

**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. 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.