ATTACHMENT II
TO APPENDIX B OF THE UNOS BYLAWS

Criteria for Designated Histocompatibility Laboratories

A histocompatibility laboratory that meets the following criteria shall be qualified as a designated histocompatibility laboratory to perform histocompatibility testing for designated transplant programs.

I. **Key Personnel Qualifications.** Consistent with current Clinical Laboratory Improvement Act (CLIA) regulations, the laboratory must have a Director, a Technical Supervisor, and a Clinical Consultant. One person can fill one, two or all three positions. All personnel must be licensed or meet the standards required by Federal, State and local laws.

A. **Key Personnel Qualifications**

A1. **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 an OPTN/UNOS approved training program or three years experience under a qualified OPTN/UNOS Histocompatibility Director.

A2. **Director Candidates**

(i) Current Directors of OPTN/UNOS labs prior to (effective date of bylaw) will be grandfathered and not be required to submit the documentation of training required.

(ii) The director candidate must provide documentation of appropriate training and experience through submission of a portfolio of cases (see iii and iv, below) covered during the training in a OPTN/UNOS approved transplant center or must have certification by the American Board of Histocompatibility and Immunogenetics. Evidence of active laboratory involvement and interaction with transplant groups must also be documented and submitted.

(iii) The director candidate must have documentation sent directly to UNOS from the director(s) of the histocompatibility laboratory(ies) under which training/experience was obtained, verifying that the candidate has successfully met the requirements specified in A1 (ii).

(iv) In addition, the director candidate must provide a letter describing his/her experience in immunology and clinical histocompatibility testing, time spent in the laboratory, technologies covered, level of responsibility, type of experience (hands on testing, review of results, development of testing, supervision of staff, etc), and a current Curriculum Vitae.

(v) If the candidate chooses to submit a portfolio, the portfolio review may be performed as fulfillment of an application to a OPTN/UNOS approved accrediting agency. Alternatively, a portfolio may be reviewed by the OPTN/UNOS Histocompatibility Committee. The following information must be included in the portfolio:

June 24, 2005
• A log of 50 cases reviewed in each technology (e.g. serology, DNA, flow cytometry techniques etc.) involved in organ transplantation (deceased donor solid organ, living donor etc.). Documentation should include the date of laboratory procedures and a record identification number, along with a brief description of the case or reference the case from a category of testing where the technology is used.

• Include a minimum of 10 complete cases with all related worksheets and notes. Inclusion of difficult cases that demonstrate the applicant’s analytical skills and ability to recognize issues in testing and interpretation and to make recommendations for additional testing or clinical care must be included.

A.3. Technical Supervisor

(i) The Technical Supervisor must meet the requirements specified in 42CFR493.1447 and A.1 and A.2, above. (S)he must have a minimum of two years of post-doctoral training and/or experience in immunology, histocompatibility/immunogenetics or a related field; or have completed a residency in clinical pathology or combined clinical-anatomic pathology. In addition, (s)he must have at least two years of training in an OPTN/UNOS approved training program or three years experience under a qualified OPTN/UNOS Histocompatibility Director.

A.4. Clinical Consultant

(i) The Clinical Consultant must be an MD or DO with a current medical license from the State in which he/she is practicing, or a PhD who is Board-Certified by one of the agencies accepted by HHS, and must have experience in clinical transplantation.

B. Personnel Responsibilities

It is the responsibility of the Laboratory Director to assure that the laboratory fulfills its obligation to provide high quality and comprehensive Histocompatibility and/or Immunogenetics testing. Below are lists of the information necessary to provide evidence that the Director and/or Technical Supervisor and/or Clinical Consultant fulfill his/her responsibilities.

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 qualified general supervisor is on-site for all routine testing.

(vii) Ensure that there are current job descriptions and task authorizations for all personnel.
(viii) Ensure that the evaluation and documentation of the performance of individuals is performed at least semi-annually during the first year, and at least annually thereafter.

(ix) Must have regular interactions with and be familiar to all staff members and be available to address issues/problems of concern to the staff.

(x) Ensure that test systems provide quality results.

(xi) Ensure that the laboratory enrolls in appropriate proficiency testing programs.

(xii) Ensure that the laboratory has quality control and quality assurance programs.

(xiii) Ensure that remedial action whenever test systems deviate from performance specifications.

(xiv) Ensure that there is documentation of all required information on test reports.

(xv) Employ sufficient numbers of personnel with appropriate training and experience.

(xvi) All delegated responsibilities of the Director must be documented, including a list of any duties that may be delegated, the times and/or situations when these duties may be delegated, the qualifications and a competency assessment of each delegate, and the quality systems to ensure each responsibility is correctly performed.

B.2. Responsibilities of a Technical Supervisor of a Histocompatibility Laboratory

(i) Select appropriate test methodologies.

(ii) Establish performance criteria, validation, and quality control for all tests.

(iii) Ensure proficiency testing is performed properly and reviewed with staff.

(iv) Ensure that technical problems are resolved, and corrective action is taken when appropriate.

(v) Ensure that test reports are issued only when test systems are functioning properly.

(vi) Identify training needs and provide in-service training as needed to assure competency.

(vii) Evaluate personnel competency and performance.

(viii) All delegated responsibilities of the Technical Supervisor must be documented, including a list of any duties that may be delegated, the times and/or situations when these duties may be delegated, the qualifications and a competency assessment of each delegate, and the quality systems to ensure each responsibility is correctly performed.

B.3. Responsibilities of a Clinical Consultant of a Histocompatibility Laboratory

(i) Ensure that test reports include pertinent information required for test interpretation.

(ii) Ensure that consultation is available to laboratory clients at all times for the evaluation of patient/donor compatibility for solid organ transplantation and that such availability is
communicated to the laboratory clients. Consultation must be available in the following areas:

(iii) Assist clients in test selection.
(iv) Assist clients in the interpretation of reported test results.
(v) Assess risks associated with the degree and specificity of all-sensitization and assessing crossmatch results.

C. Guidelines/Criteria for Evaluation of Adequate and Appropriate Directions, Technical Supervision, and Clinical Consultation.

The overall performance of a laboratory is the ultimate measure of whether appropriate and sufficient direction, technical supervision, and/or clinical consultation are being provided. The following areas are monitored and assessed by the OPTN/UNOS Histocompatibility Committee and/or deemed accrediting body(ies), and shall be used as measures of these individuals’ performance.

C.1. Critical areas that mandate a review of the Director’s, Technical Supervisor’s, and/or Clinical Consultant’s performance:

- Less than 100% successful performance in an ABO external proficiency program.
- Less than 80% successful performance in an external proficiency testing program (other than ABO) within a year.
- Revocation, limitation, or focused re-inspection of the laboratory by a deemed accrediting body.

C.2. Deficiencies or unsatisfactory performance by the laboratory in two or more of the following areas, on an annual basis, should also be subject to review:

- Error rates must be within acceptable limits as defined by the laboratory written QA program.
- Turn-around time of test results must be within acceptable limits as defined by the laboratory written QA program.
- Training, continuing education and competency evaluations for all personnel must be completed according to UNOS criteria.
  - All testing personnel, director, technical supervisor and clinical consultant must have records of all continuing education.
  - There must be documented evidence and director review of training, and competency evaluation for all testing personnel annually.
- Deficiencies during inspections (conducted by deemed agencies) that are in violation of UNOS Standards. If relevant deficiencies are cited, there must be evidence that the deficiencies have been corrected.
- Complaints from transplant staff, OPO, and other clients must be documented, investigated and resolved.
- Laboratory must be compliant with OPTN/UNOS forms submission policies and have no outstanding forms >180 days.
- Significant discrepancies in deceased donor HLA typing results.

C.3. Supplemental information that may be requested from laboratories demonstrating unsatisfactory performance:

- Letters from transplant program(s) physicians and/or coordinators describing the level of interaction and involvement of the Director and/or Technical Supervisor and/or Clinical Consultant.
- Interviews with transplant program(s) staff.
- Departmental complaint log and documentation of complaint resolution from other health care professionals.
• Sample of laboratory reports that show evidence of review of patient history, notation of unusual results, and recommendations for additional testing.
• Other material as appropriate.
• Documentation of time commitments outside of the histocompatibility laboratory, including for items listed below, may be requested:
  o Titles presently held
  o Present employment outside of the laboratory
  o Current institutional committee assignments
  o Teaching commitments, including graduate or postgraduate students mentored
  o Research commitments; Grants (including estimates of time committed)
  o Other patient care responsibilities
  o Other professional commitment