

**OPTN/UNOS Living Donor Committee
Meeting Minutes
January 11, 2017
Web Conference**

**Krista Lentine, MD, PhD, Chair
Randolph Schaffer, MD, Vice Chair**

Introduction

The Living Donor Committee (the Committee) met by web conference on 1/11/2017 and discussed the following agenda items:

1. Living Donor Collective Update
2. Removing Disincentives for Candidates to Consider Living Donation
3. Current Projects
4. Potential New Projects
 - Plain language version of the informed consent policies
 - Add warning regarding aborted procedures – must be reported in Tiedi and PSS
 - Templates for Informed consent policies

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

Living Donor Collective Update

Cindy Henrich with the Scientific Registry of Transplant Recipients (SRTR) provided an overview of the Living Donor Collective. The Collective is a HRSA funded project to obtain long-term data on living donors and the SRTR will be seeking feedback from the Committee as the pilot project moves forward.

She provided a list of the 10 living donor programs that will participate in the pilot, recent achievements and future steps for the pilot program. Public comment on the pilot program is in progress. Training for the pilot programs should occur in September and the pilot programs should begin collecting donor information in October.

The pilot project will include the formation of a committee of living organ donors. This will be a prospective study and will include any potential living donor who presents at one of the pilot program sites for evaluation. Following potential donors who ultimately do not donate an organ may provide valuable information.

The SRTR will provide another update during the March 27, 2017 in-person meeting.

Removing Disincentives for Candidates to Consider Living Donation

The Committee discussed the status of this project. The Committee previously opined that the professional resource is an appendix and should not be considered a white paper or guidance document and consequently the project should not require public comment. If this project does not require public comment, the timeline for this projects is less complicated. The project could

go the Executive Committee of the Board or to the full Board based whenever the committee has completed work on this project.

The Committee is planning to complete work on this project by the end of February so it can be sent to other committees for consideration at their spring meetings.

Lead author will provide an updated draft early next week.

Lay Person Language Version of the Informed Consent Policies and Templates

A lay person version of the informed consent requirements would be an educational initiative and consequently will not require Policy Oversight Committee approval.

During public comment on the Committee's proposal to update the living donor informed consent requirement, the Committee heard feedback on the complexity of the informed consent requirements including that the informed consent requirements may be difficult to understand for potential living donors. In response, the Committee plans to develop a "lay person" language version of the informed consent policy requirements. As currently envisioned, this would be a print on demand resource composed at an appropriate reading level which hospitals could choose to use on a voluntary basis. The Committee would assume responsibility for developing the resource and keeping the resource up-to-date to reflect any future policy changes. Additionally, the Committee would want to provide a Spanish version of the resource.

Also during public comment, the Committee received requests for a template for the informed consent policy requirements to assist members with policy compliance. Historically, templates for the informed consent requirements had been provided through the OPTN website. The Committee discussed that some hospitals might assume they are meeting all policy requirements if they use the template. If templates are provided, it will need to include a disclosure stating that using the template does not guarantee policy compliance. For example, a hospital might not be using the most up-to-date version of the template and consequently miss a new informed consent requirement.

A member commented that developing a template would not require a lot of effort, and a member suggested that it should be easier to use a bulleted list of requirements rather than long sections of policy language.

The Committee liaison will begin work on this project and prepare a draft for the Committee to review during the next meeting.

Add Warning Regarding Aborted Procedures in Tiedi and the PSS

During a previous meeting, some members commented that they did not understand why living donor aborted procedures must be reported through both Tiedi and the Patient Safety System. Members asked for instructions or warnings to be added to both systems to instruct the user that aborted procedures must be reported in both systems. UNOS IT is working on this problem.

New Tools to Assist Hospitals with Living Donor Follow-up

This project will be assumed by UNOS Research. Committee members will be involved in an advisory role.

UNOS Research is developing new tools to assist hospitals with living donor follow-up. The current plan would involve developing new Tableau reports for transplant centers to help the centers better understand their follow-up data and understand why some of their follow-up data might not contribute to the minimum required threshold for donor follow-up.

The Committee requested a progress to date report at the March 27, 2017 meeting.

Potential New Project

The Committee proposed previous projects that were put on hold in response to the new strategic plan which should be reconsidered. Committee leadership will review this list of projects for future discussion.

One of these projects is entitled Proposal to Require the Recipient Centers to Report the Status of Living Donor Transplants. This was a project suggested by the Membership and Professional Standards Committee (MPSC). The MPSC asked the Committee to consider if the transplant recipient's center should be required to report the outcome of a planned living donor organ transplant within some specific period of time. Historically, the Committee did not support amending existing policy which requires the living donor recovery center to report living donor adverse events. A committee member requested investigating if there have been any recent incidents when a living donor adverse event was not reported within timeline required in current policy.

A member suggested resuming work on the a proposed project entitled Guidance on the Use of Social Media by Transplant Candidates, Potential Donors and Transplant Hospitals. The project could be revised to focus on using social media safely rather than using social media to increase the number of transplants.

The Committee previously considered a project to improve the categorization of living donor adverse events. Aborted procedures would be better categorized as "unanticipated" rather than adverse events.

A member suggested investigating the promotion of software (e.g. Breeze) for the evaluation of potential living donors.

Members supported plans for a "brainstorming" session at the upcoming in-person meeting to identify potential new projects.

Miscellaneous

A member questioned if a micro albumin level is an acceptable response for the urine protein question on the living donor follow-up (LDF) form. The micro albumin level is now the preferred test at many hospitals. At this point, the micro albumin level cannot be reported on the current LDF (form) and the LDF form is an OMB which requires government approval to change.

A member requested an update on the white house initiative project to house living donor resources on the UNOS website.

Upcoming In-Person Meeting

Members favor having the Sunday evening group dinner in a private room.

Upcoming Meetings

- February 8, 2017

The meeting was adjourned.