

**OPTN Ethics Committee  
Meeting Minutes  
December 19, 2019  
Teleconference**

**Elisa Gordon, PhD, MPH, Chair  
Keren Ladin, PhD, Vice Chair**

## **Introduction**

The OPTN Ethics Committee met via Citrix GoToMeeting teleconference on December 19, 2019 to discuss the following agenda items:

1. Update: Social Media Project
2. General Considerations in Assessment for Transplant Candidacy (CAT) Rewrite Project Update
3. Pediatric Committee Project Collaboration Update
4. New Project Idea: Building Trust in Vaccines (Vaccinated and Non-Vaccinated Transplant Recipients)
5. Donate Life America: Living Donor Registry Initiative

The following is a summary of the OPTN Ethics Committee's discussions.

### **1. Update: Social Media Project**

The Committee was updated on the Living Donor Committee's Social Media (SoMe) Project.

#### Summary of discussion:

The Living Donor Committee's Social Media guidance document will be available for review and coming during Winter 2020 public comment cycle. The Ethics Committee was well reflected in the final overall project. There were a number of sections that were highlighted and there is a section on ethical concerns for social media solicitation that is included in the document as well.

The Ethics Committee will be able to review and provide feedback on the document during Public Comment.

#### Next steps:

- The SoMe document will be finalized and available for review during Public Comment. The Ethics Committee will be able to review and provide feedback on the document at that time.

### **2. General Considerations in Assessment for Transplant Candidacy (CAT) Rewrite Project Update**

The Committee Vice Chair provided members with an update on the Committee's CAT Rewrite project.

#### Summary of discussion:

The CAT Rewrite Subcommittee held their first meeting on December 18<sup>th</sup>, where they reviewed the current CAT document, and discussed the opportunities and potential new criteria that could be included in the revision of the document. There were some new criteria ideas that were suggested which will be reviewed in further detail during the next meeting.

Next steps:

The CAT Rewrite Subcommittee will hold their next meeting on Wednesday, January 15, 2020.

**3. Pediatric Committee Project Collaboration Update**

The Committee received an update on a proposed project collaboration with the OPTN Pediatric Committee.

Summary of discussion:

The Pediatric Committee is proposing a project to collaborate with the Ethics Committee that would include a gap analysis of the current allocation policies. This would entail an examination of each organ-specific allocation policy by revisiting the Ethical Principles, and identifying any gaps that may be present in regards to addressing pediatric priority.

Currently, the OPTN Pediatric Committee Leadership is drafting an outline of the project. Additional information will be provided once this has been completed.

Next steps:

The Ethics Committee will be kept updated as the outline of this project develops.

**4. New Project Idea: Vaccination White Paper**

The Committee Chair provided an overview of a new project idea.

Summary of discussion:

The Committee Chair provided members with background information on a new project idea regarding the potential development of a white paper to educate transplant programs and the community about ethical implications of vaccinated and non-vaccinated transplant candidates and recipients. It was clarified that this document would be more education oriented and not mandating practice.

The Committee Chair added that from previous discussions with colleagues, there have been interest in this topic and engagement with this project effort from other OPTN Committees.

The next step would be to form a small group to develop a project outline and overall goals of the project

Next steps:

A small group of Committee members will be formed to develop a project outline and overall goals of project.

**5. Donate Life America: Living Donor Registry Initiative**

Representatives from Donate Life America provided Committee members with an overview of their National Donate Life Living Donor Registry and Testing Kit.

Summary of discussion:

The goal of the Donate Life America initiative is to increase living donation by routinely introducing the opportunity to be a living donor to people registering to be an organ donor. The process begins with individuals registering to be an organ donor through the National Donate Life Registry (NDLR). After registering, these individuals will be exposed to the opportunity to consider becoming a living donor.

A member asked who would have access to the information that is being registered. A Donate Life America representative clarified that individuals who work with organ donation programs, are credentialed and have approval to get into the system would be able to access the information. The information would be stored on the same platform that is currently being used and will be housed on the same platform as the organ donor registry. The altruistic living donor would direct their information by self-selecting a transplant programs they are interested in working with.

The member continued by asking if an OPO or transplant program would still have the ability to look for a good human leukocyte antigen (HLA) match and ABO match without the donor's consent? The Donate Life America representative explained that uploading the living donor's lab analysis information would complete the process. They will have a menu they can select to whom they are choosing to release their information. This system is not intended to make matches.

Another member asked if the potential living donors would be required to fill the date of birth of the intended recipient field. The Donate Life representative stated that the granularity of this topic was not discussed but that this feedback would be taken into consideration for further discussion.

A member asked that in regards to the health screening questions, why are they being asked in the manner it is being proposed (with no medical values being made available). The Donate Life America representative clarified that while these are comorbidities that may be deal breakers for some transplant centers, Donate Life America was attempting to provide a filter on the front end that would allow transplant programs to define their evaluation of potential candidates.

The member suggested having a quiz with points involved where patient would report their points for a better way to have transplant programs to evaluate this information rather than have individuals report.

The Committee Chair asked how this initiative is reconciling the different perspectives of living donation. The Donate Life America representative clarified that this initiative is not a resource. Donate Life America is an advocacy group that explicitly promotes organ donation and that the OPTN only serves as an advisory role in this initiative.

The Committee Chair continued that from the Human Resources and Services Administration's (HRSA) point of view, there would be a concern about promoting. Given that OPTN is on advisory board, would there still be a concern about this from HRSA's point of view?

The Donate Life America representative stated that this concern has not been raised before. The objective of this initiative would be to introduce living donation and then there would be links that provides basic information. The potential donor would have already registered to be an organ donor before the kit is introduced to them. Most of the questions related to regulatory concerns have been around consent. This comment would be sent to the Workgroup for further consideration.

The Committee Chair then asked how the public would be made aware of living donation in a way that is effective. The Donate Life America representative clarified that this system will not replace the requirements for informed consent, which is required for all organ transplant programs in the country. The facts and risk that would be shared with individuals will be basic facts that include typical recovery time, insurance and expected costs, short-term and long-term health risks, and possible links to more detailed information that is available. At the point a potential altruistic living donor selects and has been moved to a transplant center, the rigor of informed consent would be performed there.

The Committee Chair asked how Donate Life America would inform the public about this option. The Donate Life America representative stated that this option would be available to individuals who taken upon themselves to do more than register their interest in being a donor at the Department of Motor

Vehicles (DMV). The individuals would have to get online and register to being a deceased donor. This is not a broad solicitation, but instead this initiative is building on a registry where individuals have already taken a step in registering as a donor. There is no current plan for a campaign of this initiative

The Committee Chair suggested that it would help to see how the concept of living donation is introduced to those who have registered to being a deceased donor. The Committee Chair then asked how a transplant center is selected that would ultimately perform the living donor evaluation. The Donate Life America representative stated that after the individual returns their donor kit, the donor would be able to geoselect a radius of how far they would be willing to travel. They would then be provided a drop down menu of transplant centers that they could select.

A HRSA representative asked for clarification that there is no coercion of these individuals to be a part of this process. The Donate Life America representative stated that there is no coercion within this process and that there are certain steps that an individual would have to take prior to speaking to a transplant program.

The Committee Vice Chair asked that when individuals provide their information into the system, do they know where this information would be sent? Do they consent for the transmission for the information? The Donate Life America representative clarified that the potential altruistic donors would have to take the action of activating their donor registration. The donor would select the transplant center who they would like to send their information to and the transplant program will follow up with the donor according to their processes.

There were no additional comments or questions. The Donate Life America representatives will take back the feedback they received to their workgroup and will follow up with an update for the Ethics Committee during an upcoming full committee meeting.

#### Next steps:

The Committee members were encouraged to send any additional feedback or questions which will be taken into consideration to the Workgroup for further review and discussion.

An update on the Donate Life America initiative will be provided during an upcoming meeting as the project develops.

The meeting was adjourned.

#### **Upcoming Meeting**

- January 16, 2020