

ATTACHMENT II TO APPENDIX B OF THE OPTN BYLAWS

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. When the appropriate criteria, as defined by CLIA, are met one individual may serve in any or all capacities for which the individual is qualified.

A Director/Technical Supervisor (a) must hold an earned doctoral degree in a biologic science, or be a licensed physician, and (b) subsequent to graduation must have had four years experience in immunology or cell biology, two of which were devoted to formal training in human histocompatibility testing. Credit toward these two years can be applied at the rate of 0.4 years for each year of appropriate working experience in human histocompatibility testing. The Director must have documentation of professional competence in the appropriate activities in which the laboratory is engaged. Competence must be based on a sound knowledge of the fundamentals of immunology, genetics and histocompatibility testing and reflected by external measures such as participation in national or international workshops and publications in peer-reviewed journals. The Director shall be available on site commensurate with the workload at the laboratory, shall provide adequate supervision of technical personnel, shall utilize his/her special scientific skills in developing new procedures and will be held responsible for the proper performance, interpretation and reporting of all laboratory procedures and the laboratory's successful participation in proficiency testing.

A Clinical Consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the appropriateness of human histocompatibility and/or transplantation immunology tests ordered and the interpretation of test results in relation to patient diagnosis and management. A Clinical Consultant must comply with the personnel qualifications set forth in the final version of the Clinical Laboratory Improvement Act (CLIA '88) Regulations.

All personnel must be licensed or meet the standards required by Federal, State and local laws.

- II. Reporting Changes in Key Personnel.** When the laboratory learns that a key person (Director, Technical Supervisor, or Clinical Consultant) upon whose participation the laboratory's OPTN approval is based, plans to leave, the OPTN Contractor must be notified immediately. At least 30 days (if possible) prior to the departure of the key person, the laboratory shall submit to the OPTN Contractor the name of the replacement key person, Curriculum Vitae, and information demonstrating and documenting compliance with OPTN criteria for designated laboratories. Failure to inform the OPTN Contractor of changes in key personnel may result in disciplinary action.

- III. Facilities and Resources.** The size and training of the staff must be sufficient to perform the volume and variety of tests required without a degree of pressure that will result in errors. Laboratory space must be sufficient so that all procedures can be carried out without crowding to the extent that errors may result.

The laboratory must establish and employ policies and procedures for the proper maintenance of equipment, instruments and test systems by 1) defining its preventive maintenance program for each instrument and piece of equipment, and by 2) performing and documenting function checks on equipment with at least the frequency specified by the manufacturer.

- IV. Testing Requirements.** The laboratory must have available and follow written policies and procedures regarding specimen collection. The laboratory must perform tests only at the written or electronic request of an authorized person. The laboratory must assure that the requisition includes: 1) the test subject's name or another unique identifier to assure accurate reporting of results; 2) the name and address or other suitable identifiers of the authorized person who ordered the test; 3) date of specimen collection; 4) time of specimen collection, when pertinent to testing; and 5) the test(s) ordered. Oral requests for laboratory tests are permitted

only if the laboratory subsequently obtains written authorization for testing within 30 days of the request.

All procedures in use in the laboratory must be detailed in a procedure manual that is immediately available where the procedures are carried out. The procedure manual must be reviewed at least annually by the Director and written evidence of this review must be in the manual. Any changes in procedures must be initialed and dated by the Director at the time they are initiated.

- V. Laboratory Testing Standards.** The laboratory shall meet such requirements for accuracy and completeness of testing as established from time to time by the OPTN Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for laboratory testing standards.