

DIRECTOR TRAINING & CREDENTIALING REVIEW COMMITTEE

New Directors:

The Director Training & Credentialing Review Committee will perform the review of new Director qualifications and experience as follows for new Areas of Accreditation.

AREAS of ACCREDITATION are:

HSC/BM Transplantation: Related Donor
HSC/BM Transplantation: Unrelated Donor
Solid Organ Transplantation: Deceased Donor
Solid Organ Transplantation: Live Donor
Parentage Testing
Histocompatibility Testing for Other Clinical Purposes
Transfusion Support

1. The candidate's CV – credentials will be evaluated by the DTRC chairperson and Reviewer(s) and the ARB member participating in the oral interview, all of whom will serve on the oral exam committee.
2. The ASHI Director serving as mentor will oversee the review of cases and document on a notarized Director Training Verification document that the following have been successfully completed by the candidate:
 - a. Log of cases reviewed for each Area of Accreditation for which approval is sought;
 - b. 10 cases for each Area of Accreditation must be written up with worksheets, interpretations, comments, further testing needed, etc. (1-2 case studies for each Area of Accreditation must be submitted along with the application. See #5)

By signing the Director Training Verification Document, 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.

The mentor must be an ASHI-approved laboratory director.

3. The mentor must provide a summary of training program and letter of support for the applicant.
4. The candidate must meet all of the educational, certification, and training requirements as stated in the current version of the ASHI standards.
5. The DTRC may request that the candidate submit an additional complete case study that he/she has personally reviewed for each Area of Accreditation.
6. For each 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. The list does not necessarily have to be what is actually done in the candidate's laboratory. The purpose of this exercise is to show that the candidate is knowledgeable about the methods available to an HLA laboratory and how to use them in a clinical setting.

7. Upon receipt of above materials, the DTRC will send the candidate 1-2 of its own case studies for each Area of Accreditation that is being requested for approval. The applicant will review the case studies and send the DTRC a written 1-3 page summary for each case study.

Note: This exercise may be waived by the DTRC for applicants who have successfully passed the Diplomate (ABHI) exam.

8. Oral examination by the DTRC: After successful completion of the case study reviews, the DTRC Chair will contact the candidate to arrange an interview.
 - a. The interview committee will consist of the DTRC reviewer(s) an ARB representative (co-chair or program director), and the DTRC chair.
 - b. The Accreditation Manager will transcribe comments concerning the interview.
 - c. The interview will be an opportunity for the applicant to respond to open-ended questions about laboratory practice and to discuss these with the interviewers. The interview usually takes 1-2 hours.
 - d. The role of the ARB during the oral interview is ensure the candidate is questioned fairly and extensively.

The interview can be conducted via a conference call or in-person at an ASHI regional or national meeting.

9. The DTRC Committee will vote on whether to approve the Director for the specified Areas of Accreditation. If approved, the Chair of the DTRC will notify the Accreditation Manager of the decision and the Database will be updated to reflect ASHI approval for the Director in the specified Areas of Accreditation.
10. The letter of approval for new Directors will be signed by both the DTRC Chair and the ARB Program Director.
11. If not approved, the DTRC will work with the applicant to determine the course of action needed to obtain approval. This may include documentation of additional training and experience, additional case file reviews, etc.
12. The Appeal process will consist of the candidate stating in a letter the reason why he/she is appealing the decision of the DTRC. The appeal letter will be reviewed by a panel consisting of the DTRC reviewer(s), the Chair of the DTRC, and representative(s) from the ARB. The appeal process will be concluded within 60 days of receipt of the appeal letter. The decision of the Appeal Committee will be issued in a letter to the candidate.

Adding new Area of Accreditation for previously ASHI-approved Director

ASHI-approved directors who wish to add a new Area of Accreditation must submit to the DTRC the following materials:

1. Outline/ Summary of Training
2. Log of Cases reviewed (refer to Director Training Verification document)
3. An example of a complete case file with detailed analysis, including worksheets, interpretations, comments, further testing needed, etc.
4. 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. The list does not necessarily have to be what is actually done in the candidate's laboratory. The purpose of this exercise is to show that the candidate is knowledgeable about the methods available to an HLA laboratory and how to use them in a clinical setting.
5. Written analysis of case studies provided by the DTRC.

Note: This exercise may be waived for applicants who have successfully passed the Diplomate (ABHI) exam.

6. 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.

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

Adding new Technology or Testing Category for previously ASHI-approved Director

The Accreditation Review Board (ARB) will process the validation for new Technologies or Testing Categories and will no longer require separate DTRC approval.

1. If the Director was involved in the validation of a new Technology or Testing Category, then the validation packet submitted to the Commissioner is sufficient documentation of training and review.
2. If the Director moves to a laboratory that does a Technology or Testing Category for which he/she was not previously approved, the Director must submit a log of case reviews to the Commissioner. (Include 1-2 case studies with data for each Technology or Testing Category.) This should be completed prior to the on-site inspection for a New Director.

For new Technologies and Testing Categories the minimum number of cases required for review is:

50 HLA typings	10 Cellular assays
20 HLA crossmatch tests	10 Engraftment studies
50 HLA antibody screens/IDs	10 Flow Phenotype cases
50 Parentage testing cases	

3. The Director/Technical Supervisor must demonstrate sufficient experience with the Technologies or Testing Category employed in order to know their strengths and limitations. The following documents must be submitted to ensure that the test is working properly, that the Director/Technical Supervisor is able to interpret results correctly and troubleshoot when necessary. The QC and QA program must be in place and functioning for the new Technology or Testing Category.
 - Signed copies of QC data
 - Signed copies of proficiency testing reports
 - Signed copies of procedures and protocols in use in the laboratory
 - Evidence of review of worksheets by applicant with recognition of potential or actual problems
 - Description of action taken to address problems with testing

New Method - For established laboratories that wish to add a new Method under a Technology or Testing Category for which the laboratory already has Accreditation, only the Validation Packet needs to be submitted to the Commissioner. This can be done at any time and does not have to coincide with an on-site inspection. Once the validation has been reviewed by the Commissioner and approved by the co-Chair, a new Accreditation letter indicating the new Method will be issued to the laboratory.

Technologies:	Testing Categories:	Methods included under Technology:
Serology/Solid Phase	HLA Typing Crossmatching HLA Antibody Screen/ID Parentage Testing	Cytotoxicity, ELISA, Microarray
Molecular-Polymorphism analysis	HLA Typing Parentage Testing	SSO, rSSO, SSP, RFLP
SBT / Fragment Analysis	HLA Typing Chimerism Parentage Testing	Sequencing, Engraftment, STR, VNTR, Heteroduplex
Flow Cytometry	Crossmatching HLA Antibody Screen/ID Immunophenotyping	Methods for Quantitation, Direct Labeling, Indirect Labeling, Internal Labeling, External Labeling
Cellular		MLC, PLT, CTL, Mitogen or Antigen stimulation, and Immune Cell Function (ex. e.g., by measuring thymidine incorporation or ATP production)
ABO/Rh		ABO grouping, Rh typing, anti-A1 titers

Other methods not listed above will be reviewed for determination of appropriate Technology area.

Director Training Verification Documentation

Name of Director-in-Training: _____

Board Certification Yes / No

Board: _____

Number: _____

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. **Parentage 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

Date

(Please have signature notarized)

Notary signature

ID #

Date of expiration

Date

DIRECTOR PORTFOLIO REQUIREMENTS

The complete Director portfolio will no longer be required to be sent to the DTRC Committee, but will be reviewed by the mentor and signed off (see Director Training Verification document above) when the mentor is confident that the applicant is fully trained. The DTRC may request the applicant to submit one or more of the case study analyses for each Area of Accreditation for which approval is being sought. In addition, the ARB will have the Inspector document that the portfolio was complete during the next on-site inspection. (Retain cases for a minimum of two years.)

1. The purpose of this portfolio 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 Parentage 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. Complete Case Files

At least 10 (ten) complete cases for each Area of Accreditation must be reviewed and approved by the mentor. The DTR may request that one or more of these cases be submitted for each Area of Accreditation. These case files should include:

- All testing performed including raw data with interpretation of result, signed and dated by applicant and ASHI approved Director.
- The final report provided to the physician.
- Correlation of results from the different tests.
- A Cover Sheet must be included for each complete case submitted.

Please make sure that all names and other identifiers are removed.

d. Cover Sheet requirements for Complete Case Reviews

A cover sheet for each case should discuss the thought process involved in reaching the conclusions presented and how the interpretations of data were made. Cover sheets should be detailed. They should address the testing performed in the case and make technical as well as interpretive comments regarding that testing.

The cover sheet for the case files should reflect the applicant's expertise in:

- 1. Test selection:** The Director/Technical Supervisor/Clinical Consultant 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/Clinical Consultant 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. Further, the Director/Clinical Consultant 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. At least 5 cases should be selected to demonstrate problem solving of 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. The DTRC will have test case files that will be sent to the Applicant for review, written interpretation, and comments. After review of the Applicant's response to the written case reviews, the DTRC may request submission of additional case studies if there is concern that the Applicant is not yet ready for the oral examination.

Submission of Director Application Material

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.

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.

DTRC Appeals Process - Instructions for Filing an Appeal

Background and Introduction

The ASHI Director Credentialing process involves a multilevel evaluation by a Director Training Review and Credentialing Committee (DTRC) Reviewer, DTRC Chair, and a member of the Executive ARB (E-ARB) that includes the Program Director or co-Chairs. The credentials are reviewed and this group performs the final oral review and the outcome of the evaluation determined by both a member of the Executive Accreditation Review Board and the DTRC Chair with the DTRC Reviewer. The structure of this process provides a high assurance of a thorough, fair, and impartial evaluation of compliance with the minimum Standards that must be followed to assure fulfillment of the minimum acceptable qualifications as a laboratory director. Nonetheless, when approval is denied, the applicant shall have the opportunity to appeal the decision.

Exceptions: Applicants who refuse to cooperate with reasonable requests for additional information, data, or documentation; or who deny an inspector access to the portfolio documentation for purposes of performing an on-site inspection review; or who knowingly and willfully obstruct the evaluation process shall not have the right to appeal the Director Review and Credentialing Committee's decision.

Description of the Process

When there is NOT a condition of immediate threat to patient care or danger to the general public, the Appeal Process occurs in two stages.

First, the Appeal Board reviews documents submitted by the applicant and the DTRC/E-ARB evaluation documentation to determine if an Appeal Hearing is warranted. A hearing is warranted when there is clear evidence suggesting the decision of the Director Training Review and Credentialing Committee (DTRC) and/or the Executive Accreditation Review Board (E-ARB) resulted from bias, misrepresentation, or unavailability of critical information. If the Appeal Board determines that a hearing is not warranted, the initial decision of the DTRC/E-ARB is upheld and the Appeal Process ends. If the Board determines that a hearing is warranted, the process moves to a second stage in which a hearing is conducted. For purposes of the hearing, the Appeal Board may request additional documentation from any members of the DTRC and/or E-ARB, or the applicant that must be provided if the Appeal is to proceed. The Appeal Board will meet and will conduct interviews of relevant individuals either at the meeting site or by teleconference. Subsequent to the hearing and within 60 days of the filing of the appeal, the Appeal Board will render its decision in cases. The Appeal must be submitted within 5 days and the Appeal Board will review and render a decision within 10 days. In these cases, an appeal does not stay the decision of the DTRC/E-ARB.

All documents associated with the hearing shall remain confidential. The applicant shall receive a summary statement of the basis of the Appeal Board's decision. If the Appeal Board upholds the initial decision of the DTRC/E-ARB, the action of the DTRC/E-ARB will be imposed immediately and the applicant shall be billed for all costs associated with the appeal process. These costs will include but are not necessarily limited to: phone calls, photocopying, personnel costs, shipping, legal fees. If the Appeal Board reverses the decision of the DTRC/E-ARB, Director approval will be granted.

Materials and testimony are to be limited to documentation of conditions existent at the time of the new director evaluation. No actions taken and no data generated subsequent to the evaluation are to be considered. The evaluation process itself is not to be evaluated but rather whether or not the findings of the DTRC/E-ARB were correct and factual. The decision of the Appeal Board shall be final.

For an appeal application to be valid, it must contain all necessary documents and a check or money order to cover the filing fee. One-third of the filing fee is a non-refundable processing fee. If the Appeal Board finds against the applicant, part or all of the remaining two thirds of the filing fee will be applied to the cost of the Appeal Process. If the Appeal Board finds in favor of the applicant, two thirds of the filing fee will be returned to the applicant. If the application for an appeal is incomplete, the applicant will have 48 hours to submit the necessary materials or shall forfeit the right to an appeal.

Instructions for Filing an Appeal

Submit the following materials prior to the deadline for filing an appeal that was indicated under Description of the Process to Appeal.

A. Five copies of documents providing evidence that the findings of the DTRC/E-ARB were incorrect. These materials must be page numbered, bear the director applicant's name, and be bound together in a ring binder or other system that provides reasonable assurance of maintaining the order of the documents.

The first page of the packet must be a table of contents.

The front of each document must indicate the citation(s) address by the information/data contained in the document. This material must be limited to information about conditions that existed at the time of applicant's review and must not contain materials that discuss actions taken or data generated subsequent to the action of the DTRC/E-ARB.

B. A check, bank draft, or money order made payable to ASHI in the amount of \$750.

C. A signed agreement of financial obligation.

D. A written summary of no more than 2 pages in length, highlighting the bases of refuting the DTRC/E-ARB decision.

All materials must be sent by overnight courier and must be traceable.

Send materials specified in A - D, above, to:

Melissa McElroy

Accreditation Manager

ASHI Accreditation Office

90 West County Road C

Suite 300

St. Paul, MN 55117

(651) 487-2806 / Fax: (651) 489-3387

melissa@cmehelp.com