Introduction

The OPTN Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 04/13/2022 to discuss the following agenda items:

1. Modify Living Donor Exclusion Criteria

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

1. Modify Living Donor Exclusion Criteria

The Committee reviewed post-public comment changes to their Modify Living Donor Exclusion Criteria proposal.

Summary of discussion:

*Exclusion criterion: Active malignancy, or incompletely treated malignancy*

The Committee supported the language “Active or incompletely treated malignancy that either

- requires treatment other than surveillance or
- has more than minimal known risk of transmission”

It was noted that the new format of the exclusion criterion helps make it clear that treatment and risk of transmission relate to both active malignancies and incompletely treated malignancies.

The Committee supported the rationale given during the April 4, 2022 meeting for the post-public comment changes.

*Exclusion criterion: High suspicion of donor coercion*

The Committee discussed the term “inducement” and whether it should be further defined. The Chair stated that due to the language of “high suspicion”, the ultimate judgement for what may have improperly induced a donor is the transplant program's responsibility. Another member stated that the intent of the language is easily understood. The member stated that the language of modified exclusion criterion is adequate and sufficient, and believes that it will not be misinterpreted. The Vice Chair agreed. The Vice Chair reminded the Committee that the original reason for the proposed modifications to this exclusion criterion was to align language in OPTN living donor policy.

The Committee supported the language “High suspicion of donor inducement, coercion, or other undue pressure”. The Committee supported the additional rationale given during the April 4, 2022 meeting to make no post-public comment changes.

*Exclusion criterion: High suspicion of illegal financial exchange between donor and recipient*
The Committee supported the language “High suspicion of knowingly and unlawfully acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ”

The Committee supported the rationale given during the April 4, 2022 meeting for the post-public comment changes.

Exclusion criterion: Diabetes

The Committee discussed adding language into the type 2 diabetes exclusion criterion to clarify that the unacceptable lifetime risk is determined by the transplant program. It was noted that the exclusion criterion specifies an individualized assessment is required to determine lifetime risk of complications. Therefore, it is connected that the transplant program is the one performing that assessment and determining unacceptable risk. Additionally, Table 14-10 in OPTN Policy 14.4.E. Living Donor Exclusion Criteria states that “kidney recovery hospitals must exclude all donors who meet any of the following additional criteria”, which also references transplant programs as the determining entity.

The Committee supported the language “Type 1 diabetes”; and “Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals either

- evidence of end organ damage or
- unacceptable lifetime risk of complications”

It was noted that the new format of the exclusion criterion helps add clarity.

The Committee supported the additional rationale given during the April 4, 2022 meeting for the post-public comment changes.

VOTE

Does the OPTN Living Donor Committee support sending the proposed language to the OPTN Board of Directors at their June 27, 2022 meeting?

The Committee unanimously supported to sending the proposed policy language to the OPTN Board of Directors for consideration during its June 27, 2022 meeting.

Upcoming Meetings

- May 18, 2022 (teleconference)
Attendance

- **Committee Members**
  - Aneesha Shetty
  - Angie Nishio Lucar
  - Camille Rockett
  - Doug Penrod
  - Erik Lum
  - Heather Hunt
  - Henkie Tan
  - Katey Hellickson
  - Mark Payson
  - Mary Beth Stephens
  - Nahel Elias
  - Roberto Hernandez-Alejandro
  - Stevan Gonzalez
  - Tyler Baldes
  - Vineeta Kumar

- **SRTR Staff**
  - Bert Kasiske
  - Krista Lentine

- **UNOS Staff**
  - Lauren Motley
  - Lindsay Larkin
  - Meghan McDermott
  - Tina Rhoades

- **Other Attendees**
  - Brad Kornfeld
  - Nancy Marlin