

Update Histocompatibility Bylaws

OPTN Histocompatibility Committee

Purpose of Proposal

- Clarify and update histocompatibility OPTN Bylaws
- Align with upcoming Clinical Laboratory Improvement Amendments (CLIA) changes

Proposal

- Allow multiple OPTN-approved laboratory directors at a histocompatibility lab
- Update laboratory director education and training requirements to align with CLIA
- Clarify and expand requirements for laboratory agreements with transplant programs and OPOs
- Modify required personnel and add primary data coordinator to act as OPTN point of contact (POC)

Proposal

- Update laboratory subcontracting requirements
- Remove requirement for the laboratory director to review and approve all subcontracting results before release
- Expand inactivation and withdrawal notification requirements
- Remove or clarify requirements that are redundant to existing regulatory requirements for labs

Rationale

- In 2020, the Subcommittee developed proposed changes to Bylaws
 - Histocompatibility Committee supported proposed changes and Membership and Professional Standards Committee (MPSC) endorsed initial draft language
- MPSC revised transplant hospitals and OPO Bylaws
- In 2023, Centers for Medicare and Medicaid Services (CMS) published a final rule updating CLIA
 - CLIA updates will be effective on December 28, 2024

Member Actions

- **Histocompatibility Labs**
 - Will be required to evaluate their transplant hospital and OPO agreements to ensure they meet the new requirements
 - Laboratories may choose to submit additional laboratory director applications but are not required to do so
- **OPOs and Transplant Programs**
 - May need to alter their agreements with laboratories if they do not meet the new requirements

What do you think?

- Should OPTN laboratory director education and training requirements be more stringent than CLIA, or align with CLIA as proposed?
- Are the components required within the transplant program and OPO laboratory agreements sufficient and clear?
- Should the Committee consider proposing a minimum number of cases a laboratory director must review per year for a future proposal?