THE NATIONAL CATHOLIC BIOETHICS CENTER

Upholding the Dignity of the Human Person in Health Care and Biomedical Research since 1972

March 23, 2022

Jerry McCauley, M.D., M.P.H., President, Board of Directors
Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23218

RE: Public Comment Proposal: Modify Living Donor Exclusion Criteria

Dear Dr. McCauley:

Thank you for the opportunity to provide public comment on behalf of The National Catholic Bioethics Center (NCBC) and the National Catholic Partnership on Disability (NCPD) concerning the 2022 OPTN Public Comment Proposal: *Modify Living Donor Exclusion Criteria*. We wish to focus on the existing and proposed modifications to reduce barriers to living donation exclusion criteria, specifically:

> "High suspicion of donor inducement, coercion, or other undue pressure; and high suspicion of knowingly acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ;"
>
> "Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals evidence of end organ damage or lifetime risk of complications;"
>
> "Is both less than 18 years old and mentally incapable of making an informed decision;" and the decision not to exclude "actively incarcerated individuals from living donation;" and
>
> "Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality."

The 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. The Catholic Church is the largest provider of non-governmental, non-profit health care in the United States. The NCBC serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for implementing OPTN/UNOS policies on organ donation and transplantation that comply with the *Ethical and Religious Directives for Catholic Health Care Services.* [U.S. Conference of Catholic Bishops, 2018]. The NCBC has 1300 members throughout the United States and provides consultations to hundreds of institutions and individuals seeking its opinion on these and other matters as they pertain to the appropriate application of Catholic moral teaching in the delivery of health care.

The National Catholic Partnership on Disability (NCPD) is a non-profit agency that promotes the full and meaningful participation of persons with disabilities in the life of the Catholic Church. It affirms the dignity of every person, working collaboratively to ensure meaningful participation of people with disabilities in all aspects of society. As an organization NCBC advocates for policies respectful of all persons, especially those with disabilities including those with mental health diagnoses. The NCPD wishes to express its concern for any government sanctioned program that could compromise persons with disabilities, even for the laudable cause of providing organs for transplant, thus, violating society's obligation to the human person. Also, unless strict policies are implemented, living donor donation of organs or tissues can compromise existing health, creating a disability.

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. Of course, this is with the understanding that the Dead Donor Rule is rigorously respected and implemented. In terms of living donors, the same generosity of donors is recognized, if there is respect for true informed consent as well as the protection of the bodily integrity of the donor. That is why rigorous standards for psychosocial and medical evaluation must be in place and regularly monitored for compliance by OPTN. Furthermore, any protocol that provides for the creation of a disability represents an attack on the human person.

Specifically, herein, we wish to respond to your stated inquiries:

Do you agree with the living donor exclusion criteria modifications as proposed? If not, why?
Do the proposed modifications need to be more or less restrictive? If so, in what way and what are the suggested modifications?
Are there additional modifications to exclusion criteria that are needed?

We will address each proposal presented by OPTN.

1. High suspicion of donor inducement, coercion, or other undue pressure; and high suspicion of knowingly acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ: **NCBC and NCPD do not agree with these living**

donor exclusion criteria modifications as proposed and see the need for them to be more restrictive.

While NCBC and NCPD agree with the addition to the exclusion criteria of "donor inducement" and "pressure," as we have stated in the past, ***any*** suspicion of coercion should be thoroughly researched, as well as any indication of pressure, whether "undue" or not. If there is the suspicion of any coercion or pressure this should preclude donor donation until there is certainty that these factors have no influence on the donor's decision to donate. Furthermore, any indication of agreed-upon donor inducement, including knowingly acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ ***or tissue*** automatically should preclude donation. Since such inducement is illegal, any such suspicion would require a forensic investigation.

Living tissue donation often is between family members or persons known to each other (donor and recipient). Such relationships are fraught with the dangers of psychological and social pressures that can create coercion, which can range from subtle to overt. But due to the potentially mutilating nature of living donation, regardless of the relationship or absence thereof, or how safe the procedure and anticipated results are for the donor, the donor is losing a whole or part of a functioning organ or tissue. True informed consent requires that it be given freely. Donors need to be protected from the irretrievable loss that may be induced without a thorough psycho-social assessment of the reasons for the donation. Furthermore, no living donation of an organ or tissue that results in the mutilation of a healthy physiological function of the donor should be allowed, despite the presence of the informed consent of an altruistic donor. This would include the donation of a uterus. See NCBC, NCPD, et al., interagency public comment of September 29, 2021 (RE*: 2021-2024 OPTN Strategic Plan as it pertains to Public Comment: Proposal Establish Membership Requirements for Uterus Transplant Programs*). **Thus, we provided the following suggested modifications:**

> "*Any* suspicion of donor inducement, coercion, or other undue pressure *is to be thoroughly researched, including a rigorous psychosocial evaluation to assure that there exists true informed consent consistent with the best interest of the donor*;" and "*Any* suspicion of knowingly acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ *or tissue is to be thoroughly researched forensically, and if determined to be true automatically precludes donation*;" and the addition of,
>
> **"**No living donation of an organ or tissue that results in the mutilation of a healthy physiological function of the donor is allowed, despite the presence of the informed consent of an altruistic donor."

2. Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals evidence of end organ damage or lifetime risk of complications. **NCBC and NCPD do not agree with this living donor exclusion criteria modification as proposed and see the need for it be more restrictive**.

Type 2 Diabetes carries with it lifetime risks of complications regardless of demographics or comorbidities. It is difficult to predict such future complications, but the medical literature is full of the cautions requiring alterations in habits and lifestyles which can compound such risks. This is especially true for ongoing damage that can be caused by diabetes to essential organs, whether paired or not. See: Mayo Clinic, "Type 2 Diabetes," *Patient Care & Health Information: Diseases & Conditions* (Jan 20, 2021), https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193. Just as Type 1 Diabetes automatically precludes donation, so should Type 2 Diabetes. **Thus, we provided the following suggested modifications to the exclusion:**

> "Diabetes ~~- Type 1 diabetes; Type 2 diabetes where an individualized assessment of donor demographics or comorbidities reveals evidence of end organ damage or lifetime risk of complications~~."

3. "Is both less than 18 years old and mentally incapable of making an informed decision;" and the decision not to exclude "actively incarcerated individuals from living donation." **NCBC and NCPD do agree with retaining the living donor exclusion criteria for minors and those mentally incapable of making an informed decision, as stated in the Proposal but reject the consideration of modifications in the existing criteria not to exclude actively incarcerated individuals from living donation**.

A minor, the incarcerated, and by their very definition, those mentally incapable of making informed decisions, cannot give true informed consent. They cannot vote, and minors and the mentally incapable cannot even consent to have their ears pierced. For the incarcerated this clearly carries with it the potential of an inducement, such as for parole or early release for an altruistic act, which may not truly be altruistic. These provisions could be characterized as an assault and illegal. Furthermore, ensuing potential for lawsuits could be very real. Perhaps there is the potential to achieve full informed consent from an incarcerated individual for a donation to a blood relative or spouse. However, to leave such a decision to the local transplant program, in conjunction with their Ethics teams, as stated in the Proposal, is fraught with the potential for abuses. Their needs to be a well-developed proposal with detailed and explicit criteria for allowing such donations.

4. Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality.

While psychosocial and medical evaluation for all donors is needed, this is essential for living donors, especially for mutilating procedures. Of specific concern for all living donors is the need for an assessment for ***any*** evidence of a diagnosable psychiatric condition, including chronic conditions, or suicidal ideation. Such evidence should trigger a denial of donor status. Psychiatric conditions can be labile, and a decision of someone whose condition is controlled today by medication, may not represent the psychiatric status of the person in the future when they are suffering from the loss of an organ or tissue. Of significant importance is that exclusion

criteria for all living donations need to be expanded for psychiatric disorders that fall in the diagnostic categories beyond adjustment disorders, such as psychosis (regardless of whether they are "controlled"), as well as exclusion for any evidence of chronic substance abuse. It could be envisioned that surrogate decision-makers of living donors may be permitted, as they are for the deceased. This would represent a significant abuse of those with disabilities and needs to be prohibited. Furthermore, any evidence of coercion should be an automatic exclusion. **Thus, we provided the following comments and suggested modifications***:*

> We support retaining: "Living Donor Psychosocial Evaluation Requirements states that the living donor must be assessed by a psychiatrist, psychologist, or social worker whether their 'decision to donate is free of inducement, coercion, and other undue pressure;'" and recommend the following modifications for an exclusion,
>
> ~~Uncontrolled~~ Diagnosable psychiatric conditions requiring *maintenance treatment* ~~before donation~~, including any evidence of suicidality *or chronic substance abuse*.

5. Domino Donors

We remain concerned about the non-applicability of these policies to "Domino" donors. There is the enormous potential for subtle coercion that needs to be assessed. The policies we recommend herein would be protective of these potentially vulnerable donors, if these policies were applied to Domino donors.

6. Policy Evaluation

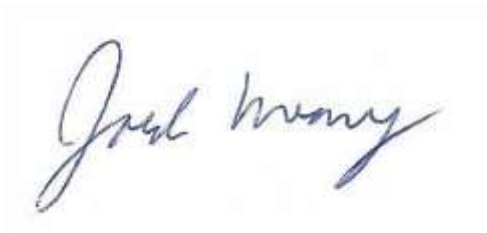
We support evaluating outcomes through monitoring reports using pre vs. post comparisons which will be presented to the Committee after approximately 6 months, 1 year, and 2 years. However, the Metrics do not address the safety concerns identified here. There is no provision for long-term follow-up of the impact on donors who are: diabetic; those with psychiatric diagnosis; the incarcerated; and the potential for donor-regret stemming from challenges in achieving true informed consent. Evaluative indices for assessing these elements long term need to be developed.

Thank you for this opportunity to provide public comment on this critical issue. We recognize the immense value of organ transplantation and the tremendous good accomplished

by OPTN/UNOS but wish to protect both donor and recipient from outcomes that may be unanticipated, despite every good intention.

If you have any questions, feel free to contact Dr. Marie T. Hilliard at 215 871-2016.

Sincerely yours,



Joseph Meaney, Ph.D.
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Michael Boyle

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