

# Opportunities for Organ Donor Intervention Research

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Saving Lives by Improving the Quality and  
Quantity of Organs for Transplantation

**Webinar**  
**October 19, 2017**

# Committee Roster



## Committee on Issues in Organ Donor Intervention Research

**JAMES F. CHILDRESS** (*Chair*), University of Virginia

**DIANA CLARK** (*Retired*), LifeCenter Northwest

**I. GLENN COHEN**, Harvard Law School

**MICHELE BRATCHER GOODWIN**, University of California

**JONATHAN KIMMELMAN**, McGill University

**WILLIAM H. MARKS** (*Retired*), Swedish Medical Center

**KENNETH MORITSUGU** (*Retired*), RADM, USPHS, First Samurai Consulting

**GLENN PIERCE** (*Retired*), Biogen

**LAINIE FRIEDMAN ROSS**, University of Chicago

**ROBERT D. TRUOG**, Harvard Medical School and Boston Children's Hospital

**PETER A. UBEL**, Duke University

**JAMES B. YOUNG**, Case Western Reserve University

# Study Sponsors



American Association for the Study of Liver Diseases  
American Society of Transplant Surgeons  
American Society of Transplantation  
Association of Organ Procurement Organizations  
Gift of Life Donor Program  
Health Resources & Services Administration  
Laura and John Arnold Foundation  
National Heart, Lung, and Blood Institute  
National Institute of Allergy and Infectious Diseases  
National Institute of Diabetes and Digestive and Kidney Diseases  
National Kidney Foundation  
OneLegacy Foundation  
The Transplantation Society

# Abridged Statement of Task



An ad hoc study will examine the ethical, policy, regulatory, and organizational issues relevant to the conduct of research involving deceased organ donors. The committee will examine the gaps, barriers, and opportunities for clinical research involving deceased donors that aims to increase the quality and quantity of donated organs available for transplantation, with particular attention to interventions administered to the donor and thus potentially affecting all of the donor's organs.

# Study Timeline



## 2016

- September – First committee meeting
- December – Second committee meeting and workshop

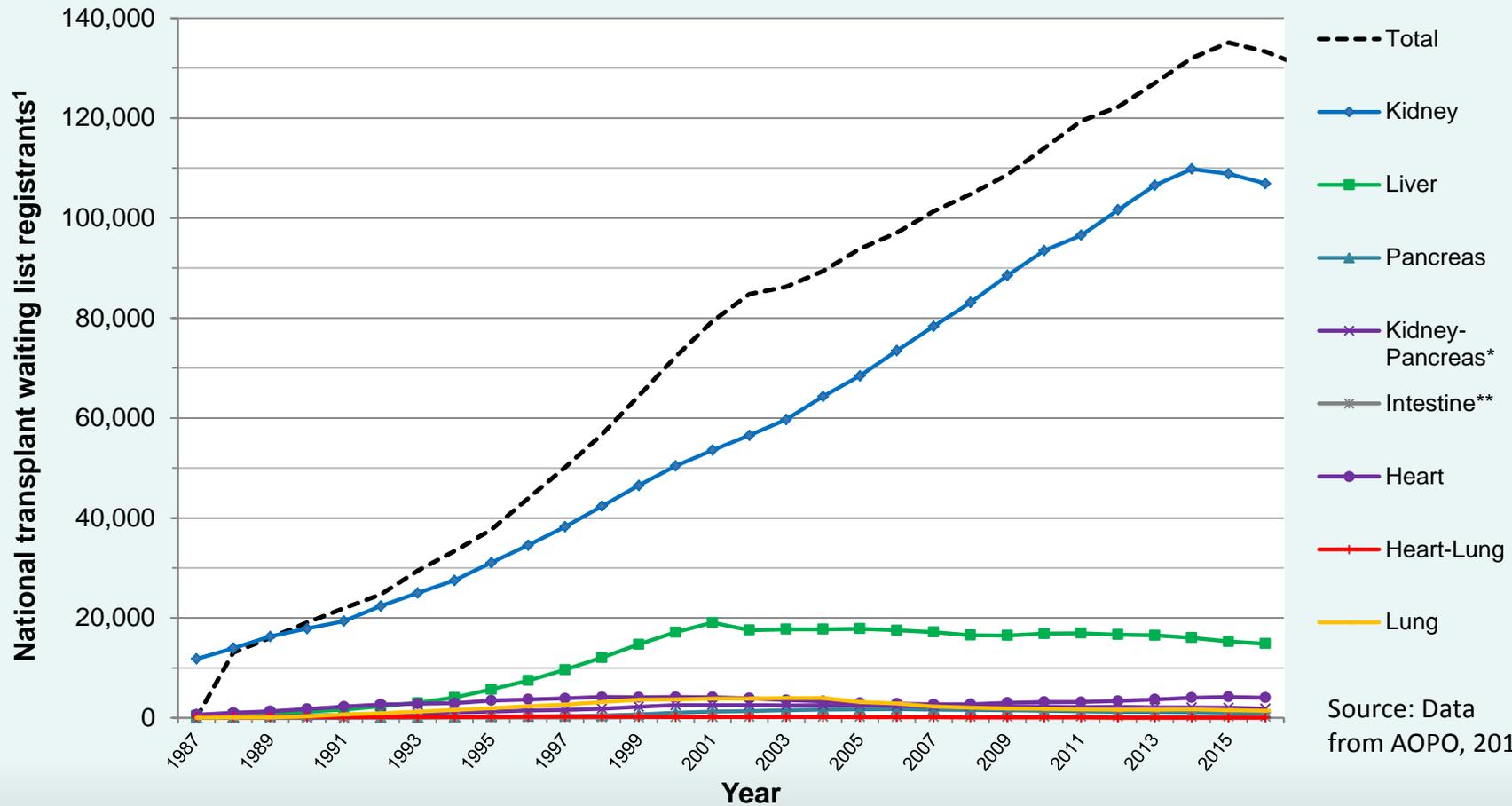
## 2017

- March – Third committee meeting
- May – Fourth committee meeting
- June/July/August – Report review and response
- October – Public release
- Report dissemination



# Why Focus on Organ Donor Intervention Research Now?

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Source: Data from AOPO, 2017

# Why focus on organ donor intervention research now?



## Organs from deceased donors discarded in 2016, by type

Organ	Number
Intestines	8
Hearts	31
Lungs	221
Pancreases	320
Livers	741
Kidneys	3,631
Total discarded	4,952

Source: OPTN, 2017

# Why focus on organ donor intervention research now?



## Recovered organs used for research purposes, 2013 – 2015

Parameter	2013	2014	2015
All deceased donors	8,268	8,596	9,079
Organs recovered for transplant but ultimately submitted to research	811	1,067	1,080
Organs recovered for research purposes	3,265	4,214	4,549
Total research organs	4,076	5,281	5,629

Source: AOPO, 2017



# Challenges in Deceased Organ Donor Intervention Research

# Challenges



## Challenges across all fields of clinical research:

- Multi-site trials
- Differentiating between quality-improvement studies and research studies
- Implementing appropriate levels of oversight and protections for human subjects
- Ensuring that potential participants understand the risks, benefits, and alternatives to participating in research
- Delineating consensus on standards of practice
- Limited funding sources and resources

# Challenges



## Challenges unique to organ donor intervention research

- Multiple individuals—Research conducted in the deceased donor being assessed in the recipient(s)
- Non-target organ recipients—Research intervention on the target organ may have impacts on other organs
- Unknown at the outset of the research who will be involved in the research study:
  - Numerous potential organ recipients
  - Numerous OPOs, donor hospitals, and transplant centers
- Rapid decision making required for the transplant program and the potential recipient
- Recent changes in the organ allocation system to move from a local and regional focus to a national approach
- Guidelines for research may interact with the guidelines for allocation in such a way that the distribution of the organs is altered, so it is possible that some transplant candidates might wait longer to receive an organ than they would in the absence of research.



# Terminology

# Terminology



***Neurologic determination of death*** refers to the determination of death by irreversible cessation of all functions of the brain including the functions of the brain stem.

***Circulatory determination of death*** indicates a determination of death made by observing the irreversible cessation of cardiac and respiratory function.

***Target organ*** refers to the organ targeted by the research intervention to improve the viability of this organ for transplantation

***Non-target organs*** refer to organs that are not the intended target of the research intervention.

# Authorization vs. Consent



The available literature and public policies use several of the following: “donation,” “consent to donation,” “authorization for donation,” “donor authorization,” “make an anatomical gift,” “become an organ donor,” “register as a donor,” “agree to donate,” etc.

While each of these may be useful in some contexts, this report gives priority to the term “**authorization**,” both for the decedent’s prior decision to donate his or her organs and for the surrogate’s decision to donate those organs in the absence of the decedent’s prior decision.



# Report Overview

# Ethical Principles



***Respect for persons:*** respect for persons' autonomous choices

***Beneficence (utility):*** balance of probable benefits against probable harms

***Fairness:*** equitable distribution of benefits, risks, costs, and burdens

***Validity:*** generation of evidence that is sufficiently reliable to guide decision making

***Trustworthiness:*** confidence in and reliance on others to act competently and in accord with ethical principles and legal and regulatory standards

# Goals



**Goal 1:** Improve transparency and public trust in the organ donation process for research followed by transplantation.

**Goal 2:** Improve the coordination and sharing of information about donor preferences.

**Goal 3:** Clarify legal guidance on organ donation for the purpose of research followed by transplantation (organ donor intervention research)

**Goal 4:** Promote informed consent for transplant recipients' participation in organ donor intervention research in a manner that is compatible with the logistical complexities of organ transplantation.

**Goal 5:** Establish centralized management and oversight of organ donor intervention research in order to ensure equitable, transparent, and high-quality research

**Goal 6:** Promote transparency regarding organ donor intervention research, and enable the implementation, tracking, and analysis of organ donor intervention research to improve transplantation outcomes

# Goal 1



**Goal 1:** Improve transparency and public trust in the organ donation process for research followed by transplantation.

**Recommendation 1:** The Organ Procurement and Transplantation Network (OPTN), organ procurement organizations (OPOs), the Health Resources & Services Administration (HRSA), advocacy organizations, and professional associations involved in educating the general public and obtaining individual and surrogate authorization should explore, develop, and test communication strategies and materials that explain organ donor intervention research and should implement and disseminate those resources for which effective messaging has been identified.

*Specific actions are detailed below this recommendation in the report.*

# Goal 2



**Goal 2:** Improve the coordination and sharing of information about donor preferences.

**Recommendation 2:** All active donor registries in the United States should coordinate in order to ensure a single, unified secure national donor registry that is easily accessible to OPOs. All donor registry information collected by departments of motor vehicles should automatically feed into this single national registry. Model state legislation should be developed to facilitate this merger.

# Goal 3



**Goal 3:** Clarify legal guidance on organ donation for the purpose of research followed by transplantation (organ donor intervention research).

**Recommendation 3:** The National Conference of Commissioners on Uniform State Laws should explore revisions to the Uniform Anatomical Gift Act (UAGA) that would clarify the authorization of organ donation for the purpose of research followed by transplantation.

- When a decedent has stated a general intent to make an anatomical gift, without further specification, research followed by transplantation is permitted.
- OPOs should be explicitly empowered to seek from a donor's surrogate the expansion of the authorization for an existing gift for any purpose to be used for research followed by transplantation.

# Goal 3 Continued



The committee also considered two options for resolving the ambiguities in the UAGA and state laws, but sensitive to trust and transparency felt this issue requires more public consultation. Therefore, the committee recommends that the OPTN and transplant community should engage in public consultation and determine whether to amend the UAGA and state laws to:

- Specify that when the decedent has authorized transplantation this denotes that the gift is authorized for research followed by transplantation, or
- Specify research followed by transplantation as an additional purpose of donation that would be added to the list of choices for the donor.

# Goal 4

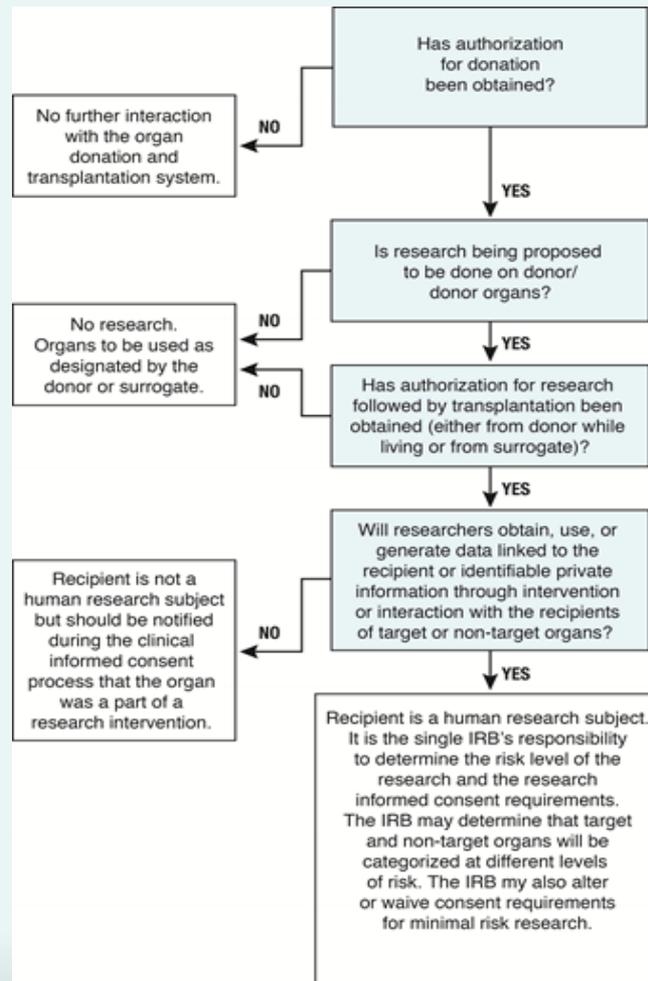


**Goal 4:** Promote informed consent for transplant recipients' participation in organ donor intervention research in a manner that is compatible with the logistical complexities of organ transplantation.

**Recommendation 4:** Transplant centers and OPOs, in collaboration with OPTN/UNOS, professional associations, and patient advocacy organizations should develop and implement a protocol for notifying and educating potential organ transplant recipients about the possibility of being offered an organ that has been exposed to a research intervention and seeking informed consent if they agree to be part of the research study.

*Specific actions are detailed below this recommendation in the report.*

# Research authorization and consent decision points



# Goal 5



**Goal 5:** Establish centralized management and oversight of organ donor intervention research in order to ensure equitable, transparent, and high-quality research

**Recommendation 5:** The Organ Procurement and Transplantation Network (OPTN), in collaboration with the National Institutes of Health (NIH), the Health Resources & Services Administration (HRSA), organ procurement organizations (OPOs), donor hospitals, transplantation centers and programs, professional associations, patient advocacy organizations, community representatives, and other relevant organizations, should establish and sustain a standing Donor-Research Oversight Committee (D-ROC) to guide, coordinate, evaluate, prioritize, and disseminate research on deceased organ donor interventions. D-ROC should include the administrative structure to establish independent data safety monitoring boards to ensure the scientific integrity of organ donor intervention research and assess its risks and benefits as studies progress. A single IRB should be established or contracted with to ensure human subject research protections for donor intervention research studies.

# Goal 6



**Goal 6:** Promote transparency regarding organ donor intervention research and enable the implementation, tracking, and analysis of organ donor intervention research to improve transplantation outcomes

**Recommendation 6:** D-ROC, in collaboration with OPTN, NIH, HRSA, professional associations, OPOs, patient advocacy organizations, and transplant centers and programs should create organ donor intervention research electronic tools to ensure that organ donor intervention studies are listed on a publicly available website, that clinicians have the information to provide to potential recipients; that researchers can conduct studies effectively, that research outcomes are tracked and monitored appropriately, and that research outcomes are widely available in aggregate.

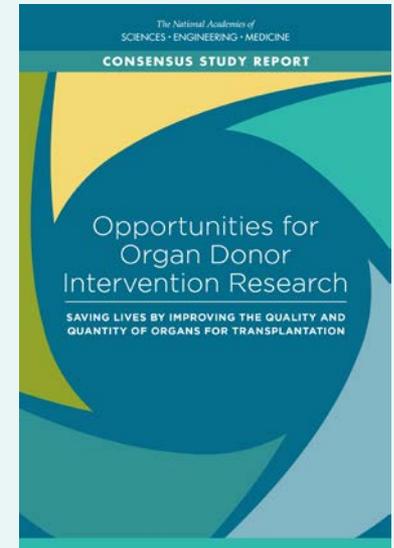
- Access to real-time study information used to maintain study continuity and monitor key elements of active studies necessary for project management;
- Additional data fields in UNet and other relevant databases to allow for the designation of the organ as a research organ and to note other relevant information about the research protocol for clinical use and in the tracking of research outcomes;
- An online registry of pending, approved, active, closed, and discontinued organ donor intervention research studies; and
- Links to research outcome data, abstracts, and scientific publications.

# Q&A and Additional Information



## Report Materials:

- 4 page summary
- Recommendations summary
- Slide set
- Link to free PDF of the report



[nationalacademies.org/OrganDonorResearch](https://nationalacademies.org/OrganDonorResearch)