

AST Donation and Transplant Optimization Community of Practice
August 12, 2022

Guidelines Regarding Communication to Donor Families in Cases Where Normothermic
Regional Perfusion (NRP) is Planned

AST and ASTS leadership are asking for guidance from the DTO COP regarding donor family communications in cases where the new and emerging practice of NRP may be initiated in the DCD clinical scenario. Guidance is requested as it specifically applies to the current practices of authorization and disclosure for donation using this approach with next of kin coordinated by organ procurement personnel.

It is important to acknowledge that currently (August 2022), NRP practices are emerging at both the transplant and organ procurement organization levels and consensus within the U.S. regarding resolution of ethical concerns and legal considerations has not been achieved. Guidance presented here does not address those issues and is based on limited experience. There is an important opportunity for research into expectations, preferences, and comfort levels of the public and donor families. Guidance is offered here as a matter of preserving the fidelity of the donation process, maintaining the public trust through principles of transparency and ensuring appropriate stewardship of gifted organs.

Recommendations:

- 1) Goal of the Communication: The purpose of communication with donor families regarding specific NRP protocols that will be utilized in the donation process should be clearly established and should be guided by the following principles:
 - a. Transparency – to ensure donor families are informed regarding how the donation process will proceed.
 - b. Respect – to obtain authorization/permission as may be appropriate or required to respect the rights and interests of the donor and/or their surrogate decision makers and to respect applicable laws or regulations (for example, the NRP protocol may be under a research approval requiring donor research permission).
 - c. Stewardship – to acknowledge the responsibility of the procurement and transplant team to coordinate the gift as intended in keeping with family wishes and established hospital DCD protocols.

- 2) Form of the communication: The form of communication to donor families regarding expected initiation of NRP should be conducted in a manner consistent

with how other aspects of post-mortem interventions are communicated by the organizations involved. For example, if donor families are typically provided written information in the authorization or disclosure form regarding the placement of organs *ex vivo* on a device, this should be considered in determining the form of communication regarding NRP. The form of communication may be verbal or a combination of written and verbal. This could include language in the donation authorization form, a separate permission form and/or informational documents or talking points for procurement personnel. The goal of the communication should help guide the appropriate form the communication should take. For example, if donor authorization for research is required because the NRP is under a research protocol, written documentation may be required. Written communications never replace the need for verbal communication.

- 3) Content of the Communication: Communications to donor surrogate decision makers about NRP should include relevant information at a level that can be easily comprehended and provide a level of detail commensurate with the goal of the communication. For example, the goal of transparency does not require communication of every detail of the surgical process for organ recovery but rather communication of the relevant information such as how the process will align with the intended gift. This may include as applicable:
- a. Procedures to maximize the gift for the purpose intended (transplant and/or research)
 - b. Interventions to improve transplant outcomes for the recipient of gifted organs
 - c. Whether the process could create any risks for other desired outcomes (for example open casket)
 - d. Following the required hands-off period and declaration of death, additional procedures are typically initiated to ensure optimal perfusion of only organs intended for transplant when NRP is subsequently implemented
 - e. When thoracic abdominal NRP (TA-NRP) will be implemented in the recovery of organs, additional information including the fact that heart function may be restored to provide blood flow to the organs for the purposes of transplantation
 - f. Whether the process could create any risks for the intended outcome (transplant)

The content of the communication should include any elements required by application law, regulation, or institutional requirement (for example as conditioned in an institutional approval to implement the NRP Protocol).

It is not recommended that the content of the communication include perceived legal risks or ethical concerns. Donor families should not be in a position of resolving any such concerns in the moment of a donation decision. If family members raise any questions related to these concerns, they should be

answered honestly and directly with plain language in accordance with established best practices for family communication.

- 4) Communication with Donor Hospital Teams: It is strongly recommended that procurement teams prepare talking points and/or informational documents for donor hospital personnel to ensure the NRP protocol is fully explained and will assist them in understanding their role in the donation process. Any concerns expressed by the donor hospital care team should be addressed prior to initiating a case.

The DTO COP will continue to monitor and update recommendations as this practice evolves.