Introduction
The Living Donor VCA Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference 05/06/2020 to discuss the following agenda items:

1. Follow-up from last meeting and Policy 14 drafting

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

1. Follow-up from last meeting and Policy 14 drafting

The Workgroup received an update regarding the question of adding parental rights language to the informed consent requirements. Since parental laws vary from state to state, it is recommended the policy only include language requiring programs to have a conversation about parental rights. It was suggested this language would be too broad and cause confusion on how to interpret the requirement. The Workgroup decided not to include this requirement.

The Workgroup then continued their discussion on whether to expand the informed consent table to cover “all reproductive organs”. The Workgroup was presented with four table options:

- Option 1: the original draft table which distinguishes between all living VCA donors, all living non-uterine VCA donors, and uterine VCA donors
- Option 2: a draft table which includes categories for all living VCA donors, all living non-reproductive organ VCA donors, and all living reproductive organ VCA donors
- Option 3: a draft table which includes categories for all living VCA donors, all living non-reproductive organ VCA donors, all living uterine organ VCA donors, and all living non-uterine reproductive organ VCA donors
- Option 4: a draft table which includes categories for all living VCA donors, all living non-genitourinary organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2: Definitions, and all living genitourinary organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2: Definitions

The Workgroup was informed the addition of “reproductive organ” terminology would require a unique definition to be added to OPTN Policy 1. It was explained Option 3 was created in response to Workgroup comments received on Option 2. However, it was felt the table was too long and that language between living uterine organ VCA donors and non-uterine reproductive organ VCA donors was similar enough it may cause confusion for programs. The Workgroup was informed Option 4 was created based on the updated definition of VCA that will soon be implemented in OPTN Policy. In the updated definition, “genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder)” is listed under body parts to be considered VCAs. Therefore, to
align with the definition in OPTN Policy, the table in Option 4 distinguishes between all living VCA donors, all living non-genitourinary organ donors according to the definition of Vascularized Composite Allograft (VCA) in *Policy 1.2: Definitions*, and all living genitourinary organ donors according to the definition of Vascularized Composite Allograft (VCA) in *Policy 1.2: Definitions*. Option 4 also consolidated the repetitive language in Option 3.

The Workgroup discussed the presented options. The Living Donor Committee Chair commented there are some elements within the reproductive organ informed requirements that would not apply to all types of reproductive organ transplant (ex. uterus vs. testicular). The Workgroup recognized that the VCA definition of genitourinary includes “urinary bladder” which may not be applicable, however they appreciated the alignment to the definition of VCA in OPTN Policy.

The Workgroup further discussed how to consolidate language in the Option 4 table while differentiating between non-genitourinary and genitourinary organ donors. The Living Donor Committee Chair stated the language shouldn’t be too broad or generic as it would be difficult to follow and enforce. To consolidate language and add more specificity, the Workgroup updated the language for psychosocial and surgical risks and narrowed the categories down to all living non-genitourinary organ donors according to the definition of Vascularized Composite Allograft (VCA) in *Policy 1.2: Definitions* and all living genitourinary organ donors according to the definition of Vascularized Composite Allograft (VCA) in *Policy 1.2: Definitions*.

**Table 14-X: Additional Requirements for the Informed Consent of Living VCA Donors**

<table>
<thead>
<tr>
<th>The recovery hospital must:</th>
<th>These additional elements as components of informed consent for living VCA donors:</th>
</tr>
</thead>
</table>
| Disclose to all living non-genitourinary VCA organ donors according to the definition of Vascularized Composite Allograft (VCA) in *Policy 1.2: Definitions* | Potential financial impacts:  
- Procedure may not be covered by health insurance |
|                            | Psychosocial risk:  
- Feelings of emotional distress or grief if the transplant recipient does not experience a successful outcome (i.e. functional, cosmetic) |
|                            | Surgical risks may be transient or permanent and include but are not limited to:  
- Loss of function  
- Physical disability  
- Physical disfigurement |
The recovery hospital must:

**Disclose to all living genitourinary VCA organ donors according to the definition of Vascularized Composite Allograft (VCA) in Policy 1.2: Definitions**

These additional elements as components of informed consent for living VCA donors:

<table>
<thead>
<tr>
<th>Potential financial impacts:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Procedure may not be covered by health insurance</td>
<td></td>
</tr>
</tbody>
</table>

Psychosocial risk:

| • Feelings of emotional distress or grief if the transplant recipient does not experience a successful outcome (i.e. functional, cosmetic, or reproductive) |  |

Surgical risks may be transient or permanent and include but are not limited to:

| • Inability to bear children (women) |  |
| • Decreased fertility (men) |  |
| • Physical disfigurement (men) |  |
| • Need for hormonal replacement therapy |  |
| • Pain or discomfort with intercourse |  |
| • Urinary tract injury or dysfunction |  |
| • Bowel injury |  |

The Workgroup then discussed the draft table for Medical Evaluation Requirements for Living VCA Donors under OPTN Policy 14.4: Medical Evaluation Requirements for Living Donors. In light of the informed consent table’s expansion to cover all reproductive organ donors, the Living Donor Committee Chair questioned if this table should be expanded as well. The Workgroup was informed the language in the table is currently aligned with language in the VCA Data Collection Workgroup’s proposed updates to the Living Donor Registration form. A Workgroup member commented the elements of this table were developed based on the data and experience of prior uterine transplants and that data and experience doesn’t exist yet for other reproductive organ types. The Workgroup will continue their discussion of the proposed table on the next call.

**Next Steps**

The Workgroup will have their final meeting on May 14 to finalize the Policy 14 draft. An updated draft will be sent to the Workgroup prior to the meeting.

**Upcoming Meeting**

- May 14 – Teleconference