

# AMERICAN SOCIETY FOR HISTOCOMPATIBILITY & IMMUNOGENETICS

## Criteria for Approval of Histocompatibility & Immunogenetics Training Programs

(Board Approved: 08/25/2011)

### CRITERIA FOR APPROVAL OF TRAINING PROGRAMS

#### 1. Curriculum

Curricula for training programs should provide trainees with the necessary knowledge, experience and skills to competently fulfill the responsibilities of a histocompatibility director. Such responsibilities may be quite diverse, as illustrated in the following description of a histocompatibility laboratory director's required expertise:

The first responsibility of the Director of the Transplantation Histocompatibility Laboratory is to define the program of the laboratory by developing protocols, introducing and updating specific procedures, establishing laboratory standards with appropriate controls, and maintaining surveillance of laboratory accuracy, efficiency, and overall performance. A Director's responsibility may consist, wholly or in part, of defining phenotypical or genotypical HLA polymorphisms in samples from patients and/or donors for solid organ or bone marrow transplants, and/or from those being evaluated for disease markers linked to the HLA region, or for genetic determination of parentage. In the case of a transplantation evaluation, additional competency is required in methods of evaluating the potential for hyperacute rejection or early graft loss, as well as the biological relevancy of any pre-existing anti-HLA or tissue specific antibodies prior to transplant. Each area of evaluation may require individualized testing, depending on the tissue being transplanted, the condition of blood/tissue samples, and the clinical status of potential donors and recipients. Thus, the Director should be familiar with all relevant typing techniques to be used by the histocompatibility laboratory. These techniques focus on three major areas: serology, flow cytometry and molecular biology, one or all of which may be required to obtain clinically relevant information on HLA polymorphism.

Importantly, as new technologies develop, the Director should be able to evaluate and apply new techniques as necessary for improved patient care.

In addition to the primary responsibility of the scientific and technical direction of the laboratory, a histocompatibility director must be able to correlate laboratory data with clinical and pathologic findings. He/she should be able to provide consultation on individual patients, recommending additional testing when appropriate. To do this effectively, the director must have some basic understanding of the clinical aspects of the patient populations served by the laboratory. Laboratory directors must also serve as manager and administrators; therefore, knowledge of management principles is essential. To ensure coverage of these important areas, each training program shall establish a curriculum that includes the following topics:

- a) **Science of histocompatibility testing: immunogenetics, immunobiology, and transplantation immunology; principles of serological, flow cytometric, and DNA methods used in histocompatibility testing.** Specific topics in histocompatibility should include the genetics and biochemistry of public and private HLA epitopes; the genetics and biochemistry of other MHC components; analysis of antibody specificity; principles of immune regulation, and the principles of various crossmatching techniques. Instruction may be provided by didactic presentations/courses, seminars, reading assignments or a combination of these.
- b) **Clinical aspects of diseases for which histocompatibility testing is useful.** Histocompatibility directors should have an appreciation of the diseases that may lead to specific organ failure and the clinical management of recipients pre- and post-solid organ transplantation. Trainees should be aware of potential risk factors, such as previous sensitization, and learn what precautions or additional testing is warranted in such cases. Trainees should also become familiar with the increasing number of diseases treatable by bone marrow transplantation; the prognosis associated with these different disorders; and the comparative benefits/risks associated with related versus unrelated marrow donors. Trainees should also be familiar with diseases for which HLA associations have been demonstrated. Instruction may be provided by trainee

participation in clinical rounds or seminars with clinical fellows or residents. Trainees should also participate in regular transplant conferences for the evaluation of potential transplant recipients.

- c) **Technical considerations of methods used in histocompatibility testing.** Training programs must provide "hands-on" experience. A senior technologist or bench supervisor may conduct bench training. It is essential that trainees be given ample experience to learn the technical details and problems inherent with test methods in order to be competent to "trouble-shoot" procedures, as well as to correctly interpret assays requiring subjective evaluation, eg. crossmatches, under the stress and time constraints which usually accompany solid organ histocompatibility testing.
- d) **Interpretation of test results and recommendations for further testing.** A most important area of training is the actual participation by the trainee in the interpretation of test results and consultation with physicians regarding further recommended testing or follow-up studies. Because transplantation is such a large component of histocompatibility testing, sufficient experience should be obtained by trainees such that they will be competent to: 1) Develop a patient file according to the individual needs of each type of transplant operation; 2) Interpret the patient file by analyzing the composite results and provide a clinically useful assessment of these data to the managing physician; and 3) Provide pre- and post-transplant monitoring. Experience in this area is best gained by co-reviewing cases with the director of the training program.
- e) **Management Principles.** Each training program must offer trainees instruction in basic management principles, as well as in topics unique to histocompatibility/transplantation laboratories. Because many histocompatibility labs are now independent, rather than hospital or university based, knowledge of laboratory management is vital to trainee-directors since they may not have institutional managers to assist in the administration of their future labs. Instruction may be provided by seminars, existing courses, or by sending trainees to management workshops. The following topics should be included:
- Federal, state and other accreditation regulations and standards.
  - Development of contracts, cost centers, referral basis.
  - Personnel management - recruitment, selection, training, and continuing education.
  - Organization of laboratory - effective use of personnel, distribution of workload.
  - Personnel Health and Safety - OSHA standards; safeguards for biologic, chemical, and radioactive hazards.
  - Details of ESRD Cost Report.
  - Fee scheduling, cost accounting, budget preparation.
  - Risk Management.
  - Legal/professional liability.
- f) **Patient files: Data management and analysis.** A laboratory director must have ready access to both the laboratory data and pertinent clinical information in order to provide meaningful consultation on individual patients. For transplant patients, this information will include: HLA phenotype or genotype; level and specificity of any antibodies; medical history and primary diagnosis; prior transplants, transfusions, pregnancies, medications or other risk factors. Because ready access to this information is vital, it is best stored and classified in computer programs. The trainee should be given the opportunity to design or assist in the design of necessary data base files. Utilizing these files or pre-existing ones, the trainee must have the opportunity to analyze the data and their statistical significance. If needed, the trainee should be encouraged to take courses in the basic principles of statistics, computer operations, and programming.
- g) **Research and Development.** Because histocompatibility testing is continually evolving, each trainee should be given the opportunity to pursue a research project. This project could be in the development and standardization of new techniques, or in clinically applied research, but should be relevant to clinical applications of histocompatibility.

## 2. Faculty

Each training program shall be directed by an individual who is qualified according to the ASHI Standards to direct a histocompatibility laboratory. The director(s) should have expertise in all areas of the training curriculum or there should be other, appropriately qualified, doctoral level personnel available. The director(s) shall be

available throughout the two-year training for regular tutorial sessions with the trainee(s) to review and discuss test results and interpretations. The interaction of the trainee with the laboratory director is an important component of the training program; therefore, at least 50% of the Director's time should be committed to laboratory activities. There should be at least a 20% time commitment to the training program that can be divided among participants if multiple directors are involved in the program.

### **3. Facilities**

To be approved, a training program must be centered in an ASHI-accredited laboratory currently holding approval in the following areas of accreditation:

1. HSC/BM Transplantation: Related Donor
2. HSC/BM Transplantation: Unrelated Donor
3. Solid Organ Transplantation: Deceased Donor
4. Solid Organ Transplantation: Live Donor
5. Histocompatibility Testing for Other Clinical Purposes
6. Transfusion Support

The laboratory should have sufficient space and equipment to permit bench training and research by the trainee(s).

If not all categories are held by the training program laboratory, it is acceptable to arrange for the trainee to spend time in another laboratory that is accredited in the appropriate category(ies).

## **APPLICATION PROCEDURE**

Centers wishing to submit post-doctoral training programs description to be considered for approval should submit the following:

### **1. Program Curriculum**

A two-year curriculum should be submitted with details of each rotation or lab experience that will be available for trainees. The description should include the proposed time to be spent in each rotation. Any special courses or seminars to be taken by trainees should also be included, as well as rotations in other laboratories. The scope and level of activity in each program area must be adequate for comprehensive training. The application must include a copy of Subpart B, Laboratory Activities, from the most recent ASHI Accreditation renewal.

### **2. Program Director and other personnel**

The application should include a list and description of responsibilities for the program director and other pertinent personnel, eg. Associate Directors, laboratory supervisors, or senior technologists. Curriculum vitae should be included for the Program Director/Laboratory Director and for any other personnel with major teaching responsibilities. Letters of commitment, which define the extent of support through clinical rounds, conferences, etc., should also be included from the director(s) of transplant program(s) and/or organ procurement organization.

### **3. Facilities**

A brief description of laboratory space and equipment should be included and should also indicate the availability of research/development space. A description of past and current research and development projects should be provided, including titles of funded grants and/or contracts.

### **4. Program Funding**

The application should indicate support for the training program, including: fellowship or stipends available for trainees; support available for trainee research projects; and funds available for rotations in other approved laboratory training programs.

## **5. Institutional Approval**

As required by each institution, each application should include letters of commitment from the appropriate institutional official(s). These letters should state institutional non-discrimination policies, citizenship requirements, etc., which may affect candidate selection.

## **6. Application fee**

An initial application fee of \$1,500.00 will be charged to cover the costs of the on-site review. At the end of the five-year period of approval, all programs must fully reapply and submit another application fee.

## **7. Application submission**

The original copy of the application should be sent to the ASHI Executive Office and a copy to the Chair of the Director Training Review Committee. If available an electronic copy should be sent to the committee chair. If an electronic copy cannot be sent, 8 additional copies must be sent to the ASHI office.

## **APPLICATION REVIEW**

Upon receipt of an application, the Committee Chair will review each application for completeness and obtain additional information as needed. The full committee will review the application and provide comments to the chair regarding the appropriateness of the application. One committee member will be responsible for scheduling a site visit to evaluate the facilities and to review the proposed curriculum with the laboratory director and other training program faculty. A second committee member may participate in the site visit. A summary report of the site visit and an overall evaluation for each applicant will be distributed to the entire committee for review. The Chair will assess the opinion of the committee for the final decisions on the approval of training programs by email or the chair may convene the committee through a conference call. To be approved, at least three-fourths of the committee members must vote favorably for a program. The committee may give provisional approval to programs if there appear to be only minor deficiencies with the proposed curriculum or facilities. In such cases, applicants will be notified in writing of the committee's evaluation and suggestions. Upon receipt from the applicant of a modified curriculum or correction of any deficiencies, the program may be fully approved. If an applicant is denied approval, the decision of the Training Program Review Committee may be appealed to the ASHI Board. A letter requesting review by the Board must be sent to the ASHI President within 30 days of the receipt of the committee's decision.

### **1. Program responsibilities**

**Accreditation will be for 5 years.** During that time, the training program director should notify the DTRC committee chair when trainee directors begin and end training programs.

### **2. Renewal of Program Approval**

The Program Directors from each approved program will be required to submit a renewal application every five years. This renewal application must contain the same information as required in the initial application and should indicate any changes in the curriculum, key personnel or facilities. The same deadlines and procedures for committee review will apply to renewal applications as for initial ones. Evaluation of renewal applications will be on the same basis as for initial applications.