

## Quick Response to UNOS Histocompatibility Proposals Request

Dear ASHI Members,

Upon further review of the [UNOS proposals](#) out for public comment, it was discovered that the proposed revisions to the UNOS bylaws would have a significant negative impact on the amount of HLA training necessary to direct a histocompatibility laboratory.

While ASHI is going to officially comment on these proposals again as a unified group, it is important to remember that even though we represent Histocompatibility professionals, ASHI's official comment is viewed by OPTN/UNOS as a single comment. Thus, it is important that each of us responds to UNOS ***individually*** on these proposals, so that the final revisions of their bylaws truly reflect the specific education and experience necessary to direct a Clinical Histocompatibility Laboratory and provide proper supervision of day-to-day testing.

Our concerns regarding these proposed revisions are stated below.

### **Revision to standard A1**

#### **UNOS BYLAWS ATTACHMENT II TO APPENDIX B OF THE UNOS BYLAWS**

#### **CURRENT:**

##### **I. Key Personnel Qualifications**

###### **A.1. Director Credentials**

(i) The Director must be an MD, DO, or PhD in science, and must meet the qualifications of director of high complexity testing according to Federal CLIA requirements defined in 42CFR 493.1441.

(ii) In addition to A1 (i), at least two of the years of the Director's training and/or experience must be in histocompatibility testing in a OPTN/UNOS approved training program or three years experience under a qualified OPTN/UNOS Histocompatibility Director.

#### **PROPOSED REVISION: UNOS BYLAWS ATTACHMENT II TO APPENDIX B OF THE UNOS BYLAWS**

##### **I. Key Personnel Qualifications**

(i) The Director must be an MD, DO, or PhD in science, and must meet the qualifications of director of high complexity testing according to Federal CLIA requirements defined in 42CFR 493.1441. **An M.D. or D.O. must also have a license to practice medicine in the state where the laboratory is located.**

(ii) In addition to A1 (i), **at least two of the years of the Director's training and/or experience must be in histocompatibility testing in a OPTN/UNOS an approved training program or Three years experience if the candidate is also the technical supervisor of the laboratory, they must have completed two years general immunology plus two years histocompatibility experience under a qualified OPTN/UNOS Histocompatibility Director doing histocompatibility testing for solid organ transplantation.**

***ASHI's Concern:*** The revision strikes out the need for specific histocompatibility training, which would permit any MD or DO or a doctoral level individual qualified to direct a high complexity laboratory to be able to direct a histocompatibility laboratory. This includes making clinical judgments on test results and how they may impact an individual's pre-

and post-transplant progress. The problem with the original standard is that it stated "...two of the years of the Director's training and/or experience must be in an OPTN/UNOS approved training program." There are no OPTN/UNOS approved HLA training programs, only those approved by ASHI or CAP. The only revision to the original standard should be to replace this statement with the phrase "...two years of training or experience in an OPTN/UNOS approved laboratory under the oversight of OPTN/UNOS approved Director", similar to what is suggested for the Technical Supervisor.

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## Revision to Standard B1

### **Proposed Revision**

#### **B.1. Responsibilities of a Director of a Histocompatibility Laboratory**

- (i) Ensure that the laboratory facilities are adequate and safe from physical, chemical, and biological hazards.
- (ii) Provide consultation to clients on test results.
- (iii) Must be accessible to the laboratory to provide onsite, telephone or electronic consultation, as needed.
- (iv) Ensure that an approved procedure manual is available to all technical personnel.
- (v) Ensure and monitor that all delegated duties are properly performed.
- (vi) Determine that a laboratory has a qualified general supervisor. **is on-site for all routine testing.**

**ASHI's Concern:** The removal of the phrase "...is on site for all routine testing" might open the door for a journeyman-type of General Supervisor that is rarely onsite and would "tele-supervise" multiple laboratories and not provide the rigorous day-to-day evaluation of personnel and laboratory activities to ensure quality results, patient safety, and quality patient care. It is recommended that the original wording "...is on site for all routine testing" remain in the standard and leave it to the laboratories to develop a means to be compliant with the standard.

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## Revision to C9

### **Proposed Revision**

#### **C9.000 Subcontracting**

C9.100 A UNOS approved laboratory may engage another laboratory to perform testing by subcontracting the work to that laboratory. In that event, if histocompatibility and/or transplantation immunology testing is referred, the subcontracting laboratory must be CLIA certified/**exempt** and either UNOS approved or ASHI / CAP accredited for that testing...

## Removal of the word “exempt”

**ASHI’s Concern:** The original wording of the standard (above) includes **CLIA exempt** laboratories under the heading of those laboratories that may be approved subcontractors to OPTN/UNOS laboratories. Exempt laboratories by definition do not do **High Complexity Testing** and are not eligible under CLIA to do Histocompatibility Testing. An approved subcontracting laboratory must either be OPTN/UNOS approved or ASHI / CAP accredited for that testing and the word “exempt” removed.

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### Respond to the UNOS proposals in three easy steps:

1. Click [here](#)
2. Scroll down to proposal #7 and click on the “Go” button on the far right side of your screen.
3. Complete the applicable areas of the comment submission form, indicating whether you are or are not in agreement with the revisions, and click submit at the bottom of the page.

We realize that the deadline to respond is in two days and that the holidays are nearing, but we are asking that each and every one of you take a couple minutes to send your response to UNOS so that our voice, the voice of the HLA community, is heard loud and clear. Thank you in advance!

**Remember - responses must be submitted to UNOS by December 23, 2011.**