AMERICAN SOCIETY FOR HISTOCOMPATIBILITY & IMMUNOGENETICS

Criteria for Approval of Histocompatibility & Immunogenetics Fellowship Programs

(DTRC Approved 11/18/2013; ASHI Board Approved 7/24/2014; CMS Approved: 1/6/2015)

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I: CRITERIA FOR APPROVAL OF FELLOWSHIP PROGRAMS

1. Curriculum

Curricula for Fellowship 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 Fellowship 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**. Fellowship 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 Fellowship Program.

e) **Management Principles.** Each Fellowship 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 and immunogenetics.

h) **Meetings/Conferences.** Opportunity for attendance at a nationally recognized conference in clinical science is mandatory. (i.e. the ASHI annual meeting or regional workshops.) The trainee is encouraged to make an oral or poster presentation at a national meeting, presenting their research or an interesting case in histocompatibility and transplant immunology.

2. Faculty

Each Fellowship 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 Fellowship 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 Fellowship Program that can be divided among participants if multiple directors are involved in the program.

Performance must be documented and reviewed with the trainee. Documentation of reviews must be maintained by the trainee and the program for at least 5 years.

If a trainee withdraws from a Fellowship Program, the DTRC should be notified by the program by contacting the ASHI Accreditation Office.

3. Facilities

To be approved, a Fellowship 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 (optional)

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 Fellowship Program laboratory, it is acceptable to arrange for the trainee to spend time in another laboratory that is accredited in the appropriate category(ies).

II: APPLICATION PROCEDURE

Centers wishing to submit post-doctoral Fellowship 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.

2. Program Director and other personnel

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

4. Program Funding

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

5. Institutional Approval

As required by each institution, each application must 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 & Inspection
An application fee of $700.00 will be charged to cover the costs of the application review. In addition, the DTRC will send 1 or 2 committee members to inspect the program, and all expenses accrued will be billed to the program, in accordance with the ASHI travel policy.

7. Application submission

Two (2) copies of the application should be sent to the ASHI Accreditation Office. The application can be in paper format or electronic format (CD or flash drive.) The accreditation manager will forward the application to the DTRC Chair & Co-Chair for review and find acceptable inspectors for the program's onsite inspection.

III: APPLICATION REVIEW

Upon receipt of an application, the DTRC Chair & Co-Chair will review each application for completeness and obtain additional information as needed. One or two DTRC committee members will perform the onsite inspection of the program, depending upon the size and scope of the program. A summary report of the site visit and an overall evaluation for each trainee will be distributed to the entire committee for review. The DTRC Chair will assess the opinion of the committee for the final decisions on the approval of Fellowship 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 program will be mailed a hard-copy approval letter as well as an emailed copy, signed by the DTRC Chair. 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, program directors 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 the applicant program is denied approval, the decision of the DTRC may be appealed to the ASHI Board of Directors. A letter requesting review by the Board of Directors must be sent to the ASHI President within 30 days of the receipt of the DTRC's decision.

Program responsibilities for renewal/Interim years:

Accreditation will be valid for 6 years. During that time, the training program director must notify the DTRC committee chair when the trainee(s) begin and end training programs. Application for re-approval will need to be submitted to the DTRC one year before the expiration date to guarantee continuity and no lapse in approval.

As long as a trainee is in the Fellowship Program, yearly progress reports are required. Programs are required to re-apply and be re-inspected if: the training mentor changes, areas of accreditation are added, there are significant changes in the center or educational support, or if it has been an active program without a trainee for more than 2 years.

ASHI-DTRC FELLOWSHIP PROGRAMS

Onsite Inspection Checklist

Institution:	
Address:	
Program Director(s):	
Trainee(s):	

1. Resources & Sponsorship / Institution Type	**YES**	**NO**
University and other medical center		
Public health laboratory		
Hospital and clinics		
Reference clinical laboratory		
Other:		
Was a walk through performed – including whether the trainee has a desk space, a bench space (for clinical and if applicable research work), access to lab and if applicable clinical databases, interactions of the fellow with technologists and faculty members?		
If possible, perform a one on one private interview with the trainee regarding his or her assessment of the strengths and areas of possible improvement of the program.		
COMMENTS:		

2. Accreditation	YES	NO
Are the sponsoring and/or collaborating institutions accredited, certified, or licensed by recognized agencies as required by existing laws or accepted practice?		
Are the responsibilities of the sponsor and each affiliate/collaborating institution for program administration, instruction, supervision, and documentation clearly documented?		
Are resources adequate to support the number of trainees admitted to the program? Does the program have sufficient physical resources, equipment, and supplies, and an adequate library with materials related to the curriculum?		
Does the program have a qualified program director(s) and adequate support staff?		
Is the training laboratory accredited in all areas of histocompatibility testing (Transfusion support is optional)?		
If the above is answered "No", is there a plan for the trainee to rotate through another lab with the appropriate accreditation?		
COMMENTS:		

3. Trainee Selection	YES	NO
Does the program provide each trainee with a clear description of the program and its contents?		
Does the program admit only trainees who have earned a doctoral degree (Ph.D., M.D., D.O., Sc.D., Dr. P.H.) with graduate education in hematology, immunology, or a related field, or appropriate Board certification?		
Is the decision for selecting a trainee documented in writing and is the documentation retained for 5 years?		
Does the program have documentation to prove that they forbid discrimination based on race, sex, ethnicity, religion or sexual orientation?		
Does the program have complete records of trainee selection process; periodic assessment of trainee's competency; and trainee's technical, clinical and scholarly productivity (for all trainees during the last accreditation period)?		
COMMENTS:		

4. Program Curriculum *NOTE: Curriculum contents and instructional methods are the prerogative of the sponsoring institution; however, major training objectives should be available for the total program.*	**YES**	**NO**
Does the program provide the necessary education, training, and practice in all of the specialty areas of histocompatibility & Immunogenetics, including hands-on bench work? INCLUDING THE FOLLOWING:		
Science of histocompatibility testing: immunogenetics, immunobiology, and transplantation immunology; principles of serological, flow cytometric, and DNA methods used in histocompatibility testing		
Clinical aspects of diseases for which histocompatibility testing is useful		
Technical considerations of methods used in histocompatibility testing		
Interpretation of test results and recommendations for further testing		
Management principles		
Patient files: Data management and analysis		
Research & development		
Attendance at meetings and conferences?		
COMMENTS:		

5. Laboratory Management	**YES**	**NO**
Does the program provide the necessary education, training, and practice in general laboratory management?		
Does the program provide training in laboratory quality management?		
Does the program provide training in the principles of laboratory management?		
COMMENTS:		

6. Program Evaluation	YES	NO
Does the program provide training in the requirements of private and governmental agencies (i.e. CLIA '88) that accredit, certify or license clinical laboratories?		
Does the program provide training in the application and utilization of automated or semi-automated systems for Histocompatibility testing?		
Does the program provide the trainee the opportunity to consult and advise transplant physicians?		
Does the program provide the trainee the opportunity to develop a protocol and research methodology to test a hypothesis?		
Does the program provide experience and practice in preparing for laboratory inspections?		
Does the program provide training and practical experience in the testing, submission and analysis of Proficiency Testing samples?		
Does the program have a means to evaluate all phases of the instructional program?		
Is the trainee's performance and competence documented and reviewed with the trainee in a regular and timely fashion?		
Does the program maintain a record of the training program and/or performance of each trainee for at least 5 years?		
Is there evidence of periodic and systematic review of the program's effectiveness?		
Is there evidence of cooperation from collaborating institution(s)?		
COMMENTS:		

APPENDIX I

American Society for Histocompatibility and Immunogenetics/Director Training Review and Credentialing Committee Annual Director-In-Training Progress Report

A signed annual training summary must be completed and verified by both the Program Director and the Fellow. You can fax it to (651) 305-3838 or mail it to the ASHI Accreditation Office, 1716 Field Avenue, St. Paul, MN 55116, Attn: Melissa Weeks. Or you can scan it, attach it to an email, and send it to mweeks@ahint.com.

Name of Fellow: _____

Name of Director: _____

Training Program:_____

Inclusive Training Dates (month/year): From ____ / ____ to ____ / ____

Signature of Director & Date: _____

Signature of Fellow & Date: _____

Please fill in the following table:

AREA or TECHNOLOGY	TRAINING METHODS (approx. % of effort)			
	Est. Duration (weeks)	Bench Experience Including test interpretation	Didactic Training*	Self Study
HLA Serology (typing and/or XM/antibody testing)		%	%	%
Molecular HLA Typing (Solid Organ Transplant)		%	%	%
Molecular HLA Typing (HSC/BM Transplant)		%	%	%
HLA Antibody Detection/Identification		%	%	%
Flow Cytometry crossmatching		%	%	%
Chimerism Testing		%	%	%
Disease Association		%	%	%
Transfusion Support		%	%	%
Lab Management**		%	%	%
Research Project/Methodology				
On-Call Training***				

*Didactic training includes instruction such as lectures or formal discussions. Please estimate percentage of effort using a 40-hour week as a denominator.

**Including laboratory safety, management, regulations, quality assurance, proficiency testing, automation/instrumentation, and specimen requirements.

*** Including clinical consultation and direct communication with physicians regarding test interpretation and recommendations, and clinical meetings.

1) Please list all pertinent meetings (scientific, clinical, educational) the trainee has attended during this training period.

2) Please list all presentations, lectures, or teaching the trainee has performed during this training period.

3) Please list all publications (abstracts or manuscripts) this trainee has a part of during this training period.

4) Is this trainee 'on-track' with their training?
   Yes_____ No_____
   If you answered "No", please explain.

APPENDIX II

Confidential Trainee Assessment of Director-In-Training Program (To be filled out by the Trainee)

A signed annual training summary must be completed and verified by the trainee. You can fax it to (651) 305-3838 or mail it to the ASHI Accreditation Office, 1716 Field Avenue, St. Paul, MN 55116, Attn: Melissa Weeks. Or you can scan it, attach it to an email, and send it to mweeks@ahint.com.

Trainee's Name _____

Trainee's Signature & Date_____

Laboratory _____

Mentor_____

Start Date (month and year) _____

Check one:
Which time period are you completing this questionnaire?
____ 1st year (10-12 months after start)
____ Other (Please describe_____)

1. Has your mentor/supervisor provided adequate support (educational, financial, infrastructural) for your career development?
   ____Yes ____No
   If you responded "No", please explain:

2. Has your mentor/supervisor taken an active role in your training?
   ____Yes ____No
   If you responded "No", please explain:

3. Do you feel that you are receiving adequate and appropriate training?
   ____Yes ____No
   If you responded "No", please explain:

4. Please provide any additional comments regarding your training experience.