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

1. Welcome, Announcements, and Introductions
2. OPTN Policy Oversight Committee Update
3. Modify Living Donor Exclusion Criteria
4. Research Orientation
5. Living Donor Data Collection

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

1. Welcome, Announcements and Introductions
The Committee offered introductions.

2. OPTN Policy Oversight Committee Update
The Vice Chair updated the Committee on the ongoing work of the OPTN Policy Oversight Committee (POC).

Summary of discussion:
The Chair asked if limited information technology (IT) capacity are related to broader IT challenges, such as cybersecurity challenges. Staff responded that the limited IT capacity is more related to committee work developing larger, more complex projects.

There were no additional comments or questions.

3. Modify Living Donor Exclusion Criteria
Summary of discussion:
Exclusion criterion: Active malignancy, or incompletely treated malignancy
The Committee discussed public comment feedback that suggested specifying “known” risk of transmission.

The Vice Chair supported adding “known” risk of transmission into the proposed modifications. The Vice Chair explained it is reasonable to assess risk of transmission, and for transplant programs to consider what is known about risk of transmission. Another member also offered support and stated that the addition of the word “known” reinforces the concept that transplant programs need to be aware of what is currently known regarding assessment of transmission risk. Other members supported the addition of the word “known” in relation to risk of transmission.
The Committee discussed feedback regarding the addition of potential malignancy transmission in transplant recipient informed consent processes.

The Vice Chair cautioned the addition of potential malignancy transmission in transplant recipient informed consent processes due to living donor confidentiality concerns. Another member agreed and stated that prescribing how transplant programs should perform informed consent processes does not fall under the purview of this Committee’s specific project. The member added that should a transplant program choose to expand their living donor evaluation and acceptance practices based on the proposed modifications, it would be in the transplant program’s discretion on how to adopt any changes to their informed consent processes.

A member stated some feedback highlighted the need for more detailed requirements related to malignancy workups and evaluations. The member stated that current OPTN living donor policy has broad requirements for cancer screening, which leaves transplant programs more autonomy.

*Exclusion criterion: High suspicion of donor coercion*

The Committee discussed public comment feedback which suggested rephrasing the criterion to state “undue donor inducement”.

A member stated the rephrasing would suggest the potential for “due donor inducement”, to which the member does not agree. The member supported the language as submitted for public comment. Another member agreed. The member stated that “undue” means inappropriate or unwarranted and in the context of living donation there is no appropriate inducement or coercion. Other members agreed.

A member reminded the Committee that the original reason for the proposed modification was to align language to other areas of OPTN living donor policy. Members agreed to support the original intent of the modification.

The Vice Chair stated that public comment feedback cited that every donor is induced to donate, and there is acceptable inducement; however undue inducement is not allowable or appropriate. A member suggested removing the word “inducement” from the criterion.

The Chair stated that policy should signal the donor’s capability to make the right decision while emphasizing the protection from external inducement, external coercion, and other pressure. The Chair stated that the proposed language accomplishes that. Another member suggested including the word “external” to specify type of inducement. A member disagreed and stated that the addition of the word “external” may not add any benefit.

One member supported the suggested rephrasing. The member explained that “inducement” means something that persuades or influences someone to do something. The member stated that donors are induced to some degree, so specifying “undue inducement” may be a worthwhile clarification.

*Exclusion criterion: High suspicion of illegal financial exchange between donor and recipient*

The Committee discussed public comment feedback that suggested clarifying “anything of value”.

A member stated that the suggestion to add a sentence, “Reimbursement of living donor out-of-pocket expenses by recipients is allowable as stated in the Organ Donation and Recovery Improvement Act of 2004” would narrow the scope to only financial expenses covered by the recipient. The member suggested specifying “illegal” exchanges within the criterion as those are the instances in which an individual should be excluded from proceeding as a living organ donor. Other members agreed. A member stated that a kidney paired donation (KPD) transaction is a legal transaction, therefor including the term “illegal” or “unlawful” will provide needed clarity.
Another member questioned how “exchange” is defined. The member stated that they do not consider reimbursement to be an exchange. A member agreed and stated that including “illegal” or “unlawful” will clear any confusion. Another member stated that adding in caveats to defining what a legal transaction may be limiting and will require the criterion to continually be updated due to potential future changes in organ donation.

**Exclusion criterion: Diabetes**

The Committee discussed public comment feedback regarding including language related to age. A member opposed including an age threshold in policy as it is too prescriptive. The member suggested specifying that the lifetime risk should be “unacceptable”. The member explained this clarification will help address age within the criterion without having to specify an age threshold. Other members agreed.

The Committee considered specifying who the risk is unacceptable for. A member stated that it should not be stated as “lifetime risk unacceptable to the potential donor” because potential donors may have a skewed perception of what they deem acceptable. The Committee agreed to leave the determination of what is unacceptable up to individual transplant programs, and not prescribe a definition.

The Committee discussed public comment feedback that suggested to define diabetes, or modify language, to state type of diabetes management. A member disagreed with defining type 1 and type 2 diabetes within the policy. The member explained that further definition will take away transplant program autonomy and the intent of the modifications is to allow individualized decision making. Another member agreed. The member also opposed rephrasing the criteria to state “insulin dependence” and “non-insulin dependence”. The member stated that the proposal is to modify exclusion criteria, not define inclusion criteria.

A member stated that one advantage of rephrasing the criteria based on insulin dependence is it may translate across any future changes in diabetes definitions. Another member responded that it may be difficult to define the exclusion criteria based on treatment type due to individual changes with diabetes management. The member added that the policy language should balance living donor safety and transplant program autonomy. A member agreed and emphasized that the policy is directed towards excluding individuals, and should refrain from adding any further qualifiers or descriptors.

4. **Research Orientation**

The Committee received an orientation on the UNOS Research Department’s structure and processes.

**Summary of discussion:**

There were no comments or questions.

5. **Living Donor Data Collection**

The Committee reviewed a project plan and discussed living donor data collection.

**Summary of discussion:**

SRTR staff reminded the Committee that the Living Donor Collective is a HRSA sponsored effort that is seeking to create a lifetime living donor registry. SRTR staff explained that this effort seeks to register all candidates who are evaluated at a participating transplant program. SRTR staff added that the SRTR is who performs the long-term follow up, not transplant programs.

The Chair suggested that the report to the OPTN Board of Directors should include a holistic timeline and detailed steps that result in project completion regarding the entire objective of long-term data
collection on living organ donors. Additionally, the Chair suggested that the report include a fiscal note to identify the cost to the system. The Chair explained that considering fiscal challenges is necessary to include from the beginning.

The Vice Chair asked whether the Committee should discuss ease of transmission of data, such as application programming interface (API), to include in this project. UNOS staff responded that the Committee is able to discuss and make it a recommendation.

The Chair requested that the Committee review the Norwood Report to understand the questions that HRSA seeks to answer regarding long-term living donor outcomes. Additionally, the Chair expressed interest in the legislative history behind the section of code directing HRSA to report on long-term outcomes of living organ donors. HRSA staff responded they will find out whether the report is publicly available.

SRTR staff asked whether the review of living donor data collection is confined to current timeframes established in OPTN policy. UNOS staff responded that the Committee is able to provide recommendations to for any timeframe of data collection.

A member asked whether the Committee should further define the purpose of the data collection review prior to individually reviewing data elements. The member explained that data element review will depend on the types of outcomes the Committee seeks to understand.

SRTR staff stated it would be beneficial to harmonize baseline data collection between the Living Donor Collective and OPTN data collection. SRTR staff asked if the review of data elements will include review of the data elements within the Living Donor Collective. UNOS staff responded that ultimately this project is an OPTN effort, but will work to ensure that communication and collaboration with SRTR is ongoing. The Chair recommended for SRTR to continue to provide input on the project in order for a holistic data review.

The Chair requested information on previous efforts to expand long-term living donor data collection. It was noted that previous efforts were contentious given that it is an unfunded mandate. HRSA staff added that the Committee had previously advocated for five or ten year follow up of living donors but received pushback from the transplant community, so two-year timeframe for follow up was the compromise. Pushback from the transplant community was related to financial and staffing concerns.

A member emphasized that long-term data collection on living donors needs to be accomplished, whether or not the broader transplant community supports. Another member agreed.

A member suggested that the report to the OPTN Board of Directors includes a recommendation that long-term follow up of living donors needs to be a funded mandate. UNOS staff responded that CMS decides reimbursement practices, and a report from an OPTN Committee to the OPTN Board of Directors is unable to make those types of recommendations. SRTR staff stated that the Living Donor Collective is funded by HRSA but participation is voluntary and they are seeking to increase that. SRTR staff wondered whether registering living donors could be categorized as organ acquisition on cost reports.

SRTR staff asked when professional societies should be engaged in this project. UNOS staff responded that the Committee can strategize to determine the best time period at which to involve stakeholder organizations. The Chair recommended to include the stakeholder organizations as early as possible.

The Committee reviewed the Data Element Standard of Review Checklist.

Next steps:
The Committee will continue discussing living donor data collection.

Upcoming Meetings

- April 13, 2022 (teleconference)
- May 18, 2022 (teleconference)
Attendance

- **Committee Members**
  - Aneesha Shetty
  - Angie Nishio Lucar
  - Heather Hunt
  - Henkie Tan
  - Katey Hellickson
  - Mark Payson
  - Mary Beth Stephens
  - Nahel Elias
  - Stevan Gonzalez
  - Tyler Baldes
  - Vineeta Kumar
  - Yee Lee Cheah

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

- **HRSA Staff**
  - Adriana Martinez
  - Arjun Naik
  - Raelene Skerda
  - Vanessa Arriola

- **UNOS Staff**
  - Cole Fox
  - Jennifer Wainright
  - Kim Uccellini
  - Lindsay Larkin
  - Meghan McDermott
  - Samantha Weiss
  - Tina Rhoades

- **Other Attendees**
  - Brad Kornfeld