We submit this plan in response to the Health Resources & Services Administration (HRSA) Associate Administrator Suma Nair's Directive, on behalf of the Secretary of Health and Human Services (HHS), to the Organ Procurement and Transplantation Network (OPTN) on March 5, 2025, regarding the practice of normothermic regional perfusion (NRP). This March 5 directive builds off of a previous directive from HRSA, dated September 27, 2024, in which HRSA directed the OPTN and an OPTN Contractor (UNOS)[1] to collect information from all OPOs regarding their policy regarding the use of NRP within their Donation Service Area; the current list of third-party vendors with which the OPTN OPO member contracts or formerly contracted for NRP; and the OPO's training requirements, licensure requirements, and/or procedures around the use of NRP in any of the following clinical settings: donor hospitals, privately held OPO surgical facilities, or OPO-operated, hospital-based surgical units. All of this information was previously collected by UNOS and transferred to HRSA in October 2024.

In the current directive, The OPTN was tasked with providing a detailed plan (Plan) to HRSA outlining:

1. Proposed OPTN policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations 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 in patients from whom organs may be procured.

In developing the Plan, HRSA also requested that the OPTN provide HRSA with additional information regarding NRP in four parts:

Part A: Provide additional information to HRSA regarding OPTN's previous analysis and actions regarding NRP taken prior to September 27, 2024.

Part B: The OPTN must collect from OPOs additional information to inform HRSA's review of non-standard OPO protocols, which are not currently subject to OPTN policy requirements regarding NRP may contribute both to widely variable conditions under which patients may undergo NRP protocols in the attempt to procure organs, as well as variable processes under which NRP may be administered.[2]

Part C: The OPTN must collect from OPOs additional information about OPO authorization or consent processes regarding NRP to provide to HRSA.[3]

Part D: Provide HRSA with additional information and updates about the OPTN Operations and Safety Committee project to standardize NRP practices, including how the OPTN plans to use the

[1] For the sake of clarity, now that there are multiple Contractors hired by HRSA to support the work of the OPTN, we will refer to the specific Contractor directed to do this work by its business name, UNOS. References to UNOS should be interpreted as UNOS performing work under the OPTN Contract.
[2] See Appendix B for detailed data collection elements requested by HRSA for Part B.
[3] See Appendix C for detailed data collection elements requested by HRSA for Part C.

information HRSA requests vis a vis this Directive to develop policies, data collection, and patient safety monitoring practices regarding NRP.

Below, the OPTN highlights an estimated schedule of milestones related to the work, a proposed high-level approach, as well as highlighting relevant assumptions and challenges specific to the objective outlined, as appropriate. These estimates and approach are all subject to the following **assumptions**:

- HRSA has determined that all work being Directed to the OPTN and UNOS is authorized NOTA, the OPTN Final Rule and the OPTN Contract.
- The HRSA Contracting Officer (CO) has waived UNOS's requirements under the OPTN Contract Performance Work Statement (PWS) Task 3.5, and subsections therein, to collect all official OPTN data on forms approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, and therefore OMB approval is not required for this one-time data collection.
- The scope of this Directive does not change. If scope is expanded, by either the OPTN or HRSA, the resources, timelines, and approach will be impacted.
- The timelines within this proposal assume consistent and constant progress on the initiative. The timelines do not account for time spent on other directives or time sensitive requests from HRSA.
- The timelines within this proposal do not include additional time HRSA may deem necessary for reviewing information, providing feedback, or granting approvals.
- Given the importance and complexity of the topics within this Directive, HRSA's active participation is essential for the successful execution of this plan.
- This work will not begin until HRSA provides approval of this Plan and requests to execute the Plan in writing to both the OPTN and the OPTN contractor(s) supporting this work.
- HRSA will instruct the OPTN and UNOS regarding appropriate privacy protections for any patient data submitted pursuant to this Directive.
- HRSA will instruct the OPTN and UNOS regarding appropriate sharing of the data collected pursuant to this Directive with OPTN committees, as well as with potential external requesters.
- HRSA will instruct the OPTN and UNOS regarding appropriate linkage of the data collected pursuant to this Directive with existing OPTN data.
- The OPTN previously recommended to HRSA that the same or similar data be collected from transplant hospitals as well, as transplant hospitals often perform the NRP procedures and would likely be in possession of additional standards, protocol, and other relevant data.[4] The OPTN continues to believe these data should be collected from transplant hospitals in order to complete a more fulsome review of the practice of NRP for the benefit of patient safety. However, this Plan is limited to collecting data only from OPOs and OPTN Business Members, as requested by HRSA.

[4] Formica, Rich, Letter to Dr. Suma Nair, "OPTN Response to Sept. 27 Critical Comment re: NRP," October 8, 2024.

**OPTN Response Part A:**

**HRSA's Request:** Provide additional information to HRSA regarding OPTN's previous analysis and actions regarding NRP taken prior to September 27, 2024, including:

1. The date, agenda, recordings, and discussion notes for each item at a Board of Directors meeting, OPTN Committee meeting, and/or OPTN regional meeting during the period from January 1, 2021 to September 27, 2024, specifically related to the need for and development of standards and policies related to the use of NRP.
2. The OPTN response describes a "*rise in NRP cases*" around January 2023 as noted by the Membership and Professional Standards Committee (MPSC). The OPTN notes that this "*rise*" led to a communication with OPTN members.[1]
    a. Please provide all records, including but not limited to dates, agendas, recordings, and discussion notes, related to the identification of this "*rise*" in NRP cases as identified by the MPSC.
    b. Please describe if, and when, the MPSC informed the OPTN board regarding the "*rise in NRP cases*," and all actions considered by the MPSC and/or OPTN board to address this "*rise*."
3. Please describe if, and when, the OPTN instructed any committee, workgroup, or task force to gather information when NRP is planned, attempted, or successfully performed in the clinical procurement of organs, including, but not limited to, any actions prior to September 26, 2024.
4. Please provide all records, including but not limited to dates, agendas, recordings, and discussion notes, related to the OPO Committee's proposed data collection tool for machine perfusion, including NRP, proposed on or around March 27, 2024.[2]
5. Please verify the OPO Committee's stated timeline of submitting a proposed machine perfusion data collection for public comment in July 2025,[3] and target for submission to OPTN Board for approval in December 2025.[4] Please specify at what target date the OPTN anticipates requiring such data collection if Board approval occurs in December 2025.[4]
6. Please describe if, and how, the OPO Committee's and/or Machine Perfusion Data Workgroup's proposed data collection fields address potential donor patient safety concerns or potential adverse events in NRP.
7. Please provide, for each OPTN business member, confirmation if the business member has provided third-party NRP services under contract or other agreement with an OPO or transplant center since January 1, 2021, a description of those services, and identification of the OPOs and transplant centers to which such business member provided those services and timeframe during which they were provided.

**Preliminary Work:** A robust review of OPTN meeting materials is necessary to support this Directive. While most of these materials are already available to HRSA on the OPTN Deliverables Platform and OPTN website, the effort required to assess the content of these materials is outlined below.

**Lead:** This work will be completed by UNOS. If needed, collaborating OPTN committees will be consulted for any outstanding questions.

**Collaborating Committees:** OPO, MPSC, DAC

**Approach:**

**A.1:** UNOS will conduct a thorough review and assessment of all OPTN Board, Committee, and Regional Meeting summaries from January 1, 2021 to September 27, 2024 specifically regarding the need for and development of standards and policies related to the use of NRP. This will include a review of meeting summaries from 134 active committees, subcommittees, and workgroups, 77 regional meetings, and 46 Board meetings during this time period for references to NRP. A list of relevant meeting dates, agendas, recordings, and meeting summaries will then be provided to HRSA.

**A.2.a-b:** Similarly, UNOS will conduct a thorough review of all OPTN Membership & Professional Standards Committee (MPSC) and OPTN Board meeting agendas and summaries during the same period to identify instances in which the Board or MPSC discussed NRP or a "rise" in NRP cases, and actions considered in response. Further, the OPTN will describe if, and when, MPSC informed the OPTN Board regarding the "rise in NRP cases" and all actions considered by the MPSC and/or OPTN board to address this "rise." A list of relevant meeting dates, agendas, recordings, and meeting summaries will then be provided to HRSA.

**A.3:** As UNOS is reviewing and assessing meeting materials described in A.1, any instances of OPTN Board or Executive Committee (Ex Comm) instruction from January 1, 2021 to September 27, 2024 to gather information on NRP will be identified and included in the final list described above. OPTN project work related to NRP includes:

| Project Name | Sponsoring Committee | Milestone Dates | Project Status |
|---|---|---|---|
| Enhancements to OPTN Donor Data and Matching System Clinical Data Collection | OPO | Project approval: 3/24/22<br>Public Comment: 8/3/22-9/28/22<br>Board Approval: 12/5/22<br>Implementation: TBD | Board approval (Dec 2022), Implementation pending OMB approval |
| Ethical Analysis of Normothermic Regional Perfusion | Ethics | Project approval: 6/26/22<br>Public Comment: 7/27/23-9/19/23<br>Board Approval: 12/4/23<br>Implementation: 1/23/24 | Implemented |
| Machine Perfusion Data Collection | OPO | Project approval: 9/26/24<br>Public Comment: Expected Summer 2025<br>Board Approval: Expected December 2025<br>Implementation: TBD | In development (See sections A.5-A.6 for more details) |

| | | | |
|---|---|---|---|
| Standardize Practice in the Use of Normothermic Regional Perfusion in Organ Procurement Guidance Document | Operations and Safety | Project approval: 9/26/24<br>Public Comment: TBD<br>Board Approval: TBD<br>Implementation: TBD | Paused |
| Review of Donation After Circulatory Death (DCD) Policies | OPO | Project approval: 11/1/24<br>Public Comment: Expected Summer 2025<br>Board Approval: Expected December 2025<br>Implementation: TBD | In development (See sections A.5-A.6 for more details) |

**A.4:** UNOS will conduct a thorough review and assessment of the OPO Committee's discussions related to the proposed data collection tool for machine perfusion. These meeting dates, agendas, recordings, and meeting summaries will be included in the list as described in A.1.

**A.5**: As of April 30, 2025, the OPTN can verify that the OPTN OPO Committee intends to complete its current work on the "Machine Perfusion Data Collection" project (1483) originally approved for project development by the OPTN in September 2024, and will submit a data collection proposal, including proposed new data fields relating to NRP and other types of machine perfusion, to the OPTN Policy Oversight Committee (POC) and Ex Comm for approval for the summer 2025 public comment period. The target date when the data would become required to be collected and submitted to the OPTN following Board approval will be contingent upon approval from the OMB under the Paperwork Reduction Act. The OPO Committee will update the POC and Ex Comm should any late barriers arise that would delay meeting the original approved target dates.

**A.6:** The purpose of the OPTN OPO Committee's "Machine Perfusion Data Collection" project is to improve data collection on the use of machine perfusion devices including normothermic regional perfusion. The Committee formed a Workgroup, the Machine Perfusion Data Workgroup, which focused on identifying data that would be informative for organ offer evaluation and assessing post-transplant recipient outcomes.

Accordingly, the potential new data fields identified in the project thus far are intended to support identification of potential adverse events for transplant recipients following organ procurement using NRP. Potential donor patient safety concerns may be reported to the OPTN via the OPTN Patient Safety Reporting Portal or anonymously via the OPTN Confidential Reporting line.

**A.7**: Upon approval of the Plan and at the request of HRSA for the OPTN and UNOS to implement the plan, UNOS will pull a list of all OPTN business members from the OPTN membership database. UNOS will then request from those known OPTN business members confirmation if each business member has provided third-party NRP services under contract or other agreement with an OPO or transplant hospital since January 1, 2021. If an OPTN business member responds that they have

provided those services, then UNOS will also request a description of those services and identification of the OPOs and transplant hospitals to which each business member provided those services and the timeframe during which those services were provided. UNOS will then provide this information to HRSA.

**Schedule of Delivery and Milestones**

| **Phase** | **Timeline** |
|---|---|
| Review and assessment of committee and regional meeting materials | 20 business days |
| Review and assessment of MPSC, Ex Comm, and Board materials | 2 business days |
| Requested timeframe for collecting the information from OPTN business members | 10 business days |
| **Total Estimated Duration Until Delivery of Inventory to HRSA** | 30 business days following approval of the Plan by HRSA |

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**OPTN Response Part B:**

The estimates and approach for data collection in Part (B) (1-11) and Part (C) (1-4) share the same **assumptions** as noted below:

- This is a one-time retrospective data collection activity.
- The HHS Secretary is directing OPOs to submit the data included in this directive, which means the data are official OPTN data; UNOS is facilitating the data collection process and will retain the data until otherwise directed by HRSA.
- While the data collected as part of this Directive are official OPTN data, said data is not automatically available for request through the OPTN data request process unless HRSA so directs. UNOS will follow HRSA's direction regarding sharing these data, including whether any information collected should be redacted or discussed during closed Committee or Board sessions.
- UNOS will request the data from the OPOs pursuant to this Directive using the language in the Directive; the OPTN and UNOS will not interpret the language for OPOs. Because different OPOs

may interpret the requests differently, the quality of the data collected, and the ability to analyze the data, may be impacted.[5]

- Duration estimates for the data collection aspects of this Plan are based upon skilled resources working exclusively on the collection activities.

**Preliminary Work:** UNOS will organize the requirements and scope for the data collection and perform a discovery with staff and OPO system vendors to strategize on the most efficient and effective methods for collecting the requested information. UNOS will develop standardized data collection instruments for the OPOs to use that will collect both structured patient-level data and unstructured documents, forms and artifacts. While this is a one-time retrospective data collection exercise, the structured data will be collected in such a manner that it can be easily consolidated, aggregated and available for data analysis.

**Lead:** This work will be completed by UNOS.

**Collaborating Committees:** UNOS will collaborate with OPO subject matter experts, ideally those volunteering on the OPO Committee or MPSC, and will hold a discovery session with the OPO electronic donor record (EDR) vendors to identify efficient methods to collect high quality data.

**Approach:** UNOS will collect the requested data outlined in Part B (1-11) from OPOs using structured data collection instruments. Additionally, UNOS will establish a secure method for sharing structured and unstructured data files between all parties involved in data collection and sharing. This data collection approach follows best practices for data management and includes the following phases: planning; development; testing; execution; and merge/transfer. The data will be collected in a standardized manner to support future HRSA, OPTN Committee, or Board requests for aggregation and analysis. An OPO data submission schedule was not specified in the Directive, however UNOS will develop a schedule and propose OPO submission cadence and timelines to HRSA. If the submissions are staggered (for example, if each OPO is required to submit one year's worth of structured patient-level data at a time) UNOS recommends starting with 2024 data and working backwards, as the NRP activity levels have likely increased yearly over the data collection time period.

Below is the summary plan and duration. See Appendix A for the detailed plan.

[5] For example, in HRSA's description of the data to be collected, the phrase "donor patient" is used. This is not a phrase that appears in the OPTN lexicon. The OPTN Final Rule definition of "organ donor" "means a human being who is the source of an organ for transplantation into another human being." 42 C.F.R. §121.2. The OPTN has its own discrete definition for "deceased donor": "An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death." OPTN Policy 1.2: Definitions; Definition of Deceased Donor.

**Summary Plan and Duration***

| Phases | Duration (weeks) |
|---|---|
| Planning | 8 |
| Development | 5 |
| Testing | 3 |
| Execution | 16** |
| Merge and Transfer | 4 |
| **Total Estimated Duration** | 9 months following approval of the plan by HRSA |

*Summary Plan includes Part (B) and (C) data collection

**OPO submission timeline estimated 120 days/4 months

**B.12.** On December 5, 2022, the OPTN Board of Directors approved the collection of data collection on whether NRP recovery was performed on a donor (yes/no) and date and time of initiation of NRP.[6] This data collection has not yet been implemented as it is pending approval by the Office of Management and Budget.[7]

As outlined in A(5), the OPO Committee and its Machine Perfusion Data Collection Workgroup intend to submit a data collection proposal to the POC and Ex Comm for public comment approval for the summer 2025 public comment period. This new proposal would build on the December 2022 data collection and include new data fields relating to NRP and machine perfusion.

The OPTN will direct a committee to review the items described in (B) (1-11) and consider if any of these items should be incorporated into a subsequent proposal.

**Anticipated Challenges:**

- Some OPOs may need more support than others in providing the data and documents in a timely manner.
- Since the OPO practices are not standardized for NRP, it is expected that some data collection will require some level of interpretation. As stated above in the Assumptions for Part B, UNOS will request the data using the language provided by HRSA in the directive. OPOs may interpret the requests differently, which may lead to inconsistent data submission.

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**OPTN Response Part C:** The estimates and approach for data collection in Part (C) share the same assumptions as Part (B). Please refer to Part (B) for this information.

**Preliminary Work:** UNOS will consolidate the data collection requests from Parts (B) and (C) together and take a consistent approach to collecting the requested information.

**Lead:** This work will be completed by UNOS.

[6] https://optn.transplant.hrsa.gov/media/uk3nv1ku/policy-notice_dn-data-collection_opo.pdf
[7] https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-approved-actions/

**Collaborating Committees:** As mentioned in Part (B), UNOS will collaborate with OPO subject matter experts, ideally those volunteering on the OPO Committee or MPSC, and will hold a discovery session with the OPO electronic donor record (EDR) vendors to identify efficient methods to collect high quality data.

**Approach:** UNOS will collect the requested data outlined in Part (C) (1-4) as part of a one-time data collection from the OPOs. The same approach defined in Part (B) will be followed for Part (C) and the Summary Plan table presented in Part (B) reflects a combined estimate. See Appendix A for the detailed plan.

**C.5.** The purpose of the OPTN OPO Committee's "Machine Perfusion Data Collection" project is to improve data collection on the use of machine perfusion devices including NRP. The Committee formed a Workgroup, the Machine Perfusion Data Workgroup, which focused on identifying data that would be informative for organ offer evaluation and assessing post-transplant recipient outcomes.

Accordingly, the potential new data fields identified in the project thus far are intended to support identification of potential adverse events for transplant recipients following organ procurement using NRP. Potential donor patient safety concerns may be reported to the OPTN via the OPTN Patient Safety Reporting Portal or anonymously via the OPTN Confidential Reporting line, and these reports will be maintained as confidential according to existing confidentiality practices.

**Anticipated Challenges:**

Part (C) has the same challenges as those identified in Part (B)

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**OPTN Response Part D:**

**HRSA's Request:** HRSA understands that the OPTN Operations & Safety Committee has been charged with establishing requirements for standardized practice in the use of NRP in organ procurement by both OPOs and transplant hospitals, and that the Committee was expected to provide a progress report to the OPTN Board in November 2024.

1. Please indicate how the OPTN plans to use the specific information HRSA requests in (B)(1)(a)-(f), above, to develop new NRP policies, policy definitions and data collection, including quality standards and standardized practices, that address patient safety. If not, explain why the OPTN has chosen to develop NRP policies in the absence of patient-level data regarding safety and outcomes.

2. Please indicate how the OPTN plans to use the specific information HRSA requests in (B)(2)-(11), above, to develop new NRP policies, policy definitions, data collection and standards for monitoring processes for patient safety relating to NRP. If not, please explain how the OPTN will develop new NRP policies, definitions, data collection, and monitoring processes in the absence of member-level information regarding adverse events, potential adverse

events, complaints, concerns from stakeholders, and/or current protocols and quality assurance processes.

3. Please indicate how the OPTN plans to use the specific information HRSA requests in (C)(1)-(4) to develop new NRP policies, policy definitions, and data collection.

**OPTN Response Part D (1-3):**

**Background:**

During their meeting on September 26, 2024, the Ex Comm approved a resolution charging the OPTN Operations and Safety Committee (OSC) with establishing requirements for standardized practice in the use of NRP in organ procurement.[8] During their subsequent meetings on October 24 and November 7, 2024, the OSC discussed this direction from the Ex Comm and developed specific recommendations for guidance, policy, and data collection project options for the OPTN Board of Directors to consider.[9,10] The OSC submitted a progress report to the OPTN Board of Directors summarizing these options in preparation for the Board's meeting on December 2, 2024.[11]

During the Ex Comm meeting on December 12, 2024, the Vice Chair of the OSC provided an update on the proposed options for establishing standards in the use of NRP in organ procurement. Following the presentation and subsequent discussion, the Ex Comm instructed the OSC to develop a guidance document on the practice of NRP, to be released for public comment in early 2025.[12]

Over the subsequent months, the OSC worked diligently to develop this guidance document and was prepared to vote to send the guidance document out for public comment on February 27,

[8] OPTN Executive Committee Meeting Summary, September 26, 2024. Available at: https://optn.transplant.hrsa.gov/media/pjyjxsdq/20240926_executive-committee_summary.pdf
[9] OPTN Operations and Safety Committee Meeting Summary, October 24, 2024. Available at: https://optn.transplant.hrsa.gov/media/2ueb1ju0/10242024_operations-and-safety-committee-meeting-summary.pdf
[10] OPTN Operations and Safety Committee Meeting Summary, November 7, 2024. Available at: https://optn.transplant.hrsa.gov/media/u3onx2nz/1172024_operations-and-safety-committee-meeting-summary.pdf
[11] OPTN Operations and Safety Committee Briefing to the OPTN Board of Directors on Response to Normothermic Regional Perfusion (NRP) Resolution, December 2, 2024.
[12] OPTN Executive Committee Meeting Summary, December 12, 2024. Available at: https://optn.transplant.hrsa.gov/media/1c2m55y1/20241212_executive-committee_summary.pdf

2025.[13,14,15,16] As part of this process, the OPTN and the OPTN Contractor worked expeditiously to accommodate an Open Forum speaker to provide the OSC with an important perspective on the use of NRP in advance of the OSC's vote.[17]

However, prior to the OSC vote to send the document out for public comment, HRSA requested the OSC consider "pausing approval" of the document for "a short time," in anticipation of the letter from HRSA to the OPTN regarding NRP, eventually sent on March 5, 2025 (which is the Directive to which the OPTN now is responding). Specifically, HRSA suggested that a short pause would, "allow the OPTN to be more efficient in its work and permit better alignment of materials released for public comment to the community." The OSC considered this request from HRSA and decided not to hold a vote to approve the guidance document for public comment review. In light of the Directive, the OPTN will consider whether the OSC Guidance document should move forward to public comment, or if a different path forward is preferred to address patient safety and the use of NRP.

In addition to the work of the OSC, other OPTN Committees have developed or are in the process of developing OPTN products related to the effective use of NRP. These efforts include the *Ethical Analysis of Normothermic Regional Perfusion,* which was developed by the OPTN Ethics Committee and approved by the OPTN Board on December 4, 2023, and the *Enhancements to the OPTN Donor Data and Matching System Clinical Data Collection* project, which was sponsored by the OPTN OPO Committee and approved by the OPTN Board in December 2022.[18,19] The OPO Committee's data collection project included the incorporation of NRP-related data elements in the OPTN Donor Data and Matching System. However, these new data elements have not been implemented, as they remain under review of the OMB.

Furthermore, the OPTN OPO Committee is currently developing a project to expand data collection related to machine perfusion and NRP. This project is described in more detail elsewhere in this

[13] OPTN Operations and Safety Committee Meeting Summary, December 19, 2024. Available at: https://optn.transplant.hrsa.gov/media/bemb0k4l/12192024_operations-and-safety-committee-meeting-summary.pdf
[14] OPTN Operations and Safety Committee Meeting Summary, January 23, 2025. Available at: https://optn.transplant.hrsa.gov/media/cuhi1pxb/1232025_operations-and-safety-committee-meeting-summary.pdf
[15] OPTN Operations and Safety Committee Meeting Summary, February 20, 2025. Available at: https://optn.transplant.hrsa.gov/media/minf12gc/2202025_operations-and-safety-committee-meeting-summary.pdf
[16] OPTN Operations and Safety Committee Meeting Summary, February 27, 2025. Available at: https://optn.transplant.hrsa.gov/media/u5pleetb/2272025_operations-and-safety-committee-meeting-summary.pdf
[17] Ibid.
[18] *Ethical Analysis of Normothermic Regional Perfusion*, OPTN Ethics Committee, OPTN Board Approved: December 3, 2023, Available at: https://optn.transplant.hrsa.gov/media/mq2m43uf/20240123-ethics_nrp_wp_final.pdf
[19] *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection*, OPTN OPO Committee, OPTN Board Approved: December 2, 2022, Available at: https://optn.transplant.hrsa.gov/media/uk3nv1ku/policy-notice_dn-data-collection_opo.pdf

document and the OPTN plans to release the prosed data collection elements for public comment consideration in the summer of 2025.

**Lead:** The OPTN will assign an OPTN Committee to develop additional NRP policies, policy definitions, and data collection to address patient safety as it deems appropriate.

The OPTN recognizes that the Ex Comm approved a resolution directing the OSC to establish requirements for standardized practice in the use of NRP in organ procurement in September 2024. As noted above, the OSC worked on an expedited timeline to develop an OPTN Guidance Document in response to this charge. However, given the evolving nature of OPTN work and the expected focus of the OSC on other OPTN projects, the OPTN will reassess if the OSC or a different OPTN committee should continue work to further develop NRP policies, policy definitions, or data collection to address patient safety, should the OPTN determine such policies, policy definitions, or data collection are necessary.

**Collaborating Committees:** The OPTN will determine if any OPTN Committees should collaborate on any future work to develop NRP policies, policy definitions, or data collection related to patient safety as it deems appropriate.

**Approach:** As previously described in this response, UNOS will release a data collection tool for OPOs to provide the requested data to HRSA. Assuming HRSA permits the data to be released to the OPTN for use in policy development and assuming the OPTN charges an OPTN Committee to initiate work on a project to develop additional policies, policy definitions, or data collection for patient safety related to NRP, the relevant OPTN committee could decide to submit a request for this data to be analyzed to inform the policy development process.

The OPTN plans to release the OPO Committee's Machine Perfusion Data Collection project for public comment in Summer 2025. Based on feedback received on this proposal and the data collected as part of this HRSA Directive, the OPTN will determine if additional efforts are required to develop NRP policies, policy definitions, or data collection related to patient safety. As part of these potential subsequent efforts, the OPTN will determine if and how the data collected as part of this directive should inform those projects. Any future projects would follow the standard policy development process and the responsible Committees would use available OPTN data as they deem appropriate.

**Schedule of Delivery and Milestones:** The OPTN plans to release the OPO Committee's Machine Perfusion Data Collection project for public comment consideration in Summer 2025, followed by an anticipated Board of Directors review in December 2025. In the meantime, the *Enhancements to the OPTN Donor Data and Matching System Clinical Data Collection* project will be implemented upon OMB approval of the proposed new data collection. The OPTN will also consider if the NRP Guidance Document, developed by the OSC, should move forward to the public comment process. The OPTN expects each of these projects to contribute to patient safety as related to NRP.

After reviewing public comment feedback received on the OPO Committee's Machine Perfusion project after the Summer 2025 public comment period, and upon submission of the data requested by HRSA, the OPTN will consider if additional efforts are required to address patient safety as it relates to NRP. If

the OPTN determines further efforts are required, the OPTN will charge a committee to consider if the data collected from OPOs through this Directive is necessary to develop such policies, policy definitions, or data collection.

**Anticipated Challenges Overall**

In addition to the challenges mentioned on the discrete components of the plan above, the OPTN anticipates the following challenges to the plan proposed as a whole:

- **Volunteer Capacity:** The availability and limited capacity of volunteers assigned to committees can impact the timeline and progress of policy development. Working on OPTN committees is not a full-time job for the OPTN volunteers.
- **Prioritization of OPTN Work**: As of the drafting of this plan, the OPTN is currently managing several HRSA directives, as well as OPTN operational work and other policy development work. The OPTN will need to prioritize the work accordingly to ensure progress continues, but timelines will be impacted. See Appendix D for Initial Assessment of Prioritization of OPTN Work.
- **HRSA Capacity**: HRSA feedback and input throughout the development process is crucial to avoiding rework and compromised timelines. HRSA representatives, like OPTN colleagues, also have other OPTN work to prioritize, and may find it difficult to provide the engagement needed to ensure an efficient project.
- **Data Collection Challenges**: HRSA is requesting a large amount of additional data from OPTN OPO members. The data collection may impose a large strain on OPO staff, and could potentially take a long time to complete. This could slow HRSA's and the OPTN's ability to use these data for near-time development of policies, guidance, or other OPTN work product. Additionally, the quality of the data collected is dependent in part on how consistently the data are reported to the OPTN for this data collection Directive. The ability for HRSA, the OPTN, and UNOS to analyze the data may be impacted by the quality of the data collected.

## Conclusion

The OPTN is committed to collaborating with HRSA to ensure the safety of all transplant patients, including donors, candidates, and recipients. We look forward to HRSA's feedback on this Plan.

## APPENDIX A – PLANNED STEPS FOR PARTS (B) and (C) DATA COLLECTION

| Phase | Step | Planned Steps - Part (B) and (C) Data Collection<br>* indicates milestone | Dependency | Duration (Weeks) |
|---|---|---|---|---|
| Planning | 1* | Finalize data collection requirements<br>- Estimating two types of data collection - patient and OPO level<br>- Define any data validation checks to execute post data collection<br>- Validate data collection requirements and scope with HRSA | | 3 |
| | 2 | Discovery with OPO vendors<br>- Identify discrete data available in OPO applications<br>- Discuss methods to efficiently collect requested data | | 2 |
| | 3* | Define the data collection instruments to use | 1,2 | 2 |
| | 4* | Review planned data collection instruments with HRSA and stakeholders | 1, 2, 3 | Meeting |
| Development | 5* | Develop data collection instruments | 4 | 4 |
| | 6 | Develop data collection schedule and review with HRSA | 4 | 1 |
| | 7 | Develop communications for data collection | 4, 6 | 2 |
| | 8 | Develop support materials to go out with data collection and set up mailbox | 4 | 2 |
| Testing | 9 | Set up and test accounts on data sharing platform | 4 | 2 |
| | 10 | Test data collection instruments end to end | 5 | 3 |
| Execution | 11* | Launch data collection activity<br>- communications, instruments and support model | 1-10 complete | Event |
| | 12* | OPOs collect data and submit according to schedule | | 16 week period |
| | 13 | Monitor data collection progress | | ongoing |
| | 14 | Respond to OPO questions and issues via mailbox | | ongoing |
| | 15 | Execute data validation checks against incoming patient level data | | At receipt |
| | 16 | Assist OPOs with data corrections that are discovered during this exercise | | Ad hoc |
| Merge and Transfer | 17 | Merge all OPO data collection into a database structure | 11 | 4 |
| | 18 | Consolidate and store OPO documents/artifacts | 11 | 2 |
| | 19* | Transfer patient and OPO level data collection to HRSA | 17, 18 | 1 |
| | 20 | Close out meeting with HRSA and OPTN leaders | 1-19 complete | Meeting |

**APPENDIX B: PART B DATA COLLECTION ELEMENTS**

Below is the collection request for Part (B) of the Directive:

HRSA requests the following information from the OPTN to further HRSA's review of NRP use in patients by OPOs to date:

1. For each OPO, please collect every patient record since January 1, 2021 for patients with attempted or actual recovery as donation after cardiac death (DCD) donor patients, including UNet DonorID and the OPO's unique patient identifier.
    a. For each patient record, please specify whether each patient had NRP:
        i. planned,
        ii. attempted (i.e., unsuccessful cannulation or initiation of circuit perfusion),
        iii. perfused and halted (i.e., perfusion for less than one hour or less than the preoperatively planned timeframe before cross-clamp), or
        iv. successfully performed.
    b. For each patient record, please specify:
        i. Cannula placement location: aortic, iliac, or femoral.
        ii. If femoral venous and/or arterial access was made pre-mortem, either for diagnostic purposes or to aid in post-mortem cannulation, please note for each line attempt:
            1. The source of consent
            2. The location of the procedure (intensive care unit (ICU), operating room (OR))
            3. The personnel performing the procedure (hospital, OPO, transplant center, other)
            4. Whether local anesthetic was used
            5. Whether sedation was given or adjusted
            6. Whether cannulae placed pre-mortem became dislodged
            7. Whether any complications were noted (hemorrhagic, embolic, ischemic, or infectious)
            8. Whether a clinical note was entered into the patient's hospital chart
            9. For patients who did not expire within the OPO's timeframe for DCD organ recovery, note whether femoral access was removed, and if so, by what personnel and at what time point (in OR, in ICU).
    c. For each of these patient records, please specify if, and which of the following procedures were used to limit extent of arterial blood flow:
        i. Clamping of brachiocephalic vessels with a single clamp
        ii. Clamping of brachiocephalic vessels individually
        iii. Suture or staple ligation of brachiocephalic vessels
        iv. Clamping of the descending aorta
        v. Suture or staple ligation of descending aorta
        vi. Balloon occlusion of the descending aorta, with indication of this as temporary or definitive control.

        For each case, please specify if the artery was divided above the level of vascular control, and if so, whether it was left open to either atmosphere or to a return line

for the NRP circuit. For cases where a clamp was used, please specify whether a single or double clamp was applied.

d. For each of these patient records, please specify how adequacy of cerebral blood flow interruption was assessed, including:
   i. If continuous arterial blood pressure monitoring was performed above the level of the clamp, and at what anatomic point.
   ii. Which individual roles, either hospital staff, OPO staff, contractor staff, or operative team staff, had designated responsibility to monitor for evidence of cerebral perfusion and/or neurologic activity on the part of the donor patient.
   iii. How use of paralytic agent in the perfusate may impact monitoring for evidence of neurologic reanimation.
   iv. The protocol response to concerns of cerebral perfusion and/or neurologic reanimation during NRP.
e. For each record, please specify whether the patient:
   i. had organs procured (and list procured organs),
   ii. expired in the operating room but had no organs procured, or
   iii. did not expire in the operating room.
f. For each patient record, please specify the terminal point of the OPO's record, including cardiac time of death (whether in operating room or on the floor) and/or discharge.
   i. For each patient with pre-mortem arterial access without a cardiac time of death, please specify if the OPO examined the patient for an ischemic injury at the cannulation site.
   ii. For each patient with pre-mortem arterial access without a cardiac time of death, please specify if the OPO noted an ischemic injury at the cannulation site.

2. For each OPO, please provide each patient record for all cases in which there was concern for neurologic perfusion and/or neurologic activity after the initiation of NRP.
   a. For each patient, provide a description of which modality of monitoring or activity detected this concern, including whether it was observed by hospital, OPO, transplant center, third party procurement, or other staff.
   b. For each patient, describe the response on the part of staff in the categories described in (B)(6)(a) above, including whether NRP was continued or aborted, and whether organs were recovered from the donor patient.
   c. For each patient, provide all post-case actions and/or education undertaken by OPO which were conducted to prevent reoccurrence of neurologic perfusion.
3. For each OPO, please specify if the NRP protocol permits drapes to be stapled to potential donation after cardiac death (DCD) donor patients procured in the operative environment.
   a. Each OPO should specify if this policy applies to all DCD potential donor patients, or only those undergoing NRP.
4. For each OPO, please specify whether the NRP protocol includes direction regarding methods of vascular control, as in (B)(l)(c) above, including any, some, or all of the following actions to be taken with cranial aspects of occluded vessel(s):
   a. Clamped,
   b. Cut,

   c. Vented externally,
   d. Aspirated from the surgical field, and/or
   e. Returned to the circuit.
5. For each OPO, please specify whether the NRP protocol does or does not include a notification or reminder to the operative team that the patient may have intact hearing or perception.
   a. If the OPO NRP protocol does not specify this notification, please include if the OPO protocol for DCD potential donor patients includes a reminder to the operative team that the patient may have intact hearing or perception.
6. For each OPO, please specify whether the NRP protocol includes methods to limit donor patients' auditory or visual awareness of surroundings during transport to the operating room and/or withdrawal of life-sustaining therapy.
   a. If the OPO NRP protocol does not specify such methods, please include if the OPO protocol for DCD potential donor patients includes methods to limit donor patients' auditory or visual awareness of surroundings during transport to the operating room and/or withdrawal of life-sustaining therapy.
7. For each OPO, please specify whether the NRP protocol permits a perfusionist or other member of the organ recovery team to remain in the patient room prior to declaration of death to manage patient movement or perform maintenance of any cannula placed pre-mortem.
8. For each OPO, please specify what, if any, OPO protocols, policies, guidelines, or third party contractual agreements describe or otherwise elaborate on potential ethical considerations that may arise in the use of NRP.
   a. Please provide all policies, guidelines, and/or educational materials provided by OPOs to hospitals regarding the use of NRP in patients in organ procurement.
   b. Please provide all agreements between OPOs and hospitals that describe, permit, or otherwise discuss the use of NRP in patients, including permission or limitations on pre-mo1iem femoral access for the purpose of NRP.
9. For each OPO, please specify the process by which the OPO verifies or otherwise documents the appropriate licensure and training of operative staff performing NRP procedures.
   a. Please provide the method by which the OPO verifies the credentialing of procuring surgeons using NRP in the OR.
      i. If the OPO specifies the Association of Organ Procurement Organization (AOPO) Credentials Information Network (ACIN), please provide a list of each ACIN data field that includes NRP information.
   b. For each OPO, please specify whether the NRP protocol permits non-licensed practitioners to participate in any component of clinical care related to NRP, including but not limited to: pre-mortem cannulation, placement of clamps for head vessel occlusion, and/or venting of the descending thoracic aorta.
      i. If the OPO contracts with a third-party procurement service, please specify if the contracted agreement permits non-licensed practitioners to participate in any, and if so, which, components of clinical care related to NRP, including but not limited to: pre-mortem cannulation, placement of clamps for head vessel occlusion, and/or venting of the descending thoracic aorta.
10. For each OPO, please specify what, if any, thresholds for neurological status exist in protocol for patient eligibility for NRP.

   a. If the OPO protocol does specify a neurological status threshold, please include the OPO rationale for this determination.
11. For each OPO, please specify what, if any, thresholds for age exist in protocol for the eligibility for patient for NRP.
   a. If the OPO protocol does specify an age threshold, please include the OPO rationale for this determination.
   b. If the OPO protocol does not specify age restrictions, please document the number of pediatric donor patients recovered via NRP by age <1, 1-5, 6-10, and 11-17 since January 1, 2021.

## APPENDIX C: PART C DATA COLLECTION ELEMENTS

Below is the collection request for Part (C) of the Directive.

HRSA seeks additional information from the OPTN regarding educational materials provided by OPOs to the families of patients related to the following:

1. For each OPO, please provide all educational materials provided to family (or LNOK) regarding NRP practice.
    a. If the OPO protocol permits NRP in pediatric patients, please specify if the OPO provides different or supplementary information regarding NRP to family (LNOK) of pediatric potential donor patients.
    b. If the OPO protocol permits NRP in high neurological status patients, please specify if the OPO provides different or supplementary information regarding NRP to family (LNOK) of high neurological status potential donor patients.
2. For each OPO, please provide the form under which a family (or LNOK) provides authorization or consent to NRP.
    a. For each OPO, please specify if, and if so, where, information about pre-mortem cannulation is provided to family (or LNOK) in the process of authorization.
    b. For each OPO, please specify if, and if so, where, OPOs provide information to family (or LNOK) regarding risks of injury from pre-mortem cannulation if the patient survives extubation.
3. For each OPO, please collect and provide all hospital- and/or family (LNOK)-initiated complaints or concerns made since January 1, 2021 for patients that were consented for NRP.
    a. Please provide the OPO's documentation of the complaint or concern, any investigative findings, and any root cause analysis completed.
    b. Please indicate if the complaint or concern was reported to the OPTN under the requirement of OPTN Bylaw 1.1.G. If not, please provide the OPO's rationale for <u>not</u> reporting the complaint or concern to the OPTN.
4. For each OPO, please collect and provide all hospital- and/or family (LNOK)-initiated complaints or concerns made since January 1, 2021 for patients that underwent NRP.
    a. Please provide the OPO's documentation of the complaint or concern, any investigative findings, and any root cause analysis completed.
    b. Please indicate if the complaint or concern was reported to the OPTN under the requirement of OPTN Bylaw 1.1.G.
        i. If not, please provide the OPO's rationale for <u>not</u> reporting the complaint or concern to the OPTN.

**APPENDIX D: Initial Assessment of Prioritization of OPTN Work**

Similar to the OPTN's submission in response to the Allocations Out of Sequence (AOOS) Directive, we provide below an initial assessment of OPTN activities that could be deprioritized to support the activities described in this Plan. Final prioritization decisions will need to be made by HRSA and the OPTN before the Plan is executed. Additional UNOS resources may be required to conduct a more detailed assessment and support additional prioritization activities. Please note that work in response to the AOOS Directive, in conjunction with work on this Directive, would be cumulative. Because of the significant demand created for OPTN resources (volunteer time, etc.) the OPTN recommends HRSA only require one Plan to be executed at a time. If HRSA requests the OPTN do work on both directives at the same time, there will be additional constraints to consider. Therefore, we recommend that HRSA hosts a prioritization meeting with the OPTN and relevant contractor(s) prior to directing work under other Directives.

This initial assessment was based on factors such as risk to patient safety, percentage completion of project, overlap of volunteer assignments, and contractor resources required to support current activities versus activities described in this proposed plan.

OPTN committee projects and other committee work to be paused due to the NRP Directive:

| Committee | Type of Work | Item to be Impacted |
|---|---|---|
| AHIRC | Monthly Meetings | Monthly meetings to be paused after June Board meeting |
| DAC | Research Report | Annual Data Report; Revisions due in September/October to present to BOD in November |
| DAC | Board Report | June Board Report would not be prioritized |
| DAC | Project Development | One of the following:<br>- Improving data quality by enhancing API functionality<br>- Expedite implementation of OPTN data changes<br>- Creation of public facing data dictionary<br>- Modifying Policy 18 to address accountability and data quality<br>- Establishing and defining critical OPTN data fields |
| DAC | Project Development | One of the following:<br>- Improving data quality by enhancing API functionality<br>- Expedite implementation of OPTN data changes<br>- Creation of public facing data dictionary<br>- Modifying Policy 18 to address accountability and data quality<br>- Establishing and defining critical OPTN data fields |
| Ethics | Project Development | Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation |
| Ethics | Monthly Meetings | Monthly meetings to be paused |
| Liver | Public Comment Update | Update Community on Continuous Distribution; Summer 2025 |

| | | |
|---|---|---|
| Lung | Project Development | Modify Lung Allocation by Candidate Biology; contingent on new project approval |
| Heart | Public Comment Update | Update Community on Continuous Distribution; Summer 2025 |
| MAC | Project Implementation | Monitor Ongoing eGFR Modification Policy Requirements |
| MAC | Monthly Meetings | Monthly meetings to be paused after June Board meeting |
| MOT | Research Report | Potential Data Request on minimum acceptance criteria for priority shares policy |
| MOT | Research Report | 6 Month Modify Effect Acceptance MR; Work planned to begin in April |
| MOT | Research Report | Any new MOT DRs (they are about to receive/already received 3 large DRs) |
| MPSC | Research Report | 3 Year Performance Monitoring Enhancement MR; October due date |
| MPSC | Project Development | Establish Multi-Organ Post-Transplant Graft Survival Review |
| MPSC | Post-Implementation Evaluation | Transplant Program Performance Monitoring Enhancement project post-implementation evaluation of effectiveness of review process for each metric |
| MPSC | Project Development | OPO Performance Monitoring Enhancement project consideration of SRTR metrics |
| MPSC | Project Development | Guidance for members contracting with third party vendors |
| NOOC | Project Development | Revisit of Reasons for Permissible Use of OPTN Computer System for Research |
| NOOC | Policy Work | While NOOC could continue to meet in an operations oversight role, would not have support to create or modify OPTN policy |
| OSC | Project Development | Re-evaluation of Deceased Donor Testing Requirements |
| OSC | Project Development | Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement |
| OSC | Research Report | 1 Year Data to Evaluate Organ Logistics and Allocation MR; Current April/May due date |
| OSC | Research Report | 2 Year Data to Evaluate Organ Logistics and Allocation MR; Early 2026 due date |
| OSC | Research Report | 6 Month Required Kidney Offer Filters MR; Current July due date |
| OSC | Research Report | 1 Year Required Kidney Offer Filters MR; Early 2026 due date |
| OSC | Research Report | 6 Month Deceased Donor Support Therapy MR; Early 2026 due date |
| Pancreas | Project Development | KP Offer Filters |
| PAC | Monthly Meetings | Monthly meetings to be paused |
| Pediatric | Project Development | Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care |
| Pediatric | Monthly Meetings | Monthly meetings to be paused |
| TAC | Monthly Meetings | Monthly meetings to be paused |

| | | |
|---|---|---|
| TCC | Project Development | Inactive Candidate Status Notifications (pending project approval) |
| TCC | Monthly Meetings | Monthly meetings to be paused |
| VCA | Research Report | 1 Year Update Transplant Outcomes Data Collection MR; dependent on IT data conversion; potential May due date |
| VCA | Research Report | 1 Year VCA into UNet MR; dependent on IT data conversion; potential May due date |
| VCA | Research Report | 1 Year Graft Failure Definition MR; dependent on IT data conversion; potential May due date |
| VCA | Research Report | 1 Year Uterus Program Membership Requirements MR; Current May due date |
| VCA | Monthly Meetings | Monthly meetings to be paused |
| VCA | Dataset Analysis | Updates to Analysis VCA transplant datasets |

Other OPTN tasks/projects that could be paused due to prioritization of NRP work:

- CMS Quarterly ESRD data update
- Equity dataset updates
- Ongoing Analysis dataset documentation
- NTIS data addition to death verification process
- Initiation of new OPTN committee project work