December 3, 2014

Carl Berg, MD
President, Board of Directors
Organ Procurement and Transplantation Network/United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

RE: Proposal to Implement the OPTN’s Oversight of Vascularized Composite Allografts (VCAs). See: http://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf.

Dear Dr. Berg:

The National Catholic Bioethics Center wishes to respond to the call for comment concerning the Proposal to Implement the OPTN’s Oversight of Vascularized Composite Allografts (VCAs): hereafter, Proposal. As you know the Secretary of the U.S. Department of Health and Human Services has expanded the definition of human organs and added Vascularized Composite Allografts, to the covered list of human organs for transplant under the OPTN modified Final Rule. This proposal is in response to a directive from the Health Resources and Services Administration to develop VCA policies prior to implementation of the modified Final Rule which became effective July 3, 2014. These policy changes were approved by the OPTN/UNOS Board of Directors during its June 23-24, 2014 meeting, with a “sunset” date on September 1, 2015. The Board will review and consider public comments for approval during the June 1-2, 2015 meeting. We trust that our comments will be seriously considered. These transplant policies violate informed consent, donor and recipient safety, as well as human physical integrity.

The National Catholic Bioethics Center (NCBC) is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences, including biomedical research. The NCBC serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for DCD. The Center has 2500 members throughout the United States, and provides consultations to hundreds of institutions and individuals seeking its opinion on this and other matters as they pertain to the appropriate application of Catholic moral teaching.
As we have shared with you in the past, the Catholic Church encourages organ donation as providing a gift of life to those in need. In terms of both living and deceased donors, the same generosity of donors is recognized, as long as there is respect for true informed consent, donor and recipient safety, and human physical integrity. The Proposal accomplishes none of these for the living donor, and little of these for the deceased donor and the recipient. Thus, we urge rejection and reconsideration of a new proposal to address the concerns listed below.

The Proposal cites Blake, et al, in defining VCAs, which “refers to transplants composed of several different kinds of tissues (i.e., skin, muscle, bone), such as those in the hand, arm, or face, transferred from donor to recipient as a single functional unit.” While citing nine criteria for inclusion as a VCA, the Proposal specifically refers to upper and lower limbs, the abdominal wall, and the face. Additionally, the Proposal states:

Under the modified final rule, any OPTN policy that applies broadly to solid organs would apply to all body parts meeting the definition for VCAs unless otherwise specified. Therefore, other VCA procedures meeting the nine criteria to define a body part as a VCA, would also be subject to general OPTN policies.

Furthermore, the Proposal cites the inclusion of reproductive tissue, including the uterus of a living donor, as an example of a VCA transplant. Most disturbingly, the Proposal specifically cites that will living donors not be excluded, and the report of the Living Donor Committee to the Board of OPTN/UNOS states:

UNOS’ Director of Policy was asked to explain if the Final Rule envisioned living VCA donation and to comment on the OPTN’s authority under the Final Rule. He explained that based on consultation with UNOS’s legal staff, the Final Rule is not specific to deceased donation. The OPTN does not have the authority to prohibit living VCA donation, but does have the authority to make membership requirements, performance standards, and patient safety requirements regarding living VCA donation. [Emphasis added]

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2 The nine criteria for VCAs are: 1) That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation; 2) Containing multiple tissue types; 3) Recovered from a human donor as an anatomical/structural unit; 4) Transplanted into a human recipient as an anatomical/structural unit; 5) Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement); 6) For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor); 7) Not combined with another article such as a device; 8) Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and 9) Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient. Proposal, p. 6.
3 Proposal, p.7
4 Proposal, p. 12.
5 Proposal, p. 12.
6 Mary Amanda Dew, PhD, Chair, Krista Lentine, MD, PhD, Vice Chair, “OPTN/UNOS Living Donor Committee Report to the Board of Directors” (St. Louis, MO: November 13-14, 2014), Exhibit B.
How such a violation of administrative procedural fairness can occur raises significant concerns. These concerns are compounded by the fact that informed consent is not required for such donation, but only “authorization,” which previously in OPTN policy has been distinguished from, and less rigorous than, true “informed consent.”

The NCBC recognizes that those on donor organ lists must specify a willingness to be a VCA donor. However, surrogate authorization will be allowed. The fact that the Proposal states that the VCA Transplantation Committee clarified that existing donor authorization criteria are meant to be specific to deceased donors, and that the VCA Transplantation Committee expects the Committee to approve clarifying language in post-public comment, violates the entire process for seeking public comment. There are no such criteria on which to comment in the Proposal, another violation of administrative procedural fairness. Furthermore, the VCA Transplantation Committee, while recognizing the need to reinforce the concept of separate consent for VCA donors with appropriate support and educational materials, states in the Proposal that such requirements are to be “non-binding to members” [transplant hospitals].

In addition, as in all OPTN policies concerning non-discrimination against potential recipients, there are no protections to assure that persons with disability are not denied transplants based on their disability.

Lastly, the Proposal states: “A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.” The existing designated transplant programs have not included VCA’s, thus there is no assurance of the requisite skill level of personnel, as well as adequate resources, for this new type of transplantation to protect both donor and recipient. The only VCA-specific requirement is that the transplant hospital’s request to do VCA transplants be signed by a: “reconstructive surgeon with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction.” Furthermore, there will be no added new routine monitoring of OPTN members [transplant hospitals]. The proposal allows the mutilation of the human donor, yet there is no significant or stringent, monitoring — specific to VCAs — concerning implementation of this new policy.

These combined facts herald a catastrophic abuse of the historically valued and respected organ donation for transplantation social policy advanced for the public good. We

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7 ORGAN PROCUREMENT ORGANIZATION (OPO) COMMITTEE, UNITED NETWORK FOR ORGAN SHARING, PROPOSAL TO CHANGE THE TERM “CONSENT” TO “AUTHORIZATION” THROUGHOUT POLICY WHEN USED IN REFERENCE TO ORGAN DONATION (2011), http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_297.pdf [hereinafter PROPOSAL]. The NCBC recognizes that those on donor organ lists must specify a willingness to be a VCA donor. However, surrogate authorization will be allowed.

8 Proposal, p. 15.


10 Proposal, p. 18.


12 Proposal, p. 17.
urge an entire rejection of this policy and a redrafting to address the blatant violations of informed consent, donor and recipient safety, and human physical integrity, as well as the prevention of bodily mutilation to the living donor. No living donor should be included in VCA donation policies.

Sincerely yours,

[Signature]

Marie T. Hilliard, JCL, PhD., RN
Director of Bioethics and Public Policy