

# RECOMMENDATIONS

OCTOBER 2017 • OPPORTUNITIES FOR ORGAN DONOR INTERVENTION RESEARCH

## **RECOMMENDATION 1: IMPROVE TRANSPARENCY AND PUBLIC TRUST IN THE ORGAN DONATION PROCESS FOR RESEARCH FOLLOWED BY TRANSPLANTATION**

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. Information resources to be developed include:

- Template language to be used by all U.S. organ donor registries (e.g., departments of motor vehicles [DMVs], national registry) to ensure consistency across registries in the language used to obtain authorization for organ donation. This language should explain organ donation options in language that takes into account the wide range of degrees of health literacy among the public.
- Templates for DMVs, OPOs, and other entities that advocate for organ/tissue donation to use for communicating a consistent set of facts about organ donor intervention research across websites and other dissemination methods.
- Standardized talking points for communicating with donor surrogates and families about organ donor intervention research. These should include, at a minimum, information about donation, transplantation, and research in language that takes into account the wide range of degrees of health literacy among the public.

## **RECOMMENDATION 2: IMPROVE THE COORDINATION AND SHARING OF INFORMATION ABOUT DONOR PREFERENCES**

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.

## **RECOMMENDATION 3: CLARIFY LEGAL GUIDANCE ON ORGAN DONATION FOR THE PURPOSE OF RESEARCH FOLLOWED BY TRANSPLANTATION (ORGAN DONOR INTERVENTION RESEARCH)**

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. The following possible clarifications to the UAGA should be considered:

- 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.

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.

#### **RECOMMENDATION 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**

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. Specifically,

- At intake and at regular intervals thereafter, all potential recipients should be provided with information about organ donor intervention research and asked whether, at the time of organ offer, they would potentially consider accepting an organ (target organ or non-target organ) that was part of a research study. As a result of time constraints at the time of the organ offer for transplantation, only potential recipients who have previously agreed to consider research organs should be approached with the option to accept an available research organ.
- At the time of being offered an organ for transplantation, each transplant candidate who will potentially receive an organ that is part of a research study—be it a target organ or a non-target organ—should be provided with information about the specific research protocol and should follow the single IRB's approved informed consent process for participating in that specific research study (including possible alteration or waiver of informed consent) and accepting the particular research organ offered. Given the importance of minimizing delays, information about the research protocol should be imparted through a process that ensures equitable, effective, and efficient placement and transplantation.

#### **RECOMMENDATION 5: ESTABLISH CENTRALIZED MANAGEMENT AND OVERSIGHT OF ORGAN DONOR INTERVENTION RESEARCH IN ORDER TO ENSURE EQUITABLE, TRANSPARENT, AND HIGH-QUALITY RESEARCH**

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.

#### **RECOMMENDATION 6: PROMOTE TRANSPARENCY REGARDING ORGAN DONOR INTERVENTION RESEARCH AND ENABLE THE IMPLEMENTATION, TRACKING, AND ANALYSIS OF ORGAN DONOR INTERVENTION RESEARCH TO IMPROVE TRANSPLANTATION OUTCOMES**

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. These tools could use or link to new or current relevant databases but should, at the minimum, provide the following functions:

- 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.

**TO DOWNLOAD THE FULL REPORT AND TO FIND ADDITIONAL RESOURCES, VISIT  
[WWW.NATIONALACADEMIES.ORG/ORGANDONORRESEARCH](http://WWW.NATIONALACADEMIES.ORG/ORGANDONORRESEARCH)**