ASHI Comments on new OPTN/UNOS Proposals due December 5, 2014.

#5 – Proposal: Data Collection and Submission Requirements for Vascularized Composite Allografts (VCAs)

ASHI Comment: This proposal includes many requirements for tests for candidates and donors but does not include any requirement at all for HLA typing either candidates or donors although the proposal does require that the pre-transplant cPRA be reported (Exhibit A, page 15) and that donor specific antibodies be reported after transplant (Exhibit A page 18). It seems to us that HLA typing for the donor should be required at least in cases when the patient has significant levels of HLA antibodies either before or after transplant. Good clinical practice would suggest that the patients with HLA antibodies should also be HLA typed themselves to ensure the validity of the specificities detected but that need not also be required.

#15 – Proposal: Policy Rewrite Parking Lot "Quick Fixes"

ASHI Comment: Since the OPTN/UNOS Board already approved the additional requirement for OPO laboratories to provide DQA1 and DPB1 types for deceased donors, and, in view of the need for correct nomenclature, we would suggest changing section 2.11.A #10 in relation to required deceased donor typing as marked here:

Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DRB1, DR51, DR52, DR53, ~~and~~ DQA1, DQB1 and DPB1 antigens. The lab is encouraged to report splits for all loci as outlined in Policy 4: Histocompatibility.

#7 – Proposal: Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)

ASHI Comments: Two of the proposed requirements for Histocompatibility Laboratory Directors are more stringent than either ASHI Standards or CMS requirements and should be revised.

- First, the proposed requirements do not provide an option for laboratory Directors who were approved and serving as Directors prior to the 2003 requirement for their board certification to have that requirement waived. There are several such highly respected and currently approved Laboratory Directors and we would wonder what would happen to them. The relevant ASHI Standard alternative option, which the OPTN/UNOS should include too, is copied here and is also included in CMS regulations: *E.2.1.3.4 Or, before February 24, 2003, must have served as a director of an ASHI-accredited laboratory performing human histocompatibility and immunogenetics testing and must meet the requirements in E.2.1.1, E.2.1.2, and E.2.1.3.*

- Second the new requirement that new directors have *publications in peer-reviewed journals.* is VERY stringent and excessive and should be deleted (the word associated with this requirement used to be "should" but that "should" word is now deleted) - it is very difficult for new clinical laboratory directors who are not involved with research to have one let alone more than one (since the word is plural) publication in a peer-reviewed journal; the other new director requirements listed on page 12 are sufficient to ensure adequate experience:

In addition, One of the new proposed Criteria for Performance Review of a Histocompatibility Laboratory (Section C.6A. page 18) is really excessive since the words "satisfactory" and "unsatisfactory" apply to results for individual send-outs; it should be changed to go back to the use of the word "unsuccessful" as defined in the ASHI Standards and by CMS as less than 80% in two out of three testing events (instead of in only one testing event). The OPTN new proposed language is this: *A. Criteria for Mandatory Performance Review of ~~Director, Technical Supervisor or Clinical Consultant~~ a Histocompatibility Laboratory. The OPTN Contractor may review a histocompatibility laboratory if at any time it has any of the following performance indicators: § Failure to comply with the requirements and regulations according to C.1. Histocompatibility Laboratory Compliance. § Any of the following performance indicators on external proficiency testing: 1. Less than 100% ~~successful~~ satisfactory performance in an ABO external proficiency testing program. 2. For programs other than ABO, a less than 80% ~~successful~~ satisfactory performance in an external histocompatibility proficiency testing program within ~~a year~~ the previous twelve months.*

This language should be changed to this: *A. Criteria for Mandatory Performance Review of ~~Director, Technical Supervisor or Clinical Consultant~~ a Histocompatibility Laboratory. The OPTN Contractor may review a histocompatibility laboratory if at any time it has any of the following performance indicators:*

§ Failure to comply with the requirements and regulations according to C.1. Histocompatibility Laboratory Compliance. § Any of the following performance indicators on external proficiency testing: 1. Less than 100% ~~successful~~ satisfactory performance in an ABO external proficiency testing program. 2. For programs other than ABO, ~~a less than 80%~~ unsuccessful ~~satisfactory~~ performance in an external histocompatibility proficiency testing program ~~within a year the previous twelve months~~ (i.e., less than 80% satisfactory performance in any two of three consecutive testing events).