Introduction
The Ethics Committee met via Citrix GoToMeeting teleconference on 09/17/2020 to discuss the following agenda items:

1. Review CAT Rewrite
2. Presentation: Modify Living Donation Policy to Include Living VCA Donors
3. Presentation: Modify Data Collection on Living VCA Donors
4. Presentation: Continuous Distribution

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

1. Review CAT Rewrite
   The Committee reviewed and discussed a draft version of the white paper *General Considerations in Assessment for Transplant Candidacy* (CAT).

   **Summary of discussion:**
   UNOS staff reviewed the proposed timeline for the CAT project. The Committee will vote to send the white paper to public comment at the October 7th virtual in-person meeting. This is dependent on if Committee is in agreement that it is ready to be voted on.

   The CAT will then be submitted to the Policy Oversight Committee (POC) and the Executive Committee (ExComm) for review and approval before moving to public comment during the January 21st- March 23rd, 2021 cycle. It is intended that the proposal will be reviewed for approval by the Board of Directors (BOD) at the June 14, 2021 BOD meeting.

   The “Final Rule Analysis” section is currently being developed by an internal UNOS team.

   Additional work needs to be done to strengthen the ethical analysis components of the white paper in its current state.

   The Chair provided background that this project is a revision of an existing white paper written by the Ethics Committee. The approach taken by the CAT Subcommittee was to evaluate the criteria listed in the original white paper, expand to include criteria that are being discussed by transplant community, and develop a brief analysis outlining ethical principles as they pertain to these criteria.

   The Committee reviewed the “Preamble” section of the CAT draft.
**Preamble**

An ex officio member commented that the term “candidate” should only refer to those listed on the waiting list. To be consistent in terminology, the Committee chose to use the term “potential transplant candidate” when referring to individuals who are being considered for listing.

A member suggested including the term “psychosocial aspects” when describing non-medical criteria and this term is commonly used in the field. The Committee agreed to include this language.

UNOS staff suggested referencing the previous version of the document. Previous versions of OPTN documents are retained and would continue to be accessible.

The Vice Chair suggested adding a sentence to clarify the use of the term “individual.”

An ex officio member shared they were on the Ethics Committee between 2007-2010 when the original white paper was written. The current version is enhanced. They agreed that the use of the word “individual” is confusing because it conflicts with the goal to make sure all patients are treated the same. They recommended explicitly defining “individual” as well as the intent behind using this term.

A member suggested rewording the sentence in a way that reads that the criteria outlined need to be applied to each individual to avoid needing an entire paragraph. The Chair commented that while concerned with inconsistent or opaque decision making, the Committee wants to preserve the ability for patients to be treated as individuals. This sentiment will be included in the white paper.

A member questioned why the Committee is so focused on the individual especially when it comes to health behaviors since these can often be institutionally biased and not due to the direct action of the individual. Zip code can be just as impactful to your health care as your choices. The environment and community one is exposed to is as important.

The Chair referenced the “Potentially Injurious Behaviors” section. These factors that can be contributed to individuals may be beyond their control. The purpose is to provide ethical analysis of the use of these criteria as they are applied at an individual level since each patient is evaluated as an individual.

The member agreed that this sentiment is covered in the “Potentially Injurious Behaviors” section but requested that it is also be included in the “Preamble.”

The Committee decided to change the language in the second paragraph of the “Preamble” to “Importantly, these factors should be consistently applied to all potential transplant candidates while ensuring the evaluation process is transparent, evidence-based (where available), and revisable.” The intent is to reword the statement to emphasize the need for consistent application versus emphasizing the individual. Members agreed to this edit.

A member commented that although psychosocial support is included as a Centers for Medicare and Medicaid Services (CMS) requirement in evaluating candidates, there is no requirement for the weight this assessment has in the decision to list.

**Next steps:**

The Committee was asked to send comments and references to strengthen the document to UNOS staff and Ethics leadership.

2. **Presentation: Modify Living Donation Policy to Include Living VCA Donors**

Heather Hunt, Chair of the OPTN Living Donor Committee presented on the Modify Living Donation Policy to Include Living VCA Donors proposal currently out for public comment.

**Summary of discussion:**
There was representation from the Ethics Committee in the development of this proposal. The purpose of this proposal is to expand the current living donor policy to include vascular composite allograft (VCA) donors in order to establish safeguards for VCA donors and create living donor compliance standards for VCA programs.

This proposal requests that VCA specific data elements are added to informed consent requirements and medical evaluation requirements. There are no changes to the general living donor requirements.

VCA living donor, specifically uterus, is rising in the US with 19 living donor uterus transplants since 2016. VCA donation is unique and requires specific data elements to be added to informed consent and medical evaluation requirements. The proposed data elements were informed by member expertise, literature review, IRB protocols, and the Disease Transmission Advisory Committee (DTAC) leadership. The proposed policy is flexible enough to evolve alongside of advances in the VCA field.

Informed consent requirements distinguish between living non-genitourinary and genitourinary VCA donors. Due to the wide range of VCA donation, the consent should include considerations beyond scarring as there may be other outcomes. Additionally, psychosocial risks and financial risks are included in the consent process.

The medical evaluation requirements add toxoplasma testing to all VCA living donors. The other additions are specific to uterus donors and include gynecological and obstetric history including prior childbirth, pap smear, pelvic exam, radiological assessment to determine uterus is suitable for transplant, and transmissible disease screening. VCA specific transplant programs will need to become familiar with new requirements and incorporate the new informed consent and medical evaluation requirements into their protocols.

A member asked if there are established thresholds for when other VCA donations beyond uterus will require specific language and policy modifications i.e. after 10 transplants are performed of a specific VCA transplant. The proposal was written to be flexible enough to include other VCA transplants, but there are not established thresholds to determine when to address. UNOS staff noted that uterus transplant is the only living donor VCA transplant that has occurred under the OPTN. There are 65 approved VCA programs in the US so there is an opportunity that there will be other living donor VCA donations in the future. The VCA Chair commented that most VCA transplants are from deceased donors.

A member commented that there may be requests for penile transplants or offers to donate uteruses from members of the transgender community when seeking gender affirming surgeries.

A member suggested spelling VCA out in the proposal.

A member questioned the classification of uterus as VCA since the expertise and workflow required for uterus transplantation is very different from that of other VCA transplants. The Vice Chair noted that they support the proposal and mentioned that despite uterus not being a lifesaving organ, it is still eligible to undergo the same consent process as other living donor donations. HRSA does not include uterus in its definition of organs which is why it is categorized as VCA.

Next steps:
The Committee was asked to send any additional comments to UNOS staff.

3. Presentation: Modify Data Collection on Living VCA Donors

Dr. Bohdan Pomahac, Chair of VCA presented on the proposal Modify Data Collection on Living VCA Donors which is currently out for public comment.
Summary of discussion:

The purpose of the proposal is to improve the OPTN’s ability to monitor patient safety through data collection on VCA living donors. The data elements, informed consent requirements, and medical evaluation requirements included in the proposal align with the Living Donor policy proposal reviewed prior.

The proposal adds the VCA specific data elements to the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms. This includes policy changes to program VCA living donor data collection in UNet™.

The proposed data elements to the pre-donation LDR include toxoplasma IgG to all VCA living donors. For living uterus donors, the proposed data elements include infectious disease testing, uterine imaging, gravidity, parity, spontaneous abortion, induced abortion, and prior full term live births.

Proposed data elements for the surgical LDR for living uterus donations is similar to that of living kidney donations and include intended procedure type, conversion from robotic to open, operative time, and whether ovaries were removed. It is not recommended to remove ovaries during donation because of potential negative outcomes for the donor. Proposed data elements to all VCA living donors include intra-operative complications.

Data elements proposed to the post-operative LDR include length of stay for uterus donors and post-operative complications, reoperation, and readmission after initial discharge for all VCA donors.

On the LDF, the data elements proposed for living uterus donors are complications since uterus donation, menopausal symptoms, and new onset psychological symptoms. For other VCA donors, the data element complications since VCA donation is proposed. Menopausal symptoms are associated with negative health outcomes for living uterus donors.

Transplant hospitals will need to submit data on VCA living donors in UNet™. Histocompatibility labs will need to submit donor histocompatibility information for VCA living donors in UNet™.

A member asked the purpose of excluding donors who have had induced abortion if clinically insignificant to the reproductive function of the uterus. This data is not being used to evaluate donor eligibility but rather just to track outcomes.

A member commented that abortion and miscarriages are different as miscarriages may be the result of an underlying condition that may affect the reproductive viability of the uterus. If an abortion occurred and then the patient had pregnancies to term, this would medically indicate there was no significant impact to the uterus.

A member raised a concern about the collection of induced abortion data and associated unconscious biases relating to women who have undergone induced abortions if clinically insignificant. The data elements and how they are presented to the potential donor should not seem punitive and there should be a disclosure about why the data is being collected and whether or not it affects their eligibility to donate. The use of the term abortion could be reconsidered. Questions about abortions and miscarriages can cause secondary trauma to the patient and if deemed unnecessary, should be considered for removal.

Next steps:

The Committee was asked to send any additional comments to UNOS staff.
4. **Presentation: Continuous Distribution**

James Alcorn, UNOS Senior Policy Strategist, provided an update on the *Continuous Distribution of Organs* project sponsored by the OPTN Lung Transplantation Committee.

**Summary of discussion:**

UNOS staff gave an overview of the ethical considerations of Continuous Distribution as well as the process being used to develop a composite allocation score.

Continuous Distribution isn’t just a new way of allocating organs, it’s a different way to develop organ allocation policy. It brings together multiple methodologies. Allocation consists of both clinical and ethical considerations. Determining how important system efficiency is versus equity or medical urgency versus post-transplant outcomes can be controversial.

The first step in this project has been completing a discrete choice experiment to establish baseline scores for how much weight is being placed on distance, outcomes, medical urgency, and other allocation factors under existing policy. This baseline will be used to compare to future scoring systems. The new weights are being determined by using Analytic Hierarchy Process (AHP). This is a way of asking the community to assess and communicate priorities when allocating lungs. The Committee is invited to participate in this exercise.

The information collected from various community members will be presented to the Lung Committee. Discussion will be held to determine how these results compare to the existing policies. Even if the results are consistent across the responses received, there will be assessment to identify any bias. The Lung Committee will also compare the results with the OPTN’s legal requirements. A few different scenarios will be created and will be sent to SRTR for modeling. The results will be available online and will be put forward as a public comment proposal. Visualizations will also be created in order to better understand how allocation will be affected.

A member asked about the consensus process. The transplant community is multi-faceted, serve different populations, and are in different locations which may lend to differing values.

UNOS staff shared that ultimately the board will vote on a proposal from the Lung Committee. Demographic information, organ specialty, location, and member type will be included in cluster analyses when reviewing the results of the prioritization exercise. From the results received so far, there is a fair amount of consensus. Comments will be reviewed to determine why one group voted one way versus another. The Lung Committee will work iteratively until an agreement is reached. If an outlier member group is identified, the Committee will facilitate focus groups to learn more. The aim is to create a transparent, deliberate, and inclusive system.

**Next steps:**

The Committee was asked to send any additional comments to UNOS staff and participate in the prioritization exercise. Information will be sent via email.

**Upcoming Meeting**

Attendance

- **Committee Members**
  - Aaron Wightman
  - Amy Friedman
  - Andrew Flescher
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Elisa Gordon
  - George Bayliss
  - Giuliano Testa
  - Keren Ladin
  - Lynsey Biondi
  - Mahwish Ahmad
  - Michael Davis
  - Roshan George
  - Sanjay Kulkarni
  - Tania Lyons

- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman

- **UNOS Staff**
  - Eric Messick
  - James Alcorn
  - Kaitlin Swanner
  - Lindsay Larkin
  - Ross Walton
  - Sarah Booker
  - Sarah Konigsburg
  - Susan Tlusty

- **Other Attendees**
  - Bohdan Pomahac
  - Heather Hunt