ISHLT Response to OPTN Proposal: *HRSA Directive for OPTN Donation after Circulatory Death Policy Development*

The International Society for Heart and Lung Transplantation (ISHLT) appreciates the opportunity to review the OPTN proposal, *"HRSA Directive for OPTN Donation after Circulatory Death Policy Development."* As a global professional society representing clinicians, scientists, and allied health professionals dedicated to advanced heart and lung disease and transplantation, ISHLT welcomes the OPTN's efforts to strengthen safeguards, transparency, and consistency in the donation after circulatory death (DCD) process.

ISHLT supports the overall direction and intent of the proposed policy changes and views them as a timely and necessary step to enhance patient safety, standardize practices across organ procurement organizations (OPOs) and donor hospitals, and reinforce public trust as DCD continues to expand, including within thoracic transplantation. The proposal appropriately emphasizes ethical rigor, clear accountability, and improved communication at critical decision points in the donation process.

ISHLT supports the proposal's focus on standardized and transparent communication with donor families. Clear, consistent disclosure of what families may expect during the DCD process—including applicable safeguards, potential contingencies, and retained rights—is essential to informed decision-making and maintaining trust during emotionally acute circumstances. ISHLT recognizes, however, that the scope and complexity of required disclosures may pose implementation challenges in real-time clinical settings, underscoring the importance of accompanying education, training, and coordination among OPOs and clinical teams.

ISHLT also supports the establishment of a clearly defined and enforceable unplanned DCD pause mechanism. The ability to pause procurement when concerns arise regarding neurologic function or patient comfort is a critical safeguard, particularly in high-acuity and time-sensitive environments. As these policies are implemented, ISHLT encourages continued attention to operational clarity and flexibility, including clearer delineation of which situations should and should not trigger a pause, how differences of opinion are evaluated and resolved, and how decisions are documented and communicated.

ISHLT further notes that the range of real-world clinical scenarios may extend beyond those explicitly described in the proposal and encourages the OPTN and HRSA to remain responsive during early implementation and to refine guidance as needed. In complex cases, engagement of ethics, palliative care, or risk management expertise may further support objective decision-making and reinforce confidence in the process.

With respect to the proposal's "Considerations for the Community," ISHLT offers the following observations. To mitigate the risk of undue influence on decisions to withdraw life-sustaining therapies, ISHLT believes it is appropriate to consider clearer separation between education about DCD and formal authorization, while maintaining the principle that authorization may only occur after a decision to withdraw support has been made. ISHLT agrees with the committee's rationale for not incorporating automatic neurologic triggers for an unplanned pause, given the variability of clinical presentations, but supports the development of shared, evidence-informed guidance and

education to assist clinicians and OPOs in identifying concerning changes in neurologic status or patient comfort.

ISHLT supports defining a minimum waiting period of circulatory cessation and notes that a five-minute interval is supported by available evidence and aligns with the goal of minimizing the risk of autoresuscitation. ISHLT also finds the proposed reporting requirements for unplanned DCD pauses to be generally clear and encourages the OPTN to emphasize the use of reported data for safety learning and quality improvement rather than punitive oversight. In addition, ISHLT encourages consideration of how donors who are initially activated but later deemed unsuitable are captured within reporting and evaluation frameworks, to support both patient safety and system efficiency and to avoid premature designation of donors who may not yet meet appropriate clinical criteria.

ISHLT further notes that additional clarity or reference to objective criteria used in assessing adverse neurologic prognosis—such as neurophysiologic testing or other established clinical markers—may help promote consistency across centers and strengthen confidence in determinations related to withdrawal of life-sustaining therapies, while recognizing that such assessments appropriately remain within the purview of the treating clinical team.

Summary of Key Recommendations

- Clarify operational expectations for the unplanned DCD pause mechanism, including who may initiate a pause, how concerns are evaluated, and how decisions are documented and communicated.
- Maintain flexibility during early implementation and refine guidance as real-world scenarios emerge.
- Consider clearer separation between DCD education and formal authorization to mitigate risk of undue influence, while maintaining that authorization occurs only after a decision to withdraw life-sustaining therapies has been made.
- Support shared, evidence-informed guidance and education for neurologic assessment and identification of concerning changes, without requiring rigid automatic triggers.
- Define a minimum waiting period of circulatory cessation; ISHLT supports a five-minute interval to minimize the risk of autoresuscitation.
- Ensure reporting supports safety learning and quality improvement and consider how donors initially activated but later deemed unsuitable are captured to support safety and system efficiency.
- Consider additional clarity or reference to objective criteria used in assessing adverse neurologic prognosis to promote consistency across centers.

ISHLT appreciates the OPTN's leadership in addressing these complex and evolving issues and encourages continued engagement with the transplant community, OPOs, donor hospitals, and donor families as these policies are finalized and implemented.

ISHLT Level of Support: Support the Proposal