Staff Summary
OPO 34505N overlooked a finding of a right testicular embryonal carcinoma in a donor autopsy report.

Please note that this accompanying summary information is included to only supplement the original documentation, and assist the Committee members in their thorough review of the source documentation provided in the site survey, desk review or case investigation packet.

Please review the summary of potential policy violations and corrective action plans submitted to determine if a policy violation exists, to determine if the corrective action plan addresses the problem, and to identify an appropriate recommended action. Please provide a basis for your decision in the comments section.

Possible Action (based on historical MPSC action in similar cases):

- Notice of Noncompliance for Policy 15.4.A.

Staff Summary: OPO 34505N received an autopsy report specifying a donor had right testicular embryonal carcinoma. Physical assessment during procurement had noted scrotal swelling. The Medical Director reviewed the report, per the usual OPO process, but overlooked this finding. The liver recipient center contacted OPO 34505N after the liver recipient showed a germ cell tumor, prominently embryonal in type. The other recipient from this donor, a heart transplant patient, had already died due to graft rejection and organ failure.

OPO 12345N provided corrective actions including scanning autopsy reports into the OPO's EMR, resulting in an immediate email to the medical director (MD) and Executive Director (ED) prompting review of the autopsy. The MD and ED, or their designees, will both review every preliminary and final autopsy. The OPO added a checkbox indicating the autopsy report has been received and reviewed to the EMR. The Donor QA Committee will audit compliance with these new processes. The OPO will also educate all medical examiners in its DSA about possible donor-to-recipient disease transmissions and the importance of communicating early findings to the OPO. As part of the corrective action plan, other test results reviewed solely by the MD were identified and will now be reviewed by two parties.

Relevant Policies:
15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions states "The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows…Malignancy or other findings highly suggestive of malignancy…To…1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal…"

MPSC History:

- The OPO has no relevant MPSC history for the past three years.

Survey information: A routine on site survey of the OPO occurred on December 14-15, 2016. The OPO had a clinical score of 95 percent and some administrative errors. The MPSC reviewed the results of the survey at its meeting in July 2017 and requested a focused desk review in one year. The desk review occurred on June 4, 2018. The MPSC reviewed the survey in October 2018 and released the OPO from monitoring.

OPO Volumes

Year	Donors Recovered	Organs Recovered
2016	160	596
2017	139	499
2018	163	563
2019	24*	85*

*As of March 31, 2019

Historical MPSC actions: The MPSC would typically issue a Notice of Noncompliance in cases involving late reporting of donor malignancy. The MPSC has considered higher actions (Letter of Warning, etc.) if the member has a significant compliance history, if the nature of the violation poses a significant patient safety risk, if the member did not adequately correct the root cause of the violation, etc.

Possible Action:

- Vote YES if you agree with the proposed decision above.

- Vote NO if you feel that the issue should be closed with no action, a different action is warranted and/or you would like for the case to be placed on the discussion agenda for the PCSC and include your recommendation in your comments.