# Public Comment Proposal

OPTN
Organ Procurement & Transplantation Network

## Proposed Normothermic Regional Perfusion (NRP) Policy

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|---|---|
| **Sponsor Committee** | Board-Directed NRP Workgroup |
| **Public Comment** | November 13 – December 28, 2026 |
| **Board Approved** | November 6, 2026 |
| **Effective Date** | November 6, 2026 |

## Executive Summary

The Health Resources and Services Administration (HRSA) shared a critical comment with the Organ Procurement and Transplantation Network (OPTN) in September 2024 regarding concerns over potential restoration of blood flow to the brain in patients recovered as organ donors using normothermic regional perfusion (NRP).[1,2] As part of the response to this critical comment, the OPTN Board of Directors established the NRP Workgroup. The Workgroup includes individuals with surgical, organ procurement, patient perspective, and ethics expertise, and is dedicated to ensuring and improving patient safety and family experience for donors undergoing NRP.

This document describes the NRP Workgroup's proposed policy changes, which provide safeguards for potential NRP donors, promote clear communication with families, describe standards for safe NRP practice, and enhance reporting of adverse events during the practice of this organ recovery technique. This proposal would update OPTN policies to further define and standardize NRP practices across organ procurement organizations (OPOs). Additionally, if finalized, this proposal would require OPOs to report unplanned NRP pauses to inform future OPTN policy development and NRP oversight activities.

This document presents the motivation and authority for this proposed policy change, explains how the proposed policy would be implemented, and details how it would be incorporated into the existing OPTN policies governing organ procurement and NRP practices.

## Purpose of Policy Development

The NRP Workgroup was formed in response to concerns raised in the 2024 critical comment alleging noncompliance with OPTN Policies and OPTN Management and Membership Policies (M&M Policies) regarding deceased donor organ procurement.[2] The OPTN is tasked with adopting quality standards for acquiring donated organs and collecting data on organ donation and transplantation under section 372 of the Public Health Service Act, as added by the National Organ Transplant Act of 1984 (NOTA), Pub. L. No. 98-507, 98 Stat. 2339.[3] The NRP Workgroup is charged with developing recommendations for

[1] See 42 C.F.R. § 121.4(d)
[2] OPTN Critical Comments and Directives. Available at: https://www.hrsa.gov/optn/policies-bylaws/optn-critical-comments-and-directives
[3] 42 U.S.C. § 274(b)(2)(E), (I).

proposed OPTN policy, including proposed standards related to NRP and patient safety, for consideration by the OPTN Board of Directors, and developing clear, actionable, and patient-centered guidance for OPTN members on the responsible use of NRP.

## Policies Affected

| *Policy Number* | *Policy Name* |
|---|---|
| **2.2** | OPO Responsibilities |
| **2.3** | Required Disclosure Information for the Donor or Donor's Agent |
| **2.15** | Requirements for Controlled Donation after Circulatory Death (DCD) Protocols |
| **18.5** | Reporting of Patient Safety Events |

## Proposal History

### *Background*

Under section 372(c) of the Public Health Service Act, as amended by the National Organ Transplant Act (NOTA), 42 U.S.C. § 274(c), and HHS's implementing regulation at 42 CFR § 121.4(d), any interested individual or entity may submit written critical comments to the Secretary of Health and Human Services (Secretary) regarding the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. The Secretary considers such comments in light of NOTA and 42 C.F.R. part 121 and may seek, as appropriate, the OPTN's comments on issues related to OPTN policies or practices.

In a letter to the OPTN on September 27, 2024,[4] HRSA stated that it received a letter concerning activities related to potential violations of multiple OPTN Policies and OPTN Management and Membership Policies, and raising concerns about the OPTN's obligations under NOTA in connection with deceased donor organ procurement. After review, HRSA considered the incident reporter's letter to be a critical comment under NOTA and the OPTN Final Rule. The critical comment asserted, among other things, that the OPTN lacked policy requirements and data collection for the procurement of organs using NRP. To assist its consideration of the critical comment, HRSA requested that the OPTN provide additional information regarding policies relevant to organ procurement involving NRP, enforcement of those policies, and OPTN member compliance with applicable organ procurement policies and membership requirements.

After reviewing the OPTN's response, in a letter to the OPTN on March 5, 2025, HRSA directed the OPTN to submit a detailed plan outlining: (1) proposed OPTN policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations (OPOs) using NRP in patients from whom organs may be procured; and (2) proposed OPTN data collection regarding the attempted and/or successful use of NRP. HRSA also requested additional information regarding NRP. The OPTN submitted the requested plan and information to HRSA on April 30, 2025.

[4] Health Resources and Services Administration, Letter to the Organ Procurement and Transplantation Network, September 27, 2024. Available at: https://www.hrsa.gov/sites/default/files/hrsa/optn/09272024-nrp-critical-comment-letter-508-v2.pdf

The OPTN provided the requested information to HRSA on October 8, 2024. On September 26, 2025, HRSA directed the OPTN Board of Directors to establish an NRP Workgroup, under the OPTN Operations and Safety Committee, to develop recommendations addressing patient safety and family experience in connection with the use of NRP. The Workgroup includes representatives with perspectives from multiple areas of the OPTN, including the Patient Affairs Committee, Ethics Committee, and Organ Procurement Organization Committee.

HRSA directed the Workgroup to consider recommendations for best practice in NRP, including methods to prevent cerebral blood flow during NRP, venting practices, neuromonitoring, and pre-mortem cannulation, and to gather and evaluate information regarding NRP policies and practices across OPTN members. The Workgroup's development of proposed policy elements has also been informed by reported safety events, existing OPTN policy, ethical considerations, current practices across the national system, and relevant research and guidance.

Through its deliberations, the Workgroup identified areas in which proposed national policy requirements and standards may be appropriate and developed the policy elements presented in this proposal.

### *Legal Authority for Development of NRP Policy*

Section 372(b)(2) of the Public Health Service Act, as amended, 42 U.S.C. § 274(b)(2), establishes the duties of the OPTN. Among those duties, 42 U.S.C. § 274(b)(2)(E) requires that the OPTN "adopt and use standards of quality for the acquisition and transportation of donated organs." Section 42 U.S.C. § 274(b)(2)(I) further requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants.

HHS's implementing regulations at 42 C.F.R. part 121 further establish the framework for the development, implementation, review, and enforcement of OPTN policies. Under 42 C.F.R. § 121.4(a), the OPTN Board of Directors is responsible for developing,with the advice of OPTN members and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Public Health Service Act and the Secretary's contract for operation of the OPTN, including policies on other matters as the Secretary directs. Section 121.4 also establishes requirements for public comment, Secretarial review of certain proposed policies, implementation of OPTN policies, and communication to OPTN members regarding those policies and their rationale.

The regulations also establish requirements relevant to implementation and oversight of OPTN policies. Under 42 C.F.R. § 121.1(d), OPOs designated under section 1138(b) of the Social Security Act are subject to the requirements of 42 C.F.R. part 121. Section 121.10 provides for review and evaluation of OPO and transplant program compliance with applicable regulations and OPTN policies and establishes mechanisms for addressing potential noncompliance. Section 121.11 establishes record-maintenance and reporting requirements applicable to the OPTN, OPOs, and transplant programs, including requirements relating to donor and transplantation-related records and information..

## OPTN Governance and Compliance Framework

In addition to the statutory and regulatory framework described above, OPTN governance, policy development, and member compliance are further addressed in the OPTN Bylaws and the OPTN Management and Membership Policies (M&M Policies). The OPTN Bylaws address the governance structure and roles of the OPTN, while the M&M Policies address administrative aspects of the OPTN, the policy-development process, and requirements and standards for OPTN membership. The M&M Policies establish requirements applicable to OPTN members, including OPOs. Pursuant to *Appendix B.4.e Organ Allocation Plans* of the M&M Policies, OPOs must have policies and procedures demonstrating compliance with OPTN Obligations:

> *An OPO must demonstrate it has policies and procedures that meet or exceed OPTN obligations. An OPO's failure to comply with these requirements will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L Reviews and Actions.*

*OPTN Policy F.1.g Reporting Potential Noncompliance* with OPTN Obligations of the M&M Policies further requires that:

> *Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential noncompliance by the member itself. All instances of potential noncompliance are referred for further review as outlined in OPTN Policies. Any member who fails to comply with OPTN Obligations may be subject to actions as set forth in OPTN Policies.*

Under *Policy E Adoption of Policies* of the M&M Policies, "The Board of Directors is responsible for approving and implementing policies that reflect the mission of the OPTN." Policy E establishes the process through which OPTN committees develop policy proposals for consideration by the Board of Directors and through which the Board may adopt, amend and adopt, reject, or return proposals for further deliberation.

The M&M Policies also establish processes for reviewing potential noncompliance with OPTN Obligations and for taking action in response. *Appendix L Reviews and Actions* describes the review process and the range of actions the OPTN may take. Consistent with that framework, the Membership and Professional Standards Committee (MPSC) reviews potential member noncompliance, monitors member compliance with applicable OPTN requirements, and, where appropriate, takes action or makes recommendations for further action to the OPTN Board of Directors.

## Summary of Changes

- **Change 1:** Would clarify and reorder the steps in *Policy 2.2 OPO Responsibilities* to better reflect the stages of the donation process.

- **Change 2:** Would update *Policy 2.3 Required Disclosure Information for the Donor or Donor's Agent*[5] to include a reference to *Policy 2.15.N.i Authorization for NRP*.
- **Change 3:** Would update *Policy 2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* to establish requirements governing the use of NRP as part of the controlled DCD process. The proposed requirements would address, among other matters, authorization for NRP and specified surgical practices related to patient safety, and would require OPOs to upload information related to NRP to OPTN data systems.
- **Change 4:** Would update *Policy 18.5 Reporting of Patient Safety Events* to establish additional reporting requirements for specified patient safety events associated with NRP.

## Specific Proposed Requirements

The NRP Workgroup developed the following proposed requirements for using NRP to support patient safety; promote consistency in NRP practices; support the experience of donor patients and their families; and establish clear reporting requirements for safety incidents that occur when using NRP.

In developing these proposed requirements, the Workgroup considered options to lessen the risk of harm to donor patients during NRP, as well as technical and procedural strategies to improve awareness of potential adverse events. The Workgroup considered peer-reviewed literature and consensus statements from professional societies, as well as the effectiveness of available approaches to detect potential concerns and the practical feasibility of diagnostic techniques across a range of donor hospital environments. The Workgroup used these considerations to identify approaches that could provide clear, consistent safeguards while remaining feasible to implement across different clinical settings. Where multiple approaches were available, the Workgroup considered their relative ability to support patient safety, consistency, monitoring, and practical implementation. The rationale for selecting specific proposed requirements is described below.

The proposed policy establishes or clarifies requirements related to surgical techniques used in NRP; authorization and consent for NRP and related procedures; communication among OPOs, transplant hospitals, third-party procurement teams, donor patients, and their families; and reporting of specified information associated with NRP.

### *Surgical Technique*

The following requirements are proposed for any procurement team participating in NRP:

- If pre-mortem cannulation is planned, the planned procedure must be disclosed to the donor or the donor's authorized representative, who must consent to the procedure. If the donor's death does not occur within the applicable timeframe established for the DCD process, the OPO must report the pre-mortem cannulation and any related donor outcomes as a patient safety event to the OPTN in accordance with *Policy 18.5: Reporting of Patient Safety Events*.

[5] The OPTN Policies currently posted by HRSA list Policy 2.3 as Evaluating and Screening Potential Deceased Donors. The title used in this proposal reflects the proposed/recently approved change to Policy 2.3 and may not yet be reflected in the publicly posted OPTN Policies.

- Apart from authorized or consented pre-mortem cannulation, no NRP procedure may begin until at least five minutes have elapsed following pulselessness and the donor has been pronounced dead by a member of the hospital patient care team authorized to make the declaration of death. Minimum timeframes should remain consistent with DCD cases in which NRP is not used, as per OPTN *Policy 2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*.
- For any technique through which oxygenated perfusate could enter the cerebral circulation, the cannulating team must ligate or securely clamp the proximal arterial segment(s) and transect and vent the cephalad segment(s) to atmospheric pressure or suction before initiating oxygenated perfusion. The NRP team must verbally confirm that each vessel has been secured, transected, and vented. The OPO must document the date and time when all required vessels have been confirmed as transected and vented.
    - For Thoracoabdominal NRP (TA-NRP) this includes securing all aortic arch vessels to the head and upper limbs and venting of all cephalad segments. This must be accomplished prior to initiation of perfusion, and must be followed by verbal confirmation and documentation of the time of cephalad transection.
    - For Abdominal NRP (A-NRP), ligation or clamping of the aorta, with venting of the cephalad aspect. This must be accomplished prior to initiation of perfusion, with a verbal confirmation and documentation of the time of cephalad transection.
    - If further clamps or other obstructions to flow are applied cephalad to any vented segments in TA-NRP or A-NRP, venting must be repeated above this level.
    - Aortic and arterial vents must remain open and unobstructed throughout the course of perfusion.
    - NRP safety precautions should extend to any technique that includes oxygenated perfusion (e.g., rapid recovery with extended ultraoxygenated preservation [REUP]). The aortic arch vessels still should be transected and vented.
    - Paralytic agents must not be administered in conjunction with NRP because they may obscure physical responses (e.g., movement of respiratory muscles) that could indicate potential failure to prevent cerebral reperfusion.

### *Authorization*

*Note:* Applicable state and local laws govern the legal effect of a donor's first-person authorization, including whether and to what extent another person may revoke, amend, or object to that authorization. When no first-person authorization exists, authorization for organ donation may be provided by a person authorized to do so under applicable state or local law.

OPOs may choose to use a separate authorization form for NRP or to include NRP authorization in their standard authorization form for organ donation.[6] Regardless of which option the OPO chooses, the OPO must provide the required disclosures regarding NRP and document that the disclosures were provided. The form or other documentation used to record authorization for NRP must identify NRP and include, at a minimum, the following information:

[6] Authorization for NRP does not replace any consent required for procedures or drug administration performed before death, including specific consent for pre-mortem cannulation.

- NRP is performed after death to restore perfusion to selected organs in the donor's body to support organ preservation and function for transplantation. NRP may increase the likelihood that recovered organs are suitable for transplantation and function after transplant.
- In NRP, perfusion is restored to certain organs, and those organs may resume function; for example, the heart will beat, the liver will make bile, and the kidneys will make urine. The organs perfused will depend on the method of NRP— thoraco-abdominal NRP (TA-NRP) or abdominal NRP (A-NRP).
- There is a risk of restoring blood flow to the donor's brain during NRP. The NRP team must use the safeguards required by OPTN policy to prevent cerebral reperfusion, including securing specified blood vessels and transecting and venting them cephalad to the point of occlusion.
    - If, before initiation of NRP, the required barriers to cerebral perfusion cannot be established, the NRP team must not initiate perfusion until the adequacy of those barriers has been confirmed. If the required safeguards cannot be established, NRP must not proceed.
    - If, after NRP has begun, there is concern that cerebral perfusion may have occurred, including observation of a physical response such as respiratory effort, NRP must be discontinued and the organ recovery process halted. The individual must be returned immediately to the supervision of the primary care team for evaluation.
    - Before NRP is initiated, a documented plan must be in place describing the response to a concern for cerebral perfusion or other signs of life, including the process for immediately returning the individual to the supervision of the primary care team.
- If pre-mortem cannulation is planned, the patient or the patient's agent must specifically consent for the procedure.

*Communication*

Prior to any procurement team departing for the procurement site, the OPO must conduct a pre-departure huddle. Attendees must include an OPO representative and the lead surgeons from all procurement and NRP teams. At a minimum, the huddle must address: the type of NRP (TA-NRP vs. A-NRP), details of cannulation, vascular control and other surgical approach considerations; the location of withdrawal of life-sustaining therapy (eg., intensive care unit [ICU], post-anesthesia care unit [PACU]/pre-operative area, operating room); applicable procedural timeframes agreed upon by the hospital and participating teams; confirmation of who is managing the airway and time for resuming ventilation, if applicable, and verification of surgical team members who will be present.

The OPO must coordinate with the transplant hospital to ensure an approved recovery surgeon representative from the transplant center or third-party procurement team can participate in the pre-departure huddle.

The OPO must document completion of the pre-departure huddle, including the date and time of the huddle, participants, required topics discussed, and any decisions or agreed-upon procedural parameters resulting from the discussion.

The pre-departure huddle may be deferred only when there is a single procurement/NRP team and both the OPO and the procurement/NRP team determine that a separate pre-departure huddle is

unnecessary. If the huddle is deferred, the OPO must document the deferral and the basis for that determination.

Prior to withdrawal of life-sustaining therapy (WLST), the OPO must lead an on-site huddle that includes OPO staff, donor hospital operating room staff, each procurement team, and the NRP team. At a minimum, the huddle must include: a reminder about how to raise concerns, including how to initiate an unplanned pause, discussion of type of NRP (TA-NRP vs. A-NRP), location of withdrawal (ICU, PACU/pre-operative area, operating room), applicable procedural timeframes, the steps in procurement procedures including cannulation and vascular control, sequence for organ removal, confirmation of who is managing the airway and, if applicable, when ventilation may resume and responsibilities of each participating team.

Before NRP is initiated, the participating teams must review and confirm a documented plan for immediately returning the donor to the supervision of the hospital patient care team if concerns arise regarding cerebral perfusion, physical responses, or other signs of life during NRP.

The OPO must document completion of the on-site huddle, including the date and time, participants, required topics discussed, the agreed-upon roles and procedural parameters, and confirmation that the plan for returning care to the hospital patient care team was reviewed.

Documentation of the required huddle discusions must be made in the OPO's electronic medical record, and must be uploaded to OPTN data systems along with other records describing perimortem and intraoperative events for all cases in which NRP was attempted or completed.

WLST may not occur until the on-site huddle has been completed with all required participants present. If WLST occurs before completion of the required huddle, the OPO must report the occurrence as a patient safety event in accordance with Policy 18.5: Reporting of Patient Safety Events.

If a transplant program or third-party procurement team does not participate in the required on-site huddle, the OPO must not proceed with that team's participation in the procurement until the requirement has been satisfied. Any decision affecting an organ offer must be made in accordance with applicable OPTN policies.

## Post-implementation Monitoring

### *Member Compliance*

HHS regulations require the OPTN to maintain appropriate plans and procedures for conducting ongoing and periodic reviews of member OPOs and transplant hospitals for compliance with OPTN policies.[7] The regulations also require OPOs and transplant programs to maintain specified records related to organ donation and transplantation and permit review of those records consistent with applicable requirements.[8]

[7] 42 C.F.R. § 121.10(b)(1)(iii).
[8] See 42 C.F.R. § 121.11(a)(2).

This proposal would not otherwise change the OPTN's existing routine member-monitoring processes. However, compliance with the proposed NRP requirements would be subject to OPTN review through applicable member-monitoring, patient-safety, and compliance-review processes.

The OPTN may review information and documentation relevant to compliance with the proposed NRP requirements, including documentation of required authorization or consent, pre-departure and on-site huddles, required procedural safeguards, patient safety events, and other records required by the proposed policy. The OPTN will continue to investigate potential noncompliance identified through its established monitoring and patient-safety processes.

Any data entered into OPTN computer systems may be reviewed by the OPTN, and members are required to provide documentation as requested.

### *Policy Evaluation*

After implementation, the OPTN would evaluate the effects of the NRP policy to assess whether it is operating as intended and to determine whether further policy changes are appropriate. When evaluating the policy, the Membership & Professional Standards Committee (MPSC) would review data collected by the OPTN, including data regarding NRP cases and reported patient safety events. These data would be used to evaluate implementation of the policy, identify trends in reported patient safety events and other NRP-related outcomes, assess how identified patient safety concerns are addressed, and evaluate relevant organ procurement and transplantation outcomes.

Exhibit 1 identifies the proposed metrics for post-implementation evaluation and the subgroups for which stratified analyses may be conducted. The MPSC will review the metrics identified in Exhibit 1 through monthly reports and more detailed quarterly reports. The MPSC may also request additional metrics, analyses, or an extended monitoring period based on the post-implementation evaluation findings.

The MPSC will receive and review the selected metrics through monthly reports and more detailed quarterly reports, accounting for applicable OPTN data-submission lag, as appropriate. The MPSC may request additional analyses, metrics, or an extended period of monitoring when warranted by the findings of the post-implementation evaluation.

Exhibit 1. Potential Metrics of Interest

| ***Metric of Interest*** | ***Subgroups*** |
|---|---|
| Number of donors for whom NRP was initiated | • Overall<br>• Region<br>• OPO<br>• Demographics<br>– Age<br>– Sex |
| Proportion of DCD donations that included NRP | |
| Number of times that NRP was stopped after initiation due to a concern regarding possible cerebral perfusion, physical responses, or other signs of life | |
| Number of times NRP was restarted after being stopped due to a concern regarding possible cerebral perfusion, physical responses, or other signs of life | |
| Number of organs procured following use of NRP | |
| Number and proportion of organs intended for procurement that were procured following use of NRP | |

| *Metric of Interest* | *Subgroups* |
|---|---|
| Number of patients who provided, or for whom an authorized representative provided, consent for pre-mortem cannulation who did not die within the applicable timeframe for DCD | – Race<br>• Organ(s) procured |
| Rate of NRP-related patient safety events among cases in which NRP was initiated | |
| Number of patient safety events reported involving NRP | |

## Considerations for the Community

The Workgroup would like to solicit feedback from the community on the following considerations:

- The OPTN policies references the term "time of cross-clamp" in OPTN *Policy 2.15.D.i Process for a Pause*. Clamp time is defined on the OPTN website as "The time at which the flow of blood to a particular organ has been clamped off during a procurement."[9] Is this definition sufficient and aligned appropriately with the intentions of NRP policy?
- OPTN Members are responsible for complying with all OPTN Obligations, per OPTN *Management and Membership Policy F.1.e Member Compliance*, which include acting to avoid risks to patient health or public safety. Do you agree that policy should specify the following: In the event that there are questions about whether the potential donor is exhibiting signs of life, OPO providers and relevant staff must remain in the room until the patient care team is available to receive patient hand-off.
- Do the potential metrics of interest in Exhibit 1 adequately capture initiation and stoppage of NRP? What additional metrics should the OPTN consider monitoring at the time on circuit for NRP? How can the OPTN monitor that action is taken to halt NRP "without delay" or "within a short period of time" when signs of life are observed during the NRP process?

## Projected Fiscal Impact

### *Projected Impact on the OPTN*

It is estimated that $24,000 - $35,500 would be needed to implement this proposal. Implementation would involve updates to the OPTN Computer System that include developing the solution, coding, and testing to support the updated policy requirements and associated system tools. In addition, implementation would include building communications and education materials, updating process documents, and community outreach. In addition, ongoing support will include a monitoring report for the 6-month, 1-year, and 2-year timeframes.

[9] Health Resources and Services Administration, Glossary, March 2026. Available at: https://www.hrsa.gov/optn/patients/glossary#C.

## Appendices

*Appendix A – Affected Policy Language*

## Appendix A: Affected Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated, as necessary.

### *2.2 OPO Responsibilities*

~~The host OPO is responsible for all of the following:~~

~~1. Identifying potential deceased donors.~~
~~2. Providing evidence of authorization for donation.~~
~~3. Evaluating referred patients for potential deceased donation.~~
~~4. Registering all patients authorized for deceased donation in the OPTN Donor Data and Matching System no later than the time at which the OPO decides to proceed with the donation process.~~
~~5. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.~~
~~6. Verifying that death is pronounced according to applicable laws.~~
~~7. Informing all stakeholders involved in the donation after circulatory death (DCD) process of the process for requesting an unplanned DCD pause in accordance with *Policy 2.15.D: Process for an Unplanned DCD Pause*. Stakeholders include the patient or patient's agent, donor hospital staff, OPO staff, transplant programs, and third-party procurement and preservation staff operating on behalf of the OPO.~~
~~8. Ensure accurate documentation of neurological assessments. If there is discordance between OPO and patient care team assessments, appropriate escalation within the OPO must occur.~~
~~9. Establishing and then implementing a plan to address organ donation for diverse cultures and Public Comment Proposal ethnic populations.~~
~~10. Ensuring the clinical management of the deceased donor.~~
~~11. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.~~
~~12. Assessing deceased donor organ quality.~~
~~13. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.~~
~~14. Executing the match run and using the resulting match for each deceased donor organ allocation.~~
~~15. Documenting and maintaining complete deceased donor information for seven years for all organs procured.~~
~~16. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information*, is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.~~
~~17. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:~~
~~a. ABO source documentation~~
~~b. ABO subtype source documentation~~
~~c. Infectious disease results source documentation~~
~~d. Death pronouncement source documentation~~

~~e. Authorization for donation source documentation~~
~~f. HLA typing source documentation~~

~~18. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.~~

The host OPO is responsible for all of the following:

1. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
2. Identifying potential deceased donors.
3. Evaluating referred patients for potential deceased donation.
4. Registering all patients authorized for deceased donation in the OPTN Donor Data and Matching System no later than the time at which the OPO decides to proceed with the donation process.
5. Providing evidence of authorization for donation and, if NRP is planned as part of the procurement, evidence of authorization for normothermic regional perfusion (NRP).
   a. Providing evidence that the patient or patient's agent specifically consented to any planned pre-mortem cannulation in accordance with *Policy 2.15.D Consent for DCD*.
6. Informing all stakeholders involved in the donation after circulatory death (DCD) process of the process for requesting an unplanned DCD pause in accordance with *Policy 2.15.D Process for an Unplanned DCD Pause*. Stakeholders include the patient or patient's agent, donor hospital staff, OPO staff, transplant programs, and third-party procurement and preservation staff operating on behalf of the OPO.
7. Ensuring accurate documentation of neurological assessments. If there is discordance between OPO and patient care team assessments, appropriate escalation within the OPO must occur.
8. Ensuring the clinical management of the potential donor.
   a. In the case of a donor declared dead by neurological criteria, the OPO is responsible for the clinical management of the donor.
   b. In the case of a DCD patient, clinical care remains under the authority of the hospital clinical team until death is declared.
9. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
10. Assessing deceased donor organ quality.
11. Executing the match run and using the resulting match for each deceased donor organ allocation.
12. Conducting the required pre-procurement huddles in accordance with *Policy 2.15.N.ii Pre-departure Communication*.
13. Verifying that death is pronounced according to applicable laws and hospital policies.
14. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16 Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
15. Documenting and maintaining complete deceased donor information for seven years for all organs procured.

16. Ensuring that all deceased donor information, according to *Policy 2.11 Required Deceased Donor Information*, is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
17. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
18. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.
19. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.

### *2.3 Required Disclosure Information for the Donor or Donor's Agent*

The OPO must have a written protocol specifying the information that must be provided to the donor or the donor's agent when the authorization for donation is confirmed. At a minimum, this information must include the following:

1. List of organs that may be recovered and most likely uses for recovered organs
2. Description of the donor evaluation and organ recovery process, to include:
    a. Estimated time frames for donor evaluation and organ recovery
    b. The need and process for a donor risk assessment interview
    c. Laboratory evaluations including testing for infectious diseases according to Policy 2.9 Required Deceased Donor Infectious Disease Testing
    d. Description of procedures and medications that may be administered during the organ evaluation process
    e. Allocation process and time frames for updates on allocation progress
3. The possibility that organs may ultimately not be transplanted
4. That any financial charges related to the donation process are the responsibility of the OPO
5. The potential impact donation may have on funeral preparations such as timing and viewing
6. Contact information for OPO staff if questions or concerns arise following authorization
7. Copy of signed authorization form or ~~first person~~ first-person authorization document

When requesting authorization for donation after circulatory death (DCD), the OPO must provide additional information according to *Policy 2.15.~~F~~G Authorization for DCD*. If NRP is planned as part of the organ procurement, the OPO must also provide the information and obtain and document authorization for NRP as required by *Policy 2.15.N.i Authorization for NRP*.

Any written authorizations and related discussions must use language and explanations appropriate to the donor's/donor's agent's level of understanding.

### 2.15.C Potential DCD Donor Evaluation

The primary healthcare team and the OPO must evaluate potential DCD donors to determine if the patient meets the OPO's criteria for DCD. If the patient meets the OPO's criteria for DCD, the OPO must confirm the plan for continued patient care if the patient does not expire within a time frame that allows for DCD to occur.

~~The OPO and primary healthcare team must confirm that withdrawal of life-sustaining therapies remains appropriate.~~

This reassessment must occur at least every 12 hours from the time the OPO initiates the donation process, and within 2 hours prior to the planned withdrawal of life-sustaining therapies.

### 2.15.D Process for Unplanned DCD Pause

#### *2.15.D.i Process for a Pause*

OPOs must establish and document a process by which an unplanned pause in the DCD process may be requested due to an unresolved difference of opinion as to whether a patient meets the donor hospital's criteria for withdrawal of life-sustaining therapies. Such an unplanned DCD pause may be requested by any stakeholder identified in *Policy 2.2.6 OPO Responsibilities* in the DCD process between the time that authorization for DCD is granted per *Policy 2.15.G Authorization for DCD* and the time of cross-clamp. The process must specify how the OPO determines if the DCD process can proceed following a request for an unplanned DCD pause. At a minimum, this process must include convening all existing stakeholders, including the individual who requested the unplanned DCD pause, to consider the rationale for requesting the pause and actions to be taken to address the unplanned DCD pause.

#### *2.15.D.ii Required Notification of the Process for a Pause*

At the time of authorization, the OPO must inform the patient, if applicable, or patient's agent of the process for requesting an unplanned DCD pause. Each OPO must establish and document a process by which the OPO will inform stakeholders identified in *Policy 2.2.6 OPO Responsibilities* involved in each case how to request an unplanned DCD pause at no fewer than two timepoints: 1) within two hours of the time of case initiation and 2) at the timeout prior to initiating withdrawal of life-sustaining therapies in accordance with *Policy 2.15.I Withdrawal of Life Sustaining Therapies*. Only those stakeholders involved in the case at the time of case initiation and at the timeout prior to initiating withdrawal of life-sustaining therapies are required to be informed.

### 2.15.E Response to a Request for an Unplanned DCD Pause

When the OPO determines that the DCD process can resume following an unplanned DCD pause, the OPO must obtain acknowledgment prior to organ recovery from all transplant programs that accept an organ from the donor and from any contracted representatives, such as ~~third-party~~ third-party contractors, involved in organ recovery that they are aware that the unplanned DCD pause occurred and that they acknowledge the decision to proceed.

The OPO must inform the OPTN of any unplanned DCD pause and its outcome according to *Policy 18.5.C Required Reporting by OPOs*.

### 2.15.F OPTN Member Required Unplanned Pause Education

OPTN Members must educate their applicable staff and contracted third parties involved in organ procurement, preservation, offer triage, and acceptance on *2.15.D Process for Unplanned DCD Pause* and *2.15.E Response to a Request for an Unplanned Pause*. Education must be documented and verified.

### 2.15.G Authorization for DCD

Authorization for a DCD recovery must be obtained from *either* of the following:

1. The patient
2. Persons defined by applicable state or local law to authorize organ donation, such as the patient's agent.

In addition to the requirements in *Policy 2.3 Required Disclosure Information for the Donor or Donor's Agent*, the OPO must provide to the patient or the patient's agent, at a minimum, the following:

- Location in the donor hospital where withdrawal of life sustaining therapies will occur
- Time frame between withdrawal of life sustaining therapies and declaration of death for DCD to occur
- Plan for continued patient care if the patient does not expire in a time frame that allows for DCD to occur
- If the OPO anticipates that normothermic regional perfusion (NRP) may be used as part of the organ recovery process, an explanation that NRP may be used and the disclosures required by *Policy 2.15.N.i Authorization for NRP*, including:
    - The rationale for using NRP.
    - That ~~circulation~~ perfusion will be restored to selected organs and that some organ functions may resume during NRP.
    - The safeguards required to prevent blood flow to the brain
- That any stakeholder in the DCD process, including the patient or patient's agent, may request an unplanned DCD pause according to *Policy 2.15.D Process for Unplanned DCD Pause*
- Reasons why a stakeholder may request an unplanned DCD pause
- That the donation process will stop if there is a decision not to move forward with withdrawal of life-sustaining therapies

If NRP is planned as part of the organ recovery process, the OPO must obtain and document authorization for NRP in accordance with *Policy 2.15.N.i Authorization for NRP*. OPOs may choose to have a separate authorization form for NRP or to include authorization for NRP in their standard authorization form for organ donation. Regardless of which option the OPO chooses, the OPO must maintain documentation demonstrating that the required NRP disclosures were provided and that authorization for NRP was obtained, which must include the following information in plain and understandable language:

- NRP restores perfusion to selected organs after death to support organ preservation and function for transplantation. NRP may increase the likelihood that recovered organs are suitable for transplantation and function after transplant.
- In NRP, perfusion is restored to certain organs, and those organs may resume function—e.g., the heart may beat, the liver may make bile, the kidneys may make urine. The organs perfused will depend on the method of NRP—thoraco-abdominal NRP (TA-NRP) or abdominal NRP (A-NRP).
- There is a potential risk of unintended restoration of blood flow to the donor's brain during NRP. The NRP team must use the safeguards required by OPTN policy to prevent cerebral reperfusion, including securing specified blood vessels and transecting and venting them cephalad to the point of occlusion, as applicable to the NRP technique used.
    - If the required barriers to cerebral perfusion cannot be established before initiation of NRP, NRP must not begin until those barriers have been established. If the required safeguards cannot be established, NRP must not proceed.
    - If there is a concern that perfusion may have been restored to the brain (e.g., an observed physical response, including respiratory effort), the NRP procedure must be discontinued, and the recovery process halted. Physical responses must be evaluated immediately by the patient's primary care team, and care of the patient must be returned to that team.
    - A plan for continued patient care following concern for brain perfusion or other physical responses must be established prior to the initiation of NRP as detailed in *Policy 2.15.N.iv Process for Raising Concern after Initiation of NRP*.

### 2.15.H Consent for Procedures Pre-DCD

The OPO must confirm that the patient or the patient's agent has given consent for any DCD related invasive procedures or drug administration that occur prior to patient death.

If any premortem cannulation occurs, the patient or the patient's agent must specifically consent to the cannulation and must be advised of complications that may occur during the procedures, or that may occur if the patient does not expire in a time frame that allows for DCD to occur.

### 2.15.I Withdrawal of Life-Sustaining Therapies

Prior to the donor hospital withdrawing life-sustaining therapies, the OPO is required to conduct a timeout with the hospital patient care team to confirm:

1. The patient's identification
2. The process for withdrawing life-sustaining therapies
3. Roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team
4. The hospital's plan for continued patient care if the patient does not become a donor, and appropriate communication with the next of kin
5. If NRP is planned, the documented plan for immediately returning the patient to the supervision of the hospital patient care team if concerns arise regarding cerebral perfusion, physical responses, or other signs of life, in accordance with *Policy 2.15.N.iv Process for Raising Concern after Initiation of NRP*.

No recovery personnel (surgeons and other recovery practitioners) may be present for the withdrawal of life sustaining therapies. No member of the organ recovery team or OPO staff may guide or administer palliative care or declare death.

### 2.15.J Pronouncement of Death

The donor hospital healthcare team member who declares death cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs. Death is declared in accordance with hospital policy and applicable state and local statutes or regulations.

### 2.15.K Organ Recovery

Organ recovery will only proceed after circulatory death is determined, inclusive of a waiting period of no less than 5 minutes of circulatory cessation to ensure no auto-resuscitation occurs unless organ recovery is performed pursuant to *Policy 2.15.M Potential Brain Dead Donors Recovered Using DCD Protocols*.

### 2.15.L Potential DCD Donor Who Converts to Brain Death after an Organ Offer Has Been Made

When a potential DCD donor converts to brain death, the host OPO must re-execute the match system and allocate the organs according to the organ allocation policies. *Policy 5.4 Organ Offers* does not apply when a DCD donor converts to brain death. Additionally, OPOs should initiate allocation of organs that may have been ruled out due to the donor's initial DCD status.

However, the host OPO may choose not to reallocate organs from a DCD donor who converts to brain death for any one of the following reasons:

1. Donor instability
2. Lack of donor family approval and authorization
3. Other extraordinary circumstances

The host OPO must document the reason for not reallocating organs when a DCD donor converts to brain death and make this documentation available to the OPTN on request.

### 2.15.M Potential Brain Dead Donors Recovered Using DCD Protocols

When a potential donor is declared brain dead and the deceased donor's agent directs that recovery be done under DCD protocols the OPO must do all of the following:

1. Document in the OPTN Donor Data and Matching System the justification for undergoing DCD recovery
2. Notify transplant programs that a DCD match run will be used by documenting that notification in the OPTN Donor Data and Matching System
3. Execute the match run as a DCD donor

### 2.15.N Normothermic Regional Perfusion (NRP)

#### *2.15.N.i Authorization for NRP*

OPOs must obtain and document authorization for NRP, including the required disclosures, in accordance with *Policy 2.15.G Authorization for DCD*.

*2.15.N.ii Pre-departure Communication*

Prior to any procurement team departing for the procurement site, the OPO must conduct a pre-departure huddle. Attendees must include an OPO representative and the lead surgeons or designated lead representatives from all procurement and NRP teams. At a minimum, the huddle must address:

a. Type of NRP (TA-NRP vs. A-NRP)
b. Details of cannulation and other surgical approaches
c. Location of withdrawal (e.g., intensive care unit [ICU], post-anesthesia care unit [PACU]/pre-operative area, operating room)
d. Applicable WLST and procedural timeframes agreed upon by the donor hospital and participating teams
e. Confirmation of who will manage the airway and, if applicable, the time at which ventilation may resume
f. Verification of the surgical team members who will participate in the procurement and their respective roles

The OPO must document completion of the pre-departure huddle, including the date and time of the huddle, participants, required topics discussed, and any decisions or agreed-upon procedural parameters resulting from the discussion.

The OPO must coordinate with the transplant hospital to ensure that an appropriate recovery surgeon representative from the transplant program or third-party procurement team participates in the pre-departure huddle.

A transplant program or third-party procurement team required to participate in the pre-departure huddle must satisfy the huddle requirement before participating in the procurement. Any decision affecting an organ offer must be made in accordance with applicable OPTN policies.

The pre-departure huddle may be deferred only when there is a single procurement/NRP team and both the OPO and the procurement/NRP team determine that a separate pre-departure huddle is unnecessary. If the huddle is deferred, the OPO must document the deferral and the basis for that determination.

*2.15.N.iii Pre-withdrawal Communication*

Prior to WLST, in addition to the timeout specified in *Policy 2.15.I Withdrawal of Life-Sustaining Therapies*, the OPO must lead an on-site huddle that includes OPO staff, donor hospital operating room staff, each procurement team, and the NRP team. At a minimum, the huddle must include:

a. A reminder regarding how participants may raise concerns, including how to request an unplanned DCD pause in accordance with *Policy 2.15.D Process for Unplanned DCD Pause*.
b. Discussion of the type of NRP (TA-NRP vs. A-NRP)
c. The location of withdrawal of life-sustaining therapies (ICU, PACU/pre-operative area, or operating room)

d. Applicable WLST and procedural timeframes agreed upon by the donor hospital and participating teams
e. The planned steps in the procurement procedure and sequence of organ removal
f. Confirmation of who will manage the airway and, if applicable, when ventilation may resume
g. Clarification of the roles and responsibilities for each participating team
h. Review of the plan for immediately returning the patient to the supervision of the hospital to the hospital patient care team if concerns arise regarding cerebral perfusion physical responses, or other signs of life during NRP, in accordance with *Policy 2.15.N.iv Process for Raising Concern after Initiation of NRP*.

The OPO must document completion of the on-site huddle, including the date and time of the huddle, required participants and the OPTN member on whose behalf they are acting, required topics discussed, agreed-upon roles and procedural parameters, and confirmation that the plan described in paragraph (h) was reviewed.

WLST may not occur until the on-site huddle has been completed with all required participants present. If WLST occurs before completion of the required huddle, the OPO must report the occurrence as a patient safety event in accordance with *Policy 18.5.C Required Reporting by OPOs*.

A transplant program or third-party procurement team required to participate in the on-site huddle must satisfy the huddle requirement before participating in the procurement. Any decision affecting an organ offer must be made in accordance with applicable OPTN policies.

*2.15.N.iv Process for Raising Concern after Initiation of NRP*

OPOs must establish and document a process by which any stakeholder involved in the NRP process may raise a concern regarding possible cerebral perfusion, physical responses, or other signs of life after initiation of NRP.

If such a concern is raised, including observation or report of a physical response such as respiratory effort, the NRP circuit must be turned off immediately, and the OPO's established process must be followed.

A concern may be raised at any time after initiation of NRP by any stakeholder identified in *Policy 2.2.6 OPO Responsibilities*.

At a minimum, the process must specify that the hospital patient care team must be contacted immediately and that the individual must be returned immediately to the supervision of the hospital patient care team for evaluation. The process must also identify the individuals responsible for contacting the hospital patient care team and transferring supervision.

The OPO must document the concern, including the date and time the concern was raised; the nature of the concern; the date and time the NRP circuit was turned off; the actions taken in response; and the date and time supervision was returned to the hospital patient care team. The OPO must report the event to the OPTN in accordance with *Policy 18.5.C: Required Reporting by OPOs*.

*2.15.N.v Surgical Technique*

If NRP is planned as part of a DCD procurement, the OPO and NRP team, as applicable to their respective responsibilities, must adhere to the following:

- If pre-mortem cannulation is planned, the patient or patient's agent must specifically consent to the procedure in accordance with *Policy 2.15.H Consent for Procedures Pre-DCD*. If the patient does not die within the time frame for DCD disclosed in accordance with *Policy 2.15.G Authorization for DCD*, the OPO must report the pre-mortem cannulation and any required information regarding the procedure and associated patient outcomes as a patient safety event to the OPTN in accordance with *Policy 18.5.C Required Reporting by OPOs*.
- Apart from authorized or consented pre-mortem cannulation, no NRP procedure may begin until the donor has been pronounced dead in accordance with *Policy 2.15.J Pronouncement of Death* and the minimum five-minute period of circulatory cessation required by *Policy 2.15.K Organ Recovery* has elapsed.

If the decision is made to proceed with NRP, the OPO and NRP team, as applicable to their respective responsibilities, must adhere to the following:

- For A-NRP, before initiation of perfusion, the aorta must be occluded above the level of the celiac origin, and the proximal aorta must be transected cephalad to the occlusion and vented to atmospheric pressure or suction. The NRP team must verbally confirm completion of these steps. The OPO must document the date and time the proximal aorta is confirmed as transected and vented. The vent in the aorta must be maintained throughout the entirety of the perfusion period. If additional clamping is performed, adequacy of cephalad venting must be reverified and confirmed.
- For TA-NRP, before initiation of perfusion, all aortic arch vessels must be occluded, and each artery must be transected cephalad to the occlusion and vented to atmospheric pressure or suction. The NRP team must verbally confirm completion of these steps. The OPO must document the date and time the proximal aorta is confirmed as transected and vented. All arterial vents must be maintained throughout the entirety of the perfusion period. If additional clamping is performed, adequacy of cephalad venting must be reverified and confirmed.
- NRP safety precautions should extend to any technique that includes oxygenated perfusion (e.g., rapid recovery with extended ultraoxygenated preservation [REUP]). The aortic arch vessels still should be transected and vented.
- Paralytic agents must not be administered during NRP because they may obscure physical responses (e.g., movement, including respiratory muscle movement) that could indicate possible cerebral reperfusion or failure of the required vascular safeguards.

*2.15.N.vi. Required documentation in OPTN data systems*

Within 24 hours of completion of a DCD procurement attempt involving attempted or actual NRP perfusion, the host OPO must upload the following to the OPTN data system: DCD flowsheet, death note, operative note, and documentation from pre-withdrawal huddle described in *2.15.N.iii Pre-withdrawal Communication*.

### 18.5.C Required Reporting by OPOs

OPOs must report the following events to the OPTN according to *Table 18-5* below.

*Table 18-5: Required Reporting by OPOs*

| Host OPOs must report if: | To the: | Within: | After: |
|---|---|---|---|
| For a case in which NRP is planned, withdrawal of life-sustaining therapies occurs before completion of the on-site huddle required by ***Policy 2.15.N.iii Pre-withdrawal Communication*** | OPTN Patient Safety Reporting Portal | 24 hours | The OPO becomes aware |
| After initiation of NRP, a concern regarding possible cerebral perfusion, a physical response, or other sign of life is raised that requires a temporary pause in the surgical recovery and/or discontinuation of NRP under ***Policy 2.15.N.iv Process for Raising Concern after Initiation of NRP*** | OPTN Patient Safety Reporting Portal | 24 hours | The OPO becomes aware |
| Pre-mortem cannulation was performed, and the patient does not die within the applicable time frame for DCD, as described in ***Policy 2.15.N.v~~i~~ Surgical Technique*** | OPTN Patient Safety Reporting Portal | 72 hours of initiation of the unplanned DCD pause or within 24 hours of resolution of the unplanned DCD pause, whichever occurs first | The OPO becomes aware that DCD will not occur within the applicable time frame |
| An auto-resuscitation event occurs beyond the waiting period required by *Policy 2.15.J Organ Recovery* | OPTN Patient Safety Reporting Portal | 24 hours | The OPO becomes aware |
| Transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required | OPTN Patient *Safety Reporting Portal* | 72 hours | The OPO becomes aware |
| An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in *Policy 2.6.C Reporting of Deceased Donor Blood Type and Subtype*, and after the OPO has executed a match run | OPTN Patient *Safety Reporting Portal* | 72 hours | The OPO becomes aware |

### 18.5.C.1 Required Reporting of Unplanned DCD Pause

When an unplanned pause is requested in the DCD process according to *Policy 2.15.D Process for Unplanned DCD Pause*, the notification to the OPTN must include:

- OPTN donor ID
- Date and time the OPO decided to proceed with the donation process
- Date and time the OPO became aware of the request for an unplanned DCD pause
- Role of the stakeholder requesting the unplanned DCD pause
- Rationale for requesting the unplanned DCD pause
- The date and time each of the following individuals or entities, at a minimum, was notified of the unplanned DCD pause:
    - Patient, if applicable, or patient's agent
    - Patient's healthcare team
    - Hospital leadership team
    - OPO leadership team
    - Any transplant programs with an organ offer acceptance

When the DCD process resumes following an unplanned pause, the OPO must provide the following information to the OPTN within 24 hours of resumption of the DCD process:

- OPTN donor ID
- Actions taken by the OPO to address the unplanned DCD pause
- Identification of the transplant programs and procurement staff that were notified of the unplanned DCD pause
- Date and time when the DCD process resumed
- Rationale for resuming the DCD process

When the DCD process is stopped due to an unplanned DCD pause, the OPO must provide the following information to the OPTN within 24 hours of submitting the donor organ disposition:

- OPTN donor ID
- Actions taken by the OPO to address the unplanned DCD pause
- Date and time when the DCD process was stopped
- Rationale for stopping the DCD process
- Identification of the transplant programs and procurement staff that were notified that the DCD process was stopped

The OPO must preserve all records related to the unplanned DCD pause and make those records available to the OPTN on request.