



Board of Sponsors

**Nobel Laureate*

* Peter Agre
* Sidney Altman
* Philip W. Anderson
* David Baltimore
* Paul Berg
* J. Michael Bishop
* Michael S. Brown
* Linda B. Buck
* Ann Pitts Carter
* Martin Chalfie
* Stanley Cohen
* Leon N. Cooper
* E. J. Corey
* Johann Deisenhofer
* Ann Druyan
* Paul R. Ehrlich
* George Field
* Val L. Fitch
* Jerome I. Friedman
* Walter Gilbert
* Joseph L. Goldstein
* David J. Gross
* Roger C. L. Guillemin
* Leland H. Hartwell
* Dudley R. Herschbach
* Roald Hoffmann
* John P. Holdren
* H. Robert Horvitz
* Eric R. Kandel
* Wolfgang Ketterle
* Brian Kobilka
* Robert J. Lefkowitz
* Roderick MacKinnon
* Eric S. Maskin
* Jessica T. Matthews
* Roy Menninger
* Matthew S. Meselson
* Richard A. Meserve
* Mario Molina
* Stephen S. Morse
* Ferid Murad
* Ei-ichi Negishi
* Douglas D. Osheroff
* Arno A. Penzias
* David Politzer
* George Rathjens
* Richard J. Roberts
* Randy Schekman
* Phillip A. Sharp
* K. Barry Sharpless
* Robert M. Solow
* Joseph Stiglitz
* Daniel Tsui
* Harold E. Varmus
* Frank von Hippel
* Robert A. Weinberg
* Steven Weinberg
* Torsten N. Wiesel
* Eric Wieschaus
* Frank Wilczek

23 June 2021

Dear Chairman Krishnamoorthi, Ranking Member Cloud, and Members of the House Subcommittee on Economic and Consumer Policy of the House Committee on Oversight and Reform,

We are writing in support of the Committee's bipartisan investigation examining the nation's system for securing transplant organs for patients suffering from organ failure.

Through the Federation of American Scientists, the OPO Innovation Cohort will share data to establish open and transparent lines of communication between OPOs as nonprofit government contractors and the public they serve, including branches of the federal government, in an effort to build trust and support further reforms that will save patient lives. We are committed to the following principles:

- **Transparency:** *public sharing of data/analysis in order to set a standard to which all OPOs can be held;*
- **Accountability:** *support for the OPO final rule, and any efforts to move up the implementation date so all parts of the country can be served by high-performing OPOs as soon as possible in 2024; and*
- **Equity:** *commitment to analyzing/publishing data to ensure all parts of community served.*

On transparency, please see the appendix below for details into the data we will be sharing publicly, believing transparency to be in the public interest. We look forward to the research and findings that such transparency enables, in the belief that data analysis can drive improvements in organ recovery and transplantation, leading to more lives saved. We also note that this is data which can be easily and readily shared by all OPOs, and, as suggested by Chairwoman Maloney, encourage our peers to join us in enabling sound, data-informed, pro-patient policymaking through such transparency.

On accountability, we welcome Chairman Krishnamoorthi's call to accelerate reforms - noting that as the Department of Health and Human Services already has the data it needs to hold OPOs accountable, and that HHS should use the next available year's data (2022) to ensure all parts of the country are served by high-performing OPOs by 2024. Doing so translates to 14,000 lives saved, as well as \$2 billion saved to Medicare in foregone dialysis costs.

Additionally, as two of us have published before: *"There were originally 128 OPOs, and after decades of consolidations there are now [57] OPOs; never has this process been disruptive. Forcing OPOs to continually earn their contracts is a patient-centric accountability mechanism, ensuring that OPOs operate with the urgency befitting the life-and-death consequences of this work."* We highlight a report from the Bridgespan Group laying out a roadmap for CMS to oversee seamless implementation of the final rule.

Board of Trustees and Experts

Gilman Louie <i>Chair</i>	Rosina Bierbaum <i>Vice Chair</i>	Nishal Mohan <i>Secretary-Treasurer</i>	Dan Correa <i>Acting President</i>
Board of Trustees Daniel Gerstein Don Lebell Jan Lodai Catherine Lotrionte	Robert Solow* Frank von Hippel* *Ex officio	Board of Experts Alton Frye Robert Gard Martin Hellman Martha Krebs	Jan Lodai Maxine Savitz Michael Telson Valerie Thomas



On equity, we note the disproportionate burden of organ failure on communities of color. And as highlighted by the Federation of American Scientists, given COVID-19's potential to affect and attack organs, coupled with its disproportionate impact on communities of color, the need for reform is only intensifying. Further we believe all grieving families, regardless of race, should be offered the opportunity to donate in a caring, sensitive manner when it exists.

We note that the undersigned OPOs left the Association of OPOs (AOPO), noting the Committee's investigation into AOPO's "lobbying against life-saving reforms." We offer ourselves as a resource for Congressional staff, and look forward to briefing you on what we are learning - noting our commitment to transparency, accountability, and equity, setting a standard to which all OPOs should be held.

Yours sincerely,

Diane Brockmeier, Mid-America Transplant

Helen Irving, LiveOnNY

Ginny McBride, Our Legacy

Patti Niles, Southwest Transplant Alliance

Kelly Ranum, Louisiana Organ Procurement Agency

Matthew Wadsworth, LifeConnection of Ohio

Janice Whaley, Donor Network West

Dan Correa, Federation of American Scientists

Jennifer Erickson, Federation of American Scientists

Appendix

Format: For all datasets below, OPOs will share in CSV file format for analysis

1. Donors and organs recovered by month, from the earliest period you consider feasible and applicable (ideally 1/1/2010), fractionated by the following:

- Race/ethnicity
- Sex
- Height
- Weight
- Age group (peds, 18-34, 35-49, 50-64, 65+)
- HIV status
- Hospital
- Donation after Circulatory Death (DCD) (Y/N)
- Circumstance of death
- Mechanism of death
- Tissue authorized (Y/N)



- Tissue recovered (Y/N)
- Time from referral to onsite response
- Research authorization (Y/N)
- KDPI (if calculated)
- Medicare beneficiary status (Y/N)

2. Process data by month/race/age/sex/HIV status/hospital with time stamps. These data will be used to track every referral to every endpoint:

- Referrals with time stamp
- Vented or previously vented referrals with Cardiac Time Of Death (CTOD)
- Referrals medically ruled out (i.e. MROs)
- Initial onsite responses with time stamp
- Approaches (any conversation between OPO and legal next of kin (LNOK))
- Authorizations (FPA or non-FPA)
- Family declines (FPA or non-FPA)
- Terminal step
 - Law enforcement/Medical Examiner/coroner/Justice of the Peace decline
 - Allocation exhausted
 - Cardiac arrest prior to OR
 - DCD - patient did not expire
 - Closed before OR (describe)
 - Closed in OR (describe)
 - Other (describe)
- Referrals with hospital interference or “block” for approach, authorization, or recovery of organs
 - Documentation of report to hospital regarding interference, with date and time of referral, date and time of extubation, and CTOD
 - Documentation of remediation plan for hospital interference
- Unreported/missed ventilated referrals by hospital by month. Unreported/missed referrals (also known as “critical misses”) should be categorized as:
 - Hospital deaths not reported to OPO (never referred)
 - Referrals made to OPO without adequate time for evaluation/approach (i.e., late referrals made before withdrawal, or any referral made by hospital that did not meet OPO’s requirements for timeliness but prior to extubation)
 - Referrals made to OPO after extubation (i.e., late referrals after withdrawal)
 - Unplanned extubations after referral made to OPO (referred but extubated without notice to OPO)
 - Other (any unreported/missed referral that does not qualify for the above categories)
 - Documentation of report to hospital
 - Documentation of remediation plan for missed referral
 - Total number of vented or previously vented referrals by hospital by year
- All unstructured case notes



- For every instance in which an organ was lost, damaged, delayed in transit, including organs shipped or overseen by the UNOS Organ Center as well as organs for which transportation was arranged, overseen, or otherwise handled by the OPO or any other entity, the name of the recovering OPO and the recipient transplant center

3. Clinical requests

- Current and past versions of suitability screening
 - 10 years of clinical organ criteria, including age cutoffs, BMI, comorbidities, organ function
 - Including OPO-based automatic rule outs
 - Any policies around escalation of categories of referrals for review to administrators and/or medical directors
 - OPOs rule out policy:
 - Who makes the initial determination?
 - Does this determination have to be validated by a second staff member?
- Complete description of current death record review process
- 10 years of clinical triggers used by any hospital systems in DSA, listed by hospital and with descriptions of any triggers that narrow the potential referral of donors through additional restrictive criteria
- 5 years of criteria to respond onsite at hospital
- Number/characterization of hospital complaints by hospital and system
- Description of process for referral classification.
 - E.g, does this happen immediately, or by the following month? Who completes these classifications?

4. Staffing (for last 10 years - as data available)

- Completed organizational chart
- Racial composition of OPO personnel at front-line, management, and board levels
- Total number of hourly or direct labor employees for the positions of organ recovery coordinator and/or similar position (e.g., procurement coordinator), family approach coordinator, tissue recovery coordinator, hospital development coordinator, and call center staff
- Average regular and overtime pay rates for each position, as well as the total hours paid at each rate
- Maximum shift length, if any (e.g., 12 vs 24 hrs)
- Total fees paid to traveling coordinators as well as the total hours worked;
- Average years of experience
- Requirements for experience and education for each coordinator role
- Total yearly expenditure on salaries, wages and benefits, broken out for staff versus management, including ratio of total compensation for CEO vs. average for organ recovery coordinators
- For each coordinator on staff, total years of experience in organ donation, including:



- Total time in role after orientation
- Total time spent in training (training time as defined by any working hours spent with a preceptor or trainer, before coordinator is “signed off” or allowed to coordinate a case without direct supervision)
- Number of years of experience in clinical management of deceased organ donors

5. Financials (for 10 years)

- Yearly financials (audited or not)
- 2021 YTD financials
- Standard acquisition charges (SAC) by organ, broken out import vs. export
 - Breakdown of costs included in each (e.g, transportation)
 - Are local import offers handled in-house or outsourced?
- All wires transfers between OPO and related entities (e.g., OPO foundation)
- All documentation regarding:
 - All companies consulting agreements, or other deals in which an OPO executive and/or their family members, or OPO board member and/or their family members, have a personal financial interest and with which the OPO or any related entity maintains a business relationship (e.g., tissue bank or processor, HLA labs); and
 - the manner in which such conflicts were disclosed to the OPO board, government agencies, donor families, and/or the general public.
- Information on how the OPO reimburses the hospitals for donor cases over the last 10 years

6. Aviation

- Tail numbers for any jet or other form of private aviation owned, rented, operated, or otherwise controlled by OPO or related entity
 - For each, flight logs, including Hobbs hours
- For each flight:
 - Passenger logs, including names and credentials/positions of all passengers, for all such flights
 - Whether flight had a UNOS ID number and/or internal case identifier number
 - If not, the purpose of each such flight
 - All information and documentation regarding the entity or entities to which each flight was billed, including those flights for which there is no UNOS ID number associated, including the extent to which such flights were included in the OPO’s SAC fees

7. Organ recovery centers (ORCs)



- For any current or historical organ recovery center managed or used by your OPO:
 - Funding structure: ORC fully funded and managed by OPO; funded by OPO and hospital agreement; or funded by hospital but leased by OPO
 - Average cost per case for:
 - Donation after Brain Death (DBD) managed in ORC
 - DBD managed in donor hospital
 - DCD managed in donor hospital
 - Describe all diagnostic equipment used in the ORC
 - If the ORC is in a donor hospital, describe agreements for use of equipment (e.g., CT scans.)
 - What is the cost associated with in-house diagnostics for:
 - CT
 - Cardiac Cath
 - ECHO
 - X-Ray
 - If the ORC is in a donor hospital, describe agreements for patient order sets (i.e., are donor management orders defined by OPO or by hospital?)
 - Date ORC opened
 - Description of donors recovered at the facility:
 - Criteria for which DBD donors are transported to ORC
 - Any age-related restrictions on transport
 - Percentage of donors with organs recovered that were recovered in the OPO's ORC by year
 - Number of donors recovered by type (brain dead, DCD) by month and year
 - Number transferred by hospital by month and year

8. Tissue recovery centers

- For any current or historical tissue recovery center managed or used by your OPO, please provide:
 - Total number of unique tissue donors each year
 - Funding source(s) for tissue center (e.g., fully funded and managed by the OPO, funded by OPO and third party agreement (funeral home, coroner office) or funded by third party and leased by OPO)
 - Date the tissue recovery center opened