

# Operations Manual

## Director Training, Review and Credentialing (DTRC) Committee of the American College of Histocompatibility & Immunogenetics

*Version 10 -2026*

*DTRC Committee approved: February 23, 2026*

*ACHI Board of Directors Approved: March 5, 2026*

*ASHI Board of Directors Approved: March 25, 2026*

# TABLE OF CONTENTS

I.	Committee.....	3
	A. Mission & Purpose	
	B. Structure of the Committee & Qualifications of the DTRC Committee Members	
	C. Terms	
	D. New Member Selection	
II.	Policies & Procedures.....	4
	A. New Directors.....	5
	i. Portfolio Development & Review	
	ii. Progress Reports	
	iii. “Green Light” Email	
	iv. Portfolio Development	
	v. The Oral Competency Assessment - Review-of Portfolio and Experience	
	vi. DTRC Decision on Credentialing	
	vii. Fees	
	B. Current Directors.....	10
	C. Board Certification.....	10
III.	Portfolio Review Cycles.....	11

## APPENDIX LIST

1.	Director Training Verification Documentation.....	13
2.	Guidance for Detailed Case Development.....	14
3.	Appeals Process.....	22
4.	Progress Report Template Form.....	23
5.	Evaluation of the Portfolio Committee process.....	26
6.	Documentation of prior experience and training.....	27

# I. COMMITTEE

## A. Mission & Purpose

The Director Training, Review and Credentialing (DTRC) Committee (previously also called the Portfolio Committee) is a committee under the American College of Histocompatibility & Immunogenetics (ACHI). This committee reviews case portfolios for new HLA laboratory Directors in Training, and approved Directors seeking approval of a new area of accreditation (i.e. solid organ transplantation: live donor).

The committee is charged by the College to work with the Director Credential Evaluations Committee to review the credentials and qualifications of 1) all candidates training to be HLA Directors and Technical Supervisors of ASHI accredited laboratories, 2) HLA Directors of non-ASHI accredited USA laboratories, and (3) HLA Directors from foreign countries (including the vetting of their graduate and post-graduate education by a recognized credential evaluating service) to determine if they meet the ASHI Standards to direct and/or provide technical supervision for an ASHI accredited laboratory. The DTRC/Portfolio Committee will also review all submitted documentation including training plans, progress reports, case portfolios, statements from the mentoring director, and letters of recommendation for all prospective candidate directors, technical supervisors, and clinical consultants. The DTRC/Portfolio Committee (with assistance from the Director Credential Evaluation Committee) is charged with evaluating and approving the proposed didactic, research, and clinical schedules for individual trainees or detailed plans for permanent director training fellowship programs.

The DTRC approves doctoral level candidates as Director, Technical Supervisor, and Clinical Consultant Ph.D. candidates wishing to direct a laboratory in the U.S. Such candidates must be board certified by one of the appropriate Boards approved by HHS. M.D. candidates must be licensed to practice in the USA and be Board-certified in an appropriate medical specialty and meet all CLIA (and all other applicable regulatory) requirements.

Additionally, candidates wishing to direct an international laboratory (i.e. not subject to CLIA and other U.S. rules/regulations) may also seek ASHI credentialing. Individuals falling into this category may not be eligible to direct a CLIA-regulated laboratory.

The experience and training for a laboratory director, technical supervisor and clinical consultant for laboratories performing histocompatibility must meet CLIA and ASHI Standards. In developing the training plan, prior experience may be credited (see Appendix 6).

A Director and Clinical Consultant must have an in-depth understanding of the clinical benefits and limitations of high complexity histocompatibility testing and be able to apply this experience, case by case, when working with other clinical professionals.

To meet the requirements of a Technical Supervisor, a candidate must obtain and communicate "technical competency." Technical expertise for each technology used to evaluate patients at a candidate's institution can be communicated in a variety of ways, e.g., in the portfolio of detailed cases, during the oral competency assessment, by first author publications, in validation packages for new technolog(ies), by training of staff, and/or by writing or revising procedures. Multiple ways are usually required.

### **B. Structure of the DTRC/Portfolio Committee & Qualifications of Committee Members**

The DTRC/Portfolio Committee is comprised of varying numbers of committee member volunteers each year. The ASHI bylaws do not limit the number of volunteers serving on the committee. The DTRC/Portfolio committee heads are the Chair and Vice-Chair. The Vice-Chair will make a commitment to serve four years, two as the Vice-Chair and two more as the Committee Chair; a written agreement must be filed in the ASHI office stating that the Portfolio Committee Vice-Chair nominee is willing to make that commitment. The names of Candidates for the Vice-Chair position are submitted to the ASHI & ACHI Executive Boards for approval. Previous DTRC/Portfolio Committee experience is required. ARB experience is highly desirable but not required.

ARB Liaisons: The DTRC/Portfolio Committee Chair and Vice-Chair will serve as liaisons to the ARB. Conversely, an ARB Co-Chair or the ARB Program Director (or designee) will be present at all Portfolio Committee oral competency assessment interviews.

All committee members must have a doctoral level degree and serve as a director of an ASHI accredited laboratory, either part- or full-time.

### **C. Term**

Committee members serve a 2-year term, with the option to serve a maximum of one additional consecutive 2-year term. Committee members can be appointed vice-chair after a minimum of 3 years. The Chair and Vice-Chair serve 2 year terms. The Vice-Chair automatically becomes the Chair once the 2 year term is complete.

### **D. New Member Selection and Responsibilities**

Volunteers will be evaluated by review of their CVs and by majority approval after a vote that includes at least a majority of all current DTRC/Portfolio Committee members. All volunteers will be made aware of the individual responsibilities of members on the Portfolio Committee. Each candidate must be a DTRC/ACHI approved director of an ASHI accredited laboratory. A Portfolio Committee member in good standing should participate in at least two oral competency assessments/Interviews per year as a portfolio reviewer or oral competency assessment participant. Participation requirements may be impacted by the number of candidates undergoing review .

# I. POLICIES & PROCEDURES

## A. New Directors

### i. Portfolio Development

ASHI accreditation is granted for each Area of Accreditation. The candidate may request approval for any or all areas of accreditation. A portfolio must be submitted for each area of accreditation for which approval is being requested. The portfolio must contain at least 50 case reviews, with 10 detailed case studies for the major areas of accreditation (HSC/BM: related donor; HSC/BM: Unrelated donor; Solid Organ Transplanted: Deceased Donor and Solid Organ Transplantation: Live Donor. The portfolio must contain at least 20 case reviews and 5 detailed case studies for the areas of Histocompatibility Testing for Other Clinical Purposes and/or for Transfusion Support.

*NOTE: this exercise or portions thereof may be waived by the DTRC/Portfolio Committee for applicants who have previously established themselves in the fields of human histocompatibility testing or transplantation.*

- The detailed cases for each Area of Accreditation must include a summary (containing interpretation of results, comments, recommendations, further testing needed, etc.) as well as all relevant worksheets, evidence of review and signed reports.
- 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 portfolio, case logs, and any supporting documents can be submitted on flash drives, or as attachments to an e-mail. The submission must be electronic.
- Protected health information and patient identifiers must be removed and replaced with a numbering system that clearly indicates the case number and subject being presented. An example for a solid organ live donor case with multiple donors could be: SOLD1 P1, SOLD1 D1, SOLD1 D2, SOLD1 D3, etc. The new labeling must be consistent on worksheets, reports, and case summaries.
- It is essential that the detailed case studies communicate technical competency and critical thinking skills. A candidate should comment on the benefits and limitations of the testing performed. It is appropriate to use references to published papers and abstracts to support the interpretations and conclusions.

DIT candidates will ensure that all the interpretation provided in the case studies is original and free from plagiarism. If plagiarism is detected, the portfolio will be rejected, and this will be communicated

to both the DIT and mentor. While historical cases may be used, most cases must be contemporaneous with the DIT training.

DIT candidates are encouraged to fill in the case log and to start the detailed case summaries during training. Examples of a case log template and a detailed case template can be found at the following link: <http://www.ashi-hla.org/page/Directors/>.

## **B. Progress Reports**

Before the training is complete, approximately midway through the training period, the accreditation office will send the DIT and the mentor(s) the template for the progress report. This report will gauge that the training outlined in the registration phase is being followed and practiced and will also encourage mentor-DIT interaction.

## **C. “Green Light” Email**

When a candidate is approaching the end of the training program, and has accumulated the log of cases and detailed cases, he/she must request approval to submit the portfolio of detailed cases. The request should be made in an e-mail. The attachments should include an updated CV, a brief summary of the training and experience with a confirmation of the accreditation area approvals being sought. The signed and notarized verification of training form (Appendix 1) can be submitted at that time or along with the portfolio of cases.

If candidate’s request for approval to submit the portfolio verifies that the original training plan has been completed, the DTRC/Portfolio Committee Chair will send the “Green Light” e-mail for portfolio submission.

## **D. Board Certification**

New director candidates must be board certified before they submit the portfolio or proceed to the oral competency assessment stage. This will be made clear to all DITs in the initial registration letter. Candidates will not be sent the green light email until board certification requirements are met.

ASHI Directors must comply with ASHI standards E.2.1.3:

**E.2.1.3** Meet at least one of the following certification requirements for areas of accreditation regulated by CLIA:

**E.2.1.3.1** Be certified and continue to be certified in clinical or combined anatomic/clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or other appropriate medical board.

**E.2.1.3.2** Be certified and continue to be certified by a Board approved by HHS.

**E.2.1.3.3** For laboratories outside of the U.S.A, be certified and continue to be certified by an appropriate professional board or other certifying agency.

Referring to standard E.2.1.3.3 - Directors of non-USA laboratories must be certified and continue to be certified by an appropriate professional board or other certifying agency: If directors supervise laboratories that use ASHI accreditation to meet CLIA certification requirements, their professional board must be approved by HHS. As of August, 2011, all US HHS-approved boards are accepted by ASHI.

NOTE: Directors with MD licensure applying to be directors in the United States must be licensed as a physician in the US, otherwise will have to comply with the board certification requirements listed above.

### **E. The Oral Competency Assessment of Portfolio and Experience**

All candidates will undergo a final oral competency assessment (previously referred to as the oral ~~review~~ interview) upon completion of training and submission of the case portfolio. This will occur after review of the detailed case has been completed. The Accreditation Manager will contact the candidate to schedule the interview.

At a minimum, the interview committee will consist of 2 portfolio reviewers, an ARB representative (ARB Program Director, or co-chair), the Portfolio Committee Chair and Vice-Chair.

For the purpose of training and observation, new Portfolio Committee members may be invited to participate in oral interviews but will not be allowed to ask questions or vote on any candidate's performance.

Format of the oral **competency assessment**/review:

- The interview is intended to be an opportunity for the applicant to respond to open ended questions from the review committee about laboratory practice, common problems in testing, laboratory management, and clinical interpretation and application of testing results. Examples of possible questions raised during the oral review can be found in Appendix 2.
- The role of the ARB during the oral interview is to 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.
- The candidate is encouraged to have on hand the portfolio submitted in the event that there are questions about specific cases.
- The accreditation manager will take notes on the outcome of the call and provide all call participants, excluding the candidate, an email summary of the decision.

*NOTE: The oral review interview may be waived by the DTRC/Portfolio Committee for applicants who have previously established themselves in the fields of human histocompatibility testing or transplantation.*

## **F. The DTRC/Portfolio Committee Decision on Credentialing**

### **Decision to deny during portfolio review**

If the portfolio reviewers determine that the candidate's portfolio is substandard, the candidate will not proceed to the Oral Review. The reasons that the portfolio is considered unacceptable will be communicated to the candidate and, with the candidate's permission, to the mentor(s). The candidate will be informed about the deficiencies and will be given some possible solutions.

### **Reasons for the rejection of a portfolio may include (but not limited to):**

- The detailed case summaries do not provide the information needed to make a decision about technical competency and critical thinking skills.
- The submission is not complete in terms of number of cases or supporting documents (e.g. worksheets, preliminary and final reports, clinical outcome, etc.)
- The labeling of the documents and cases makes review difficult.
- The portfolio contains multiple transcription errors.
- Sufficient numbers of cases do not indicate a primary review by the candidate.
- Protected health information (PHI) is not redacted
- Plagiarism
- Most detailed cases are not contemporaneous with the candidate's training (i.e. detailed cases are historical in nature). One or two historical cases per area of accreditation, when of interest may be included. However, there must be evidence of review of data related to the case by the candidate.
- The cases do not display breadth or depth of concepts routinely expected for each area of accreditation (please see appendix for guidance on development of portfolio).

### **Decision after the Oral Review**

Participants on the oral review interview will vote on whether to approve the candidate for the specific area(s) of accreditation requested in the initial application. More areas of accreditation may be added (or dropped) during the training period at the written request of the mentoring director.

Within one week following a candidate's approval as a Director by the review committee:

- The DTRC Chair will confer with the Accreditation Manager as to the candidate's specific areas of accreditation
- The Accreditation Review Board database will be updated to reflect the candidate's approved status as an approved director.
- 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.
- The candidate may be approved in some areas and not others. The HLA Director must be approved for all areas of accreditation for which the HLA laboratory is accredited, if he/she is the sole Director of the laboratory.
- The DTRC decision will be conveyed to the ACHI Board.

If not approved for one or more areas, the DTRC Committee Chair will work with the applicant and mentoring director to determine the course of action needed to obtain approval. This may include documentation of focused additional training and experience, additional case file reviews, submission of

a full portfolio, another interview, working with additional mentors, and/or other means, as determined on a case-by-case basis. A training plan to address the areas of concern should be submitted and approved. A greenlight letter will then be issued following completion of the training plan. At the discretion of the DTRC, the same committee reviewers may be requested to participate in the review of any submitted cases and the oral competency assessment.

## G. Successful Outcomes

- **ASSOCIATE:** When an individual passes the ACHI Diplomate examination, they become an Associate of the ACHI. This individual can NOT yet direct an ASHI-accredited laboratory. This individual will be issued a certificate of board certification.
- **AFFILIATE:** When an individual has an MD license current in the US (with appropriate board certification) and passes the portfolio process and oral interview, they become an Affiliate of the American College of Histocompatibility & Immunogenetics. This individual can direct an ASHI-accredited laboratory and will be issued a letter & certificate of approval.

*OR*

When an individual has another HHS approved board certification (other than the ABHI Diplomate certification) or international directors approved without board certification and passes the portfolio process, and oral interview they become an **Affiliate** of the American College of Histocompatibility & Immunogenetics.

- **FELLOW:** When an individual passes the ACHI Diplomate exam, portfolio process, and oral interview they become a Fellow of the American College of Histocompatibility & Immunogenetics. This individual can direct an ASHI-accredited laboratory and will be issued a letter & certificate of approval.

If the individual fails any part of the process (portfolio review / oral interview / examination) they will be given instructions from the Accreditation Manager on how to reapply, with further training requested as needed.

## H. Fees

A fee of \$300 per new Area of Accreditation, or \$900 for review of qualifications to direct a full service laboratory must be submitted to the ASHI Accreditation Manager upon receipt of an official invoice from ASHI (sent to the candidate after the portfolio is submitted).

## I. Current Directors

"Grandfathering" clause: Individuals who were once ASHI approved but have been out of the field of HLA for >5 years will have to be reviewed by the ACHI Credentials Evaluation Committee to regain ASHI approval. Individuals who were once ASHI approved but have been out of the field of HLA for <5 years will need to provide more detailed information on their training and experience out of the field. Further training may be requested. However, the actual portfolio requirement may be abbreviated, after the ACHI Credentials Evaluation Committee has reviewed the status of the individual, and the circumstances of their absence from the field. Relevant CE must be obtained annually.

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

- Outline/Summary of Training.
- A Log of reviewed and detailed case studies for each new Area of Accreditation (See Portfolio Development and Review" section above for portfolio requirement for each area of accreditation).
- An oral review will be held at the discretion of the DTRC/Portfolio Committee after review of submitted materials. In the case of an established Director/Technical Supervisor who is adding an Area of Accreditation, the oral review may be waived, depending on the experience of the applicant.

Validation materials for any new Technologies or Methods that were established for the new Area of Accreditation will be evaluated during the next on-site inspection of the laboratory.

## II. PORTFOLIO REVIEW CYCLES

The table below was designed to coincide with ARB laboratory review cycles.

<b>Step</b>	<b>Cycle 1</b>	<b>Cycle 2</b>	<b>Cycle 3</b>
<b>Portfolio Due</b>	January 1	May 1	September 1
<b>Review Phase</b>	January 15 – March 1	May 15 – July 1	September 15 – November 1
<b>Oral Interview Window</b>	March 1 – April 1	July 1 – August 1	November 1 – December 1
<b>ARB Meeting (Approximate Date)</b>	April 1	August 1	December 1
<b>Approval/Denial Letter Sent</b>	April 15	August 15	December 15

# APPENDIX 1

## Director Training Verification Documentation

<b>Name of Director-in-Training:</b>			
<b>Board Certification</b>	<b>Yes / No</b>	<b>Board(s):</b>	<b>Number(s):</b>
<b>Training Institution:</b>			
<b>Mentor:</b>		<b>Dates of Training:</b>	

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. **Histocompatibility Testing for Other Clinical Purposes**

\_\_\_\_ Log of 20 Case Reviews completed

\_\_\_\_ Analysis of 5 interesting cases completed

\_\_\_\_ VI. **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. Please provide details on your overall impressions of this  
Director-in-training in the COMMENTS box below (optional).

Comments (optional):          
--

\_\_\_\_\_  
**Signature of Mentor**  
(Please have signature notarized)

\_\_\_\_\_  
Date

\_\_\_\_\_  
**Notary's Signature**

\_\_\_\_\_  
Date

ID #: \_\_\_\_\_

Date of expiration: \_\_\_\_\_

## APPENDIX 2

# Guidance for Detailed Case Development and Oral Competency Assessment

For each credentialing area sought, review of 50 cases is required, from which 10 challenging cases should be chosen that highlight the candidate's exposure, experience, skills and knowledge in the field. In these 10 detailed case summaries, candidates should be able to demonstrate considerable breadth and depth of knowledge including but not limited to:

- General Knowledge
- General Immunology
- Transplant Immunology
- Genetics/molecular biology
- Histocompatibility
- Immunogenetics
- Human Leukocyte Antigens (HLA)
- Genetics, Biochemistry, Structure/function: exon/intron, domains, 3-dimensional structure
- Nomenclature: G and P groups, coding/non-coding sequences, common, intermediate, well-defined (CIWD) classification, serological/molecular
- Polymorphism: Location of polymorphic sites and their relevance, splicing sites, insertion/deletion, premature stop codon.
- Antigen expression: Null alleles/ Other expression variants (S, C, Q, L, A) and polymorphisms associated with differential level of expression
- Immunobiology
- Role in transplantation (solid organ, tissue, hematopoietic cell) and cell therapy
- Molecular matching algorithms: Understanding of different algorithms that define epitopes, use of software (Matchmaker, PIRCHE, others)
- Public vs private epitopes, cross-reactive groups.
- Laboratory Management:
  - Applicable regulations/standards/policies governing the HLA lab and clinical programs covered by the laboratory: Local, regional, national and accreditation-specific (ie: joint commission) regulations based on location of the laboratory
  - Inspections and accreditations: Timing of inspections, how to conduct self-inspections, on-site inspection, documentation needed for accreditation application, requirements for the validation of new tests/methods, notification requirements, deemed status of accrediting organizations with governmental and non-governmental agencies
  - Laboratory safety: Eye wash, chemical shower, fire extinguisher, biosafety cabinet, chemical hood... How to use, required maintenance based on accreditation and

regulations where the lab is located, and training of personnel, chemical safety, reagent labelling (for US: OSHA, NFPA; other according to applicable national or local regulations)

- Legal/professional liability: Malpractice insurance, equipment and reagents, legal documents-for research use only, vendor notifications of reagent recall
- Personnel management: Pay plan and career ladder, diversity and inclusion, positions in the laboratory and job responsibilities. On-call scheduling. Hiring/firing/disciplinary actions/performance appraisal/evaluation
- Budget management: Equipment depreciation, reagents and equipment cost and/or contracting. Capital investment vs operational budget.
- Billing and reimbursement (as relevant by country): For US: CPT codes, ICD-10, independent vs hospital-based laboratory, Medicare reimbursement. Billing of test performed from archived samples
- Lab organization: Laboratory meetings. Task assignment and delegation, lab physical space. Document control and contract/written agreements with transplant programs. Continuing education (director, lab personnel)
- Risk management: Deviation of protocol-how to document, incident report for test/control/equipment failure, documentation of unacceptable samples that are discarded or acceptance of improperly labelled samples. Sample mix up, investigation of improper release of test results.
- Security of reporting systems to maintain patient/donor confidentiality regulations, training and compliance (for US: HIPAA regulation, other based on applicable national or local regulations).
- Quality assurance/quality control program: key performance indicators, corrective actions, proficiency testing requirements.
- Evaluation of competency: 6 elements of competency/technologist competency assessment, competency for key personnel under CLIA regulation (director, technical supervisor, general supervisor), IQCP (individualized quality control plan: for US DITs) regulations, current applicable ISO regulations.
- Retention requirements: specimens/records

For every technique covered:

- Instrument operation, setup, calibration, maintenance, QC, monthly performance review, and troubleshooting
- Testing protocol: Know what each reagent does and what each step accomplishes in the protocol.
- Testing methodology and hands-on experience
- Understanding of strengths and weaknesses of different assays and commercial kits.
- Data acquisition, analysis and interpretation: Need to be able to interpret test independently as well as in relation to other testing. For instance, how does the flow crossmatch test result correlate with single antigen bead data

- Reagents and controls: selection, storage, use, quality control, performance: For single antigen beads, ensure familiarity with reagent/lot specific issues such as presence of denatured antigens on some beads, reactivity patterns that are not clinically relevant
- Validation: instruments, reagents, consumables, testing methodologies, software
- Clinical correlations
- Sensitivity/specificity/limitations
- Sample types and treatments (DTT, EDTA, adsorption)
- Troubleshooting

### **HSC/BM Transplantation – Related & Unrelated Donor:**

Case write-ups should broadly cover the following skill sets, but may not be limited to these:

- Hematologic/nonhematologic diseases for which transplantation is indicated
- Testing protocols/algorithms
- Compatibility assessment: HLA, ABO
- Patient and Donor workup
- Hematopoietic cell sources, i.e. bone marrow, peripheral blood stem cells, cord blood unit (CBU)
- Patient sensitization and desensitization
- Antibody testing, crossmatching, complement-fixing antibodies
- Donor-specific Antibodies: current applicable guidelines (i.e. EBMT and ASTCT Guidelines for detection and treatment of DSA in hematopoietic cell transplantation).
- Platelet/RBCs (specially in ABOi HCT) granulocyte support in post-transplant period, especially in highly transfused patients (i.e. Severe Aplastic Anemia, Sickle Cell Disease)
- Conditioning regimens, GVHD prophylaxis including PTCy, immunosuppression, immunomodulatory therapies
- Myeloablative/non-myeloablative regimens
- Graft versus host disease (GvHD), prevention and therapies
- T cell replete/deplete/selection: TCR $\alpha\beta$  depletion, CD45RA depletion
- Graft versus leukemia (GvL) effect
- Host versus graft (HvG): graft failure, graft rejection
- Relapse, including HLA loss relapse, Donor Lymphocyte Infusion (DLI)
- Engraftment and chimerism: STR/VNTR, qPCR, ddPCR, NGS
- Maternal engraftment: i.e. in SCID patients
- HLA Loss: pre-transplant, post-transplant relapse
- Allele dropout
- Verification typing

Clinical Consultation to Include:

- Policies for Confirmatory Typing Requirements for Unrelated Donors and Patients: i.e. NMDP

- Common, Intermediate, and Well-documented HLA in World Populations: current version of CIWDs
- Donor Selection Recommendations:
  - Unrelated donors and cord blood units: e.g., NMDP/CIBMTR
  - Haploidentical: current recommendations e.g., EBMT
- Permissive Mismatches: HLA-C, HLA-DPB1, other
- Potential relevance of non-coding sequences
- Haplotype Matching.
- HLA expression level (e.g. HLA-C, HLA-DPB1)
- Haplotype assignment/segregation/recombination
- Predicted Indirectly Recognizable HLA Epitopes (PIRCHE) Score
- HLA-B Leader Matching
- Cellular Therapies: i.e. chimeric antigen receptor (CAR) therapy, autologous and allogeneic CAR-T, CAR-NK, expanded CBU, and virus-specific T-cell therapies
- KIR/NK cell genotyping/phenotyping/donor selection strategies
- Regulatory Standards: i.e. CLIA, CLSI, FACT, CAP, ASHI, EFI and local/state requirements

### **Solid Organ Transplantation – Live & Deceased Donor**

Cases selected by candidates for detailed discussion must include some aspect of interest, either from a technical laboratory perspective for the assays used within the laboratory or from a clinical perspective, or both. Cases that describe routine testing / transplantation should be avoided, as this does not help demonstrate to the committee the level of knowledge/experience expected as a director.

- Please note: Cases should be balanced in their discussion of technical considerations of the case, as well as the clinical implications of testing. Prospective laboratory directors are evaluated as both Technical Supervisors as well as Clinical Consultants, and candidates should demonstrate proficiency in both of these areas through their portfolio discussions.
- Candidates should limit the repetition of certain aspects (clinical or technical) across multiple cases. The cases selected should cover a breadth of topics relevant to histocompatibility testing and transplantation.

Portfolios should allow the reviewers to understand the standard testing practices of the laboratory in question. HLA Laboratories are varied in their approach to testing and reporting, and it is critical that the reviewers have the appropriate context to assess the trainee's experience and understanding. This should be included as either separate documents that summarize the structure of the laboratory and testing algorithms, or within the cases themselves.

- Candidates should be able to describe the rationale for all testing that is/is not performed in each case/clinical scenario. Furthermore, candidates should be able to

discuss how to troubleshoot technical issues that arise during testing.

- Candidates should also be familiar with common limitations/pitfalls of various testing methodologies, and be able to discuss how these are addressed in their laboratory

Major topics to consider discussing in case portfolio:

- Immunogenetics
- Nomenclature, Typing resolution and ambiguities
- Polymorphism across HLA
- Novel alleles and their impact on solid organ transplantation
- Laboratory Management
- ASHI Accreditation requirements for testing
- Risk Management / Quality Assurance and Quality Control
- Testing Methods
- Different techniques for HLA typing and antibody assessment
- Appropriate calibrators and controls
- Validation of new methods
- Troubleshooting of problematic samples
- Correlation/comparison of different reagent kits/vendors
- Virtual crossmatching for deceased and living donors
- Clinical Implications
- Major disease states that can cause organ failure for all organs
- Transplant vs. alternative therapies
- Donor quality evaluation
- Sensitizing events
- Immunosuppression and/or desensitization
- Rejection and treatment
- Organ allocation policy

Multiple organ categories and patient types must be included in the portfolio. Submissions should not be limited to only Kidney cases. This includes considerations for adults vs. pediatrics, and abdominal organs vs. thoracic (if submitting for deceased donors). If the training laboratory's center only performs kidney transplants, supplemental experience at other centers should be considered to enhance training. At a minimum, secondary review of cases obtained from outside centers covering these types of patients must be included.

For all testing referenced in detailed cases, raw data reports for testing must be included to allow portfolio reviewers to make their own informed assessment of results. These attachments must be the raw data itself (e.g. histograms for Flow PRAs with appropriate controls overlaid or included, Flow Cytometry plots and channel shift calculations for crossmatches, Fusion/MatchIT printouts or reports for single antigen bead testing). Summary graphs can be provided to help enhance discussion/understanding, but this must be in addition to, rather than in lieu of, primary

laboratory data.

Candidates must clearly demonstrate their involvement in consultation or interaction with the clinical teams through the case documentation or discussion. Examples include but are not limited to: Deidentified emails with clinicians, summaries of discussions of patients at multidisciplinary meetings, virtual XM assessments describing recommendations.

References included must be relevant to the specific interesting issues discussed in the case, and should be appropriately cited within the case discussion. Trainees should not simply include general references about the assay or organ discussed.

For cases involving living related donors, haplotype assignments in the format indicated in the portfolio template must be completed when possible (e.g. haplotypes a/c for the patient, a/b for mother and c/d for father).

### **Histocompatibility Testing for Other Clinical Purposes**

The 20 case reviews and 5 detailed case studies for the areas of Histocompatibility Testing for Other Clinical Purposes must include the following:

- Candidates should be familiar with appropriate application of HLA genotyping within the current diagnostic guidelines for the most common disease/condition/adverse reactions (e.g. Celiac Disease). This includes consideration of ethnic background for both indication for testing and interpretation/consultation.
- Candidates should be proficient with several mathematical and statistical tools used to assess disease association (e.g., relative risk, odds ratio, chi-square test/ Fisher's exact test, p-values, confidence intervals, Hardy-Weinberg Equilibrium, logistic regression, and linkage disequilibrium).
- Candidates should be familiar with HLA biomarkers associated with drug adverse reactions for drugs with FDA labeling sections including 'Boxed Warning' and 'Warnings' ( <https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling> ).
- It is expected that the candidate will be familiar with proposed mechanism for the adverse reaction (e.g. Abacavir).
- Candidates should be familiar with the level of typing (serologic or low/intermediate/high resolution) required to differentiate between low and high risk alleles.

## **Transfusion Support:**

The 20 case reviews and 5 detailed case studies for the areas of Histocompatibility

Testing for Transfusion Support must include the following:

- Reason for transfusion
- Patient characteristics – bone marrow patient with a potential donor (unit avoidance), emergent transfusion, etc.
- Products used for transfusion (platelets, whole blood FFP etc) and their impact on HLA testing and antibody results
- Data required for evaluation (blood count, platelet count etc).
- Antibody testing required (HLA antibody screen versus identification, platelet antibody testing, etc.
- Access to database for unit selection
- Protocol for product selection.
- Post transfusion plan and evaluation.
- Recommendation for units to be transfused.
- Recommendation for frequency of testing
- Clinical consultation and follow up patient care – identifying selected donors based on antibody profile, etc.
- Evaluation of adverse reaction (TRALI, platelet refractoriness etc.)
- Identify need for matched units

Transfusion Support: To obtain credentialing in Histocompatibility for Transfusion Support, the candidate must have experience, as demonstrated by the portfolio, in performing (or case specific guidance for) donor/unit selection. The 5 detailed case studies for the areas of Histocompatibility Testing for Transfusion Support must include the following:

- Indication for HLA testing (e.g., donor selection vs. transfusion reaction investigation)
- Synopsis (Interesting Points for Case):
  - Brief summary of reason for case selection and what will be discussed. Selected cases should provide a variety of clinical and/or technical scenarios to demonstrate clinical and/or technical expertise needed for transfusion support.
  - No more than one case should be solely dedicated to simply demonstrating the standard approach for each indication provided.
- Diagnosis & Clinical History:
  - Provide short overview of patient characteristics and medical history that led to Histocompatibility Testing for Transfusion Support. Include primary diagnosis, other contributing diagnoses (only if relevant), procedures, other relevant lab/study results.
- Sensitization/Transfusion History:
  - Indicate recent and/or historical transfusions (including product types and notable events/details if relevant for discussion). If case involves numerous historical

transfusions with limited relevance, summarizing the history is acceptable. Other relevant sensitizing events should also be included.

- Technologies/Tests/Samples Used:
  - Include what tests were performed including sample type and who was tested
- Test Results:
  - Include relevant test results for histocompatibility (and other) tests performed and reviewed by candidate. Outside testing should only be included if relevant to case and based on reflex/protocol testing specifically related to interpretation/consultation for this case. Final reports, associated worksheets, and/or raw data should be provided.
- Interpretations/Clinical Consultation/Donor Selection:
  - Provide a brief summary of overall interpretation of combined laboratory test results and clinical consultation provided for this case. If case involves donor selection, please include summary of donor selection process/criteria. Associated worksheets and reports should be included (redacted for PHI).
- Discussion:
  - Demonstrate subject matter expertise by elaborating on the details of why this case was chosen. Transfusion Medicine and Immunohematology expertise is not required, however, basic knowledge is essential to provide appropriate and optimal histocompatibility testing and consultation for transfusion support. References should be cited where applicable. In addition to technical challenges applicable under other categories, relevant topics for transfusion support should be discussed in this section. Examples include:
    - Common blood products transfused (including indications, standard compatibility testing and product selection, product life-span, impact/relevance of HLA testing)
    - Lab tests/formulas and approaches for evaluating transfusion efficacy.
    - Alternative targets for compatibility/complications (e.g., ABO, HPA, HNA, etc)
    - Alternative tests for compatibility (HLA/HPA/HNA typing, antibody screening/crossmatching assays)
    - Setting criteria for donor selection/prioritization and utilization of system's database/donor management system. Concepts of matching, match grading, least incompatible/acceptable mismatches and when they apply. Which donors are typically tested for HLA and what HLA testing do they receive and why. Special cases where a designated donor may be requested.
    - Risks/benefits/costs/timing of matching/mismatching.
    - What transfusion reactions are associated with HLA and how is HLA involved. What HLA tests are performed on recipients and donors. What are other potential causes/contributing factors/tests should be considered and when.

## APPENDIX 3

### Portfolio Committee Appeals Process

If a candidate feels that an unfavorable decision from the Portfolio Committee is not fair or justified, the candidate has the ability to appeal the decision. The candidate must initiate the appeal process by sending the following information to the accreditation manager:

1. Name, institution, contact information and mentor(s)
2. A brief (no more than two pages) synopsis of the issue and basis for refuting the original DTRC/Portfolio Committee Decision

The accreditation manager will forward the documents to the DTRC/Portfolio Committee Chairs, an ARB representative, an ASHI Board representative, and the DTRC/Portfolio Committee Appeal Board. The DTRC/Portfolio Committee Appeal Board will consist of three (3) ombudspersons with previous experience regarding Portfolio Committee policies and processes, and will act as impartial referees in the dispute. In the event of a potential conflict of interest, Appeal Board members will be recused from the case. After reviewing the documents submitted by the candidate, the Appeal Board members may gather more information regarding the case by directly contacting the candidate, the candidate's mentor(s), or request additional documents from the Portfolio Committee (archived e-mails, correspondence, portfolio materials, application materials, etc.).

After consideration of the case, the Portfolio Committee Appeal Board may reach one of several possible conclusions:

- Affirm and uphold the original Portfolio Committee decision.
- Refute the original Portfolio Committee decision, and potentially make suggestions to mitigate the dispute.
- Request additional input or guidance from other relevant parties, i.e. the ASHI Executive Committee.

The Appeal decision will be finalized within approximately 30 - 60 days of the receipt of the original appeal claim.

The decision of the Appeal Board will be communicated to the candidate in a formal letter.

# APPENDIX 4

## DIT Progress Report

**American Society for Histocompatibility and Immunogenetics/ACHI Portfolio Committee**  
**Annual Director-In-Training Progress Report**

A signed annual training summary must be completed and verified by both the Program Director/mentor and the Director in Training. 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@ahredchair.com](mailto:mweeks@ahredchair.com).

Name of Trainee: \_\_\_\_\_

Name of Director: \_\_\_\_\_

Training Program: \_\_\_\_\_

Inclusive Training Dates (month/year): From \_\_\_\_ / \_\_\_\_ to \_\_\_\_ / \_\_\_\_

Signature of Director & Date: \_\_\_\_\_

Signature of Trainee & Date: \_\_\_\_\_

*Please fill in the following table:*

AREA or TECHNOLOGY	TRAINING METHODS (approx. % of effort)				Proficiency Level (1-5)****
	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.

\*\*\*\*Proficiency Level Scores

SCORE	PROFICIENCY LEVEL
<b>1</b>	<b>Fundamental Awareness:</b> (basic knowledge)
<b>2</b>	<b>Novice:</b> (limited experience)
<b>3</b>	<b>Intermediate:</b> (practical application)
<b>4</b>	<b>Advanced:</b> (applied theory)



# APPENDIX 5

## Director in Training Process Evaluation

1. Was the time spent in the training program a positive experience?  
Yes/ No  
Comments:
  
2. Was the time spent training adequate to prepare you as an HLA laboratory Director?  
\_\_\_ Too little time  
\_\_\_ About right  
\_\_\_ Too much time  
Comments:
  
3. Were you able to adhere to your original training plan?  
Yes / No  
If not, what areas required more or less time than originally planned?  
Comments:
  
4. Did the preparation of a portfolio of cases add value to your learning experience?  
Yes/ No  
Comments:
  
5. Were the number of cases required for each area of accreditation adequate?  
\_\_\_ Too many  
\_\_\_ About right  
\_\_\_ Too few  
Comments:
  
6. Was the Oral Interview a positive experience?  
Yes/ No  
Comments:
  
7. Were the questions and discussion during the oral interview relevant to your training?  
Yes/No  
Comments:
  
8. Please comment on your overall experience as a Director-in-training.
  
9. Please provide any suggestions that may improve the training process & Portfolio Committee evaluation process.

# APPENDIX 6

Documentation of prior experience and training in Histocompatibility or General Immunology

*(see 42 CFR 493.1449 (h) and ASHI Standards (2024) E.3.1)*

Instructions:

This form is to document the qualifications for an individual to serve as Laboratory Director, Technical Supervisor and/or Clinical Consultant of a Clinical Laboratory performing tests in the subspecialty of Histocompatibility. Each 'training' or 'experience' must be documented separately particularly if your 'role and responsibilities' changed (e.g. technologist to lab supervisor, fellow to director/attending). Please fill out ONE page per experience. Part I is to be filled out by the candidate. Part II Supervisor Attestation must be filled out by the Laboratory Director, Training Program Director or appropriate institutional designee who can attest to the experience/training and must be notarized.

I. Experience of candidate in Clinical Histocompatibility and/or General Immunology (clinical laboratory-based immunology):

- Clinical Laboratory Name/Location: \_\_\_\_\_
- CLIA and ASHI number: \_\_\_\_\_
- Lab Director (or HLA section director) at the time of experience/training: \_\_\_\_\_
- Dates of training/experience (i.e. month/year): \_\_\_/\_\_\_ to \_\_\_/\_\_\_
- Is this experience prior to obtaining your PhD, MD or equivalent degree? \_\_Yes \_\_ No
- What was your role during this time (circle one): technologist/supervisor or lead tech/clinical lab fellow or pathology resident/laboratory director/technical supervisor/other \_\_\_\_\_

Please indicate (mark) what areas of clinical laboratory testing experience (such as, but not limited to: test selection, test validation/development, test performance, data and result analysis, troubleshooting or test interpretation/clinical consultation) were included in your training:

A. General Immunology testing

\_\_\_ infectious disease serology (e.g. HBV, HIV, syphilis, rubella)

\_\_\_ autoimmune testing and disorders (e.g. rheumatoid factor, ANA)

\_\_\_ immune and complement disorders (e.g. immunoglobulin, protein electrophoresis, complement assays, cytokine assays)

\_\_\_ allergy and hypersensitivity; cellular assays

\_\_\_ other immunology-based testing (e.g. ELISA, immunoassays) for other analytes (e.g. tumor markers, hormones, therapeutic drug monitoring)

\_\_\_ immunohematology (e.g. ABO/Rh typing, red cell antibody ID/phenotyping/genotyping, isohemagglutinin titers, platelet and granulocyte typing)

\_\_\_ flow cytometry (for any clinical diagnostic purpose other than histocompatibility)

\_\_\_ molecular testing for immunology purposes (e.g. NGS for immunodeficiency syndromes)

B. Clinical Histocompatibility/HLA testing (circle methods that apply)

\_\_\_ HLA typing (please circle): serology    SSP    SSO    SBT    NGS

\_\_\_ HLA antibody screening and identification/monitoring

\_\_\_ Crossmatching (please circle): CDC    flow cytometry    virtual crossmatch

\_\_\_ Non-HLA antibody testing (please circle): AT1R    endothelial    auto antibodies

\_\_\_ non-HLA molecular testing for transplant (please circle): chimerism    cell free DNA    APOL1

\_\_\_ molecular testing/immunogenetics/HLA pharmacogenetics testing for non-transplant purposes (e.g. autoimmune HLA-B27 typing, B57 for abacavir and cancer cellular therapy).

II. Supervisor Attestation

To be filled out by the Laboratory Director, Training Program Director (or appropriate institutional designee):

(a) In your assessment, combining all areas clinical laboratory-based general immunology above (Part A), including training time and clinical experience (continuous or intermittent), what is the total cumulative number of months the candidate actively accumulated? \_\_\_\_\_

(b) In your assessment, for clinical histocompatibility (solid-organ, hematopoietic stem cell and transfusion-related support, Part B), what is the total number of months the candidate actively accumulated? \_\_\_\_\_

By signing below, you attest that the individual/candidate has actively participated in clinical laboratory testing as stated above to meet current CLIA regulations around training and/or experience.

Laboratory Director/Program Director name (with degree) and signature:

Role:

Date:

NOTARIZED