

**OPTN/UNOS Living Donor Committee
Meeting Minutes
December 14, 2016
Web Conference**

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Introduction

The Living Donor Committee met by web conference on 12/14/2016 and discussed the following agenda items:

1. Infectious Disease Verification Proposal
2. Modifications to Informed Consent Requirements for Potential Living Donor Proposal
3. Removing Disincentives for Candidates to Consider Living Donation
4. Potential New Projects
 - Plain language version of the informed consent policies
 - New Tools to Assist Hospitals with Living Donor Follow-up
 - Consider modifications to Policy 18
Make Micro albumin acceptable response for urine protein question
 - Add warning regarding aborted procedures – must be reported in Tiedi and PSS
 - Templates for Informed consent policies
 - Updates to the living donor brochure

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

Infectious Disease Verification Proposal

A representative from the Operations and Safety Committee (OSC) provided an overview of a policy proposal they are preparing for spring 2017 public comment.

Under the proposal infectious disease testing requirements would be based on a center's protocols. In the proposal, timing for verification would not be prescriptive and it would not specify which staff need to be involved.

Several coordinators spoke in support of the proposal and commented that their hospitals already meet all the proposed requirements and opined that the proposal would just formalize existing process.

A member questioned if living donor infectious disease transmissions have occurred? The OSC representative responded that there have been positive living donor results that were not acted upon prior to transplant of the organ. The goal of the proposal is for the recipient's hospital to receive specific communication to prevent unintended disease transmissions. As proposed documentation of such communication would be recorded in the donor chart.

A member asked if the proposed requirements would mimic the ABO verification process. It would be similar but would not need to occur in the operating room just prior to transplant. A

member suggested that the proposal include the development of a template or checklist to assist members with policy compliance.

Modifications to Informed Consent Requirements for Potential Living Donor Proposal

After a lengthy discussion, the OPTN/UNOS Board amended this policy proposal to remove the proposed requirement for hospitals to disclose their living donor follow-up rates. The proposal was approved with a close split vote. A member questioned if there is an analysis revealing how members voted. That information may be available but it would not be appropriate to reveal how individual Board members voted on this proposal.

Removing Disincentives for Candidates to Consider Living Donation

The Committee discussed the status of this project. The Committee recently decided to delay this project one public comment cycle to allow more time for feedback from subject matter experts and review by health literacy groups. UNOS Communications recently provided draft formatting, artwork and branding for this resource.

A member questioned why this resource should require public comment. As this project will result in an educational resource for transplant candidates with a transplant professional component which will be an appendix of available resources. The Committee opined that the professional resource should not be considered a white paper or guidance document and consequently the project should not require public comment. The project form will be updated accordingly.

Lay Person Language Version of the Informed Consent Policies and Templates

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 proposed developing 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 supported developing and maintaining a new template.

Consider Modifications to Policy 18

The Committee has had an ongoing discussion regarding a review and possible proposed modification of living donor follow-up reporting requirements in Policy 18 (Data Submission Requirements). At this time, the Committee is not in favor of considering changes to Policy 18, and prefers to wait until it receives additional information on the status of living donor follow-up from the Membership and Professional Standard Committee. Committee members requested an update from the MPSC regarding donor follow-up at its next in-person meeting (March 27, 2017).

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. This issue has been discussed with UNOS IT.

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.

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.

Committee members were encouraged to propose new Goal 3 projects.

Upcoming Meetings

- January 11, 2017
- February 8, 2017

The meeting was adjourned.