Summary: Pancreata Recovered for Transplant and Research

A summary of data below (Table 1) provides responses to questions 1 through 6 of the U.S. Senate Finance Committee requests for information received March 20, 2023, related to Lifeline of Ohio's pancreas recovered from 2018 – 2022.

Table 1: Responses to Questions 1 – 6 from Senate Finance Committee on Pancreas for Research

Senate Finance Committee Requests	2018	2019	2020	2021	2022
1. *Total number of pancreata recovered*	22	18	18	25	74
2. *Total number of pancreata successfully placed for transplant*	19	12	16	8	7
3. *Total number of pancreata placed for research.*	2	5	1	13	64
4. *Total number of pancreata recovered for research and transplant reported as part of CMS performance metric calculations*	19	16	17	21	71
5. *The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.*	0	0	0	0	0
6. *Total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.* *(Data presented based on CMS definition of a donor as of August 1, 2022.)*	124	137	154	162	155

770 Kinnear Road, Suite 200 Columbus, Ohio 43212 ph [redacted] www.lifelineofohio.org

Lifeline of Ohio prioritizes the recovery of pancreas for transplantation. We only recover a pancreas for research when 1) a donor is already donating an organ and 2) the waiting list has been exhausted for a pancreas suitable for transplant, following regulations and standards set forth by CMS.

Table 2 provides the number of donors who only had pancreas removed for research. All donors indicated in this data were either 1) neonate donors (planned donations when a congenital disorder is found during pregnancy and donation for research can occur after birth) or 2) donors whose organs were determined to be not transplantable by transplant centers after recovery, leaving the option of research. Additionally, eight of the nine donors below donated more than one organ and/or tissue to research.

Lifeline of Ohio Guidance for Research Protocol between 2018 and 2022 can be found in attachments CL-126 Research for Solid Organs And Tissue 1a. – 1e. and Research Flowsheet 2. (attached)

Table 2: Pancreas-only donors for research

	2018	2019	2020	2021	2022
7. How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022.	0	0	0	1	8

In alignment with the OPO Final Rule and specified by CMS, Lifeline of Ohio only provides pancreas for "bona fide research conducted by a qualified researcher using pancreas from an organ donor." Lifeline of Ohio maintains longstanding research partnerships to provide organs and tissues for research. Among those, we have provided three organizations with pancreata for research including the International Institute for the Advancement of Medicine (IIAM), Nationwide Children's Hospital Research Institute II and The Ohio State University Comprehensive Transplant Center, Biorepository.

A breakdown of the number of pancreata Lifeline of Ohio procured for each program, per year, appears below (Table 3) and also provides financial transactions related to the pancreata recovered for these research programs. Our longstanding practice of partnering with the local research community keeps costs minimal, and reimbursement generally covers costs associated with recovery services.

Table 3: Financial Transactions/Number of Pancreata Procured for Each Research Study

8. Finally, we request copies of the research protocols, along with documentation of review and approval of these protocols for each study the OPO is providing pancreata for research and the number of pancreata procured for each study, per year, from 2018 to 2022. Please include any financial transactions between your OPO and the associated researchers or their institutions related to this research.

Research Institutions	2018		2019		2020		2021		2022	
International Institute for the Advancement of Medicine (IIAM)	$3,600	2	$3,780	1	$2,000	1	$2,000	1	$4,500*	1
Nationwide Children's Hospital, Research Institute II	$0	0	$0	0	$0	0	$0	0	$3,134.46	40
The Ohio State University Comprehensive Transplant Center, Biorepository	$0	0	$0	4	$0	0	$0	11	$400	23

*Includes reimbursement for recovery services of multiple organs recovered for research

Lifeline of Ohio provides pancreata for research to Nationwide Children's Hospital (NCH), the only U.S. pediatric hospital with a dedicated on-site islet isolation facility. A request for this research was made by Principal Investigator Balamurugan Appakalai, PhD., a pancreatic islet isolation expert.

Copies of research protocols for Nationwide Children's Hospital research and a response request for research can be found in attachments 3a. – b. A description of this research can be found in attachment 3c. or in this video from Nationwide Children's Hospital at the following link: https://www.youtube.com/watch?v=-BxlDsPSaZ0

Lifeline of Ohio holds approved agreements with IIAM and The Ohio State University Comprehensive Transplant Center, Biorepository to provide organs donated for research. These agreements ensure:

- Organs provided for research are deemed non-transplantable.
- Pancreata provided to research organizations follow organizational policies and procedures that meet industry standards.

Examples of research benefitting from pancreata placements can be found in attachments IIAM letter to OPO 4. for IIAM and CTC Biorepository 5. for The Ohio State University Comprehensive Transplant Center, Biorepository.

770 Kinnear Road, Suite 200 Columbus, Ohio 43212 ph www.lifelinkofoh.org

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
United States

Reg Brown, P.C.
To Call Writer Directly:
[redacted]

[redacted]

Facsimile:
[redacted]

www.kirkland.com

April 21, 2023

CONFIDENTIAL TREATMENT REQUESTED

VIA EMAIL

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Wyden:

On behalf of LifeQuest Organ Recovery Services ("LifeQuest"), we are writing to respond to the letter dated March 20, 2023 from the Senate Committee on Finance (the "Committee"). We appreciate your willingness to accommodate LifeQuest with an extension of time to provide a response in light of the Easter holiday.

The stated mission of LifeQuest, one of the nation's 56 organ procurement organizations ("OPO") is: "To honor individuals' donor designations, to ensure families' opportunities to donate and maximize the Gift of Life through organ and tissue donation." In its service area, LifeQuest works with more than 70 hospital partners to manage referrals and on-site evaluation for potential organ donors, and to be the steward of the Gift of Life for those who choose to donate and the patients who ultimately receive a life-saving transplant. Beyond the organ donation, LifeQuest continues engaging with the families of organ donors, providing aftercare support and outreach opportunities for these families.

In addition to facilitating the clinical aspects of organ donation, LifeQuest also works with the hospitals in its service area to provide training and education to critical care healthcare professionals involved in the identification and referral of potential donors. LifeQuest also provides public education to encourage positive decisions about donation and works closely with public agencies, who facilitate donor registrations annually.

LifeQuest respectfully responds to the questions posed in the March 20, 2023 letter as follows:

1. The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.

Please see the total number of pancreata recovered by LifeQuest from 2018 to 2022 below:

Year	No. of Pancreata
2018	26
2019	16
2020	25
2021	121
2022	200

2. The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2022.

Please see the total number of pancreata successfully placed for transplant by LifeQuest from 2018 to 2022 below:

Year	No. of Pancreata
2018	21
2019	15
2020	18
2021	18
2022	20

3. The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.

Please see the total number of pancreata placed for research by LifeQuest from 2018 to 2022 below.

Year	No. of Pancreata
2018	4
2019	1
2020	0
2021	48
2022	176

4. The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Please see the total number are the total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations from 2018 to 2022 below:

Year	No. of Pancreata
2018	26
2019	16
2020	25
2021	120
2022	200

5. The total number of pancreata recovered from research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.

LifeQuest recovered no pancreata from research specifically focused on islet cell transplantation at any point from 2018 to 2022, despite attempts to do so by following the UNOS match run for pancreas and kidney-pancreas transplantation on each donor.

6. How many total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Please see the total number of donors that LifeQuest reported as part of CMS's performance metric calculations from 2018 to 2022. The listed figures for 2018 to 2021 are based on the CMS donor definition in that year's regulatory cycle. For 2022, the listed figure is based on the 2022 CMS donor definition for the regulatory cycle starting August 2022.

Year	No. of Donors
2018	163
2019	185
2020	205
2021	217
2022	242

7. How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022.

Please see the total number of donors that LifeQuest reported as part of CMS's performance metric calculations who only had a pancreas removed for research from 2018 to 2022.

Year	No. of Donors
2018	0
2019	0
2020	0
2021	0
2022	8

7.a) Any guidance documents on protocol for pancreas recovery produced by the OPO staff from 2018 to 2022.

The enclosed documents bearing Bates numbers LQ-SFIN-00000001 – LQ-SFIN-00000033 are guidance documents on protocol for pancreas recovery.

8. Finally, we request copies of the research protocols, along with documentation of review and approval of these protocols for each study the OPO is providing pancreata for research and the number of pancreata procured for each study, per year, from 2018 to 2022. Please include any financial transactions between your OPO and the associated researchers or their institutions related to this research.

LifeQuest currently has relationships with three research entities to which it provides pancreata for research. Its longest-standing relationships are with the International Institute for the Advancement of Medicine ("IIAM") and the Network for Pancreatic Organ Donors ("nPOD"). LifeQuest also began working with the Clinical and Translational Science Institute ("CTSI") at the University of Florida, which was founded to advance scientific discoveries into improved health for patients by strengthening the university's ability to conduct translational research. CTSI is supported by multiple NIH grants and is accredited by the College of American Pathologists Biorepository Accreditation Program. LifeQuest provides pancreata specimens to the CTSI Biorepository, which provides a number of services, including providing biospecimens; biospecimen processing services; and secure, monitored storage to assist researchers. The storage facility allows researchers to access pancreas tissue for years after it has been received. LifeQuest neither reviews or approves research studies or accompanying protocols that research entities undertake, nor does it track financial transactions associated with each research study. It is the role of research institutions to communicate with researchers about approved projects.

Please see the total number of pancreata procured for each research entity from 2018 to 2022 below:

Year	No. of Pancreata to CTSI
2018	0
2019	0
2020	0
2021	43
2022	175

Year	No. of Pancreata to IIAM
2018	3
2019	1
2020	0
2021	2
2022	0

Year	No. of Pancreata to nPOD
2018	0
2019	0
2020	0
2021	3
2022	1

* * * * *

LifeQuest does not, by this response or any subsequent production, intend to waive any applicable privileges arising from common law or the U.S. Constitution, or other legal basis under which information may not be subject to production. In providing this production, LifeQuest has taken reasonable steps to prevent the disclosure of privileged material. If it were found that any of the enclosed information constitutes disclosure of otherwise privileged matters, such disclosure would be inadvertent. By the provision of such information, LifeQuest does not intend to waive and has not waived the attorney-client privilege or any other protections. LifeQuest respectfully reserves the right to supplement its production to the Committee, as appropriate.

We appreciate the opportunity to provide this information.

Sincerely,

Reginald J. Brown
Kirkland & Ellis LLP

Allison Murphy
Kirkland & Ellis LLP

Enclosures

cc: The Honorable Charles E. Grassley
The Honorable Benjamin L. Cardin
The Honorable Todd Young

AUTHORIZED FOR RELEASE BY SENATORS GRASSLEY & WYDEN

Mid·America TRANSPLANT
Inspired by life

April 3, 2023

United States Senate
Committee on Finance
Washington, D.C. 20510

Dear Senate Finance Committee Members:

Mid-America Transplant appreciates the opportunity to provide additional information on its pancreata placed for research. Our organization supports Congressional efforts to improve the organ donation system.

Mid-America Transplant believes that pancreata research-only donors should not be included in the Centers for Medicare and Medicaid's performance metrics to evaluate OPOs. At Mid-America Transplant, we move forward with authorized organ donors **only** when we believe there is an opportunity for transplantation. If the donor's pancreas is deemed unviable for transplant, we provide the pancreas for research at one of our two local academic medical centers.

We offer the following information requested in your March 20, 2023, letter:

1. Total number of pancreata recovered by Mid-America Transplant, per year from 2018 to 2022:
   2018: 32
   2019: 44
   2020: 116
   2021: 179
   2022: 257

   Total: 628

2. Total number of pancreata successfully placed for transplant by Mid-America Transplant, per year, from 2018 to 2022:
   2018: 23
   2019: 19
   2020: 25
   2021: 27
   2022: 14

   Total: 108

3. Total number of pancreata placed for research by Mid-America Transplant, per year, from 2018 to 2022:
   2018: 5
   2019: 20
   2020: 85
   2021: 138
   2022: 215

   Total: 463

midamericatransplant.org
1110 Highlands Plaza Dr. East, Suite 100
St. Louis, MO 63110 | T [redacted]

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4. Total number of pancreata recovered for research and transplant reported as part of CMS' performance metric calculations, per year, from 2018 to 2022:

   2018: 28
   2019: 39
   2020: 110
   2021: 165
   2022: 229

   Total: 571

5. Total number of pancreata recovered for research specifically focused on islet cell transplantation by Mid-America Transplant, per year, from 2018 to 2022:

   2018: 0
   2019: 0
   2020: 20
   2021: 100
   2022: 125

   Total: 245

6. How many total donors Mid-America Transplant reported as part of CMS' performance metric calculations, per year, from 2018 to 2022:

   2018: 187
   2019: 257
   2020: 263
   2021: 246
   2022: 279

   Total: 1,232

7. How many total donors Mid-America Transplant reported as part of CMS' performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022.

   2018: 0
   2019: 0
   2020: 5
   2021: 13
   2022: 22

   Total: 40

midamericatransplant.org
1110 Highlands Plaza Dr. East, Suite 100
St. Louis, MO 63110 | [redacted]

Mid·America TRANSPLANT
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8. Since 2017, Mid-America Transplant has partnered with researchers at Saint Louis University and Washington University in St. Louis to support pancreas research, as we recognize that medical advancements through research may better help treat diseases, like diabetes, and ultimately reduce the number of people who one day need an organ transplant. Our research partnerships are not limited to pancreata; we currently have 35 active research agreements with researchers at the above-mentioned institutions for organs and tissues that cannot be transplanted. All organs, including pancreata, are provided to the researchers at no charge.

   Per the Senate Finance Committee's request, attached are copies of research protocols, (as outlined in Mid-America Transplant's Material Transfer Agreements) and documentation of reviews and approvals of such protocols with three researchers from academic medical institutions in Mid-America Transplant's DSA. These researchers are:

   - Yiing Lin, MD, PhD, Associate Professor of Surgery at Washington University School of Medicine;
   - Gina L.C. Yosten, PhD, Associate Professor, Pharmacology and Physiology at Saint Louis University School of Medicine and Grant R. Kolar, MD, PhD, Associate Research Professor, Department of Pathology at Saint Louis University School of Medicine; and
   - Mohammed A. Zayed, MD, PhD, Associate Professor of Surgery at Washington University School of Medicine.

   To facilitate the equitable distribution of research pancreata, Dr. Lin is primarily responsible for recovering the pancreata within our DSA, evaluating the research quality of the pancreata that cannot be transplanted, and distributing the pancreata amongst the above-mentioned researchers accordingly. As such, one pancreas may be used by one researcher, or may support two to three different research studies. Regardless of how many studies it supports, Mid-America Transplant counts each research pancreas only once.

   Mid-America Transplant has included letters from the aforementioned researchers outlining additional information about their projects.

   The number of pancreata procured for or by Dr. Ling's research and distribution, per year, from 2018 to 2022, are as follows:

   2018: 5
   2019: 20
   2020: 85
   2021: 138
   2022: 215

   Total: 463

midamericatransplant.org
1110 Highlands Plaza Dr. East, Suite 100
St. Louis, MO 63110 | T [redacted]

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There are a total of 20 attachments supporting our research protocols. These are:

1. Research Agreements (also known as Material Transfer Agreements (MTAs)) with each Research. (11)
2. Researcher Applications, along with an example of the application review. (4)
3. Researcher Letters of Support. (3)
4. Supporting Documentation for Drs. Yosten and Kolar. (2)

Mid-America Transplant would be willing to facilitate conversations with the researchers identified above if it would provide value to the Senate Finance Committee.

Thank you for your time and the opportunity to respond to this request.

Sincerely,

Kevin J. Lee
President and CEO

Malcolm Baldrige National Quality Award
Award Recipient
2021 2015

midamericatransplant.org
1110 Highlands Plaza Dr. East, Suite 100
St. Louis, MO 63110 | T [redacted]

GIBSON DUNN

Gibson, Dunn & Crutcher LLP

1050 Connecticut Avenue, N.W.
Washington, DC 20036-5306
Tel [redacted]
www.gibsondunn.com

Michael D. Bopp
Direct: [redacted]
Fax: [redacted]

CONFIDENTIAL

April 7, 2023

VIA ELECTRONIC MAIL

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles E. Grassley
Member of Congress
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
Member of Congress
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

The Honorable Todd Young
Member of Congress
United States Senate
185 Dirksen Senate Office Building
Washington, DC 20510

Re: First Response to March 20, 2023 Letter to OneLegacy

Dear Chairman Wyden and Senators Grassley, Cardin, and Young:

We represent OneLegacy and are writing in response to the Senate Finance Committee's (the "Committee") letter, dated March 20, 2023 (the "Letter"), requesting the production of certain documents and information about pancreata recovered for research in accordance with the Centers for Medicare and Medicaid Services' ("CMS") Final Rule, "Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" (the "Final Rule"). The Letter appears focused, in particular, on the Final Rule's inclusion of pancreata for research for purposes of calculating the organ transplantation rate and donation rate.

We appreciate the Committee looking into the number of pancreata recovered and ensuring the ones earmarked for research are meeting the standard of and going toward legitimate research purposes. We are pleased to provide you with this first response to your Letter.

As you know, research into islet cell recovery, isolation, and culturing is critically needed to address the rise of diabetes in this country[1]. When CMS revised the Final Rule in 2020, it further elevated the importance of pancreas research, finding that "[p]ancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b)." The elevation of this critical research by CMS was appropriate as the research and advancement in treating diabetes would have a direct impact on addressing kidney failure and the need for kidney transplant.

Like many other organ procurement organizations ("OPOs"), OneLegacy has long placed organs that are not viable for transplant with research laboratories. For over 25 years, OneLegacy has been working with a number of reputable islet cell research agencies, including two National Institute of Diabetes and Digestive and Kidney Diseases (NIH-NIDDK)[2] laboratories: City of Hope National Medical Center ("City of Hope") and Prodo Laboratories/Scharp-Lacy Research Institute ("Prodo/SLRI"). These provider centers are two of only five national islet isolation centers in the Integrated Islet Distribution Program (IIDP)[3]. The IIDP is sponsored and funded by the U.S. Government through the NIH-NIDDK, and, since August of 2018, the IIDP has distributed 250 million islets worldwide to 350 research studies resulting in 640 peer-reviewed publications.[4] OneLegacy is proud to have contributed to this NIH-NIDDK sponsored research.

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[1] Diabetes 2030: Insights from Yesterday, Today, and Future Trends: "[I]n spite of medical advances and prevention efforts, diabetes presents a major health crisis in terms of prevalence, morbidity, and costs, and that this crisis will worsen significantly over the next 15 years… Aggressive efforts are urgently needed if we want to significantly reduce the diabetes epidemic by 2030." *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278808/. Study: Diabetes increasing among U.S. Youth: "The estimated number of U.S. residents under age 20 with type 1 diabetes increased 45% from 2001 to 2017 to 215 per 100,000, while the number with type 2 diabetes increased 95% to 67 per 100,000." *See* https://www.aha.org/news/headline/2021-08-24-study-diabetes-increasing-among-us-youth.

[2] The National Institute of Diabetes and Digestive and Kidney Diseases (NIH-NIDDK) is part of the National Institutes of Health (NIH), the nation's medical research agency. It conducts and support biomedical research, disseminating research findings and health information to the public, and is part of the U.S. government under the Department of Health and Human Services. *See* https://www.NIH-NIDDK.nih.gov/about-NIH-NIDDK/faqs#what-is-NIH-NIDDK.

[3] The IIDP consists of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Project Scientist and Program Official, an External Scientific Panel, and the Coordinating Center at City of Hope. Selection of the five (5) member centers were made following a thorough review of all applicants responding to an IIDP-issued RFP, including a scientific review conducted by multiple experts in human islet biology, isolation, and distribution. *See* https://iidp.coh.org/Centers.

[4] See https://www.cityofhope.org/research/riggs-institute/department-of-diabetes-and-cancer-discovery-science/integrated-islet-distribution-program.

The OneLegacy data presented below show a notable increase in the placement of pancreata for research since the implementation of the Final Rule, with over 99.6% of OneLegacy's recovered research pancreata being allocated to these two IIDP centers since the start of 2022[5]. With Congress having identified pancreatic research as a priority in mitigating diabetes and the need for kidney transplantation, OneLegacy has ensured that it has maximized every recovery opportunity for research pancreata and has further prioritized supplying those recovered pancreata to laboratories and programs that are supported by the U.S. Government through the NIH-NIDDK.

We note that organ donation for medical research is a specific election. Every organ donor has the opportunity to opt out of medical research, whether by first person donor registry or authorization provided by donor family members. Notwithstanding that fact, OneLegacy does not and has not pursued an organ donor solely for purposes of recovering a research pancreas. During the relevant timeframe between 2018 through 2022, there were only two instances (0.26% of the 762 research pancreata recovered by OneLegacy during this period) where a research pancreas was the only organ recovered, and in both instances, the surgical recovery was commenced with the objective of organ transplant, but the surgeon deemed the organ unsuitable for transplant and did not remove any transplantable organ. The pancreas was then recovered incident to the attempted recovery of a transplantable organ. These research pancreata were then allocated to bona fide research laboratories in furtherance of Congress' objective.

In addition to supporting important pancreatic research, OneLegacy recovered a record 647 donors in 2022— a 9.5 percent increase from the previous year. These donors, through their generous gift of life, allowed OneLegacy to facilitate the transplantation of 1,628 organs. This growth continues, with over 700 donors recovered and over 1,700 organs transplanted in the past 12 months.

* * *

[5] With the implementation of the CMS Final Rule in 2022, the most relevant data points for research pancreas allocation would be in 2022 and thereafter. 589 pancreata were recovered for research by OneLegacy in calendar year 2022 and Q1 of 2023, and of these, 587 were placed for research with either City of Hope or Prodo/SLRI. The remaining two (2) pancreata were allocated to the University of Florida.

Turning to specific requests in the Letter, we are producing with this response information that we hope the Committee will find helpful to its inquiry.

This letter contains some of OneLegacy's confidential, trade secret, and/or proprietary information. We have marked this letter "Confidential" and request that it not be disclosed beyond the Committee or made public. We ask that you treat this letter as a confidential committee record in accordance with Standing Rule of the Senate XXIX, clause 5, afford it the maximum protection available to information provided to the Committee, and that you inform us of any proposed use by the Committee of the information contained herein and provide OneLegacy with an opportunity to be heard prior to any such proposed use.

The information contained in this response is based on OneLegacy's best efforts undertaken within the timeframe provided and based on its understanding of the terms of the Letter. The representations made in this response are based on information reasonably available to the Organization and may not reflect all existing relevant information. OneLegacy reserves the opportunity to supplement information in this response. In providing information and materials responsive to the Letter, OneLegacy does not waive any rights, privileges or legal options relating to the Committee's inquiry.

* * *

Request 1:

The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.

Response:

Please find the requested data in the chart below:

	2018	2019	2020	2021	2022
Total Pancreata Recovered:	152	131	82	139	460

Request 2:

The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2022.

Response:

Please find the requested data in the chart below:

	2018	2019	2020	2021	2022
Pancreata Provided for Transplant:	34	37	29	39	17

Request 3:

The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.

Response:

Please find the requested data in the chart below:

	2018	2019	2020	2021	2022
Pancreata Recovered for Research:	106	82	43	90	441

Request 4:

The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Response:

Please find the requested data in the chart below:

	2018	2019	2020	2021	2022

Total Pancreata Recovered for Research or Transplant:	140	119	72	129	458

Request 5:

The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.

Response:

Please find the requested data in the chart below:

	2018	2019	2020	2021	2022
Pancreata Recovered for Islet Cell Research:	106	82	43	90	441

Request 6:

How many total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.

Response:

Please find the requested data in the chart below:

	2018	2019	2020	2021	2022
Total Donors Reported (Using Prior Metric):	515	557	548	591	647
Total Donors Reported (Using New CMS Metric):	468	500	476	527	601

Request 7:

How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022. Any guidance documents on protocol for pancreas recovery produced by the OPO staff from 2018 to 2022.

Response:

Please find the requested data in the chart below:

	2018	2019	2020	2021	2022
Pancreas-Only Donors Reported:	0	0	0	0	2

OneLegacy does not and has not pursued an organ donor solely for purposes of recovering a research pancreas. During the applicable timeframe, there were 2 instances where a research pancreas was the only organ recovered, and in both cases, the surgical recovery was commenced with the objective of organ transplant, but the surgeon deemed the organ unsuitable for transplant and did not remove any transplantable organ. To honor the wishes of the donor and/or donor's family to give the gift of life, including through research, the pancreas was then recovered incident to the attempted recovery of a transplantable organ.

Request 8:

Finally, we request copies of the research protocols, along with documentation of review and approval of these protocols for each study the OPO is providing pancreata for research and the number of pancreata procured for each study, per year, from 2018 to 2022. Please include any financial transactions between your OPO and the associated researchers or their institutions related to this research.

Response:

As an OPO, OneLegacy's involvement in research is as a procurement source for pancreata and other organs, including lung, liver, kidney and bladder. While

OneLegacy performs due diligence to ensure that it is only supplying research pancreata to reputable, third-party laboratories and institutions with which it has long-standing relationships. OneLegacy does not substantively evaluate or approve the research protocols of those entities. Doing so would exceed its area of expertise as an organ procurement organization.

* * *

Please feel free to have your staff contact me with any questions concerning this response.

Sincerely,

Michael D. Bopp
Partner

cc: The Honorable Mike Crapo
Ranking Member
Senate Committee on Finance

106238292.2

TEXAS ORGAN SHARING ALLIANCE™

April 6, 2023

The Honorable Ron Wyden
United States Senate
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles Grassley
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

The Honorable Benjamin Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

The Honorable Todd Young
United States Senate
185 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Wyden, Senator Grassley, Senator Cardin, and Senator Young:

Texas Organ Sharing Alliance (TOSA) received your letter dated March 20, 2023, expressing concerns that organ procurement organizations (OPOs) are falsely inflating performance metrics with questionable pancreata donation practices. The letter additionally requested information related to pancreata recovered and donated for research. TOSA appreciates the Committee's interest in the effects of the Center for Medicare and Medicaid Services' (CMS) new OPO rule adopted in 2021 on organ donation and in ensuring the new rule operates as intended, which is to increase procurement opportunities for transplantation, increase organ utilization, and ultimately save more lives. Although TOSA can only speak for itself and its activities, TOSA welcomes this opportunity to share with the Committee the successful actions we have undertaken in recent years, in collaboration with others, to save lives and honor donors' gifts through organ recovery, transplantation, and research.

Attached to this letter are reports and supporting information relating to your eight specific requests. It is our hope that this letter and the data provided shows the remarkable success TOSA has had with the establishment of a dedicated recovery center to increase recovery and transplantation rates, as well as TOSA's efforts to partner with valued research centers to provide organs for research aimed at addressing serious health issues facing TOSA's minority-majority population.

As you will note from the information provided, TOSA has achieved marked increases in the annual number of organ recoveries and transplantations since 2019 – an accomplishment in which we take great pride. TOSA achieved these increases by implementing an improved staffing model, hiring a full-time recovery surgeon, and, in large part, by successfully establishing our new dedicated organ recovery center, the Center for Life (CFL) at the University Hospital (UH). The CFL is a specialized donor care facility, which has since been recommended in The National Academies of Sciences' 2022 report on the

organ transplantation system.[1] Planning for the CFL started in 2017 and opened on February 2020, and since its opening, TOSA has dramatically increased the number of organs recovered and organs transplanted per donor in the CFL, as well as increased its collaboration with University Health Transplant Institute (Transplant Institute), which is a partnership between UH and University of Texas Health San Antonio (UTHSA).

TOSA's mission is to recover as many organs as possible for the purpose of transplant, and as a whole, we have achieved a 30% increase in all organs transplanted from deceased donors within the last year since the new rule became effective. For example, in 2019, TOSA recovered 723 organs, with 620 transplantations, representing 555 lives saved. In 2021, the year during which the new OPO rule was adopted, TOSA recovered 946 organs with 861 transplantations (as defined in the OPO rule), representing 691 lives saved. In 2022, TOSA recovered 1033 organs with 1003 transplantations (as defined in the OPO rule), representing 727 lives saved. These increased recoveries and transplants could not have been possible without the CFL.

Under the new rule, a donor is defined as "a deceased individual from whom at least one vascularized organ is transplanted, not just procured for transplant, or an individual from whom a pancreas is procured and is used for research." As with all organs, TOSA always first seeks to make recovered pancreata available for transplant. Unfortunately, not every recovered organ is medically viable or accepted for transplant, and when transplant is not possible, TOSA seeks research opportunities to ensure that the donor's gift is honored, and that the organ does not go to waste. TOSA has historically had challenges placing pancreas for transplant, even though TOSA exhausts the search every time a pancreas is available for transplant. Nevertheless, TOSA is obligated to honor donors' gifts by seeking research opportunities for organs that cannot he transplanted. Oftentimes, the determinative factor in the donation rate of organs for research is the demand, or lack thereof, that research facilities have for certain organs, based on a research facility's particular criteria and needs.

University Health's Transplant Institute has managed an organ biorepository since 2007; however, the establishment of the CFL on UH's grounds in 2020 created an opportunity for the Transplant Institute to locate a biorepository (Biorepository) within the CFL to enhance the collaboration between TOSA's CFL and the Transplant Institute's Biorepository. The Biorepository, which is independently controlled and operated by the Transplant Institute, expanded their operations in 2021, and those expansion efforts have directly resulted in their increased demand for and TOSA's subsequent donation of critical organs for research, including livers, kidneys, and pancreata. The longstanding Biorepository is currently the largest biorepository of Hispanic liver and kidneys available for research in the United States. Its goal is to research Hispanic-specific issues related to diabetes, pancreatic cancer, COVID+ donor research, and oxidative stress analysis, among others, potentially including research relating to cardiothoracic organs in the future. After the successful collaboration between the CFL and the Transplant Institute in 2021, the Transplant Institute began requesting qualified organs recovered outside of the CFL for donation to the biorepository in 2022, the result of which constituted a significant increase in the number of pancreata, liver, and kidneys donated to the biorepository for research.

Regarding pancreata in particular, and to specifically address Item 7 in your letter, we will note that TOSA did not have a single donor reported as part of CMS's performance metric calculations who only had a pancreas removed for research, for any year from 2018 through 2022. Nor do pancreata represent

[1] National Research Council, *Realizing the Promise of Equity in the Organ Transplantation System*, Washington, DC: The National Academies Press (2022), p. S-12, *available at*, https://nap.nationalacademies.org/catalog/26364 (Recommendation 11 recommends that each OPO create, establish, and manage a donor care unit (DCU)).

the largest percentage increase of donated organs for research from TOSA to the Transplant Institute's Biorepository in 2022. In fact, from 2021 to 2022, the percentage increase in donation of both kidneys and livers recovered by TOSA and donated to the Biorepository was greater than that of pancreata. For example, the Biorepository received 3 livers, 11 kidneys, and 42 pancreata from TOSA during 2021, compared to 38 livers, 95 kidneys, and 146 pancreata in 2022, which represents percentage increases to the Biorepository of 1,167% in liver donations, 764% in kidney donations, and 248% in pancreata donations, respectively.

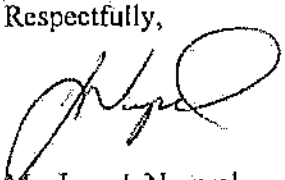
When the CFL was established, TOSA and UH intended increased collaboration between the CFL and the Transplant Institute for the purpose of improved outcomes in both transplantation and research. While the increase in recovery activities at the CFL increased overall the number of recovered organs, the Transplant Institute's current immediate need for Biorepository organs singularly explains the increase in TOSA's donation rates of pancreata, livers, and kidneys. As such, any increased performance metrics under the new OPO rule is an incidental outcome of increased research demand and improved collaboration among TOSA, UH, and UTHSA, and not the motivation for such donations.

Jillian Woodworth, the Transplant Institute's Manager of Research Operations, recently said: "We don't take for granted the enormous privilege it is to have access to such precious resources, and I see a huge opportunity for collaborative research over the coming year." With this in mind, TOSA expects collaboration with the Transplant Institute's Biorepository to continue. As long as the Transplant Institute's research need for organs persists, TOSA will continue to offer organs that are not able to be placed for transplantation. Should CMS change the rule pertaining to pancreata and the definition of donor, TOSA will continue our best efforts to fulfill our obligation to honor donor gifts by seeking every opportunity for transplantation or donation to bona fide research facilities.

We hope the information expressed above and the information provided along with this letter assists the Committee with understanding TOSA's activities and addresses the concerns the Committee conveyed in its March 20, 2023 letter. We trust that after thorough review, the Committee will observe that all organs TOSA has donated for research were donated to bona fide research facilities and made in the pursuit of TOSA's mission of saving lives and honoring donors' gifts – not to game a system.

If the Committee has any other questions or concerns, TOSA welcomes the opportunity to work with the Committee and others to save more lives and effectuate improvements in organ recovery, transplantation, and donation for research.

Respectfully,

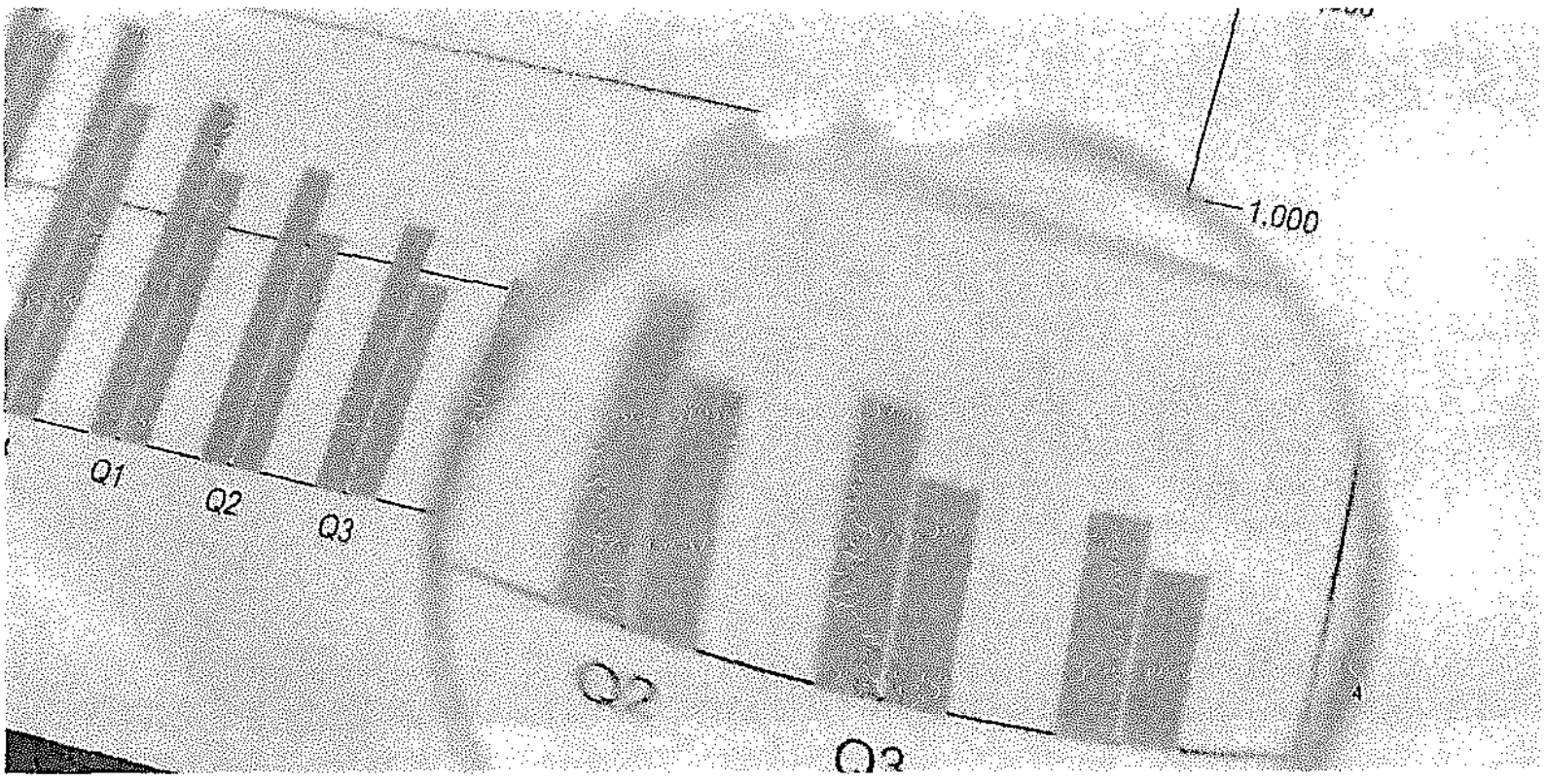


Mr. Joseph Nespral
President & Chief Executive Officer
Texas Organ Sharing Alliance
5051 Hamilton Wolfe Dr.
San Antonio, Texas 78229-4455

AUTHORIZED FOR RELEASE BY
SENATORS GRASSLEY & WYDEN

SENATE FINANCE COMMITTEE REQUESTS

DATA & SUPPORTING DOCUMENTATION



National Finance Committee Requests:

1. *The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.*

Early 2017, TOSA began developing a specialized donor care facility with the primary focus to provide a dedicated organ recovery center to increase opportunities to save more lives. The facility includes an organ recovery center, tissue recovery center, University Health's Transplant Institute donor biorepository, and perfusion lab. The Transplant Institute extended their existent biorepository to the donor population as part of the Center for Life accepting all non-transplantable donor organs available for research beginning in 2021. Starting in 2022, the biorepository was able to start accepting research organs from outside of the CFL.

2018	2019	2020	2021	2022
26	22	23	72	190

2. *The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2022.*

TOSA has historically and continues to have a difficult time placing pancreata for transplant. In 2022, TOSA exhausted the match run 81.5% (226) of the pancreata (277) we offered out to the transplant programs but were not accepted for transplant.

2018	2019	2020	2021	2022
11	5	12	11	11

3. *The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.*

Pancreata has also been difficult to place with research entities throughout the country even with an 83% authorization rate for research. The success of the donor biorepository in placing pancreas for research is evident in the table below. TOSA also saw a significant increase in kidneys and livers accepted for research in the donor biorepository.

2018	2019	2020	2021	2022
13	7	4	55	174

4. *The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.*

   TOSA strives to fulfill every decision made by the donor families and donor heroes by placing each precious gift for transplant or research. The donor biorepository has given hope to many donor families who have generously given life through research.

2018	2019	2020	2021	2022
24	12	16	66	185

5. *The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.*

2018	2019	2020	2021	2022
9	6	3	1	1

6. *How many total donors your OPO reported as part of CMS's performance metric calculations, per year, 2018 to 2022.*

   TOSA's current CEO started in 2017 with a charge to increase donation and save more lives. TOSA began operating under a new business framework with strategic objectives guiding the organization to improve processes and outcomes to maximize each donation opportunity.

2018	2019	2020	2021	2022
165	190	178	238	267

7. *How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022. Any guidance documents on protocols for pancreas recovery produced by the OPO staff from 2018 to 2022.*

   See TOSA's Work Instruction – *WI-CL-11 Organs for Research* on next page.

2018	2019	2020	2021	2022
0	0	0	0	0

NJ Sharing Network
saving lives through organ and tissue donation

April 7, 2023

The Honorable Ron Wyden
Chairman
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles E. Grassley
Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Todd Young
Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Re: Response to the Letter dated March 20, 2023

Dear Chairman Wyden and Senators Grassley, Cardin, and Young:

Please accept this correspondence in response to your letter dated March 20, 2023. In this letter, we provide detail in response to your questions.

By way of background, The New Jersey Organ and Tissue Sharing Network (NJ Sharing Network or NJSN) proudly serves the majority of New Jersey as a federally-designated 501(c)(3) non-profit organ procurement organization (OPO). Established in 1987, NJ Sharing Network stewards the gift of life through the recovery and placement of donated organs and tissue for those in need of a lifesaving or life-enhancing transplant. NJSN also provides a strong network of care and support for the courageous donor families who help save and enhance lives through donation. Additionally, through NJ Sharing Network's fully accredited Histocompatibility Laboratory (NJSN Laboratory), NJSN Laboratory performs histocompatibility testing for deceased and living organ donors and recipients as well as cutting-edge research that is continually 'transforming transplantology' to save more lives.

Beginning in 2019, NJ Sharing Network redoubled its efforts to save lives through organ donation by increasing the number of on-site clinical response staff. As a result, NJSN has approached significantly more families in each of the past 4 years. The number of recovered organs increased accordingly and continued to increase through 2022, when we reached an all-time high in the number of organ donors and organs transplanted.

On December 23, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to clarify how organs are counted for the purposes of determining the organ transplantation rate. CMS's proposed rule suggested excluding organs procured for research but not transplanted from their definition of countable organs, except for pancreata procured for islet cell

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transplantation or research (transplanted or not), as is required by Section 371(c) of the Public Health Service Act (42 U.S.C. 273).[1] On December 20, 2020, in its response to comments on the proposed rule CMS's explained:

> [t]he PHS Act, which states that "Pancreata procured by an organ procurement organization (OPO) and used for islet cell transplantation or research shall be counted for purposes of certification or recertification..." To meet this statutory requirement, we have chosen to include pancreata for research in the outcome measures in the same way that organs procured for transplantation are included.

As required by federal regulation, NJ Sharing Network complies with regulations governing organ procurement organizations, including the Conditions for Coverage[2], which require that we submit data to the Organ Procurement and Transplantation Network (OPTN). Our data is continuously submitted to OPTN via UNet.[3] UNet includes some of the following software platforms: Waitlist℠ (transplant candidate data); DonorNet® (organ donor data); TransNet℠ (safeguarding organ transport); Data Services (insights for improvement); and TIEDI® (pre/post-transplant data). Our data is submitted to UNet pursuant to the statutory definitions. Our reporting to OPTN complies with the regulations and carefully tracks the definitions provided for both "donor" and "organ."

"Donor"[4] is defined as:

> ... a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.

Similarly, "organ"[5] is defined as:

> ... a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ, even if it is used for research or islet cell transplantation.

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[1] 84 FR 70628 (2019) Federal Register https://www.federalregister.gov/d/2019-27418 Accessed April 4, 2023.
[2] 42 CFR 486.302; *see also* 42 CFR 486.328, Condition: Reporting of data; *see also* 42 CFR 121.11(b)(2).
[3] UNet information, https://unos.org/technology/unet/ Accessed April 4, 2023.
[4] 42 CFR 486.302 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-486/subpart-G/section-486.302 Accessed April 4, 2023.
[5] 42 CFR 486.302 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-486/subpart-G/section-486.302 Accessed April 4, 2023.

Therefore, NJ Sharing Network complies with the federal regulations by reporting pancreata recovered for research as an organ since the definition of "organ" includes "[t]he pancreas counts as an organ even if it is used for research or islet cell transplantation."

The pancreata, and indeed any organs or tissues recovered by NJ Sharing Network and sent for research, are provided to research organizations, researchers, and research projects which adhere to the non-profit's mission to save and enhance lives. Researchers who have fulfilled these qualifications since 2018 include: NJSN Laboratory/Personalized Transplant Medical Institute (NJSN Laboratory/PTMI), the non-profit International Institute for the Advancement of Medicine (IIAM), and the Pancreatic Islet Transplantation Program at Beta Cell Core at the University of Chicago (UChicago).

NJ Sharing Network sent pancreata for research to NJSN Laboratory/PTMI. Attached is the protocol utilized for the research completed at the NJSN Laboratory, "PTMI Pancreas (3)". (See attached bates stamped documents, NJSN 001-002). The research resulting from this protocol was detailed in the article "Differentiation of Human Deceased Donor, Adipose-Derived Mesenchymal Stem Cells in Functional Beta Cells".[6] This research manuscript published in the *Journal of Stem Cells & Regenerative Medicine* details the need for cell replacement therapy for the treatment of Type 1 diabetes, and that using deceased donor adipose tissue resulted in a promising therapeutic approach for cell replacement therapy to treat patients with Type 1 diabetes. (NJSN 003-012).

NJ Sharing Network provided pancreata for research to IIAM. The pancreas sent to IIAM in 2018, was provided pursuant to the research protocol for "IIAM Pancreas, Lung, Intestine, Spleen, Nodes, Blood – nPOD Project Number 1", which focuses on Juvenile Diabetes research. (NJSN 013-015). IIAM provided a letter dated July 13, 2018, specifically detailing how this pancreata was utilized for Type 1 diabetes research. (NJSN 016). The pancreas sent to IIAM in 2020, was provided pursuant to the research protocol for "IIAM Pancreas with Blood – VUM", which focuses on Type 1 diabetes research. (NJSN 017-018). IIAM provided a letter dated November 23, 2020, specifically detailing the research objectives regarding this Type 1 diabetes research. (NJSN 019). The pancreas sent to IIAM in 2021, was provided pursoant to the research protocol for "IIAM nPOD RP 12 Panc", which focuses on Juvenile Diabetes research. (NJSN 020-021). IIAM provided a letter dated March 10, 2021, specifically detailing the research objectives for this regarding Type 2 diabetes research. (NJSN 022-023).

NJ Sharing Network sent pancreata for research to UChicago for the Pancreatic Islet Transplantation Program at Beta Cell Core. Attached is the research protocol utilized for

[6] Rao, P., Deo, D., Marchioni, M., "Differentiation of Human Deceased Donor, Adipose-Derived Mesenchymal Stem Cells in Functional Beta Cells," *Journal of Stem Cells and Regenerative Medicine* (Accepted 14 Oct 2020; Published online 11 December 2020).

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UChicago. (NJSN 024-025). In a letter dated December 6, 202[2] to NJ Sharing Network, UChicago detailed how the human pancreata provided for research were used to optimize different steps of the islet isolation and cell processing technique. (NJSN 026-027). The research resulted in transplantation of islet isolations providing a direct benefit to patients with Type 1 diabetes and transforming the patients' lives by allowing them to stop insulin injections, thereby resuming an insulin-independent life. (NJSN 026-027). The research resulting from this protocol was detailed in "Peri-operative Reparixin therapy resulted in 50% 5 year-insulin independence rate: The University of Chicago experience"[7] This research manuscript, published in, *Clinical Transplantation The Journal of Clinical and Translational Research*, confirmed the long-term benefits of islet transplantation in patients with Type 1 diabetes and problematic hypoglycemia. (NJSN 027-030).

With regard to your specific questions, NJ Sharing Network's responses are as follows:

1. **The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.**

   RESPONSE: The total number of pancreata recovered by NJ Sharing Network, per year, from 2018 to 2022 are as follows:

Year	Pancreata Recovered by NJSN
2018	21
2019	25
2020	41
2021	73
2022	110

2. **The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2021.**

   RESPONSE: The total number of pancreata successfully placed by NJ Sharing Network for transplant, per year, from 2018 to 2022 are as follows:

[7] Letter to the Editor, Peter Witkowski, Transplantation Institute, Department of Surgery, University of Chicago, Chicago, IL, USA; "Peri-operative Reparixin therapy resulted in 50% 5 year-insulin independence rate: The University of Chicago experience" *Clinical Transplantation The Journal of Clinical and Translational Research* (Accepted 15 March 2023, Published 4 April 2023). https://onlinelibrary.wiley.com/doi/10.1111/ctr.14981

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Year	Pancreata Placed for Transplant by NJSN
2018	15
2019	14
2020	14
2021	20
2022	20

3. **The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.**

RESPONSE: Due to NJSN's increased investment in clinical staff and the overall increase in the number of organ donors, as well as the regulatory change as described above, the total number of pancreata placed for research has increased from 2018 to 2022. In order to fulfill its mission to save and enhance lives, NJ Sharing Network sent pancreata to IIAM, NJSN Laboratory, and UChicago. Since IIAM only accepted three pancreata for the years 2018-2022, more pancreata were placed with NJSN Laboratory and UChicago in accordance with their research protocols. The total number of pancreata placed by NJ Sharing Network for research, per year, from 2018 to 2022 are as follows:

Year	Pancreata Placed for Research by NJSN
2018	1
2019	1
2020	23
2021	44
2022	83

4. **The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.**

RESPONSE: NJ Sharing Network does not recover any single pancreas for the dual purpose "research and transplant" as per the question above. We assume the intent of the question is to elicit the total number of pancreata recovered, and either provided for transplant, or if declined for that purpose, utilized for research. If a pancreas is recovered for transplant, but the organ is not suitable for transplant or rejected, the pancreas may be

sent for research if the donor authorized such use. This fulfills our obligation to donors and to our purpose that all the precious gifts made by donors be put to their highest possible humanitarian use. NJ Sharing Network does not directly report the data to CMS. NJ Sharing Network reports its data to OPTN pursuant to 42 CFR 121.11(b)(2), and OPTN, in turn, provides data to CMS. There is additional information as discussed in our response to number #7. However, if the question is asking for the total number of pancreata recovered for research or transplant by NJ Sharing Network, per year, from 2018 to 2022, the information is as follows:

Year	Pancreata Recovered by NJSN for the purpose of Research or Transplant
2018	16
2019	15
2020	37
2021	64
2022	103

5. **The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.**

RESPONSE: The total number of non-transplantable pancreata recovered by NJ Sharing Network for research specifically focused on islet cell, per year from 2018 to 2022 are as follows:

Year	Pancreata Recovered by NJSN for Research Specifically focused on Islet Cell
2018	0
2019	1
2020	22
2021	43
2022	83

NJ Sharing Network
saving lives through organ and tissue donation

6. **How many total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.**

RESPONSE: NJ Sharing Network does not directly report the data as part of CMS's performance metric calculations. NJ Sharing Network reports its data to the OPTN, which, in turn, provides the data to CMS. NJ Sharing Network's total number of organ donors using the CMS definitions[8] per year from 2018 to 2022 are as follows:

Year	Organ Donors (CMS definition) for NJSN
2018	156
2019	190
2020	205
2021	211
2022	257

7. **How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022.**

RESPONSE: NJ Sharing Network does not commence the surgical recovery from any organ donor solely for the purpose of research. NJ Sharing Network always attempts to place organs for transplant first. Pursuant to the definition of "organ", the pancreas is included in the definition of an organ even if the pancreas is used for research or islet cell transplantation. 42 CFR 486.302. Also, as a clarification, NJ Sharing Network does not directly report the data as part of CMS's performance metric calculations.

[8] "Organ" means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation. 42 CFR 486.302 "Organ"; see also 42 CFR 486.302 "Donor".

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Year	Organ Donors where only a Pancreas was Recovered for Research by NJSN	Year	Organ Donors recovered by NJSN with transplant intent resulting in zero organs transplanted and a pancreas recovered and sent to research
2018	0	2018	0
2019	0	2019	0
2020	0	2020	3
2021	0	2021	5
2022	0	2022	13

8. **Finally, we request copies of the research protocols, along with documentation of review and approval of these protocols for each study the OPO is providing pancreata for research and the number of pancreata procured for each study, per year, from 2018 to 2022. Please include any financial transactions between your OPO and the associated researchers or their institutions related to this research.**

RESPONSE: The research protocols are detailed above and attached hereto.

In 2018, NJ Sharing Network did not send any pancreata for research to NJSN Laboratory. In 2019, NJ Sharing Network sent one (1) pancreas for research to NJSN Laboratory pursuant to the protocol "PTMI Pancreas (3)". (NJSN 001-002). In 2020, NJ Sharing Network sent twenty-two (22) pancreata for research to NJSN Laboratory pursuant to the protocol "PTMI Pancreas (3)". (NJSN 001-002). In 2021, NJ Sharing Network sent forty-three (43) pancreata for research to NJSN Laboratory pursuant to the protocol "PTMI Pancreas (3)". (NJSN 001-002). In 2022, NJ Sharing Network sent fifty-three (53) pancreata for research to NJSN Laboratory pursuant to the protocol "PTMI Pancreas (3)". (NJSN 001-002).

In 2018, NJ Sharing Network sent one (1) pancreas for research to IIAM for the research protocol "IIAM Pancreas, Lung, Intestine, Spleen, Nodes, Blood – nPOD Project Number 1". (NJSN 013-015). IIAM provided a letter dated July 13, 2018 specifically detailing how this pancreata was utilized for Type 1 diabetes research. (NJSN 016). In 2019, NJ Sharing Network did not send any pancreata for research to IIAM. In 2020, sent one (1) pancreas for research to IIAM for the research protocol, "IIAM Pancreas with Blood – VUM". (NJSN 017-018). IIAM provided a letter dated November 23, 2020 specifically detailing the research objectives regarding Type 1 diabetes research. (NJSN 019). In 2021, NJ Sharing Network sent one (1) pancreas to IIAM pursuant to the research protocol "IIAM nPOD RP 12 Panc". (NJSN 020-021). IIAM provided a letter dated

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March 10, 2021 specifically detailing the research objectives regarding Type 2 diabetes research. (NJSN 022-023). In 2022, NJ Sharing Network did not send any pancreata for research to IIAM.

In 2022, NJ Sharing Network sent thirty (30) pancreata for research to UChicago to the Pancreatic Islet Transplantation Program at Beta Cell Core. Attached is the research protocol utilized for UChicago. (NJSN 024-025).

With regard to any financial transactions, there were no financial transactions between NJ Sharing Network and NJ Sharing Network's Laboratory/PTMI as they are under common ownership. Regarding financial transactions between IIAM and NJ Sharing Network, over the five years of research for pancreata, IIAM paid NJ Sharing Network a total of $6,000 for 2018-2022. With regard tn financial transactions between NJ Sharing Network and UChicago for the years 2018 to 2022 there were financial transactions for transplant, but no financial transactions for research.

We hope this information is helpful. Please let us know if you have any further questions.

Sincerely,

Carolyn M. Welsh, MS
President & Chief Executive Officer
NJ Sharing Network

Enclosures – NJSN Documents NJSN 001 - 030

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

100 LIGHT STREET
BALTIMORE, MD 21202

PHONE: [redacted]
FAX: [redacted]

www.bakerdonelson.com

ALISON C. SCHURICK, SHAREHOLDER
Direct Dial: [redacted]
E-Mail Address: [redacted]

April 21, 2023

VIA EMAIL ONLY

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
Washington, DC 20510-6200

Re: First Response to March 20, 2023 Letter to Kentucky Organ Donor Affiliates

Dear Chairman Wyden and Members of the Committee on Finance:

On behalf of Kentucky Organ Donor Affiliates ("KYDA"), please accept this correspondence and the accompanying documents in response to the Committee's March 20, 2023 letter ("March 20 Letter") requesting data and information related to KYDA's procurement of pancreata for research. KYDA is eager to assist the Committee with its inquiry, and we appreciate the Committee's willingness to work with us to enable a reasonable schedule for a rolling production on behalf of KYDA.

While the March 20 Letter raises concerns about Organ Procurement Organizations ("OPOs") generally, KYDA is confident that its cooperation and responses in this process will demonstrate to the Committee that KYDA is a dedicated and mission-focused organization that appropriately and accurately reports data (including data specific to pancreata) consistent with CMS regulations. We trust that KYDA's productions will satisfy any questions or concerns the Committee may have.

By way of background, KYDA is an independent, non-profit OPO that was founded in 1987 through a combination of donation services at the University of Kentucky and the University of Louisville. KYDA's founding mission – which it seeks to advance every day – is to maximize the number of organs available for those in need and to maintain a profound respect for those who donate the gift of life. Supported by a team of more than 150 compassionate, dedicated, and accountable staff members, KYDA is proud serve approximately four million people across 112 hospitals located throughout its donation service area, which includes the majority of the State of Kentucky (114 of 120 total counties), four counties in southern Indiana, two counties in western West Virginia, and one county in Ohio. In addition to coordinating and facilitating the organ donation process, KYDA also meaningfully engages in education and outreach efforts in the

community. Today, approximately 63% of Kentuckians are registered organ donors, with that number increasing in recent years.

Another fundamental aspect of organ donation and transplant is bona fide research. Indeed, research opens the door for new and innovative treatment discoveries, maximizes donors' gifts of life, and offers another meaningful option to families and donors, particularly those whose organs may not ultimately be suitable for transplantation. While KYDA's primary goal is to recover organs for transplant, there are instances in which an intended donor's organ may not be clinically suitable for transplant. By providing the option to donate organ(s) for research, OPOs (including KYDA) offer donors and their families an alternative and meaningful opportunity to provide a potentially lifesaving gift, which supports important transplantation development and advancements.

With respect to the Committee's specific inquiry regarding KYDA's recovery of pancreata for research and KYDA's increases in those recoveries, we believe an understanding of KYDA's history as it relates to recovering organs for research in general is important.

By way of background, during the 2012 CMS recertification cycle for OPOs, KYDA was cited by the Centers for Medicare and Medicaid Services ("CMS") for not meeting the then-applicable standard that measured the number of organs for research per donor.[1] In response, KYDA timely submitted a Corrective Action Plan to CMS, wherein KYDA agreed to CMS's directive to increase the number of organs placed for research and to undertake the following: (1) conduct training with clinical staff on how to effectively place organs for research; (2) work to expand the number of local research opportunities to allow for placement of pancreata, kidneys, livers, and thoracic organs at local transplant centers and research universities; and (3) expand the number of national research organs recovered, by utilizing for-profit organizations to place organs for research (which requires approval by KYDA's Board of Directors). KYDA immediately began implementation of the Corrective Action Plan and, as of its final reporting in October of 2012, CMS found KYDA in compliance with all applicable (at the time) outcome/reporting measures, including organs for research.

In the years since, KYDA has worked diligently and carefully to implement and carry out CMS's directives efficiently, successfully, and in line with KYDA's stated objectives. As a result, the quality of KYDA's research programs and the number of organs available for research have grown exponentially for *all* organs (including pancreata) – the *precise results* CMS intended.

Additionally, and as the data provided below reflects, since at least 2019, KYDA has seen continuing increases in several key areas, including in the number of (1) organs recovered, (2) organs transplanted, and (3) organs provided for research. To the extent the Committee has concerns about recent increases in pancreata used for research, KYDA submits that those increases are consistent with these overall trends.

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[1] *See* 42 C.F.R. § 486.318(a)(3)(i-iii). 42 C.F.R. § 486.318(a)(4) states that "[t]he outcome measures described in § 486.318(a)(1) through (3) are effective until July 31, 2022."

With the above background and context in mind, KYDA responds to the Committee's requests for specific data, in turn below.

1. **The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.**[2]

2018	2019	2020	2021	2022
45	37	84	116	137

2. **The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2022.**

2018	2019	2020	2021	2022
12	9	11	10	15

KYDA notes for the Committee that the need for pancreata for transplant is exceptionally small compared to the need for all other organs. Current data from the Organ Procurement and Transplantation Network reflects that, as of April 18, 2023, 80 patients are in need of a pancreas-only transplant, whereas the total number of candidates awaiting any solid organ transplant is 103,892.[3]

3. **The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.**

2018	2019	2020	2021	2022
31	27	71	105	116

4. **The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.**

2018	2019	2020	2021	2022
43	36	82	115	131

5. **The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.**

2018	2019	2020	2021	2022
31	27	71	105	116

[2] The figures provided in response to this Request include pancreata that were successfully transplanted, placed for research, or declined for all purposes.

[3] https://optn.transplant.hrsa.gov/data/.

6. **How many total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.**

2018	2019	2020	2021	2022
125	129	171	188	240

7. **How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022. Any guidance documents on protocol for pancreas recovery produced by the OPO staff from 2018 to 2022.**

2018	2019	2020	2021	2022
1	1	2	11	27

With regard to this Request, we believe it is critical to emphasize that KYDA does not take donors to the operating room with the intent of procuring *only* pancreata for research. Importantly, with the exception of two donors in 2022, for each donor who had only a pancreas removed for research from 2018 to 2022, the donor was sent to the operating room with the intent to transplant kidneys, and kidneys were recovered. Ultimately, however, no kidneys were accepted by any transplant center for these donors. For this reason, these donors were classified as "pancreas for research only donors," although they were not initially classified as such prior to entry of the operating room.

There are two exceptions to the cases in which kidneys were also recovered in 2022. The first exception involved a case in which the donor's liver was allocated for transplant but was declined intraoperatively due to the donor's advanced age and poor biopsy results. In the second case, the donor's heart had been allocated for transplant but was similarly declined intraoperatively and was ultimately recovered for research.

Lastly, copies of KYDA's policies regarding organ recovery (including prior versions that were in effect during the requested time frame) are included with this production at the documents Bates labeled **KYDA-SFC-000001** to **KYDA-SFC-000103**. These documents are accessible via the following secure Sharefile link; which, for security reasons will expire 30 days from the date of this letter: [redacted]

* * * * * *

KYDA provides this information and documentation in an effort to cooperate with the Committee's inquiry and resolve any concerns the Committee may have. This correspondence and the accompanying documents and information may contain sensitive and/or confidential information and are subject to the Standing Rules of the United States Senate (Doc. 113-18). Accordingly, we respectfully request confidential treatment of any pages, attachments, or documents that have been marked with the following language: "CONFIDENTIAL." Given the

sensitivity of this information, we also request advance notice of any contemplated disclosure and a reasonable opportunity to respond or object prior to any contemplated disclosure.

Please feel free to contact us if you have any questions. In the meantime, we are in the process of collecting additional documents and information responsive to the Committee's remaining request and expect to provide a supplemental production to the Committee in the coming weeks.

Sincerely,

/s/ Alison C. Schurick

Alison C. Schurick, Esq.
Melodie H. Hengerer, Esq.
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, PC
100 Light Street, 19th Floor
Baltimore, MD 21202
Phone: [redacted]
Email [redacted]
Email: [redacted]

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

100 LIGHT STREET
BALTIMORE, MD 21202

PHONE: [redacted]
FAX: [redacted]

www.bakerdonelson.com

ALISON C. SCHURICK, SHAREHOLDER
Direct Dial: [redacted]
E-Mail Address: [redacted]

May 8, 2023

VIA EMAIL ONLY

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
Washington, DC 20510-6200

Re: Second Response to March 20, 2023 Letter to Kentucky Organ Donor Affiliates

Dear Chairman Wyden and Members of the Committee on Finance:

On behalf of Kentucky Organ Donor Affiliates ("KYDA"), please accept this correspondence and the accompanying documents in KYDA's continuing response to the Committee's March 20, 2023 letter ("March 20 Letter") requesting data and information related to KYDA's procurement of pancreata for research. KYDA remains eager to assist the Committee with its inquiry and again appreciates the Committee's willingness to work with us to enable a reasonable schedule for a rolling production.

As we indicated in our prior letter correspondence, KYDA's mission is to maximize the number of organs available for those in need and to maintain a profound respect for those who donate the gift of life. KYDA works to honor the gift of donation with a compassionate, dedicated, and accountable team, and believes its records reflect a commitment to advancing these important causes in an effective, professional, and appropriate manner. KYDA is confident that its cooperation and responses in this process will demonstrate to the Committee that KYDA is a compliant and mission-focused organization. We trust that KYDA's productions will satisfy any questions or concerns the Committee may have.

In this second production, KYDA provides materials responsive to Request No. 8 of the March 20 Letter, which seeks (a) "copies of the research protocols, along with documentation of review and approval of these protocols for each study [KYDA] is providing pancreata for research and the number of pancreata procured for each study, per year, from 2018 to 2022," and (b) "any financial transactions between [KYDA] and the associated researchers or their institutions related to this research."

KYDA has participated in two specific research studies related to pancreata during the years identified, titled as follows: (1) "Development and Validation of Transport Conditions for Islet Transplant" with Koligo Therapeutics, Inc. ("Koligo") (the "Koligo Study"); and (2) "Human Islet Isolation and Imaging of Human Pancreas" with the University of Louisville, Cincinnati Children's Medical Center ("UL-UC") ("the UL Study"). Additionally, KYDA has an ongoing Research Recovery Agency Agreement with the Musculoskeletal Transplant Foundation, Inc. d/b/a MTF Biologics, for procurement, medical research, and education related to certain research tissues, including pancreata ("the MTF Agreement"). The below table reflects the number of pancreata KYDA procured for each of these research studies or arrangements, per year, from 2018 to 2022:

	2018	2019	2020	2021	2022
Koligo Study	31	27	21	0	0
UL Study	0	0	50	105	116
MTF Agreement	0	0	0	0	0

Regarding the Committee's request for "research protocols" and "documentation of review and approval of these protocols for each study," KYDA provides (and notes) the following.

With respect to the Koligo Study, included with this production is a copy of the Study Protocol that Koligo provided to KYDA in support of the Koligo Study in April 2018, as well as copies of correspondence regarding funding and Institutional Review Board ("IRB") approval of the Koligo Study. These documents have been Bates labeled **KYDA-SFC-000125 to KYDA-SFC-000135**. With respect to the UL Study, KYDA does not possess copies of any "research protocols," and thus has no responsive materials to provide in response to this portion of the Committee's request. Regarding "review and approval" documents requested, KYDA includes with this production copies of two IRB review and approval letters that UL-UC provided to KYDA in support of the UL Study in May 2020. These materials are Bates labeled **KYDA-SFC-000136 to KYDA-SFC-000139**. Lastly, KYDA is unaware of any "research protocols" or associated "review and approval" documents prepared in connection with the MTF Agreement, and therefore does not possess any documents responsive to this portion of the Committee's request. Nevertheless, in an effort to assist the Committee with its inquiry and understanding of this research arrangement, KYDA includes with this production, at the documents Bates labeled **KYDA-SFC-000104 to KYDA-SFC-000124**, a copy of the MTF Agreement.

These documents are accessible via the secure Sharefile link below, and the password to access the .zip file is: [redacted]. For security reasons, this Sharefile link will expire 30 days from the date of this letter, so we encourage all intended recipients to download and save the files locally.

Link: [redacted]

Finally, with respect to the Committee's request for financial transactions related to this pancreata research, KYDA states that it has no responsive materials, as there were no funds exchanged between KYDA and any of these programs or institutions for pancreata-related research during these years.

In reviewing these materials, KYDA identified certain personal, proprietary, and/or sensitive information that is or may be confidential on its face and/or harmful to third parties if publicly disclosed. To protect those interests and simultaneously advance this process as efficiently as possible and remain cooperative with the Committee's requests, KYDA has applied redactions to limited portions of these materials to the minimum extent necessary. Additionally, KYDA expressly maintains that these materials (including but not limited to the Koligo Study Protocol) are confidential in their entirety, and thus respectfully asks that the Committee treat them as such accordingly.[1] In the event the Committee contemplates disclosing any of these materials at any time, we request that we be provided advance notice and a reasonable opportunity to respond or object prior to any contemplated disclosure.

We hope this additional information and documentation continues to be helpful in answering the Committee's questions and any concerns. Please feel free to contact us if you have any questions or would like to discuss this inquiry further.

Sincerely,

/s/ Alison C. Schurick

Alison C. Schurick, Esq.
Melodie H. Hengerer, Esq.
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, PC
100 Light Street, 19th Floor
Baltimore, MD 21202
Phone: [redacted]
Email: [redacted]
Email: [redacted]

[1] To the extent any of the materials included with this production may be subject to any privilege(s) outside the context of this investigation (e.g., the scholar's privilege or any privileges governing trade secrets and other proprietary information), KYDA expressly maintains and preserves all rights, objections, and arguments with respect to these materials and the assertion of any applicable privilege(s).

Title: Conflict of Interest			MIDWEST TRANSPLANT NETWORK
Doc#: PO-EC: 5.13	Version#: 7	Active Date: 12/31/22	

Mission: Saving Lives by Honoring the Gift of Organ and Tissue Donation with Dignity and Compassion

1.0 PURPOSE

1.1 It is the policy of Midwest Transplant Network (MTN) to prohibit its employees from engaging in any activity, practice, or conduct that conflicts with, or appears to conflict with, the interests of the organization, its customers, or its suppliers. As it is impossible to describe all of the situations that may cause or give the appearance of conflict of interest, the prohibitions included in this policy are not intended to be exhaustive

2.0 SCOPE

2.1 All Employees of MTN

3.0 RESPONSIBILITIES

3.1 It is the responsibility of the Chief People Officer to maintain oversight of the Human Resources policies and procedures

4.0 DEFINITIONS

4.1 N/A

5.0 APPLICABLE REGULATIONS

5.1 N/A

RELATED DOCUMENTS

Document Title	Document No.
Conflict of Interest Acknowledgement Form	AD 075

6.0 PROCEDURE

6.1 General Guidelines

6.1.1 Employees of MTN are expected to fulfill their duties, obligations, and privileges in their employment objectively and in the best interest of the organization. In order to serve these purposes, relationships with persons and organizations with which the organization transacts business must be free from conflict of interest

6.1.2 Conflicts of interest may be real or perceived, and in any case must be disclosed to leadership. Questions and concerns about potential conflicts should be referred to leadership

6.2 Conflict of Interest Statements

6.2.1 Employees are expected to represent MTN in a positive and ethical manner while exercising their duties

6.2.2 Employees shall not use the privileges of employment to influence any decision of the organization in favor of any person or business organization with which they have a financial interest or to promote their personal or professional interest. Employees have a "financial interest" if they have, directly or indirectly, through business, investment or family

6.2.2.1 An ownership or investment interest in any person or business organization with which MTN has a transaction or arrangement

6.2.2.2 A compensation arrangement with any person or business organization with which MTN has a transaction or arrangement; or

6.2.2.3 A potential ownership or investment interest in, or compensation arrangement with, any person or business organization with which MTN is negotiating a transaction or arrangement

6.2.2.3.1 Compensation includes direct and indirect remuneration as well as gifts or favors that are substantial in nature

6.2.3 Employees shall disclose their financial interest in any transaction or arrangement by notifying their immediate Leader or the Chief Executive Officer of MTN. Failure to do so will result in discipline, up to and including termination

6.2.4 Employees shall abstain from any involvement in any transaction or arrangement in which MTN is a party where the employee has, or may have the appearance of a conflict of interest described in the definition above

6.2.5 Employees shall refrain from unduly influencing or directing the job performance of any other MTN employee contrary to the employee's job description for the purposes of personal or professional gain

6.2.6 Employees shall, upon termination of services as an employee of MTN, hold confidential any matter proprietary to the organization

6.2.7 Every employee will be required to sign, as a condition of their employment and continued employment a Conflict of Interest Policy Acknowledgment Form

7.0 RECORDS

Record

8.0 DOCUMENT HISTORY

Refer to Q-Pulse

would have the power to indemnify him or her against such liability under the provisions of this Article X.

Section 10.8 Other Insurance:

The Corporation shall reduce the amount of the indemnification of any person pursuant to the provisions of this Article X by the amount that such person collects as indemnification under any policy of insurance that the Corporation purchased and maintained on his or she behalf.

Section 10.9 Public Policy:

Nothing contained in this Article X, or elsewhere in these Bylaws, shall operate to indemnify any Director or officer if such indemnification is contrary to law, whether as a matter of public policy, or under the provisions of any applicable state or federal law.

ARTICLE XI
INUREMENT AND CONFLICT OF INTEREST

Section 11.1 Pecuniary Gain:

No Director or officer shall receive any pecuniary gain, benefit or profit, incidental or otherwise, from the activities, financial accounts and resources of the Corporation except as provided in these Bylaws.

Section 11.2 Compensation:

No Director or officer shall receive any compensation or other tangible benefit for service on the Board. However, any Director or officer, upon submission of a travel expense report, may be reimbursed for automobile travel expenses for attendance at a Directors meeting.

Section 11.3 Transactions With Interested Parties:

The Corporation may engage in contracts with officers or Directors of the Board or authorized representatives of any corporation, partnership, association or other organization in which one or more of the Corporation's officers or Directors have a financial interest in, or are employed by provided the following conditions are met:

(a) The facts regarding the relationship or interest as they relate to the contract or transaction are disclosed to the Board prior to commencement of any such contract or transaction;

(b) The Board in good faith authorizes the contract or transaction by a majority vote of the Directors who do not have an interest in the transaction or contract;

(c) The contract or transaction is fair to the Corporation and complies with the laws and regulations of the state of Oklahoma at the time the contract or transaction is authorized, approved or ratified by the Board.

Section 11.4 Disclosure:

All officers and Directors shall disclose any interest or affiliation they may have with any entity or individual with which the Corporation has entered, or may enter, into contracts, agreements or any other business transaction. Such disclosures shall be made by all officers and Directors on an annual basis on a Conflicts of Interest Statement (the "**COI Statement**") in which the officer or Director identifies any relationship that could have an influence on the officer's or Director's ability to serve in his or her role. Depending on the nature of the affiliation the Board has the option to stipulate that such interested party refrain from voting on, or influencing the consideration of such matters. Failure to complete the COI Statement by the deadline imposed by the Chief Executive Officer in the case of the officers and the Chair of the Board in the case of Directors will result in discipline of the officer and suspension of the Director from all Board activities.

Section 11.5 Independent Action:

All officers and Directors of the Corporation shall act in an independent manner consistent with their obligations to the Corporation and applicable law, regardless of any other affiliations, memberships or positions.

ARTICLE XII
MISCELLANEOUS

Section 12.1 Facsimile Signatures:

Facsimile signatures of any officer of the Corporation may only be used whenever and as authorized by the Board.

Section 12.2 Corporate Seal:

The Board may provide a suitable seal, containing the name of the Corporation and word "Oklahoma," which seal shall be placed in the custody of the Chief Executive Officer. If and when so directed by the Board or an authorized committee thereof, duplicates of the seal may be kept and used by the Secretary/Treasurer.

Section 12.3 Books and Records:

The Corporation shall keep correct and complete books and records of account and shall also keep minutes of the proceedings of its Board, and shall keep at the registered or principal office a record giving the names and addresses of the Directors entitled to vote. All books and records

DONOR ALLIANCE Organ & Tissue Donation	STANDARD OPERATING POLICY AND PROCEDURE		Page 1 of 5
	Title: **Conflicts of Interest**		
	Document No. **AD110.02**	Revision No. **04**	Effective Date **08/30/2023**
	DC Approval By/Date: LN 08/30/2023		Change Request No. **CR2595**

1. PURPOSE

The purpose of this policy and procedure is to provide standards for employees, Board members, and committee members of Donor Alliance to conduct their personal affairs in such a manner as to avoid any possible conflict of interest with their duties and responsibilities as members of the Donor Alliance organization.

2. SCOPE

2.1 This policy and procedure applies to employees, Board of Directors members and/or Board of Directors committee members of Donor Alliance.

2.2 This procedure is written to comply with the regulatory requirements specified in **QS100.02, *Quality and Regulatory Standards.***

3. RESPONSIBILITIES

3.1 All employees, Board members and/or Board of Directors committee members are responsible for adhering to this procedure and the standards of conduct relating to conflicts of interests as outlined in **QS210.07, *Corporate Compliance Manual.***

3.2 All employees, Board members and/or Board of Directors committee members will be required to review this procedure and sign a Conflict of Interest Disclosure Form upon hire or appointment and annually thereafter.

3.3 Employees shall notify Human Resources of Donor Alliance regarding any possible conflict of interest as soon as it is known or reasonably should be known.

3.4 Board members and committee members shall notify the President/CEO of Donor Alliance regarding any possible conflict of interest as soon as it is known or reasonably should be known.

4. DEFINITIONS

4.1 **Agreement or Transaction:** Any agreement or relationship involving the sale or purchase of goods, services, or rights of any kind, the provision or receipt of a loan or grant, or the establishment of any other type of financial relationship with Donor Alliance. The making of a gift or donation to Donor Alliance is not an Agreement or Transaction within the meaning of this document.

4.2 **Committee Member:** A member of a committee appointed by the Board of Directors.

4.3 **Employee:** For purposes of this policy, full-time, part-time, per diem staff; contracted agency staff; contracted employees; and consultants (long-term consulting agreements).

4.4 **Family Member:** A spouse, domestic partner, parent, child, or spouse of a child, brother, sister, or spouse of a brother or sister, of a Responsible Person.

4.5 **Material Financial Interest:** In an entity, business or organization, a material financial interest is a financial interest of any kind that, in view of all the circumstances, is substantial enough that it would, or reasonably could, affect a Responsible Person's or Family Member's judgment with respect to transactions to which the entity is a party. This includes all forms of compensation.

4.6 **Responsible Person:** Any person serving as an officer or employee of Donor Alliance, a member of the Board of Directors of Donor Alliance, or of a committee of the Board of Directors of Donor Alliance.

5. POLICY/PROCEDURE

5.1 Policy

5.1.1 As an employee, Board of Directors member and/or Board of Directors committee member of Donor Alliance, your first obligation is to your job with Donor Alliance. Donor Alliance is sensitive to issues which may place its employees, Board members and/or committee members in a conflict of interest between the business and interests of Donor Alliance and those of the individual, or situations which cause an appearance of such conflicts of interest. In particular, employees who engage in other employment, operate other businesses, or have relationships with persons (including other employees, Board members and/or committee member of Donor Alliance, vendors or other entities or individuals with business relationships with Donor Alliance, and/or persons who perform regulatory functions with respect to Donor Alliance), which may cause these conflicts to arise must disclose their existence to Donor Alliance.

5.1.2 Donor Alliance will evaluate any such relationships, and any potential consequences that can be factually determined to result from those relationships, in order to determine whether it will prohibit their continuation as a condition of further employment, Board membership or committee membership.

5.1.3 Should an employee, Board member or committee member fail to disclose a relationship which creates such a conflict, including but not limited to a Material Financial Interest as defined above, or continue a relationship after being prohibited by Donor Alliance from doing so, disciplinary action, including termination of employment or termination of Board membership or committee membership, may occur with respect to the individual who fails to so disclose the relationship or continues the prohibited relationship.

5.2 Board Members or Committee Members

5.2.1 Before board or committee action on an Agreement or Transaction in which a Responsible Person or Family Member has or may have a Material Financial Interest, the Responsible Person shall disclose all facts material to the Conflict of Interest. The Responsible Person shall refrain from any action that may affect Donor Alliance's participation in such Agreement or Transaction. Such disclosure shall be reflected in the minutes of the meeting.

5.2.2 With respect to an Agreement or Transaction in which a Material Financial Interest exists, a Responsible Person who does not plan to attend a meeting at which he or she has reason to believe that the board or committee will act on such Agreement or Transaction shall disclose to the chair of the meeting all facts material to such Agreement or Transaction. The chair shall report the disclosure at the meeting and the disclosure shall be reflected in the minutes of the meeting.

5.2.3 Any such Responsible Person shall not participate in or be permitted to hear the Board's or committee's discussion of the matter, except to disclose material facts and to respond to

questions, or as outlined below. Such person shall not attempt to exert his or her personal influence with respect to the matter, either at or outside the meeting.

5.2.3.1 In accordance with the Donor Alliance Bylaws, any such Responsible Person may participate in or be permitted to hear the Board's or committee's discussion of the matter if:

5.2.3.1.1 The material facts as to the Responsible Person's relationship or interest and as to the conflicting interest transaction are disclosed or are known to the Board of Directors or the Committee, and the Board of Directors or Committee in good faith authorizes, approves, or ratifies the conflicting interest transaction by the affirmative vote of a majority of disinterested directors, even though the disinterested directors are less than a quorum; or

5.2.3.1.2 The conflicting interest transaction is fair as to Donor Alliance.

5.2.3.1.3 Such disclosure and approval shall be reflected in the minutes of the meeting.

5.2.3.2 Responsible Persons with a Material Interest may be counted in determining the presence of a quorum at a meeting of the Board of Directors or of a Committee which authorizes, approves, or ratifies the conflicting interest transaction.

5.3 Outside Employment of Donor Alliance Employees

5.3.1 Generally, "moonlighting" is defined as working at some activity for personal gain outside of an employee's job with Donor Alliance. If employees do perform outside work, they shall disclose this to Donor Alliance. Employees have a responsibility to avoid any conflict with Donor Alliance's business interests while performing outside work.

5.3.1.1 No Donor Alliance employee shall perform work or render services for any organization with which Donor Alliance does business, or which seeks to do business with Donor Alliance, outside of the normal course of their employment with Donor Alliance without the approval of the President/CEO of Donor Alliance.

5.3.1.2 Employees cannot solicit or compete with Donor Alliance's product or service offerings.

5.3.1.3 Outside work cannot be performed on Donor Alliance's time.

5.3.1.4 Employees cannot use Donor Alliance's equipment, materials, resources, or "inside" information for outside work. See **IS200.09, *Electronic Systems Policy***.

5.3.2 Employees cannot solicit business or clients or perform outside work on Donor Alliance's premises.

5.3.3 The Director of Human Resources and President/CEO will review employee conflict of interest disclosure forms in which a conflict is disclosed.

5.4 **Confidentiality**

5.4.1 Each Responsible Person shall exercise care not to disclose confidential information acquired in connection with such status or information the disclosure of which might be adverse to the interests of Donor Alliance. Furthermore, a Responsible Person shall not disclose or use information relating to the business of Donor Alliance for the personal profit or advantage of the Responsible Person or a Family Member or any entity, business or organization in which the Responsible Person or Family member may have a Material Financial Interest.

5.5 **Review of Policy**

5.5.1 Each Responsible Person shall be required to review a copy of this policy and to acknowledge in writing that he or she has done so.

5.5.2 Each Responsible Person shall annually complete a disclosure form identifying any relationships, positions, or circumstances in which the Responsible Person is involved that he or she believes does or may constitute a conflict of interest as described in this policy. Each Responsible Person should also disclose any actual or potential conflict of interest that may arise during the course of the year between the submissions of annual disclosure forms.

5.5.2.1 Any such information regarding business interests of a Responsible Person or a Family Member shall be treated as confidential and shall generally be made available only to the Chair, the President/CEO, and any committee appointed to address conflicts of interest, except to the extent additional disclosure is necessary in connection with the implementation of this Policy.

5.5.3 This policy shall be reviewed annually by all Responsible Persoas. Any changes to the policy shall be communicated immediately to all Responsible Persons.

5.5.4 The President/CEO will review conflict of interest disclosure forms in which a conflict is disclosed.

5.5.4.1 Whenever there is reason to believe that an actual or potential conflict of interest exists between Donor Alliance and an interested party, the President/CEO shall determine the appropriate organizational response.

5.6 **Record Control:** Records generated by following the requirements of this procedure are controlled by Quality Systems in accordance with **QS100.03, *Records Management and Retention***.

6. REFERENCED AND RELATED DOCUMENTS

Electronic Systems Policy **(IS200.09)**
Quality and Regulatory Standards **(QS100.02)**
Records Management and Retention **(QS100.03)**
Corporate Compliance Manual **(QS210.07)**
Third Amended Restated Bylaws of Donor Alliance (September 27, 2010)

DCI Donor Services
an extraordinary commitment to science, health and hope

Effective Date: 11/06/2016

Version: 10

DCIDS Standard Operating Procedure
HR.113 - Conflict of Interest - Advisory Board and Governing Board

Approval: This Standard Operating Procedure has been approved by the following:

- Carrie Crocker (TB - Sr. Director, GTP Quality Systems), Document Administrator (Document Control Administrator), Jackie Warn (Corporate Director of Quality and Compliance), Jennifer Li (Physician), Kristen Pereira (Director Of Quality Assurance & Compliance), [redacted] (Unassigned), Sheryl Curtis (Director Of Quality Assurance & Compliance), Stephanie Cozby (Sr Director of Quality and Compliance)

Electronic signatures are maintained in the DCI Donor Services Policy and Procedure Management Software.

1.0 Purpose:

1.1 To protect DCI Donor Services (DCIDS) interests when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an officer or director of DCIDS. This policy is intended to supplement but not replace any applicable state laws governing conflicts of interest applicable to nonprofit and charitable corporations. *(Article I).*

2.0 Responsible Parties:

2.1 Medical Director(s)
2.2 Executive Director(s)
2.3 Advisory Board
2.4 Governing Board
2.5 Corporate Counsel

3.0 Definitions:

3.1 Interested Person - Any director, principle officer, member of a committee with board-delegated powers, or advisory board member, who has a direct or indirect financial interest as defined below, is an interested person.

3.2 Financial Interest - A person has a financial interest if the person has, directly or indirectly, through business, investment or family:

3.2.1 An ownership or investment interest in any entity with which DCIDS has a transaction or arrangement

3.2.2 A compensation arrangement with DCIDS or with any entity or individual with which DCIDS has a transaction or arrangement

3.2.3 A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which DCIDS is negotiating a transaction or arrangement

3.3 Compensation - includes direct and indirect remuneration as well as gifts or favors that are substantial in nature.

4.0 References:

4.1 RF.211 - AATB Standards for Tissue Banking
4.2 RF.212 - AOPO Standards
4.3 RF.207 - CMS, Hospital Interpretive Guidance, Appendix A
4.4 RF.213 - EBAA Medical Standards
4.5 RF.200 - FDA CFR Title 21, Part 1271
4.6 RF.206 - UNOS OPTN Policy

5.0 Documents/Forms:

5.1 HR.112.F01 - Employee Conflict of Interest Statement
5.2 HR.113.F01 Conflict of Interest Advisory and Governing Board
5.3 QS.737 - Records Management and Retention Policy

6.0 Procedures:

6.1 **PROCEDURES** *(Article III)*

6.1.1 Duty to Disclose: In connection with any actual or possible conflicts of interest, an interested person must disclose the existence and nature of his or her financial interest to the directors and members of committees with board delegated powers considering the proposed transaction or arrangement. An interested person must abstain from voting on all issues in which that person has been determined to have a conflict of interest or a determination is pending

6.1.2 Determining Whether a Conflict of Interest Exists: After disclosure of the financial interest, that interested person shall leave the board or committee meeting while the financial interest is discussed and voted upon. The remaining board or committee members shall decide if a conflict of interest exists

6.1.3 **Procedures of Addressing the Conflict of Interest:**

6.1.3.1 The chairperson of the board or committee shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement

6.1.3.2 After exercising due diligence, the board or committee shall determine whether DCIDS can obtain a more advantageous transaction or arrangement with reasonable efforts from a person or entity that would not give rise to a conflict of interest

6.1.3.3 If a more advantageous transaction or arrangement is not reasonably attainable under circumstances that would not give rise to a conflict of interest, the board or committee shall determine by a majority vote of the disinterested directors whether the transaction or arrangement is in DCIDS best interest and for its own benefit and whether the transaction is fair and reasonable to DCIDS and shall make its decision whether to enter into the transaction or arrangement in conformity with such determination

6.1.4 **Violations of the Conflicts of Interest Policy:**

6.1.4.1 If the board or committee has reasonable cause to believe that a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose

6.1.4.2 If, after hearing the response of the member and making such further investigation as may be warranted in the circumstances, the board or committee determines that the member has in fact failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action

6.2 **RECORDS OF PROCEEDINGS** *(Article IV)*

6.2.1 The minutes of the board and all committee with board-delegated powers shall contain:

6.2.1.1 The names of the persons who disclosed or otherwise were found to have a financial interest in connection with an actual or possible conflict of interest, the nature of the financial interest, any action taken to determine whether a conflict of interest was present, and the board's or committee's decision as to whether a conflict of interest in fact existed

6.2.1.2 The names of the persons who were present for discussions and votes relating to the transactions or arrangement, the content of the discussion, including any alternative to the proposed transaction or arrangement, and a record of any votes taken in connection therewith

6.3 **COMPENSATION COMMITTEES** *(Article V)*

6.3.1 A voting member of any committee whose jurisdiction included compensation matters and who received compensation, directly or indirectly, from DCIDS for services is precluded from voting on matters pertaining to that member's compensation

6.3.2 Physicians who receive compensation, directly or indirectly, from the DCIDS, whether as employees or independent contractors, are precluded from membership on any committee whose jurisdiction included compensation matters

6.4 **ANNUAL STATEMENTS** *(Article VI)*

6.4.1 Each director, principal officer and member of a committee with board delegated powers ***shall annually sign a statement*** which affirms that such person:

6.4.1.1 Has received a copy of the conflicts of interest policy

6.4.1.2 Has read and understands the policy

6.4.1.3 Has agreed to comply with the policy, and make disclosure when appropriate; and

6.4.1.4 Understands DCIDS is a charitable organization and that in order to maintain its federal tax exemption it must engage primarily in activities which accomplish one or more of its tax-

exempt purposes (HR.113.F01 Conflict of Interest Advisory and Governing Board)

6.5 **PERIODIC REVIEW** *(Article VII*

6.5.1 To ensure that DCIDS operates in a manner consistent with its charitable purposes and that it does not engage in activities that could jeopardize its status as an organization exempt from federal income tax, ***periodic reviews shall be conducted.*** The periodic review shall, at a minimum, include the following subjects:

6.5.1.1 Whether compensation arrangements and benefits are reasonable and are the result of arm's length bargaining;

6.5.1.2 Whether acquisitions of provider services result in inurnment or impermissible private benefit;

6.5.1.3 Whether partnership and joint venture arrangements conform to written policies, are properly recorded, reflect reasonable payments for goods and services, further DCIDS's charitable purposes and do not result in inurnment or impermissible private benefit; and

6.5.1.4 Whether agreements with other health care providers further DCIDS's charitable purposes and do not result in inurement or impermissible private benefit.

6.6 **USE OF OUTSIDE EXPERTS** *(Article VIII)*

6.6.1 In conducting the periodic review provided for in Article VII, DCIDS may, but need not, use outside advisors. If outside experts are used, their use shall not relieve the board of its responsibility for ensuring that periodic reviews are conducted

GREATER DELAWARE VALLEY SOCIETY OF TRANSPLANT SURGEONS (d/b/a GIFT OF LIFE DONOR PROGRAM)

GOVERNING BOARD OF DIRECTORS CONFLICT OF INTEREST AGREEMENT

I understand that as an officer or member of the Governing Board of the Greater Delaware Valley Society of Transplant Surgeons (GDVSTS/GLDP), I am charged with fiduciary responsibilities which require me to put the interests of GDVSTS/GLDP above my personal interests, including those of my immediate family. It is my intent to serve GDVSTS/GLDP to the best of my ability and to be free of conflicts of interest between this role and other personal, business and professional positions with which I am identified or associated.

I understand that my fiduciary responsibilities require me to take steps to avoid both actual conflicts of interest and even the appearance of a conflict of interest because even the hint of impropriety can adversely affect the community's confidence in GDVSTS/GLDP. However, recognizing when a conflict or potential for conflict exists is not always easy, especially when the conflict is subtle. Some activities are considered on their face conflicts of interest and thus are prohibited, while other activities may present less obvious possibilities of conflicts. I understand that one way a conflict of interest may arise is if I or a member of my immediate family is affiliated as a trustee, director, officer, employee, or consultant with, or has a substantial interest as an owner, shareholder, or partner in, any organization doing or seeking to do business with GDVSTS/GLDP as a vendor. This is of course just one example of the manner in which a conflict of interest may arise.

I hereby agree to disclose immediately to the Governing Board or the President and CEO, any transaction or interest which results or could result in a conflict, or an appearance of a conflict, between the interest of GDVSTS/GLDP and my interest or that of an entity with which I or a member of my immediate family is associated. I agree to conduct myself with respect to the actual or potential conflict as directed by the Governing Board and as consistent with GDVSTS/GLDP policies. If the Governing Board determines it is appropriate, I may participate in discussions and be counted as present in determining a quorum for any matter to be voted on where a conflict of interest exists. However, I agree to refrain from voting on issues where it is determined that a conflict of interest exists.

Governing Board Member

_____ _____

Date Signature

_____

Print Name

TRANSPLANT FOUNDATION

BOARD MEMBER
CONFLICT OF INTEREST AGREEMENT

I understand that as an officer or member of the board of Transplant Foundation, I am charged with fiduciary responsibilities which require me to put the interests of Transplant Foundation above my personal interests, including those of my immediate family. It is my intent to serve Transplant Foundation to the best of my ability and to be free of conflicts of interest between this role and other personal, business and professional positions with which I am identified or associated.

I understand that my fiduciary responsibilities require me to take steps to avoid both actual conflicts of interest and even the appearance of a conflict of interest because even the hint of impropriety can adversely affect the community's confidence in Transplant Foundation. However, recognizing when a conflict or potential for conflict exists is not always easy, especially when the conflict is subtle. Some activities are considered on their face conflicts of interest and thus are prohibited, while other activities may present less obvious possibilities of conflicts. I understand that one way a conflict of interest may arise is if I or a member of my immediate family is affiliated as a trustee, director, officer, employee, or consultant with, or has a substantial interest as an owner, shareholder, or partner in, any organization doing or seeking to do business with Transplant Foundation as a vendor. This is of course just one example of the manner in which a conflict of interest may arise.

I hereby agree to disclose immediately to the Transplant Foundation Board or the President and CEO, any transaction or interest which results or could result in a conflict, or an appearance of a conflict, between the interest of Transplant Foundation and my interest or that of an entity with which I or a member of my immediate family is associated. I agree to conduct myself with respect to the actual or potential conflict as directed by the Governing Board and as consistent with Transplant Foundation policies. If the Transplant Foundation Board determines it is appropriate, I may participate in discussions and be counted as present in determining a quorum for any matter to be voted on where a conflict of interest exists. However, I agree to refrain from voting on issues where it is determined that a conflict of interest exists.

Transplant Foundation Board Member

_____ Date: _____
Signature

_____
Print name

06-2021

TRANSPLANT FOUNDATION

BOARD MEMBER
STATEMENT OF CONFIDENTIALITY

I understand and agree that in the performance of my duties as a member of the Transplant Foundation Board, I may have access to certain information that is confidential and constitutes valuable, special and unique properly of Transplant Foundation. I agree that I will not at any time, either during or subsequent to my Transplant Foundation Board term, disclose to others, use, copy or permit to be copied, without Transplant Foundation's express prior written consent, except pursuant to Governing Board duties hereunder, any confidential or proprietary information of Transplant Foundation. This includes, but is not limited to, information which concerns Transplant Foundation's constituents, policies and protocols, business plans, finances, strategic initiatives, employees, and the Transplant Foundation Board which is not otherwise available to the public.

Transplant Foundation Board Member

_____ Date: _____
Signature

_____
Print name

06-2021

GIFT OF LIFE FAMILY HOUSE
BOARD MEMBER
CONFLICT OF INTEREST AGREEMENT

I understand that as an officer or member of the Family House board, I am charged with fiduciary responsibilities which require me to put the interests of Family House above my personal interests, including those of my immediate family. It is my intent to serve Family House to the best of my ability and to be free of conflicts of interest between this role and other personal business and professional positions with which I am identified or associated.

I understand that my fiduciary responsibilities require me to take steps to avoid both actual conflicts of interest and even the appearance of a conflict of interest because even the hint of impropriety can adversely affect the community's confidence in Family House. However, recognizing when a conflict or potential for conflict exists is not always easy, especially when the conflict is subtle. Some activities are considered on their face conflicts of interest and thus are prohibited, while other activities may present less obvious possibilities of conflicts. I understand that one way a conflict of interest may arise is if I or a member of my immediate family is affiliated as a trustee, director, officer, employee, or consultant with, or has a substantial interest as an owner, shareholder, or partner in, any organization doing or seeking to do business with Family House as a vendor. This is of course just one example of the manner in which a conflict of interest may arise.

I hereby agree to disclose immediately to the Family House Board or the President and CEO, any transaction or interest which results or could result in a conflict, or an appearance of a conflict, between the interest of Family House and my interest or that of an entity with which I or a member of my immediate family is associated. I agree to conduct myself with respect to the actual or potential conflict as directed by the Family House Board and as consistent with Family House policies. If the Family House Board determines it is appropriate, I may participate in discussions and be counted as present in determining a quorum for any matter to be voted on where a conflict of interest exists. However, I agree to refrain from voting on issues where it is determined that a conflict of interest exists.

Family House Board Member

_____ Date: _____
Signature

_____
Print name

06/2021

EXHIBIT A

CONFLICT OF INTEREST POLICY

Article I
Purpose

The purpose of this Conflict of Interest Policy is to protect the Corporation's interest when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an officer or Director of the Corporation or might result in a possible excess benefit transaction. This Policy is intended to supplement, but not replace, any applicable state and federal laws governing conflict of interest applicable to nonprofit and charitable organizations.

Article II
Definitions

1. **Interested Person.** Any Director, principal officer, or member of a committee with governing board delegated powers, who has a direct or indirect financial interest, as defined below, is an interested person. If a person is an interested person with respect to any entity in a health care system, he or she is an interested person with respect to all entities in such health care system.

2. **Financial Interest.** A person has a financial interest if the person has, directly or indirectly, through business, investment, or family:

   a. An ownership or investment interest in any entity with which the Corporation has a transaction or arrangement,

   b. A compensation arrangement with the Corporation or with any entity or individual with which the Corporation has a transaction or arrangement, or

   c. A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which the Corporation is negotiating a transaction or arrangement.

Compensation includes direct and indirect remuneration as well as gifts or favors that are not insubstantial.

A financial interest is not necessarily a conflict of interest. Under Article III, Section 2, a person who has a financial interest may have a conflict of interest only if the Board of Directors or committee decides that a conflict of interest exists.

Article III
Procedures

1. **Duty to Disclose.** In connection with any actual or possible conflict of interest, an interested person must disclose the existence of the financial interest and be given the opportunity to disclose all material facts to the Directors and members of committees with governing board delegated powers considering the proposed transaction or arrangement.

2. **Determining Whether a Conflict of Interest Exists.** After disclosure of the financial interest and all material facts, and after any discussion with the interested person, he/she shall leave the Board of Directors or committee meeting while the determination of a conflict of interest is discussed and voted upon. The remaining Directors or committee members shall decide if a conflict of interest exists.

3. **Procedures for Addressing the Conflict of Interest**

   a. An interested person may make a presentation at the Board of Directors or committee meeting, but after the presentation, he/she shall leave the meeting during the discussion of, and the vote on, the transaction or arrangement involving the possible conflict of interest.

   b. The Chair of the Board of Directors or committee shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement.

   c. After exercising due diligence, the Board of Directors or committee shall determine whether the Corporation can obtain with reasonable efforts a more advantageous transaction or arrangement from a person or entity that would not give rise to a conflict of interest.

   d. If a more advantageous transaction or arrangement is not reasonably possible under circumstances not producing a conflict of interest, the Board of Directors or committee shall determine by a majority vote of the disinterested Directors whether the transaction or arrangement is in the Corporation's best interest, for its own benefit, and whether it is fair and reasonable. In conformity with the above determination it shall make its decision as to whether to enter into the transaction or arrangement.

4. **Violations of the Conflicts of Interest Policy**

   a. If the Board of Directors or committee has reasonable cause to believe a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.

Article VI
Annual Statements

Each Director, principal officer and member of a committee with governing board delegated powers shall annually sign a statement which affirms such person:

a. Has received a copy of the conflict of interest policy,
b. Has read and understands the policy,
c. Has agreed to comply with the policy, and
d. Understands the Corporation is charitable and in order to maintain its federal tax exemption it must engage primarily in activities which accomplish one or more of its tax-exempt purposes.

Article VII
Periodic Reviews

To ensure the Corporation operates in a manner consistent with charitable purposes and does not engage in activities that could jeopardize its tax-exempt status, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

a. Whether compensation arrangements and benefits are reasonable, based on competent survey information, and the result of arm's length bargaining; and

b. Whether partnerships, joint ventures, and arrangements with management organizations conform to the Corporation's written policies, are properly recorded, reflect reasonable investment or payments for goods and services, further charitable purposes and do not result in inurement, impermissible private benefit or in an excess benefit transaction.

Article VIII
Use of Outside Experts

When conducting the periodic reviews as provided for in Article VII, the Corporation may, but need not, use outside advisors. If outside experts are used, their use shall not relieve the Board of Directors of its responsibility for ensuring periodic reviews are conducted.

Conflict of Interests

PURPOSE

The purposes of this Conflict of Interests Policy are:

- To ensure that the business activities conducted or supported by the Versiti and its Affiliates are performed in accordance with the highest ethical, professional and scientific standards.
- To protect the tax-exempt status of Versiti and each Affiliate, and ensure the proper stewardship of each organizations charitable assets and resources.
- To ensure compliance with all applicable laws and regulations.
- To establish a consistent written process for the disclosure, reporting, management, reduction, or elimination of conflicts of interest.

SUMMARY

Directors, Officers, employees, agents and volunteers of Versiti and its Affiliates have a duty to promote the best interests of the entity they serve and are expected to exercise good judgment in the identification, disclosure and management of Conflicts of Interests. This Conflict of Interests Policy sets forth the process for the disclosure and management of potential and actual Conflicts of Interests. Questions regarding the implementation of this Policy should be directed to the Versiti President & Chief Executive Officer or Chief Legal Officer.

OUTLINE

POLICY

1. DEFINITIONS

For the purposes of this Policy, the capitalized terms shall have the meanings set forth in below:

"Affiliate" means any entity directly or indirectly supported or controlled by Versiti, including BloodCenter of Wisconsin, BloodCenter Research Foundation, Heartland Blood Centers, Michigan Blood, and Indiana Blood Center.

"Representatives" means the directors, officers, board committee members, advisory committee members, employees (full-time, part-time and temporary), agents, independent contractors and volunteers of Versiti or a Versiti Affiliate, who are responsible for operational, financial, or strategic decisions, have access to proprietary information, or provide services on behalf of Versiti or a Versiti Affiliate.

"Business Partner" means any individual or entity with whom/which Versiti or a Versiti Affiliate has an existing agreement, arrangement or transaction, or with whom/which Versiti or a Versiti Affiliate is currently negotiating an agreement, arrangement or transaction.

"Compensation" means direct or indirect remuneration, as well as gifts or favors that are substantial in nature.

"Conflict of Interests" means a circumstance in which there is a divergence between an Interested Person's Financial Interest (or other personal interest) and his or her professional or ethical obligations, such that an independent observer might reasonably question whether the Interested Person's actions or decisions may be unduly influenced by his/her Financial Interest or other considerations of personal gain.

"Disclosure Statement" means a Versiti-approved disclosure statement (example attached as Exhibit A).

"Family Member" means any person who is related by blood or marriage to an Interested Person, or whose relationship with an Interested Person is similar to that of persons who are related by blood or marriage, including:

- Spouse or domestic partner
- Parents/Grandparents
- Siblings/Step-siblings
- Children/Grandchildren
- Spouses of siblings, children, grandchildren

"Financial Interest" means a financial interest which (i) is held directly or indirectly (through business, investment or a Family Member) by a Representative; and (ii) is related to the operations (including research, transactions, or other arrangements) of Versiti or a Versiti Affiliate, including:

- An ownership or investment interest in any Business Partner, or an entity that has received or may receive charitable contributions from Versiti or a Versiti Affiliate.
- A compensation arrangement (including direct and indirect remuneration and substantial gifts and favors) with Versiti, a Versiti Affiliate, or a Business Partner.
- Employment by, or a senior leadership position with, Versiti, a Versiti Affiliate, or a Business Partner.

"Interested Person" means any Representative who has a direct or indirect Financial Interest (as defined above) that relates to a transaction or other arrangement involving Versiti or a Versiti Affiliate.[1]

"Key Employee" generally means an individual other than a Versiti or a Versiti Affiliate Director or Officer whose responsibilities, authority, or influence over Versiti or a Versiti Affiliate as a whole is similar to those of such entity's Officers or Directors. Key Employees of Versiti and its Affiliates will be identified on an annual basis.

"Proprietary Information" means all financial data, marketing information, customer information, pricing, medical or operations management strategies, strategic plans and initiatives, products, results, designs, plans, materials, records, ideas, or data of Versiti or a Versiti Affiliate.

2. DUTY TO DISCLOSE

2.1 Generally

Each Versiti and Affiliate Representative is expected to avoid Conflicts of Interests whenever possible and should not use his/her position, or knowledge gained from his/her position, to directly or indirectly obtain benefits for his/herself, a Family Member, or any other person or entity. Representatives are expected to: (i) fully disclose Financial Interests and potential and actual Conflicts of Interest in accordance with this Policy; and (ii) cooperate with the applicable entity to address such Financial Interests and Conflicts of Interests.

2.2 Ongoing Duty to Disclose

A Financial Interest is not necessarily a Conflict of Interests; and a Conflict of Interests, if it exists, may not be material enough to be of practical importance. However, it is the policy of Versiti and its Affiliates that Financial Interests and actual or potential Conflicts of Interests are fully disclosed by the Interested Person. Upon becoming aware of a Financial Interest or actual or potential Conflict of Interests, each individual Representative must disclose such Financial Interest or Conflict of Interests to one or more of the following:

- Board Chair
- President & Chief Executive Officer
- Board Committee Chairperson
- Chief Compliance Officer

2.3 Annual Disclosure Statements

In addition to the ongoing disclosure requirement described above, the following Representatives must: (i) submit an annual Disclosure Statement; and (ii) in the event an undisclosed Financial Interest or Conflict of Interests arises, update such Disclosure Statement in writing promptly:

- Directors & Officers
- Boerd Committee Members
- Organ Procurement Organization (OPO) Advisory Board Members
- Executive, Senior and Vice Presidents

- Key Employees
- Other Representatives as directed by the Chief Compliance Officer (e.g., purchasing staff)

Annual Disclosure Statements require individual Representatives to affirm that he/she (i) received a copy of the Conflict of Interests Policy; (ii) read and understands the Policy; (iii) agrees to comply with the Policy; and (iv) understands Versiti and its Affiliates are charitable organizations and, in order to maintain federal tax exemption, Versiti and its Affiliates must engage primarily in activities which accomplish one or more of its tax-exempt purposes.[2]

3. COMMITTEE REVIEW

3.1 Generally

All disclosed Financial Interests will be subject to Board/Committee review as described below. The reviewing Board/Committee will examine all material facts and discuss the Financial Interest with the Interested Person (as necessary). If present, the Interested Person shall be excused from the Committee meeting and the remaining Committee members shall determine whether an actual or potential Conflict of Interests exists. The review Committee meeting minutes shall contain:

- The name(s) of the person(s) who made the disclosures;
- The nature of any identified actual or potential Conflict of Interests;
- Any action taken to investigate identified actual or potential Conflict of Interests;
- The names of the persons who were present for discussions and votes relating to the actual or potential Conflict of Interests; and
- The Committee's final determination as to whether an actual or potential Conflict of Interests exists. (If the Committee determines that an actual or potential Conflict of Interests exists, refer to Section 4 below.).

3.2 Review of Annual Disclosure Statements

The Audit & Compliance Committee will review annual Disclosure Statements to determine whether any actual or potential Conflict of Interests exist. Annual Disclosure Statements submitted by Audit & Compliance Committee members will be reviewed by the Versiti Executive Committee. Individual Committee members will not participate in the review of his/her own Disclosure Statement.

3.3 Review of Other Disclosed Financial Interests and Conflicts of Interest

Actual and potential Conflicts of Interest that arise outside the annual review process shall be documented on a Disclosure Statement and reviewed by the Committees identified below, or the Audit & Compliance Committee.

Interested Person	Review Board/Committee
Board Directors & Officers	Board of Directors
Board/Advisory Committee Members	Applicable Board/Advisory Committee
Corporate Officers	Audit & Compliance Committee
Executive, Senior and Vice Presidents	Audit & Compliance Committee
Other Representatives	Audit & Compliance Committee

4. ADDRESSING ACTUAL OR POTENTIAL CONFLICTS OF INTEREST

4.1 Generally

If the reviewing Board/Committee determines that an actual or potential Conflict of Interests exists, the Board/Committee will develop and implement a management plan that specifies the actions that have been and shall be taken to manage such Conflict of Interests.

4.2 Documentation

The reviewing Board/Committee meeting minutes shall contain:

- All of the elements set forth in Section 3.1 above;
- The name(s) of the person(s) for whom an actual or potential Conflict of Interests exists;
- The nature of the Conflict of Interests and the agreement, arrangement or transaction;
- Any steps taken by the Board or Board Committee to avoid or mitigate the potential Conflict of Interests (e.g., investigations or alternatives, etc.);
- The names of the persons who were present for discussions and votes relating to the agreement, arrangement, or transaction, or other matter.

4.3 Exclusion from Compensation Determinations

A voting member of the Board of Directors or any Board Committee who receives compensation from Versiti or an Affiliate may provide the Board or Board Committee with information regarding compensation, but may not vote on any matter pertaining to his/her compensation. For example, the President & Chief Executive Officer from each Affiliate will recuse him/herself from any vote relating to his/her compensation.

4.4 Restricting Access to Proprietary Information

If the reviewing Board/Committee determines that an Interested Person's access to Proprietary Information creates an actual or potential Conflict of Interests, or may materially influence his or her personal financial or investment decisions, the reviewing Board/Committee shall limit or eliminate the Interested Person's access to such Proprietary Information.

4.5 Agreements, Transactions and Arrangements

4.5.1 Recusal; Exclusion. If the reviewing Board/Committee determines that an actual or potential Conflict of Interests exists with regard to any agreement, transaction,

arrangement, or other matter, the Interested Person may recuse him/herself, or be excluded from all discussions regarding that agreement, transaction, arrangement or other matter. Alternatively, after the reviewing Board/Committee has discussed the potential Conflict of Interests, the Board or Board Committee may determine that it is in the best interest of Versiti and/or its Affiliates to permit the Interested Person to present information regarding that agreement, transaction, arrangement, or other matter at the Board/Committee meeting. However, after such presentation, the Interested Person must leave the meeting during the discussion of, and the vote upon, the agreement, transaction, arrangement, or other matter.

4.5.2 Disinterested Review. If appropriate, the Board or Board Committee chairperson shall appoint a disinterested person or committee to investigate alternatives to the proposed agreement, transaction or arrangement.

4.5.3 Final Determination. After exercising due diligence, the Board or Committee shall determine whether Versiti and/or its Affiliates can obtain with reasonable efforts a more advantageous agreement, transaction or arrangement from a person or entity that would not give rise to a Conflict of Interests. If a more advantageous transaction or arrangement is not reasonably possible under circumstances not producing a Conflict of Interests, the Board or Committee shall determine by a majority vote of the disinterested members whether the agreement, transaction or arrangement is in Versiti and its Affiliate's best interest, for its own benefit, and whether it is fair and reasonable. In conformity with the above determination, the Board or Committee shall make its decision regarding the agreement, transaction, or arrangement.

5. ACCESSIBILITY, REVIEW, EDUCATION, VIOLATIONS

5.1 Public Accessibility

This Conflict of Interests Policy will be made available on Versiti and its Affiliates' intranet and internet websites.

5.2 Periodic Review

To ensure Versiti and its Affiliates operate in a manner consistent with such entity's charitable purposes and does not engage in activities that could jeopardize its status as a tax-exempt organization, the Audit & Compliance Committee shall conduct periodic reviews and report the results to the Board. Periodic reviews shall, at a minimum, include the following subjects:

5.2.1 Whether compensation arrangements and benefits, at least with respect to compensation arrangements and benefits provided to Disqualified Persons (as defined in Section 4958(f)(1) of the Internal Revenue Code), are reasonable and are the result of arm's length negotiations; and

5.2.2 Whether partnership and joint ventures, and arrangements with management organizations (if any) conform to written policies, are properly recorded, reflect reasonable investment or payments for goods and services, further Versiti and its

Standard 3.3 – Personnel Actions and Decisions

Salary, benefits, and other personal information relating to employees shall be treated as confidential. Personnel files, payroll information, disciplinary matters and similar information shall be maintained in a manner designed to ensure confidentiality in accordance with applicable laws. Employees will exercise due care to prevent the release or sharing of information beyond those persons who may need such information to fulfill their job function.

Principle 4 – Conflicts of Interest

Employees, board members, medical directors and assistant medical directors owe a duty of undivided and unqualified loyalty to the organization. Persons holding such positions may not use their positions to profit personally or to assist others in profiting in any way at the expense of the organization.

All covered persons are expected to regulate their activities so as to avoid actual impropriety and/or the appearance of impropriety which might arise from the influence of those activities on business decisions of LifeCenter, or from disclosure or private use of business affairs or plans of LifeCenter. All covered persons must yearly complete a Conflict of Interest form disclosing any potential conflicts, especially those of financial, ethical or political nature. Employees, please also see LifeCenter's Personnel Policy and Procedure Section Z: *Conflict of Interest* of the *Personnel Policy and Procedure Manual(HR100.0-2)* Employees who wish to obtain work outside of his/her LifeCenter duties must complete a Conflict of Interest Form for Employees with a Second Job. This form is then reviewed and approved by the employee's supervisor and the Executive Director to ensure there is no conflict of interest and maintained in the employee's personnel file.

LifeCenter's Executive Director, board members, medical directors, assistant medical directors, and agents are to abstain from discussion or votes on their compensation. Medical directors, assistant medical directors, and agents serving on any of the boards or committees of LifeCenter, must abstain from voting on issues that may directly affect their financial interests.

LifeCenter clinical staff that have approved second jobs must abstain from working on patients that may become a known potential organ or tissue donor if it is within their job at LifeCenter or their approved second job.

Standard 4.1 – Outside Financial Interests

While not all inclusive, the following will serve as a guide to the types of activities by a covered person or household member of such a person, which might cause conflicts of interest.

1. Ownership in or employment by, any outside entity that does business with LifeCenter. This does not apply to stock or other investments in a publicly held corporation, *provided* the value of the stock or investments does not exceed 5% of the corporation's stock. LifeCenter may, following a review of the relevant facts, permit employment or

business decisions of Gift of Life or from disclosure or private use of business affairs, initiatives, or plans of Gift of Life.

STANDARD 4.1 OUTSIDE FINANCIAL INTERESTS

While not all inclusive, the following will serve as a guide to the types of activities by Gift of Life Representatives, or household members of such persons, which might cause conflicts or interest:

1. Ownership in or employment (whether as an Employee, independent contractor or otherwise) by any outside concern which does business with Gift of Life. This does not apply to stock or other investments held in a publicly held corporation, *provided* the value of the stock or other investments does not exceed 5% of the corporations' stock. Gift of Life may, following a review of the relevant facts, permit ownership interests in such a concern which exceed these amounts, or employment in such a concern if the Gift of Life President & CEO concludes such ownership interests or employment will not adversely impact Gift of Life's business interest or the judgement of the Gift of Life Representative.

2. Conduct of any business not on behalf of Gift of Life, with any vendor, supplier, contractor, or agency, or any of their officers or employees.

3. Representation of Gift of Life by a Gift of Life Representatives in any transaction in which he or she or a household member has a substantial personal interest.

4. Disclosure or use of confidential, special or inside information of or about Gift of Life, particularly for the direct and indirect personal gain, profit or advantage of the Gift of Life Representative or a household member.

5. Competition with Gift of Life by Gift of Life Representatives, directly or indirectly, in a purchase, sale or ownership of property or property rights or interests, business opportunity, initiative or investment opportunity.

If questions arise regarding the ability to engage in any action, or the appropriateness of any action, Gift of Life Representatives should seek guidance from the President and CEO.