HRSA
Health Resources & Services Administration
Health Systems Bureau/Division of Transplantation
5600 Fishers Lane
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VIA ELECTRONIC MAIL

Dear Dr. Magee,

The Health Resources and Services Administration (HRSA) thanks the Organ Procurement and Transplantation Network (OPTN) for the April 30, 2025 response to our letter regarding the critical comment about the practice of normothermic regional perfusion (NRP). HRSA appreciates your patience as we prepare further guidance based on a thorough review of the proposed plan and current status of priority projects and resources available to the OPTN.

In the interim, HRSA recognizes the significant time and resource constraints flagged by the OPTN in the April 30 communication. Given these limitations, HRSA asks the OPTN to **prioritize, in the immediate term, the following action items to maximize impact on patient safety.** All NRP remediation work should be focused on patients and families; those considering the complex decision of organ donation are the foundation of the organ procurement and transplantation system. To earn and sustain public trust, appropriate policy, standards, and data collection pipelines regarding the practice of NRP for donation after circulatory death (DCD) must be in place.

(I) Directed Action: Development of an NRP Workgroup

Following the successful initiation and work of the AOOS Workgroup, HRSA directs the OPTN Board of Directors (BOD) to establish an NRP Workgroup under the OPTN Operations and Safety Committee (OSC), dedicated to patient safety and family experience for patients undergoing NRP ('NRP Workgroup'). The Operations and Safety Committee is well-positioned to support this effort given its mission to identify patient safety risks, promote system-wide learning, and recommend policies and practices that reduce risk and improve the safety of the national transplant system. By **October 10, 2025**, the OPTN should submit to HRSA a workgroup proposal including potential membership, meeting cadence, topics for discussion, and deliverables. HRSA is

separately directing the OPTN operations contractor to support the OSC in developing this workgroup proposal and establishing the workgroup.

The OPTN may direct this workgroup to develop policy and establish new standards for NRP and patient safety, as outlined in Part D of HRSA's March 5 letter. The workgroup may consider the following topics related to patient safety during NRP:

- Mechanical clamping of the aortic arch vessels or the descending thoracic aorta to prevent blood flow to the brain[1,2]
- Venting of the cephalad aspect of clamped vessels to atmospheric pressure to divert blood flow away from the brain[3,4]
- Neuromonitoring during NRP to monitor levels of consciousness, using methods like bispectral index and Doppler[5]
- Pre-mortem cannulation of the femoral vessels, including documentation of adverse events and procedures for management if the patient does not expire within a donation-consistent timeframe[6,7]

(II) Directed Action: NRP Member Education on Evidence-Based Guidelines, Best Practices, and Related OPTN Requirements

[1] Hoffman, J. R. H., Hartwig, M. G., Cain, M. T., Rove, J. Y., Siddique, A., Urban, M., Mulligan, M. S., Bush, E. L., Balsara, K., Demarest, C. T., Silvestry, S. C., Wilkey, B., Trahanas, J. M., Pretorius, V. G., Shah, A. S., Moazami, N., Pomfret, E. A., Catarino, P. A., & In collaboration with members from The American Society of Transplant Surgeons (ASTS), The International Society of Heart and Lung Transplantation (ISHLT), The Society of Thoracic Surgeons (STS), and The American Association for Thoracic Surgery (AATS) (2024). Consensus Statement: Technical Standards for Thoracoabdominal Normothermic Regional Perfusion. *Transplantation, 108*(8), 1669–1680. https://doi.org/10.1097/TP.0000000000005101

[2] Croome, K., Bababekov, Y., Brubaker, A., Montenovo, M., Mao, S., Sellers, M., Foley, D., Pomfret, E., & Abt, P. (2024). American Society of Transplant Surgeons Normothermic Regional Perfusion Standards: Abdominal. *Transplantation, 108*(8), 1660–1668. https://doi.org/10.1097/TP.0000000000005114

[3] Royo-Villanova, M., Sánchez, J. M., Moreno-Monsalve, T., Contreras, J., Ortín, A., Vargas, H., Murcia, C. M., Llosa, M. M., Coll, E., Pérez-Blanco, A., & Domínguez-Gil, B. (2025). A scintigraphic look at the dead donor rule in donation after the circulatory determination of death with the use of normothermic regional perfusion: A single-center interventional trial. *American Journal of Transplantation*, 25(8), 1670–1676. https://doi.org/10.1016/j.ajt.2025.03.029

[4] Sellers, M. T., Grandas, J., Warhoover, M. T., Poland, J. D., & Clapper, D. C. (2025). Normothermic regional perfusion performed by a United States organ procurement organization for nonthoracic organ donors. *American Journal of Transplantation,* 25(8), 1677–1684. https://doi.org/10.1016/j.ajt.2025.04.005

[5] Ibid.

[6] Murphy, N. B., Slessarev, M., Basmaji, J., Blackstock, L., Blaszak, M., Brahmania, M., Chandler, J. A., Dhanani, S., Gaulton, M., Gross, J. A., Healey, A., Lingard, L., Ott, M., Shemie, S. D., & Weijer, C. (2025). Ethical Issues in Normothermic Regional Perfusion in Controlled Organ Donation After Determination of Death by Circulatory Criteria: A Scoping Review. *Transplantation, 109*(4), 597–609. https://doi.org/10.1097/TP.0000000000005161

[7] Manara, A., Shemie, S. D., Large, S., Healey, A., Baker, A., Badiwala, M., Berman, M., Butler, A. J., Chaudhury, P., Dark, J., Forsythe, J., Freed, D. H., Gardiner, D., Harvey, D., Hornby, L., MacLean, J., Messer, S., Oniscu, G. C., Simpson, C., Teitelbaum, J., … Watson, C. J. E. (2020). Maintaining the permanence principle for death during in situ normothermic regional perfusion for donation after circulatory death organ recovery: A United Kingdom and Canadian proposal. *American Journal of Transplantation, 20*(8), 2017–2025. https://doi.org/10.1111/ajt.15775

Raising awareness about NRP, including sharing evidence-based guidelines and best practices to optimize patient safety, will better enable OPTN members to assess and mitigate potential risks associated with NRP. Therefore, we direct the OPTN to prioritize education initiatives that promote greater awareness of what NRP is and how it may be safely used during the organ donation and procurement process.

As part of their initial tasks, the NRP Workgroup should:

1. Draft, for HRSA review, communication to all OPTN members that explains what NRP is and highlights what purpose it serves in the organ procurement and transplantation system. This communication should be submitted to HRSA by **October 17, 2025**.

2. Solicit information on any policies or practices related to NRP from OPTN members and evaluate system-wide use of NRP. HRSA recommends that the workgroup gather this information by **October 27, 2025**.

3. Draft, for HRSA review, communications to make information gathered from individual OPTN members accessible to all OPTN members and the public, including:
    a. Information gathered from OPTN members on their policies and practices related to NRP, anonymized as appropriate,
    b. OPTN analysis of those policies and practices, and
    c. Additional relevant analysis of NRP and patient safety, such as OPTN requirements, other regulatory requirements, research papers, articles, and shared policies related to the use of NRP.

    This communication should be submitted to HRSA by **November 14, 2025.**

HRSA encourages the OPTN to gather a broad range of the most recent analysis and research in the field.[8] Making these resources more widely available will help inform and guide policymaking activities.

Additionally, to increase transparency and the general public's awareness of the organ procurement and transplant system, HRSA is separately directing the OPTN contractor to update the OPTN's *Strengthening Organ Donation and Procurement Safety* webpage[9] with content on NRP. This update will include the following components:

- **Information and Tools**: Graphic(s) and a plain-language description of what NRP is, accompanied by links to existing NRP materials (e.g., research, data, initiatives, etc.) from the OPTN website to promote more seamless information sharing across OPTN committees, members, and the public.

[8] For example, the NRP Workgroup may reference The Alliance's materials from the 2024 *Developing National NRP Best Practices and Approaches* conference to help facilitate efforts to address patient safety in the use of NRP: https://www.organdonationalliance.org/courses/2024-national-collaboration-forum/

[9] See OPTN *Strengthening Organ Donation and Procurement* webpage: https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/strengthening-organ-donation-and-procurement-safety/

- **Updates and Engagement**: Regular updates on the OPTN's progress towards developing policy regarding the safe practice of NRP in collaboration with HRSA.

HRSA anticipates the NRP content web update will be active within 30 days from issuance of this letter, with iterative improvements made over time. Iterative improvements should be made to incorporate patient, family member, and community feedback, including but not limited to the OPTN Patient Affairs Committee, Membership and Professional Standards Committee, and Ethics Committee.

(III) Directed Action: Completion of HRSA's data request for high-impact items

HRSA directs the OPTN to initiate the collection of a prioritized subset of HRSA's original data request, beginning with items that will have the greatest impact on the OPTN's ability to increase patient safeguards in NRP and ensure HRSA's ability to conduct effective oversight. For items A.1 and A.2 below, HRSA will separately direct the OPTN contractor to deliver the data requested; **no action is needed from the OPTN on A.1 and A.2.** We note that all relevant responsive materials from the contractor will be provided to the OSC NRP Workgroup.

These data should be provided to HRSA by **October 27, 2025**.

- **A.1 (Review and assess committee and regional meeting materials; to be handled by the OPTN contractor)** The OPTN response notes the scale of venues in which NRP may have been discussed ("134 active committees, subcommittees, and workgroups, 77 regional meetings and 46 board meetings"[10]). The OPTN operations contractor should provide information on whether formal or informal thematic analysis is routinely done on the discussions in any or all of these venues, and if any such analysis of the frequency or acuity of attendees' concerns was performed regarding NRP.

- **A.2 (MPSC discussions; to be handled by the OPTN operations contractor)** The OPTN operations contractor should provide all contractor staff communications and/or documentation created by the contractor team regarding proposed actions to address a "rise in NRP."[11]

- **A.3 (Instructions to committees etc. to study NRP)** The OPTN's response identifies several ongoing projects. The OPTN should align any open committee work on NRP and, as it has with the AOOS workgroup, merge the workstreams to reduce redundancy and increase efficiency of efforts.

[10] See the OPTN's April 30, 2025 letter to HRSA: https://optn.transplant.hrsa.gov/media/kziehz1t/optn-nrp-directive-reponse-04302025.pdf
[11] See page 1 of the October 8, 2024 OPTN response to HRSA's initial critical comment letter on NRP: https://optn.transplant.hrsa.gov/media/ucsnqszp/optn-response-nrp-critical-comment-10082024.pdf

- **A.4-6 (Organ Procurement Organization (OPO) Committee, including the Machine Perfusion Data Collection Workgroup)** The OPTN will update A.5 if changes to the timeline described in the April 30 proposal have occurred by the time of response to this direction. **HRSA notes that the OPTN's response to HRSA's question A.6 is that this committee was "focused on identifying data that would be informative for organ offer evaluation and assessing posttransplant recipient outcomes,"[12] not patient safety.** Given that the OPTN received HRSA's critical comment regarding allegations of patient harm in the setting of NRP use, the OPTN should update this proposed policy to ensure that relevant data are collected that assess the safety and quality of the provision of NRP. The OPTN should capture time of cannulation (pre- or post-mortem), and technique of obstructing cerebral blood flow and venting the cerebral vasculature, if performed.

- **A.7 (Gather a list of all NRP contractors doing business with OPOs)** While the original question from HRSA's March 5 letter asks for "the number of OPTN business members that may hold third party contracts with OPOs or transplant centers to provide NRP services,"[13] HRSA requests that OPO members provide information on all perfusion contractors, not just "OPTN business members." In HRSA's review of materials provided in reply to the original critical comment, 29 OPOs identified 11 third-party (i.e. non-center, non-OPO) entities who provide perfusion support for NRP. Only two of these companies are OPTN business members (BSGR, Gravitas Surgical Solutions, LLC, and BSPC, Procure On-Demand, Inc), and they serve only four OPOs. Gathering more information regarding third party contractors actively engaged with OPOs will extend the OPTN greater visibility into when and where NRP services are subcontracted, and how OPOs may assess the general safety and reliability of subcontracted NRP in organ procurement.

- **C.1-4 (Collection of education materials and reports of concern)** This data directive does not require additional review and can be accomplished by the OPTN through direct communication to OPOs without further delay.

(IV) *Additional Analysis*

In addition to the four papers from Hoffman et al., Croome et al., Royo-Villanova et al., and Sellers et al. cited earlier in this letter, HRSA would like to share the following recent publications which may be relevant to the OPTN's development of policy and standards relating to the practice of NRP.

- Shemie, S. D., & Watson, C. J. E. (2025). Normothermic Regional Perfusion in Controlled DCDD- Confirming the Absence of Brain Reperfusion. *American Journal of Transplantation*. https://doi.org/10.1016/j.ajt.2025.05.031

[12] See page 5 of the April 30, 2025 OPTN response to HRSA in the NRP critical comment process: https://optn.transplant.hrsa.gov/media/kziehz1t/optn-nrp-directive-reponse-04302025.pdf
[13] See HRSA's March 5, 2025 letter to the OPTN: https://optn.transplant.hrsa.gov/media/uh2bcrmx/critical-comment-to-optn-5march2025-nrp.pdf

- Wang, L., Cain, M. T., Minambres, E., Hoffman, J. R. H., & Berman, M. (2025). Thoracoabdominal normothermic regional perfusion-approaches to arch vessels and options of cannulation allowing donation after circulatory death multi-organ perfusion and procurement. *Annals of Cardiothoracic Surgery*, *14*(1), 70–72. https://doi.org/10.21037/acs-2025-dcd-28
- Alderete, I. S., Pontula, A., Halpern, S. E., Patel, K. J., Klapper, J. A., & Hartwig, M. G. (2025). Thoracoabdominal Normothermic Regional Perfusion and Donation After Circulatory Death Lung Use. *JAMA Network Open*, *8*(2), e2460033. https://doi.org/10.1001/jamanetworkopen.2024.60033
- Tarzia, V., Ponzoni, M., Lucertini, G., Pradegan, N., Pittarello, D., & Gerosa, G. (2025). Normothermic regional perfusion and donation after circulatory death heart-lung procurement. *Annals of Cardiothoracic Surgery*, *14*(1), 67–69. https://doi.org/10.21037/acs-2024-dcd-0076
- Domínguez-Gil, B., Miñambres, E., Pérez-Blanco, A., Coll, E., & Royo-Villanova, M. (2025). Sustained Absence of Perfusion to the Brain Must Be Ensured During Thoracoabdominal Normothermic Regional Perfusion. *Transplantation, 109*(1), e78. https://doi.org/10.1097/TP.0000000000005230

Additionally, **HRSA is continuing to engage with the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) on safe practices in the use of NRP for DCD.** ASTS has produced clinical guidelines for standards of practice for Thoracoabdominal NRP (TA-NRP) and DCD which may be of particular interest to the OPTN and the NRP Workgroup.[14] ASTS has offered to share with the OPTN the background information and research they had access to when writing these guidelines as well as update them when the OPTN releases guidance.

- Reich, D. J., Mulligan, D. C., Abt, P. L., Pruett, T. L., Abecassis, M. M., D'Alessandro, A., Pomfret, E. A., Freeman, R. B., Markmann, J. F., Hanto, D. W., Matas, A. J., Roberts, J. P., Merion, R. M., Klintmalm, G. B., & ASTS Standards on Organ Transplantation Committee (2009). ASTS recommended practice guidelines for controlled donation after cardiac death organ procurement and transplantation. *American Journal of Transplantation, 9*(9), 2004–2011. https://doi.org/10.1111/j.1600-6143.2009.02739.x
- Ethics Committee, American College of Critical Care Medicine, & Society of Critical Care Medicine (2001). Recommendations for non-heart beating organ donation. A position paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine. *Critical Care Medicine, 29*(9), 1826–1831. https://doi.org/10.1097/00003246-200109000-00029
- Potts, J. T., Jr., & Herdman, R. (1997). *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement.* National Academies Press (US). https://doi.org/10.17226/6036

[14] "ASTS Position Statement on vascular ligation and/or venting of the aortic arch vessels during Thoracoabdominal Normothermic Regional Perfusion (TA-NRP)." American Society of Transplant Surgeons. https://www.asts.org/docs/default-source/position-statements/asts-position-statement-on-vascular-ligation_venting-of-the-aortic-arch-vessels-during-ta-nrp.pdf?sfvrsn=8e8d51d3_3

- Institute of Medicine (US) Committee on Non-Heart-Beating Transplantation II: The Scientific and Ethical Basis for Practice and Protocols. (2000). *Non-Heart-Beating Organ Transplantation: Practice and Protocols.* National Academies Press (US). https://doi.org/10.17226/9700
- Childress, J. F., Liverman, C. T., & Institute of Medicine (2006). *Organ donation: Opportunities for action*. *2006*, 358. http://doi.org/10.17226/11643
- Dhanani, S., Hornby, L., van Beinum, A., Scales, N. B., Hogue, M., Baker, A., Beed, S., Boyd, J. G., Chandler, J. A., Chassé, M., D'Aragon, F., Dezfulian, C., Doig, C. J., Duska, F., Friedrich, J. O., Gardiner, D., Gofton, T., Harvey, D., Herry, C., Isac, G., … Canadian Donation and Transplantation Research Program (2021). Resumption of Cardiac Activity after Withdrawal of Life-Sustaining Measures. *The New England Journal of Medicine, 384*(4), 345–352. https://doi.org/10.1056/NEJMoa2022713
- Croome, K. P., Barbas, A. S., Whitson, B., Zarrinpar, A., Taner, T., Lo, D., MacConmara, M., Kim, J., Kennealey, P. T., Bromberg, J. S., Washburn, K., Agopian, V. G., Stegall, M., Quintini, C., & American Society of Transplant Surgeons Scientific Studies Committee (2023). American Society of Transplant Surgeons recommendations on best practices in donation after circulatory death organ procurement. *American Journal of Transplantation, 23*(2), 171–179. https://doi.org/10.1016/j.ajt.2022.10.009
- Royo-Villanova, M., Miñambres, E., Sánchez, J. M., Torres, E., Manso, C., Ballesteros, M. Á., Parrilla, G., de Paco Tudela, G., Coll, E., Pérez-Blanco, A., & Domínguez-Gil, B. (2024). Maintaining the permanence principle of death during normothermic regional perfusion in controlled donation after the circulatory determination of death: Results of a prospective clinical study. *American Journal of Transplantation, 24*(2), 213–221. https://doi.org/10.1016/j.ajt.2023.09.008

Please see the table below for a summary of the tasks outlined in this letter.

Plan Section	*Task*	*Owner*	*Due Date*
I	Develop a proposal for an NRP Workgroup under OSC and submit to HRSA	OPTN BOD	October 10, 2025
II	Draft a communication, for OPTN members, on the use of NRP and submit to HRSA	NRP Workgroup	October 17, 2025
II	Solicit information from individual OPTN members on policies and practices related to NRP	NRP Workgroup	October 27, 2025
II	Draft a communication, for OPTN members and the public, on individual OPTN member NRP policies and practices and submit to HRSA	NRP Workgroup	November 14, 2025

Plan Section	*Task*	*Owner*	*Due Date*
III	Submit to HRSA items A.1-2, as outlined in this letter and HRSA's March 5 letter.	OPTN Operations Contractor	October 27, 2025
III	Submit to HRSA items A.3-A.7 and C.1-4, as outlined in this letter and HRSA's March 5 letter.	OPTN BOD	October 27, 2025

Creating clear, actionable, patient-centered guidance on the responsible use of NRP, especially as it relates to DCD, is critical to ensuring that organs are procured as safely and effectively as possible. Given that my role as HRSA's Health Systems Bureau Associate Administrator is one of oversight, on behalf of the Secretary, I will review the OPTN's response considering the requirements of the National Organ Transplant Act and the OPTN Final Rule.

Sincerely,
/Suma Nair/

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