**ISHLT Response to Expedited Placement Variance Proposal**

Although the ISHLT supports the expedited placement variance in concept and agrees with the recommended changes to policy 1.3 required for implementation, the ISHLT has concerns that the proposed variance (including proposed policy language 5.4.G "Open Variance for Expedited Placement") lacks sufficient detail to ensure that anticipated expedited placement protocols are implemented safely, transparently and equitably with sufficient oversight to ensure that patients will not be harmed and meaningful data will be obtained.

Specific comments:

1) Given the above, as well as the fact that the proposal explicitly states that it does not meet criteria for "Emergency Action" or "Expedited Action", there is inadequate justification for the timing and duration of the special public comment period. Extending the comment period until 2/4/24 is inadequate. The ISHLT recommends that the current proposal be amended to address the concerns ISHLT and other stakeholders raise and an updated version of the proposal be added to the upcoming winter public comment period, including presentation at regional meetings to allow sufficient community feedback.

2) As proposed, key operational details are confusing or missing from the proposed variance:
    a. The document opens by stating that the executive committee will be charged with developing the proposals: "This variance works by charging the Executive Committee to develop protocols for expedited placement." (this language is mirrored on the OPTN website as well). But two pages later it expands the source of protocols: "this variance proposes that one committee (the Executive Committee) solicit and approve the protocols while multiple committees can submit protocols and review the results of the variance before a policy proposal for expedited placement is proposed." This should be clarified. The ISHLT strongly recommends that the OPTN Executive Committee NOT be the sole developer of expedited placement protocols as it lacks sufficient content expertise to effectively address all organ allocation scenarios. Moreover, the ISHLT recommends formalizing the plans for inclusion of Committees and others with appropriate content expertise in analysis of expedited placement protocol results.
    b. The ISHLT recommends the adding the following elements to requirements for expedited placement protocols:
        i. Justification, including prior protocols that support the current proposal and a statistical plan (with sufficient achievable sample size) to support proceeding.
        ii. Verification that there are no conflicting/competing protocols that would limit the ability of the proposal to collect adequate data (for this purpose, it would behoove the OPTN to maintain and make accessible a catalog of current and future expedited placement protocols with results when available – including those existing protocols referred to in the proposal).
        iii. A safety plan to ensure that patients who would otherwise be offered organs are not harmed by the expedited placement protocol (including provision for independent oversight and stopping rules)

iv. A target date by which adequate sample size will be achieved, with contingency plans for extension if needed.
v. An equity plan to ensure that the proposed protocol will not create or exacerbate inequities.
vi. A transparency plan to ensure that all potentially affected parties have access to, the protocol at a minimum, and ideally, results.

3) The ISHLT strongly encourages the development of and publication for community review a set of operational guidelines to complement the policy language and support the effective implementation of this variance.

Given the above concerns, the ISHLT recommends that the OPTN pilot a single expedited protocol to ensure that the process from proposal, review, implementation, oversight, and final analysis operate without significant concerns prior to embarking on multiple concurrent protocols. Given the fact that the driver for this project was the increasing non-utilization of donated kidneys and that kidney donation is the highest volume it would make sense to pilot a kidney project first.