

AMERICAN SOCIETY FOR HISTOCOMPATIBILITY & IMMUNOGENETICS

DIRECTORS' TRAINING, REVIEW & CREDENTIALING COMMITTEE

POLICIES & GUIDELINES

(Board Approved: 08/25/2011)

Mission:

The Director Training and Review Committee (DTRC), a committee within the ASHI Professional Standards Division, is charged by the Board to review 1) the credentials of all candidates training to be directors and technical supervisors of ASHI accredited laboratories, 2) the credentials of laboratory directors from foreign countries to determine if they meet the ASHI Standards to direct and/or provide technical supervision for an ASHI accredited laboratory and to include the vetting of their graduate and post-graduate education by a recognized credential evaluating service, and 3) all submitted documentation including case portfolios, statements from the mentoring director, and letters of recommendation for all prospective candidate directors and candidate technical supervisors. The DTRC is also charged with evaluating and approving the proposed didactic, research, and clinical schedules for individual trainees or detailed plans for permanent director training programs.

NOTE: ASHI Standard B.2.1. Laboratories issued ASHI accreditation must notify the ASHI Accreditation Program within 30 days of any changes in ownership, name, location, Director, Technical Supervisor, Clinical Consultant and/or General Supervisor. New Directors and Technical Supervisors must be approved by the ASHI Director Training Review and Credentialing Committee (DTRC) for all areas of accreditation for which the laboratory reports results. New Clinical Consultants and new General Supervisors must be approved by the ARB.

DTRC Composition:

The DTRC will be composed of eight (8) members each of whom will serve a 2 year term. There will be a Chair and a Vice-Chair, five (5) member-at-large positions, and a liaison from the ARB (1 year). One of the members-at-large will also serve as a liaison with the Directors-In-Training Subcommittee. All members, excluding the ARB-liaison, will be voting members. Terms will be staggered in such a way that no more than three at-large members will rotate in any given year. The Vice-Chair will make a commitment to serve four years, two as the Vice-Chair and two more as the Committee Chair and there will be a written agreement in the ASHI office stating that the DTRC vice-chair nominee is willing to make that commitment.

Director Qualifications:

ASHI Standards (2009)	CMS Regulation	UNOS Standards (2005)
Director Standards	Director Standards	Director Standards
<p>E.2.1.4 Meet one of the following training requirements:</p> <p>E.2.1.4.1 Have at least 2 years full-time post-doctoral laboratory training or experience in immunology, histocompatibility, immunogenetics, or a related field, or a residency in clinical or a combined anatomic/clinical pathology other related medical specialty, and have at least 2 years full-time post-doctoral training in directing or supervising high complexity testing in human</p>	<p>§493.1441 Condition: Laboratories performing high complexity testing; laboratory director.</p> <p>The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.</p> <p>.....</p> <p>b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or</p>	<p>B2.000 A Director/Technical Supervisor must hold an earned doctoral degree in a biologic science, or be a physician, and 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.</p> <p>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.</p>

<p>histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory.</p> <p>E.2.1.4.2 If a candidate has relevant pre-doctoral experience supervising <u>and/or performing</u> high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a total of 2 of 4 years of post-doctoral experience.</p>	<p>hematology and medical oncology by the American Board of Internal Medicine); or</p> <p>(b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or</p> <p>(b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and--</p> <p>(b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or</p> <p>(b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least--</p> <p>(b)(3)(ii)(A) Two years of laboratory training or experience, or both; and</p> <p>(b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing.</p> <p>(b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or</p> <p>(b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or</p> <p>(b)(6) For the subspecialty of oral pathology ...(NA)</p>	
--	---	--

Technical Supervisor Qualifications:

ASHI Standards (2009)	CMS Regulation	UNOS Standards (2005)
Technical Supervisor Standards	Technical Supervisor Standards	Technical Supervisor Standards
<p>E.3.1.4 Meet one of the following training requirements</p> <p>E.3.1.4.1 Have at least 2 years full-time post-doctoral laboratory training or experience in immunology, histocompatibility, immunogenetics, or a related field, or a residency in clinical or combined anatomic/clinical pathology or other related medical specialty, and have at least 2 years full-time post-doctoral training in directing or supervising high complexity testing in human histocompatibility and</p>	<p>Sec. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of Sec. 493.1449 of this subpart and provides technical supervision in accordance with Sec. 493.1451 of this subpart. Sec. 493.1449 Standard; Technical supervisor qualifications.</p> <p>The laboratory must employ one or</p>	<p>B2.000 A Director/Technical Supervisor must hold an earned doctoral degree in a biologic science, or be a physician, and 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.</p>

<p>immunogenetics in an ASHI-accredited or approved laboratory.</p> <p>E.3.1.4.2 If a candidate has relevant pre-doctoral experience supervising and/or performing high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a total of 2 of 4 years of post-doctoral experience.</p>	<p>more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.</p> <p>(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and</p> <p>(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either</p> <p>(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and</p> <p>(ii) Have training or experience that meets one of the following requirements</p> <p>(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or</p> <p>(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and</p> <p>(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or</p> <p>(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and</p> <p>(ii) Have training or experience that meets one of the following requirements:</p> <p>(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or</p> <p>(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general</p>	
--	--	--

	<p>immunology (2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.</p>	
<p>E.3.1.6 For laboratories performing General Immunology Testing (e.g., platelet antigen typing, platelet antibody identification and crossmatching; chimerism analysis; immunophenotyping; immune function testing; non-HLA polymorphic allele typing), the Technical Supervisor must meet the CMS requirements in general immunology which include one year of laboratory training or experience in high complexity testing within the specialty of diagnostic immunology, if the testing is performed by facilities using ASHI accreditation to meet CLIA requirements.</p>	<p>Sec. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of Sec. 493.1449 of this subpart and provides technical supervision in accordance with Sec. 493.1451 of this subpart.</p> <p>..... Sec. 493.1449 Standard; Technical supervisor qualifications. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must--; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology.</p>	<p>UNOS does not have a comparable Standard or Policy</p>
<p>E.3.1.7 For laboratories performing Virology Testing (e.g., NAT testing for HIV-RNA, HCV – RNA, HBV – DNA for deceased organ donors), the Technical Supervisor must meet the CMS requirements in virology which include one year of laboratory training or experience in high complexity testing within the specialty of microbiology with a minimum of 6 months of laboratory training or experience in high complexity testing within the subspecialty of virology, if the testing is performed by facilities using ASHI accreditation to meet CLIA requirements.</p>	<p>Sec. 493.1449(g) Condition: Laboratories performing high complexity testing; technical supervisor.</p> <p>If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must—</p> <p>(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of</p>	<p>UNOS does not have a comparable Standard or Policy</p>

	<p>Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or</p> <p>(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and</p> <p>(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or</p> <p>(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and</p> <p>(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or</p> <p>(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and</p> <p>(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or</p> <p>(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited</p>	
--	---	--

	<p>institution; and</p> <p>(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.</p>	
<p>E.3.1.8 For laboratories performing Syphilis Serology Testing (e.g., the RPR (flocculation test), the Treponemal Test (EIA) for deceased organ donors), the Technical Supervisor must meet the CMS requirements in syphilis serology which include one year of laboratory training or experience in high complexity testing within the specialty of diagnostic immunology, if the testing is performed by facilities using ASHI accreditation to meet CLIA requirements.</p>	<p>Sec. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of Sec. 493.1449 of this subpart and provides technical supervision in accordance with Sec. 493.1451 of this subpart.</p> <p>.....</p> <p>Sec. 493.1449 Standard; Technical supervisor qualifications.</p> <p>(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must--</p> <p>.....; or</p> <p>(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and</p> <p>(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology.</p>	<p>UNOS does not have a comparable Standard or Policy</p>

NOTE: There are cases where ASHI Standards may be more stringent than those of the deeming organizations (CMS or UNOS).

1. Interpretive Guidelines §493.1443(b)(2)(ii)

The type of experience required under this regulation is clinical in nature. This means directing or supervising personnel who examine and perform tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. This experience may include the laboratory director personally examining and performing tests on patient specimens. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness, is unacceptable to meet the requirement for laboratory training or experience.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens and fits within the guidelines of what is considered basic immunology or human histocompatibility or transplant immunology.

2. Training and Experience

For purposes of director training these will be considered identical terms as they both imply developing an in depth knowledge of the subject of human histocompatibility and the tests, equipment, quality controls, and assurance associated with validating and evaluating its various categories.

Process Outline and Timeline:

Steps in Procedure	Time
1. Register with the Accreditation Manager	Clock starts
2. DTRC review of initial documentation**	Week 3-4
3. DTRC approval letter to begin training	Week 4-5
5. Submission of case portfolio	Month 23-24 after the start of training
6. Case portfolio evaluation	4-5 weeks after assignment
7. Oral interview	1-2 weeks after review process
8. DTRC decision letter	1-2 days after interview

NOTE: The length of the review process varies depending on the number of areas of accreditation.

The DTRC evaluates a candidate as Director and Technical Supervisor. The portfolio must communicate a level of technical expertise and critical thinking consistent with both positions. Supporting documentation in the portfolio would include: Procedures written or extensively revised by the candidate; a technology validation package prepared by the candidate; participation in proficiency testing, teaching other technical staff to perform the testing, abstracts or publications related to the clinical application of the testing; etc.

****Initial documentation:**

1. The mentor's letter accepting the candidate
2. A detailed description and timeline of the proposed training
3. The candidate's CV and two letters of recommendation
4. Copies of graduate and/or medical diplomas, certificates of post-doctoral experience or letter from post-doctoral supervisor(s), and relevant board certifications.
5. If the candidate is a foreign medical graduate, documentation that an education equivalency agency has evaluated the candidate's graduate and post-graduate work and will send its findings directly to the Accreditation Manager's office.

The list of agencies approved by ASHI is as follows:

- a. International Education Research Foundation: www.ierf.org
- b. World Education Services: www.wes.org
- c. Educational Credential Evaluators: www.ece.org
- d. International Consultants of Delaware: www.icdel.com
- e. Foundation for International Services. www.fis-web.com

NOTE: All degrees received from educational institutions outside of the United States must be evaluated by an agency approved by ASHI. A detailed report of course-by-course evaluation is required. Evaluations must be forwarded directly from the agency and must be official.

New Directors:

The DTRC will review the qualifications and experience of all individuals applying to become a Director and/or Technical Supervisor accredited by ASHI for one or more areas:

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. Relationship Testing
6. Histocompatibility Testing for Other Clinical Purposes
7. Transfusion Support

Technologies that can be included in the accreditation application:

Technologies	Testing Categories	Methods
Serology/Solid Phase	HLA Typing Crossmatching HLA Antibody Screen/ID Parentage Testing	Cytotoxicity ELISA Microarray
Molecular/Polymorphism Analysis	HLA Typing Parentage Testing	SSOP SSP RFLP
SBT/Fragment Analysis	HLA Typing Chimerism Parentage Testing	DNA Sequencing Engraftment STR VNTR Heteroduplex
Flow Cytometry	Crossmatching HLA Antibody Screen/ID	Methods for Quantitation Direct Labeling Indirect Labeling
Cellular		MLC PLT CTL Mitogen/Antigen Stimulation Immune Cell Function (i.e. Measuring ATP production)
ABO/Rh		ABO Grouping Rh Typing Anti-A1 Titers

Procedure:

1. Registration with the Accreditation Manager

- a. Director-In-Training. Once a candidate has been identified by a mentoring director, the candidate should be registered with the Accreditation Manager before the training has begun. Registration materials should include all of the initial documentation specified above in “Process Outline and Timeline”.

NOTE: If the training is to be done on an individual basis, the mentor should submit a detailed description (syllabus) of the proposed training program at the beginning of the training period and have it approved by the DTRC before training can begin.

NOTE: After 12/31/2011, all new directors in training must register with the Accreditation Manager right away, to officially start the 2-year training period clock.

- b. Permanent Training program. If an institution has been established as a permanent training program, candidates must submit all documents specified under “1.a., except for the syllabus. The training program’s syllabus will be valid for 5 years, unless new technologies are adopted, accreditation categories are adopted or dropped, or there has been a change in the core faculty of the laboratory. When one or more of these conditions occur, the syllabus must be updated and a copy submitted to the Accreditation Manager’s office for distributing to the DTRC. During the fifth year of a program’s existence, the DTRC will determine if it can continue on a permanent basis. At that time the DTRC may request a new syllabus, a site visit, or both in order to complete their deliberations.
- c. Foreign applicant. In addition to (1.a.), the foreign applicant must have his/her graduate and post-graduate education vetted by a recognized credentialing service (see above). This will be done at the applicant’s own expense and a certified copy of this evaluation must be sent directly from the service to the Accreditation Manager’s office.
- d. “Grandfathering” clause: Individuals who were once ASHI approved but have been out of the field of HLA for >10 years will have to complete the full DTRC review process. Individuals who were once ASHI approved but have been out of the field of HLA for <10 years will need to perform the same registration steps listed above however the actual portfolio requirement may be abbreviated.

2. Registration Document Evaluation

- a. The candidate’s CV will be evaluated by the DTRC as to content and relative experience in the fields of human immunology, histocompatibility, and transplantation
- b. The candidate must meet all of the educational, certification, and training requirements as stated in the current version of the ASHI standards.
- c. A letter must be submitted from the mentoring director supporting the candidate and providing in-depth description of the proposed training. This description should include a didactic schedule, detailed proposed laboratory and clinical training, provision for research, and the amount of time dedicated to each component and must reflect the amount of time specified by the various accrediting and regulatory agencies as appropriate for training an HLA Director (2 years).
- d. Letters of recommendation must include verification of previous post-graduate training in immunology, pathology, or other appropriate experience.

3. Qualified Applicants

- a. Doctoral degreed individuals. Individuals who have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and two years postdoctoral experience in General Immunology or equivalent and must meet all of the requirements outlined in Section 2 (above).
- b. Post-graduate resident physicians.
 - i A candidate who is board certified in Clinical Pathology or combined Anatomic/Clinical Pathology will be given full credit for the 2 year requirement for post-doctoral experience in general immunology prior to Human Histocompatibility training.
 - ii A candidate who is CP or combined AP/CP certified or who has obtained board certification in certain specific areas of pathology (hematopathology, transfusion medicine, immunology, molecular pathology, or cytopathology) and if it can be demonstrated that he/she has had rigorous human histocompatibility training during this specialty training may have some of the HLA training requirement waived. The amount of HLA training time waived, however, is not to exceed four of the twenty-four months HLA-specific training required by the federal standards. The actual amount of time waived by the DTRC will be decided on a case-by-case basis.

- iii A candidate who is board certified in other specialties such as internal medicine, hematology, nephrology, transplant surgery, etc. may have all or part of the 24 month requirement for post-doctoral general immunology experience waived. The DTRC will decide this on a case-by-case basis.
 - iv A board certified physician is not required to take a histocompatibility or immunology specialty board examination, such as the ABHI Diplomate or other approved board examination, to be credentialed as a histocompatibility laboratory director. However, these candidates are strongly encouraged to take the AFDT Specialist/Director course and the ABHI Diplomate examination when offered.
- c. Foreign doctoral or medical degreed individuals.
- i. In training: The foreign applicant must complete all of the requirements outlined in Section 2 (above). The sponsorship of an ASHI Director may be waived if the mentoring director is qualified by EFI, APHIA, or any other HLA accrediting body recognized as equivalent in training and standards by ASHI. The DTRC will also evaluate these candidates on a case-by-case basis.
 - ii. Post training: If the candidate has a documented history of participating in Histocompatibility and Transplant Immunology, as evidenced by 1) presentations (posters or oral) at appropriate national/international meetings, 2) peer-reviewed publications in human histocompatibility &/or transplant journals, 3) established history of offering graduate courses and seminars in human histocompatibility &/or transplant immunology, and/or 4) established history of running a clinical histocompatibility laboratory accredited by an agency or agencies recognized by ASHI as equivalent, then the DTRC may waive some or all the requirements of director training and credentialing process. The DTRC will evaluate these candidates on a case-by-case basis.
- d. Previous histocompatibility experience.
- i Credit will be given for previous histocompatibility experience supervising and/or performing high complexity testing in human histocompatibility and immunogenetics on a prorated basis consistent with current ASHI standards (see below).
 - ii This prorated credit will apply toward the 2 year post-doctoral general immunology requirement only. The applicant will still be required to undergo 2 years formal post-doctoral histocompatibility training in an ASHI-accredited laboratory with an ASHI approved director.
 - iii ASHI Standard - E.2.1.4.2. If a candidate has relevant pre-doctoral experience supervising and/or performing high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a maximum of two of the required years of post-doctoral experience.

4. The Mentoring Director

- a. The mentor must provide a description of the training program and letter of support for the applicant.

NOTE: The Mentoring Director must be an ASHI-approved laboratory director.

- b. The mentor will oversee the training and have seen the final review and comments on all cases prior to submission of case portfolios.
 - i. S/He will document on a notarized Director Training Verification document that the following have been successfully completed by the candidate (See Appendix A).
 - ii. Log of cases reviewed for each Area of Accreditation for which approval is sought
 - iii. That the candidate was the primary reviewer of all raw data before they were analyzed by a laboratory supervisor and/or mentoring director.
 - iv. Several interesting cases for each Area of Accreditation must be written up with worksheets, interpretations, comments, further testing needed, etc (10 or 5 cases are needed depending on the Area of Accreditation, see below).

- c. By signing the Director Training Verification Document (See Appendix A), the mentor is attesting that the candidate has gained the necessary experience to be deemed “competent” in the Areas of Accreditation indicated on the checklist.

5. Case Profile Development

- a. The candidate must submit a testing protocol for each area of accreditation that s/he is seeking.
 - i. Protocol descriptions must include a list of the tests that could be used in evaluating a typical case and provide the reasoning and justification for each test in terms of optimizing patient care in a cost-effective manner.
 - ii. The list must include what is actually done in the candidate’s laboratory, whatever ancillary tests that might be necessary to complete the interpretation, and where those tests might be done if the training laboratory cannot do them.
 - iii. The purpose of this exercise is to show that the candidate is knowledgeable about the methods available to an HLA laboratory, how to use them in a clinical setting, and what external resources are available to help h/her analyze a case.
- b. The candidate must submit a Log of all cases reviewed for each Area of Accreditation of testing. Include a brief description for each case. For the required case number and details, see “Director Portfolio Requirements” below.
- c. The candidate must submit interesting cases for each Area of Accreditation with a summary (containing interpretation of results, comments, recommendations, further testing needed, etc.) accompanied by all the signed reports and worksheets. For the required case number and details, see: “Director Portfolio Requirements” below.
- d. Upon evaluation of all portfolio information and data, the DTRC may elect to send the candidate one to several unknown case studies in order to further interrogate a candidate’s breadth of knowledge on a particular category or technology. The applicant will review these unknowns and send the DTRC a written 1-3 page summary for each case study.

6. Oral Interview

- a. All candidates will undergo a final oral interview upon completion of training. This will occur within two (2) weeks after successful completion of the case study reviews.
- b. The DTRC Chair will notify the Accreditation Manager to contact the candidate to arrange an interview.
- c. The interview committee will consist of the DTRC reviewer(s) an ARB representative (ARB liaison, program director, or co-chair), and the DTRC chair &/or Vice-Chair.
- d. The Accreditation Manager will transcribe comments concerning the interview.
- e. Format
 - i. The interview is intended to be a collegial opportunity for the applicant to respond to open ended questions from the interview committee about laboratory practice, common problems in testing, laboratory management, and clinical interpretation and application of testing results.
 - ii. The role of the ARB during the oral interview is to ensure the candidate is questioned fairly and extensively.
 - iii. The interview can be conducted via a conference call or in-person at an ASHI regional or national meeting.
 - iv. The interview usually takes 1-2 hours.

NOTE: This exercise may be waived by the DTRC for applicants who have previously established themselves in the fields of human histocompatibility or transplantation.

7. Evaluation

- a. The DTRC Committee will vote on whether to approve the candidate for the specific areas of accreditation requested in the initial application. More categories and technologies may be added (or dropped) during the training period but the mentoring director must request these in writing within 30 days of their occurrence through the Accreditation Manager's office.
- b. Within one week following a candidate's approval as a Director by the review committee:
 - i. The DTRC Chair will confer with the Accreditation Manager as to the candidate's specific areas of accreditation
 - ii. The Accreditation Review Board database will be updated to reflect the candidate's approved status as an ASHI credentialed director
 - iii. An approval letter will be generated for the new Director, signed by both the DTRC Chair and the ARB Program Director and sent to the successful candidate by both electronic and standard mail.
- c. If not approved, the DTRC will work with the applicant and mentoring director to determine the course of action needed to obtain approval. This may include documentation of additional training and experience, additional case file reviews, another interview, etc.

8. Appeal Process

- a. The unsuccessful candidate will be offered a chance to appeal the decision of the DTRC. This process will consist of the candidate stating in a letter to the ASHI ombudsperson the reason why he/she is appealing the decision of the DTRC.
- b. If the ASHI ombudsperson feels there are grounds to reconsider the DTRC decision, the appeal letter will be forwarded to the DTRC for review.
 - i. The review panel will consist of the DTRC member(s) responsible for the case portfolio evaluation, the Chair &/or Vice-Chair of the DTRC, the ARB liaison, and a representative from the ASHI executive committee.
 - ii. The appeal process will be concluded within 60 days of receipt of the appeal letter.
 - iii. The decision of the Appeal Committee will be issued in a letter to the candidate.

9. Adding new Area of Accreditation for previously ASHI-approved Director

- a. ASHI-approved directors who wish to add a new Area of Accreditation must submit to the DTRC the following materials:
 - i. Outline/Summary of Training.
 - ii. The director must submit a Log of all cases reviewed for each Area of Accreditation of testing. Include a brief description for each case. The number of cases is as mentioned above (refer to "Case Profile Development" section).
 - iv. The candidate must submit several interesting cases for each Area of Accreditation with a summary (containing interpretation of results, comments, recommendations, further testing needed, etc.) accompanied by all the signed reports and worksheets. The number of cases is as mentioned above (refer to "Case Profile Development" section).
 - v. For each new Area of Accreditation, the candidate must submit a protocol for testing, which includes a list of the tests that could be used in a typical case and provide the reasoning and justification for each test in terms of optimizing patient care in a cost-efficient manner.
- b. Oral examination at the discretion of the DTRC after review of submitted materials.

NOTE: In the case of an established Director/Technical Supervisor who is adding an Area of Accreditation, the oral interview may be waived, depending on the experience of the applicant.

- c. Validation materials for any new Technologies or Methods that were established for the new Area of Accreditation must be submitted to the ARB Commissioner.

Director Portfolio Requirements:

The complete Director portfolio will no longer be required to be sent to the DTRC Committee, but will be reviewed and signed off by the mentoring director (see Director Training Verification Document above) when s/he is confident that the applicant is fully trained. The DTRC may request the applicant to submit one or more additional case studies to complete their deliberations. The DTRC will also ask that the ARB have an Inspector document that the portfolio was complete during the laboratory's next on-site inspection.

NOTE: Portfolio cases must be maintained by the sponsoring institution for a minimum of two years.

1. The purpose of the case portfolio(s) is to provide documentation of the applicant's ability to review and interpret test results obtained in various clinical situations; to provide insight into probable causes of and appropriate solutions for test failure; to recommend additional follow-up tests as needed; and to provide appropriate commentary for use by clinicians.
2. **Portfolio materials should include:**
 - a. Log of all cases reviewed for each Area of Accreditation of testing. Include a brief description for each case:
 - 50 related HSC/BM cases
 - 50 unrelated HSC/BM cases
 - 50 deceased donor Solid Organ cases
 - 50 living donor Solid Organ cases
 - 50 cases of Relationship Testing
 - 20 cases of Transfusion Support
 - 20 cases of Histocompatibility Testing for Other Clinical Purposes
 - b. The log should list:
 - The type of case.
 - A short description of the testing performed. No interpretative comments need to be included in the Log portion of the portfolio. (See Complete Case Files to be submitted below in section c).
 - Indicate if work was done in applicant's laboratory or reviewed at another lab.

Ex.1 Solid organ transplantation

CASE #1. Deceased donor renal transplant recipient.

- Initial workup including Class I HLA typing by serology, Class II typing by DNA and 3 months PRA screening by flow beads, including specificity, and AHG.
- Log of HLA Antibody data from workup to transplantation.
- Final crossmatch results by cytotoxicity and flow cytometry, including auto crossmatch.
- Donor typing result.

Ex.2 Typing for Other Clinical Purposes.

Case #25. Disease association.

- Class II typing for narcolepsy patient.

- Low resolution molecular testing for DRB1 (DRB1*15).
 - High resolution molecular DQB1 typing to determine the presence of DQB1*0602.
- c. A set of complete case files for each Area of Accreditation reviewed and approved by the mentor must be submitted. These case files should include:
- All testing performed including primary raw data interpretation and results signed and dated by the applicant and the mentoring Director.
 - The final reports provided to the physician.
 - Correlation of results from the different tests.
 - A case summary must be included for each complete case submitted.

NOTE: Ensure that all names and other identifiers are removed.

The number of cases is as follows:

- 10 cases of Related HSC/BM cases
 - 10 cases of Unrelated HSC/BM cases
 - 10 cases of Deceased Donor Solid Organ cases
 - 10 cases of Living Donor Solid Organ cases
 - 10 cases of Relationship Testing
 - 5 cases of Transfusion Support
 - 5 cases of Histocompatibility Testing for Other Clinical Purposes
- d. Case Summary requirements for Complete Case Reviews:

Case Summaries must be supplied for each case and should be detailed enough that the thought process(es) involved in reaching the conclusions and how the interpretations of data were made are evident. These should be as detailed as possible, address the testing performed in the case, and should contain technical as well as interpretive comments regarding that testing. As mentioned above, the case summaries must be accompanied by all the signed reports and worksheets.

Case summaries should reflect the applicant's expertise in:

1. **Test selection:** The Director/Technical Supervisor must be capable of determining what tests are necessary for various clinical applications and must be able to develop new tests and test strategies as dictated by changes in individual patient status.
2. **Interpretation/Consultation:** The Director/Technical Supervisor must have adequate expertise to know what information is needed to evaluate individual clinical cases and be capable of utilizing the collective body of information to assess risk level, identify possible clinical strategies, and make scientific evaluations of the immune state of the patient. Furthermore, the Director/Technical Supervisor should be capable of supporting clinical studies and of using clinical data in the ongoing development of test interpretation of results when appropriate.

3. Selection of Appropriate Case Files

- a. If cases are selected from the Applicant Director's laboratory, several routine cases may be included in the portfolio. These cases should be selected to demonstrate the candidate's problem solving ability with difficult or interesting cases.
- b. Case files may be derived from other laboratories. These cases should have a more detailed cover sheet, since the Applicant Director did not do the initial review. The coversheet should include how the Applicant Director would handle these cases, particularly where it might differ from the actual case. This may be based on newer technology or on differences in approach.

- c. If the submitted case portfolios do not provide sufficient enough information for The DTRC to complete their evaluation, the DTRC may send some unknown test cases to the applicant for review and analysis. If after reviewing the applicant's evaluation of these unknown cases, the DTRC still has concerns that s/he is not yet ready for the oral examination, they will meet via conference call with the mentor and candidate to discuss a plan for remedial training.

4. Submission of Director Application Material

- a. The case logs, complete case files, training verification documentation and checklist, and supportive letters must be submitted to the ASHI Accreditation Office in order to ascertain completeness. It will then be forwarded to the Director's Training Review and Credentialing Committee for review.
- b. A fee of \$150 per new Area of Accreditation, or \$700 for review of qualifications to direct a full service laboratory must be submitted to the ASHI Accreditation Office Manager upon receipt of official invoice from ASHI (sent to the candidate after the portfolio is submitted).

Appendix A

Director Training Verification Documentation

Name of Director-in-Training: _____

Board Certification Yes / No Board(s): _____ Number(s): _____

Training Institution: _____

Mentor: _____ Dates of Training: _____

Place an "x" to indicate each **Area of Accreditation** for which the applicant has completed training.

Place an "x" to indicate that the log of cases reviewed and in-depth analysis of clinically interesting case studies have been completed.

____ I. **HSC/BM Transplantation: Related Donor**
 _____ Log of 50 Case Reviews completed
 _____ Analysis of 10 interesting cases completed

____ II. **HSC/BM Transplantation: Unrelated Donor**
 _____ Log of 50 Case Reviews completed
 _____ Analysis of 10 interesting cases completed

____ III. **Solid Organ Transplantation: Deceased Donor**
 _____ Log of 50 Case Reviews completed
 _____ Analysis of 10 interesting cases completed

____ IV: **Solid Organ Transplantation: Live Donor**
 _____ Log of 50 Case Reviews completed
 _____ Analysis of 10 interesting cases completed

____ V. **Relationship Testing**
 _____ Log of 50 Case Reviews completed
 _____ Analysis of 10 interesting cases completed

____ VI. **Histocompatibility Testing for Other Clinical Purposes**
 _____ Log of 20 Case Reviews completed
 _____ Analysis of 5 interesting cases completed

____ VII. **Transfusion Support**

- ____ Log of 20 Case Reviews completed
- ____ Analysis of 5 interesting cases completed

I, _____, attest that the Director-in-training,
_____ has completed adequate training and has gained the necessary
experience for the areas checked above.

Signature of Mentor
(Please have signature notarized)

Date

Notary's Signature

Date

ID #: _____

Date of expiration: _____