

Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories

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Background

Spring
2013

- Phase 1 recommendations released
- General updates to reflect current clinical practice, address laboratory key personnel coverage

Spring or
Fall 2014

- Phase 2 recommendations released
- Education, certification, and experience requirements for key personnel
- Criteria for mandatory performance review

Problem

- Bylaws do not reflect current clinical practice or lab role in organ allocation

Changes

- Expanded definition of OPTN
Histocompatibility Laboratory
- Required elements for written agreements with
affiliated transplant program or OPO

Problem

- No balance between ensuring labs have adequate facilities and key personnel resources without duplicative requirements between OPTN, ASHI, CAP, and CLIA

Change

- Required compliance with the 2012 ASHI standards or 2012 CAP Checklists
- Required compliance with CLIA
- Deleting duplicative sections

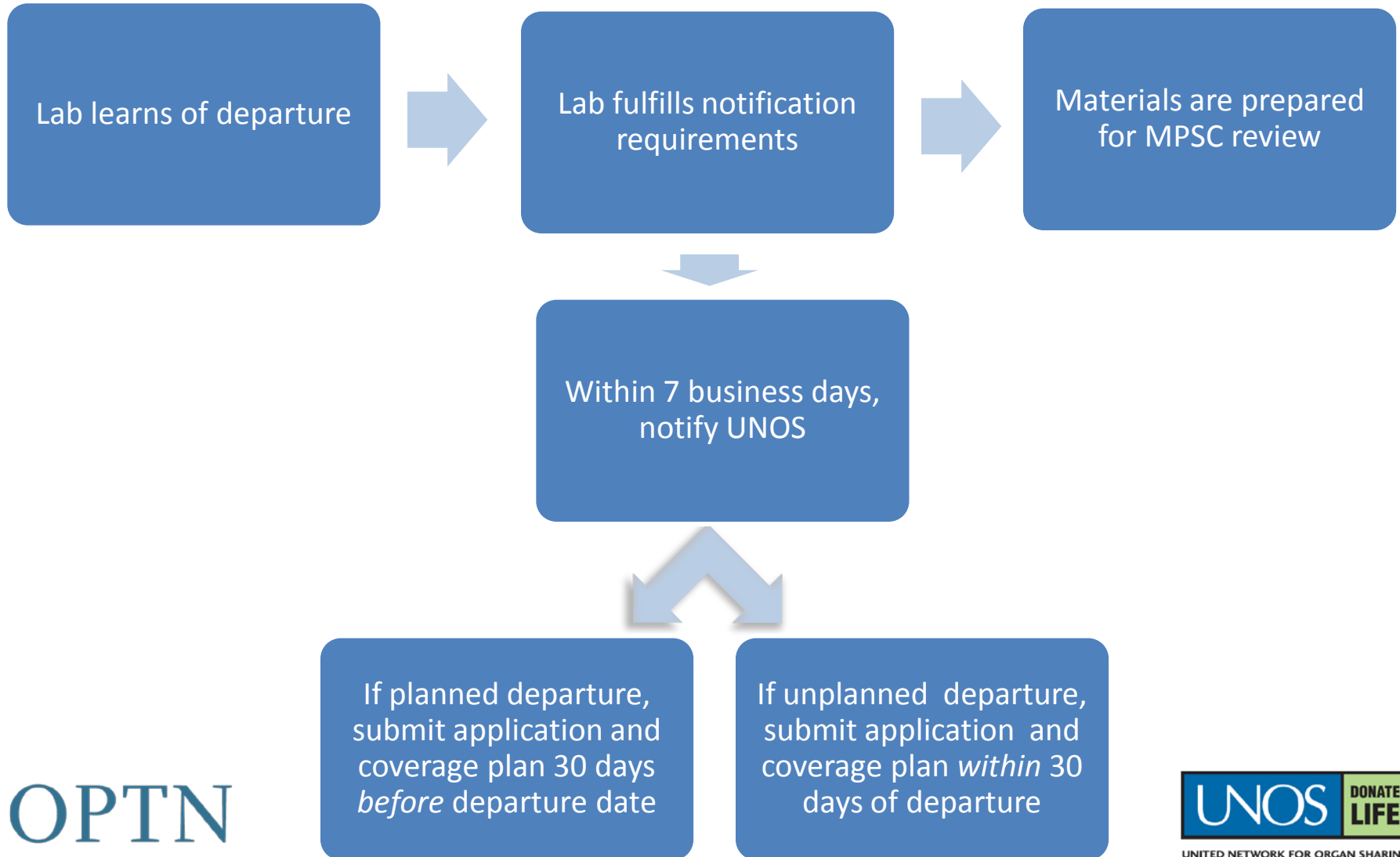
Problem

- Current Bylaws contain vague standards for notifying OPTN of laboratory key personnel changes
- Delays in notification and insufficient evidence of laboratory key personnel coverage provided

Changes

- New deadlines and documentation required for changes in key personnel and applications for new labs

Key Personnel Change Process



Laboratory Coverage Plan

- Availability of key personnel
- List of key personnel responsibilities delegated to other staff
- Documentation that qualified staff are available to perform testing (24-hour coverage if performs DD testing)
- If key personnel serve multiple labs, how continuous coverage is provided at each lab served

Spring 2013 PC Proposal

90% PT Score-
HLA typing

- Removed post-public comment
- Main source of controversy




General
Supervisor as
key personnel

- Removed post-public comment
- Fiscal impact TBD

Public Comment

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did not Consider
Individual	33	11	0	18	4
Regional	11	4	3	4	0
Committee	7	6	1	0	0

Professional Societies Feedback

Organization	In Favor	In Favor if Amended	Opposed
ASHI			
ANNA			
AST			

Major Themes: Opposing Comments

1. 90% proficiency testing grade for HLA typing
2. Compliance with 2012 ASHI or CAP documents but **not** requiring ASHI or CAP accreditation

Final Rule/OPTN Bylaws Article I.F

No OPTN member is required to become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN, comply with the bylaws of such organization, or to assume any corporate duties or obligations of any such organization.

Solution

Each histocompatibility laboratory must comply with the requirements, as they apply to solid organ and islet transplantation, of the American Society for Histocompatibility and Immunogenetics (ASHI) 2012 Revised Standards for Accredited Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality Checklist as of September 25, 2012. This requirement does not mandate membership in either ASHI or CAP.

Proposal Summary

- Expanded definition of OPTN Histocompatibility Laboratory
- Required elements for written agreements with affiliated transplant program or OPO
- Required compliance with the 2012 ASHI standards or 2012 CAP Checklists
- New deadlines and documentation required for changes in key personnel and applications for new labs

Post-Public Comment Outreach

ASHI Board of Directors

**CAP Histocompatibility
Committee and
Accreditation Team**

Resource Impact Summary

Resource Snapshot	Staff Hours Estimate	Staff Cost Estimate
Total Implementation Estimate	270	\$12,711
Annual Maintenance Cost	120	
Programming?	No	
Project Size Complexity	Small	

Resolution

***** RESOLVED, that modifications to Article 1.4 Histocompatibility Laboratory Member; Appendix C.1 Histocompatibility Laboratory Compliance; Appendix C.2 Facilities and Resources; Appendix C.3 Histocompatibility Laboratory Personnel; Appendix C.4 Changes in Key Laboratory Personnel; Appendix M: Definitions, and the creation of a new section C.4 Laboratory Coverage Plan, as set forth in Exhibit D, are hereby approved, effective February 1, 2013.**