Operations Manual

Director Training, Review and Credentialing Committee

Version 2-2016 (DTRC approved 10/28/2016)

ASHI Board of Directors APPROVED: 11/9/2016

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I. COMMITTEE

A. Mission & Purpose

The Director Training, Review and Credentialing Committee (DTRC), a committee within the ASHI Professional Standards Division, is charged by the Board to review the credentials 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 will also review 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 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 and Technical Supervisor 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 specialty.

A Director must have a 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 review, 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 Committee & Qualifications of the DTRC Committee Members

The DTRC 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 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 DTRC Vice-Chair nominee is willing to make that commitment.

The names of Candidates for the Vice-Chair position are submitted to the ASHI Executive Board for approval. Previous DTRC experience is required. ARB experience is highly desirable.

ARB Liaisons: The DTRC Chair and Vice-Chair will serve as liaisons to the ARB. Conversely, an ARB Co-Chair or the ARB Program Director will be present at all DTRC oral interviews.

All committee members must have a doctoral level degree and serve as a director of an ASHI accredited laboratory, either part time 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 2 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 DTRC approval after a vote that includes at least a majority of all current DTRC members. All volunteers will be made aware of the individual responsibilities of members on the DTRC. Each candidate must be a DTRC approved director of an ASHI accredited laboratory. A DTRC member in good standing should participate in at least two Oral Reviews per year as a portfolio reviewer or Oral Review participant.

II. POLICIES & PROCEDURES

A. New Directors

i. Registration

All new director-in-training (DIT) candidates must register with the accreditation manager before their training is officially recorded with ASHI.

The following initial documentation must be sent to the accreditation manager, who will forward it to the DTRC Chair & Vice-Chair:

- The mentor's letter accepting the candidate *see box below for examples
- A detailed description and timeline of the proposed training
- The candidate's CV and two letters of recommendation
- Copies of graduate and/or medical diplomas, certificate(s) of post-doctoral experience or letter(s) from post-doctoral supervisor(s), and relevant board certification(s).
- If the candidate is a foreign medical or Ph.D. graduate, documentation of education equivalency by an ASHI-approved agency (see below) must be provided.

Letter of Recommendation Template

Who should write the letter:
Letters of recommendation should be written by the candidate's current immediate supervisor, if applicable, and/or other individuals who have worked closely with the applicant and can assess aptitude for becoming an HLA laboratory Director.

What should the letter contain:
1. How long have you known the candidate? In what capacity?
2. Comment on the candidate past experience and plans to meet the accreditation standards of four years of post-doctoral experience with at least two years of fulltime experience in clinical histocompatibility testing for the purpose of providing care to patients.
3. Specific examples that illustrate the candidate's scientific knowledge, technical expertise, management skills and aptitude relevant to successfully completing an HLA laboratory Director training program
4. Specific examples from the candidate's experience that illustrate his/her leadership skills
5. Specific strengths that would make this candidate a good HLA Laboratory Director trainee and would predict successful completion of the program.
6. Specific areas of improvements or limitations in the candidate's competency.
7. Can you comment on the candidate's reliability and accountability?
8. Any issues that you are aware of that the candidate would need to overcome (such as time commitment to other clinical and/or research activities, communications issues, etc.)
9. Your overall assessment and recommendation
10. Actual signature of the letter's author

ii. Foreign Equivalency

A foreign applicant must have his/her graduate and post-graduate education vetted by a recognized credentialing service. 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.

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

iii. Directors of non-ASHI Accredited USA Laboratories

Directors of non-ASHI Accredited Laboratories may want ASHI DTRC approval because they are interested in (also) seeking ASHI accreditation or because they are planning to seek a position at an ASHI accredited Laboratory. In either case, such applicants must submit the following:

A. A current CV
B. Copies of diploma(s), certificates of post-doctoral training and Board Certification(s)
C. Documentation as to training/experience in areas of Accreditation and Technologies for which approval is sought, according to DTRC criteria

iv. Training Periods

1. **Evaluation of Training/Experience.**

- The DTRC considers training and experience as equivalent functions. Experience must be at a Supervisor level or higher.
- Effective January 1, 2011 all individual DIT training plans must be pre-approved by the DTRC. As of January 1, 2013 training that was not pre-approved will not be considered.
- The training/experience must be in an ASHI approved laboratory under the mentorship of an ASHI approved Director. Equivalence to this requirement will be considered for foreign programs. Accreditation standards require four years post-doctoral full-time participation by a candidate. Part-time experience will be evaluated for equivalence to hours per week on a case by case basis. Documentation is required. See the section "Meeting the four year full-time post doctoral requirement."
- At least two years of the experience must be in clinical histocompatibility testing for the purpose of providing care to patients. The experience must include participation in clinical conferences. A training program must give a candidate the opportunity to obtain technical competency and clinical competency.

- For difficult or confusing cases, the DTRC Chair may forward materials to the ASHI Executive Committee for consultation and review.

2. **Meeting the four-year full-time requirement.**
   There are several ways to meet the full-time experience requirement:
   - Four years post doctoral training or experience directing or supervising high complexity clinical histocompatibility testing for the purpose of patient care.
   - Two years post doctoral experience in immunology, histocompatibility, immunogenetics or a related field
     AND
     two years post doctoral training or experience directing or supervising high complexity clinical histocompatibility testing for the purpose of patient care.
   - A Residency and board certification in clinical or combined anatomic/clinical pathology or other related medical specialty
     AND
     two years post doctoral training or experience directing or supervising high complexity clinical histocompatibility testing for the purpose of patient care.
   - Four years pre-doctoral experience in clinical histocompatibility testing at the supervisory level
     AND
     two years post doctoral training or experience directing or supervising high complexity clinical histocompatibility testing for the purpose of patient care.

v. Portfolio Development & Review

ASHI accreditation is granted for each Area of Accreditation. The candidate may request ASHI approval for any or all of the areas of accreditation. A portfolio must be submitted for each area of accreditation for which ASHI 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 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, CDs, or as attachments to an e-mail.

- 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.

We encourage DIT candidates 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 on the DTRC web page at http://www.ashi-hla.org/lab-center/director-training-review/.

vi. 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.

The Progress Report requirement will take effect with all new DIT registrants starting in January 2014.

vii. "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 Chair will send the "Green Light" e-mail for portfolio submission.

viii. The Oral Review of Portfolio and Experience

All candidates will undergo a final oral review upon completion of training. 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 the DTRC portfolio reviewer(s), an ARB representative (ARB Program Director, or co-chair), the DTRC Chair and Vice-Chair.

For the purpose of training and observation, new DTRC 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 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 interview may be waived by the DTRC for applicants who have previously established themselves in the fields of human histocompatibility testing or transplantation.

ix. The DTRC Decision on Credentialing

Decision to deny during portfolio review

If the DTRC 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:

- 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.

Decision after the Oral Review
The DTRC Committee will vote on whether to approve the candidate for the specific area(s) of accreditation requested in the initial application. More categories and technologies 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 ASHI credentialed 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 lab.

If not approved for one or more areas, the DTRC Chair 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, and/or other means, as determined on a case-by-case basis.

x. Fees
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 an official invoice from ASHI (sent to the candidate after the portfolio is submitted).

B. 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 complete the full DTRC review process 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 perform the same registration steps listed above. However, the actual portfolio requirement may be abbreviated, after the DTRC 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 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 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.

C. Board Certification

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.

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

Excerpt from ARB Operations Manual, section VII. DOCTORAL-LEVEL POSITIONS REQUIRED BY CLIA '88 and ASHI: D. *Board certification is required for the position of Clinical Consultant. It is also required for the Laboratory Director unless he/she was serving as the Director of an ASHI accredited Laboratory on or before February 24, 2003. A Director or Clinical Consultant with an M.D. will meet this requirement if he/she is licensed to practice medicine in the State in which the laboratory is located. Directors of non-USA laboratories must be certified and continue to be certified by an appropriate professional board or other certifying agency.*

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

III. PORTFOLIO REVIEW CYCLES

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

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

APPENDIX 1

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. **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 Date

(Please have signature notarized)

_____ _____

Notary's Signature Date

ID #: _____

Date of expiration: _____

APPENDIX 2

Oral Examination: Examples of Preparatory Questions for Director Qualification

NOTE: Questions may vary widely for oral examinations and are often dependent upon the cases presented in the portfolio. The questions listed below include many of the expectations for an applicant, but may not necessarily represent the scope of the questions during an oral interview.

1. What was your level of involvement in the following: solid organ living donor, solid organ deceased donor, Non-renal solid organ, stem cell/bone Marrow?
   a. Take case and review after all reporting had been done?
   b. Cases where you were involved throughout the testing process?
2. What testing have you performed at the bench level and what is your level of proficiency in each?
3. How often does the laboratory consult you with technical problems?
   a. What are some of the problems?
   b. How do you resolve them?
   c. If technical, did you help with some of the benchwork?
4. Have you been involved in a case where hyperacute or accelerated acute rejection occurred in the face of a negative crossmatch?
   a. If so, what steps did you take to evaluate the likelihood that it was due to an immunological reaction against the MHC?
   b. Have physicians ever consulted you concerning such cases? Describe.
   c. If you haven't been involved as yet in consulting or evaluating acute rejection episodes in negative crossmatch patients, what would your evaluation plan be if asked?
5. After crossmatches were done, how many did you review before the information was transmitted to the transplant center?
6. As a new director for a laboratory doing both deceased and living renal transplant, describe the crossmatch algorithm you would set up: Types of crossmatches, number and date of sera, relationship of transplant number to the algorithm, role (if any) of PRA in the algorithm.
7. How and when is Flow Cytometry of clinical use in pre-transplant assessment?
8. What are the various strategies of PRA testing, what are their respective levels of sensitivity, and what is their reported respective clinical value?
9. How do you evaluate PRA results for antibody identity?
10. What is the value of a B-cell crossmatch in transplantation? When are the results used in organ transplantation?
11 What is the crossmatch strategy for the following elements of your program:
   a. Heart
   b. Liver
   c. Hematopoietic stem cell

12. What does your program consider a current serum for a final crossmatch? Do you agree?
13. What would you do if your laboratory obtained a specimen from out of state, where the kidney and heart were labeled but all transplant laboratory material was not? The kidney already had 15 hours of ischemic time.
14. What is the testing protocol for a local kidney or heart donor?
15. What would be your counsel to a physician regarding the following situation for a primary transplant? Would you give different advice for a regraft?
    a. Historical peak serum #1 (3.5 years old): 100% PRA –, T and B cell positive by NIH, AHG, and flow cytometry w/current donor.
    b. Historical peak serum #2 (1 month later): PRA 83%, B-cell positive by NIH and flow cytometry; T cell negative by all methods w/current donor
    c. Current serum is T and B negative by all methods.
16. What if the current donor/current serum is NIH T cell positive by NIHXM and all other T & B crossmatches were negative (primary and regraft)?
17. What if the current donor/current serum is NIH B cell positive and all other T & B crossmatches were negative (primary and regraft)?
18. Describe the local algorithm or your recommended algorithm for working up families for hematopoietic stem cell transplant.
19. How would you handle obvious parental discrepancies in a family workup?
20. Do you use molecular typing or both for assessing possible stem cell transplant combinations? What do each of these assess (advantages/disadvantages)?
21. What is your testing protocol for unrelated stem cell transplants? What loci do you test and match for, what level of resolution of testing do you recommend?
22. In an SSP gel you note the appearance of many more bands than is necessary to provide the type of the patient. What is the most likely source of these additional bands and how would you resolve the problem?
23. What are the limitations (if any) of class I molecular testing? How would you address them?
24. What is the purpose of the wipe test in molecular testing? What primers should be used? How often should it be done?
25. How often should the thermocycler be quality assessed?
26. How would you validate a new test before placing into routine operation?
27. What does color compensation accomplish in flow cytometry?
28. What is your procedure for flow crossmatching (FCXM)? (Explain the use of labeled monoclonal antibodies, etc)
29. What is gating and what does it accomplish?
30. What determines whether a FCXM is positive or not? How are the cutoffs determined? Are these determinants absolute? What influences them?
31. Describe the protocol you would follow to identify a suitable platelet donor(s) when working up a platelet refractory patient.
32. What recommendations would you make to a physician whose patient does not have access to HLA matched platelets or when HLA matched platelets cannot be found?

APPENDIX 3

DTRC Appeals Process

If a candidate feels that an unfavorable decision from the DTRC 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 Decision

The accreditation manager will forward the documents to the DTRC Executive Committee, a DTRC ARB representative, the DTRC ASHI Board representative, and the DTRC Appeal Board. The DTRC Appeal Board will consist of three (3) ombudspersons with previous experience regarding DTRC 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 DTRC (archived e-mails, correspondence, portfolio materials, application materials, etc.).

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

- Affirm and uphold the original DTRC decision
- Refute the original DTRC 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/Director Training Review and Credentialing Committee Annual Director-In-Training Progress Report

A signed annual training summary must be completed and verified by both the Program Director and the 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.

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)**				
	Est. Duration (weeks)	Bench Experience Including test interpretation	Didactic Training*	Self Study	Proficiency Level (1-5)****
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
1	**Fundamental Awareness:** (basic knowledge)
2	**Novice:** (limited experience)
3	**Intermediate:** (practical application)
4	**Advanced:** (applied theory)

5	**Expert:** (recognized authority)
N/A	**Not Applicable**

This is consistent with NIH proficiency scale

located in the following link:
https://hr.od.nih.gov/workingatnih/competencies/proficiencyscale.htm

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

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

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

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

5) Other comments/concerns

APPENDIX 5

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

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

Trainee's Name _____

Trainee's Signature & Date_____

Laboratory _____

Mentor_____

Start Date (month and year) _____

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

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

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

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

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

APPENDIX 6

DTRC 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 & DTRC evaluation process.

APPENDIX 6

HLA Laboratory Director Training Plan Template

Institution:

Address:

Candidate:

Degree (PhD or MD):

Post-doctoral experience:

Training site(s):

> **If more than one training site, indicate % time to be spent at each site and areas of accreditation covered at each site:**

Mentor(s):

> **Indicate amount of time per week to be spent with mentor(s) for teaching/training follow-up/evaluation purposes:**

If mentor(s) not on-site, indicate frequency of meetings and media used:

Other Key Personnel:

Start Date (HLA Director-in-training):

% time devoted to formal training:

Expected completion date:

Objectives:

Example. The training plan is structured to fulfill the two-year requirement for Histocompatibility and Immunogenetics training, meeting or exceeding the standards set forth under CLIA 42CFR 493.1441 and to meet the requirements for an HLA Director as prescribed by the American

Society of Histocompatibility and Immunogenetics (ASHI), the College of American Pathologists (CAP), the United Network for Organ Sharing (UNOS), and the National Marrow Donor Program (NMDP).

Goal:

Example: The candidate will be exposed to testing methods and technologies used in a Histocompatibility laboratory that supports both Solid Organ and Stem Cell transplants. After completion of the technical components, the candidate will focus on interpretation, with great emphasis placed on antibody identification and correlation with HLA typing and crossmatching. This will be accomplished by being a reviewer of testing worksheets and by incorporating interpretation comments as needed into the reports. At the end of the training, the candidate should be able to function as a Director, Technical Supervisor, and Clinical Consultant for a Histocompatibility Laboratory.

Overview of Training Plan:

The training will consist of the following components:

A. Didactic training:

(give detailed plan)

B. Technical Training:

(give detailed plan); should include validations, if possible

C. Review and Interpretation

(give detailed plan and expectations at end of training)

D. Management, QA, Miscellaneous

(give detailed plan; should include: QA reporting and monitoring, Proficiency testing review, competency assessment, evaluations of personnel, workload assessment, cost report, computer system, laboratory test management, interactions with transplant center personnel, compliance with regulatory agencies, etc.

E. Research/ Special Project

F. Training Log and Portfolio of Detailed Cases

1. The trainee should gain experience in the following areas of accreditation*:

Solid Organ Transplantation- Living Donor

Solid Organ Transplantation- Deceased Donor

HSCT- related donor

HSCT- unrelated donor

Testing for Other Clinical Purposes

Transfusion Support

**All areas of accreditation are not required. Choose only those which were included in training laboratory.*

2. The trainee will make a log of cases reviewed: minimum of 50 cases for the first four areas listed above and 20 cases for Testing for Other Clinical Purposes and Transfusion Support

3. 10 of the most interesting cases will be written up in detail for each of the four main areas of accreditation and 5 detailed cases for Testing for Other Clinical Purposes and Transfusion Support.

4. The mentor will send a 1 year progress report to the accreditation manager to ensure that the candidate is on-track to complete the training. If the trainee is not able to spend full time training, the training period may be extended to ensure that all aspects of the training plan have been completed.

Training Time Line

Year One

Example:

- Complete “hands-on” training of all HLA testing procedures
- Acquire working proficiency of principles, workflow, instrumentation and troubleshooting of technologies commonly used in histocompatibility laboratories including flow cytometry, Luminex based assays, Sanger sequencing, NGS and fragment analysis
- Learn the procedures and reasoning for all reagent QC.
- Become competent for instrument calibrations and troubleshooting
- Become familiar with the HLA computer system to be competent at accessioning, ordering tests, entering results, reporting, billing, turnaround time, and pulling data for research.
- Review all procedure manuals and propose improvements/ modifications, if applicable
- Learn the HLA nomenclature and learn parent antigens vs splits, CREG groups, common epitopes, common vs rare alleles, and NMDP rules for high resolution
- Learn how to analyze antibody identification and discuss difficult cases with mentors
- Become familiar with UNET web site; Learn how to enter typing results for deceased donors, attach HLA report, enter unacceptable, verify highly sensitized patients, make customized reports, learn Tiedi.
- Participate in relevant lectures at institution
- Attend a workshop or meeting
- Attend weekly candidate selection committee meetings for renal and HSCT programs.
- Participate in preparation of abstracts, case studies and meeting presentations.

Year Two

Example

- Perform review of worksheets and reports and prepare interpretive comments, when applicable.
- Continue to attend candidate selection committee meetings for renal and HSCT programs
- Give at least one in-service lecture to transplant team(s) and HLA staff
- Review all QC documentation and prepare QA report
- Gain knowledge of budget preparation and cost report.
- Gain knowledge of standards and regulations relevant to running an HLA laboratory
- Participate in preparation of accreditation applications and participate in self-inspections.
- Conduct research project or special project
- Complete log of case reviews and detailed write-ups of detailed cases.
- Become competent to take administrative call during deceased donor cases; understand when to defer to Director.