Operations Manual

American College of Histocompatibility & Immunogenetics


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I. COLLEGE STRUCTURE

A. Mission & Purpose
The American College of Histocompatibility & Immunogenetics (ACHI) is affiliated with the American Society for Histocompatibility and Immunogenetics (ASHI) operating as a function of ASHI’s Professional Standards Division to:

1- Evaluate the education, training and experience of doctoral professionals in the field of histocompatibility and immunogenetics for eligibility to take its professional examinations and to practice in histocompatibility and immunogenetics in the United States (according to CLIA standards) and worldwide (according to equivalent governing standards).
2- Evaluate all submitted documentation including case portfolios, statements from the mentoring director, and letters of recommendation for all prospective candidate directors and candidate technical supervisors.
3- Approve proposed didactic, research, and clinical schedules for individual trainees or detailed plans for permanent director training fellowship programs.
4- Evaluate scientific content of continuing educational activities for relevance and quality
5- Review submitted applications for non-doctoral candidates to determine appropriate eligibility of CHS, CHT and CHA candidates.
6- Develop and administer professional credentialing exams for doctoral (fellow/formerly diplomate) and non-doctoral (CHS, CHT and CHA) candidates.
7- Evaluate and accredit director training programs
8- Evaluate and certify technologist training curricula and programs

The ACHI approves doctoral level candidates as Director and Technical Supervisor Ph.D. candidates wishing to direct an ASHI accredited laboratory. If practicing in the US, such candidates must be board certified by one of the appropriate Boards approved by The U.S. Department of Health and Human Services (HHS). This evaluation process includes the vetting of graduate and post-graduate education to determine compliance with ASHI Standards to direct and/or provide technical supervision for an ASHI accredited laboratory. M.D. candidates must be licensed to practice in the USA and the state in which they wish to practice, and possess an appropriate Board certification. Educational degrees obtained outside of the US, must have their degrees evaluated and/or recognized by the National Association of Credential Evaluation Services (NACES).

A Director 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 review, by first author publications, in validation packages for new technologies, by training of staff, and/or by writing or revising procedures. Multiple ways are usually required.

The ACHI also approves Director Training Fellowship Programs, for institutions that wish to train multiple new directors over an extended period of time. This is a more robust procedure that requires an application, fee & inspection procedure. Detailed guidelines are included in Appendix 3.

The ACHI intends to develop training programs for technologists as well. This future endeavor will give technologists another route of eligibility to gain experience & training to qualify for the CHT examination.

B. The Board of Directors of the ACHI
The ACHI is comprised of varying numbers of committee member volunteers each year. The ACHI is led by a Board of Directors.

The Board of Directors shall be a Chancellor, Chancellor-Elect, an Immediate Past Chancellor, a Bursar, a Secretary and such other officers as the Board may determine. The Chancellor-Elect shall Dean the Nominations Committee, which shall be comprised of the Chancellor, Chancellor-Elect, Immediate Past Chancellor, Secretary and Bursar. The Nominations Committee shall prepare a slate of nominees for Officers and distribute to the Board thirty (30) days prior to the annual meeting. Nominees shall be ABHI/ACHI certified CHS or Diplomate level. Election of Officers shall be by ballot of the Board at the annual meeting of the Board. Results will be certified by the Secretary. Results of the election will be announced during the meeting.

The Chancellor, Chancellor-Elect, and Immediate Past Chancellor each shall hold office for a term of one year which will terminate at the annual meeting of the Board one year succeeding election or appointment. To be consistent with a 3 year term of office as with other officers, the sequence is Chancellor Elect to Chancellor to Immediate Past Chancellor will be considered one term.

The Secretary and Bursar of the corporation shall serve a term of three years which shall terminate at the annual meeting of the Board. Any officer or agent elected or appointed by the Board may be removed by the Board with cause by a vote of the majority of the Board.

The Chancellor, Chancellor-Elect, Immediate Past Chancellor, Secretary and Bursar will comprise the Executive Committee of the Board of Directors. The ASHI Board of Directors will approve any new nominations on the Executive Committee of the Board.

The number of directors on the Board shall be at least nine but not more than twenty. Appointment is desired before the ASHI annual meeting, so new members can attend. The term of each director shall be
three (3) years, which terms shall begin at the time of the ASHI annual meeting. A director may be reelected or reappointed for one additional three (3) year term.

The Board shall meet in person at least annually in conjunction with the ASHI annual meeting or another annual meeting upon which a majority of the Board shall agree. Quarterly conference calls will also be held for the full Board. All policies and procedures included in this manual or as an addendum must be approved by the full Board. Annual review and approval of changes to policies and procedures is required from the ASHI Board of Directors & CMS.

C. Committees of the ACHI

i. Credentials Evaluation Committees
   a. Directors
   b. CHA/CHT/CHS

ii. Diplomat Exam Committee

iii. CHA/CHT/CHS Exam Committee

iv. Portfolio Committee (former ASHI Director Training, Review and Credentialing Committee/DTRC)
   See the Portfolio Committee Operations Manual for details.

v. Doctoral Training Programs Certification Committee
   See the Fellowship Program Guideline document for details.

vi. Technologist curricula/programs certification committee – placeholder

vii. Judiciary & Bylaws Committee

viii. Financial Committee

ix. Other Committees/Ad hoc Committees

x. Liaison with ASHI

Director Credentials Evaluation Committee: The Credentials Committee shall consist of minimally a Dean who shall hold a doctorate degree and have been certified at the doctoral level as Diplomates of the American College of Histocompatibility and Immunogenetics. Two members should be the Dean and vice Dean of the portfolio committee. The Dean of the Credentials Committee shall be appointed by the Chancellor of the College with the approval of the Directors. The term of office for appointments to the committee shall be three (3) years. Completing another member’s term will be considered as having served one term. Members may serve a second term, but subsequent terms shall occur only after an absence of at least one (1) year, or may be extended upon the vote of the executive committee. During the third year of the term (or the sixth year if serving a second term) a Vice-Dean, who shall hold a doctorate degree and have been certified at the doctoral level as Diplomates of the American College of Histocompatibility and Immunogenetics, will be appointed to ensure a one (1) year overlap for training.
If the Dean is unable to complete the term of office, a/the Vice-Dean will be appointed by the dean to complete the term. The Director Credentials Committee shall investigate and determine the eligibility of applicants for examination. This committee shall not have the power itself to grant or issue any certificate. When disputes/cases arise, the Dean will have the ability to call on the Judiciary Committee and/or a minimum of three (3) board members who have no prior involvement with the case at hand, for help with resolution.

**CHA/CHT/CHS Credentials Evaluation Committee:** The Credentials Committee shall consist of minimally a Dean. The Dean of the Credentials Committee shall be appointed by the Chancellor of the College with the approval of the Directors. The term of office for appointments to the committee shall be three (3) years. Completing another member’s term will be considered as having served one (1) term. Members may serve a second term, but subsequent terms shall occur only after an absence of at least one (1) year, or may be extended upon the vote of the executive committee. During the third year of the term (or the sixth year if serving a second term) a vice Dean will be appointed to ensure a one (1) year overlap for training. If the Dean is unable to complete the term of office, the Vice-Dean will be appointed by the Dean to complete the term. The Dean and Vice-dean will be a certified CHS. The Credentials Committee shall investigate and determine the eligibility of applicants for examination as needed, outside of the exam company’s processing of applications. This committee shall not have the power itself to grant or issue any certificate. When disputes/cases arise, the Dean will have the ability to call on the Judiciary Committee and/or a minimum of three (3) board members who have no prior involvement with the case at hand, for help with resolution.

**Director Examination Committee:** The Director Examination Committee shall consist of a Dean and a Vice-Dean and at least seven (7) and no more than twelve (12) members and serve a four (4) year term of office with approximately one half (1/2) of the members terms expiring every two years. Members may serve a second term, but subsequent terms shall occur only after an absence of at least one (1) year, or may be extended upon the vote of the Board. Members shall be individuals who hold doctorate degrees and have been certified at the doctoral level as Diplomates of the American College of Histocompatibility and Immunogenetics. The Dean of the Director Examination Committee shall be appointed by the Chancellor of the College, with the approval of the Directors. The Director Examination Committee shall be responsible for determining the content and passing scores for examinations and for determining the administration of examinations at intervals with the approval of the Board. The results of examinations and their validation shall be recorded by the committee and made available to the Board.

**CHA/CHT/CHS Examinations Committee:** The Examinations Committee shall consist of minimally a Dean an optional Vice-Dean and of at least seven (7) and no more than twelve (12) members. The Dean of the CHA/CHT/CHS Examinations Committee shall be appointed by the Chancellor of the College with the approval of the Directors. The members of the CHA/CHT/CHS Examinations Committee shall be appointed by the Dean of the committee. The term of office for appointments to the committee shall
be three (3) years. The rotation shall be determined by the Dean, with equitable numbers of members rotating on and off the committee each year. Members shall include CHS-level certified individuals in each subarea or level in which examinations are offered. If a member other than the Dean is unable to complete the term of office, a new member will be appointed by the Dean to complete the term. Completing another member’s term will be considered as having served one term. Members may serve a second term, but subsequent terms shall occur only after an absence of at least one (1) year, or may be extended upon the vote of the executive committee. The CHA/CHT/CHS Examinations Committee, working in conjunction with the exam company (PSI) shall be responsible for determining the content and passing scores for examinations and for the administration of the examinations at intervals as are determined by the Board. The results of examinations and their validation shall be recorded by the committee and made available to the Board.

**Portfolio Committee:** This committee is the former ASHI-DTRC and ultimately responsible for approval of all ASHI laboratory directors. Detailed procedures are listed in the Portfolio Committee Operations Manual (see appendix 2). The committee is charged by the College to work with the Director Credential Evaluations Committee 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 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 and candidate technical supervisors. The 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 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 portfolio committee heads are the Dean and Vice-Dean. The Vice-Dean will make a commitment to serve four years, two as the Vice-Dean and two more as the Committee Dean; a written agreement must be filed in the ASHI office stating that the Portfolio Committee Vice-Dean nominee is willing to make that commitment. The names of Candidates for the Vice-Dean position are submitted to the ASHI Executive Board for approval. Past ARB experience is highly desirable but not required. ARB Liaisons: The Portfolio Committee Dean and Vice-Dean will serve as liaisons to the ARB. Conversely, an ARB Co-Dean or the ARB Program Director will be present at all Portfolio Committee 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.
Doctoral Training Programs Certification Committee: See the Fellowship Program Guideline document for details.

Technologist curricula/programs certification committee: Placeholder

Judiciary & Bylaws Committee: Notwithstanding any provisions of the preceding sections of this Article or of any other Article of the bylaws authorizing, permitting, or contemplating the exercise of any power or the making of any decision, finding, or determination of the Credentials and Examinations Committees or any other committee, the Judiciary Committee, shall have final authority to prescribe, determine and decide all disputed matters and questions relating to or arising under any of the provisions of these bylaws, unless overturned by two-thirds vote of the board. The Judiciary Committee shall consist of minimally a Dean. The Dean of the committee shall be appointed by the Chancellor of the College with the approval of the Directors. The term of office for appointments to the committee shall be three (3) years. The rotation shall be determined by the Dean. Completing another member’s term will be considered as having served one term. Members may serve a second term, but subsequent terms shall occur only after an absence of at least one (1) year, or may be extended upon the vote of the executive committee. During the third year or the sixth year of the term (if serving a second term), a vice Dean will be appointed so there will be a one (1) year overlap for training. The Vice-Dean of the Judiciary Committee shall be appointed by the Dean of the committee with approval from the board. When disputes/cases are referred to the Judiciary Committee, the Dean will have the ability to call on a minimum of three (3) board members who have no prior involvement with the case at hand, for help with resolution.

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 ACHI Registrar:

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 Portfolio Committee Decision

The Registrar will forward the documents to the Portfolio Committee Deans, an ARB representative, an ASHI Board representative, and the Portfolio Committee Appeal Board. The 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.

**Financial Committee:** The Bursar shall serve as the Dean of the Financial Committee. The Immediate Past Chancellor shall serve as a committee member. The term of office for appointments to the committee shall be three (3) years. If the Dean is unable to complete the term of office, a new Dean will be appointed by the Executive Board to complete the term. Completing another member’s term will be considered as having served one (1) term. The Dean may serve a second term, but subsequent terms shall occur only after an absence of at least one (1) year, or may be extended upon the vote of the executive committee.

The Bursar shall oversee the safekeeping of the funds and securities of the corporation, shall keep or cause to be kept full and accurate accounts of receipts and disbursements in books belonging to the corporation and shall keep, or cause to be kept, all other books of account and accounting records of the corporation. The Board shall have the power to make, alter, amend and repeal the Operating Budget of the corporation and to adopt a new Operating Budget, which power may be exercised by a vote of three-fourths (3/4) of the members of the Board present at a meeting at which a quorum is present or when all of the Board members vote in favor of same by mail, provided, however, that no such altered or amended or new Operating Budget shall be effective unless and until approved by the Board of Directors of the Society.

In order to maintain compliance with Generally Accepted Accounting Principles (GAAP), the corporation will share an accounting database with the Society while maintaining independent financial accounts as well as accounts payable services. The Society will not be the beneficiary of corporation funds; however, the Society may provide financial assistance to the corporation when deemed necessary by the Board of Directors of the Society.

**Other Standing Committees:** The Chancellor, with the approval of the Board, may appoint additional standing committees as the need arises.

**Ad hoc Committees:** The Chancellor of the College shall be empowered to appoint ad hoc committees, which shall report to the Board at the request of the Chancellor.
Liaison with the Society: The ASHI Board of Directors may designate a member of the Society to serve as a liaison with the College. Committees of the Society may designate advisors to the College. Society advisors and liaison members shall not vote on any matter before the College.
II. POLICIES & PROCEDURES

A. Laboratory Directors

Directors in Training:

i. Registration

All new director-in-training (DIT) candidates must register with the ACHI Registrar before their training is officially recorded with ASHI, unless they completed their training and have been assuming a full laboratory director position for at least 2 years and otherwise meet all other requirements.

The following initial documentation must be sent to the Registrar, who will forward it to the ACHI Director Credentials Evaluation Committee:

- 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. If the applicant is an MD and is currently licensed to practice medicine in the United States, this requirement is waived. This will be done at the applicant’s own expense and a certified copy of this evaluation must be sent directly from the credentialing service to the Registrar’s office.

The list of agencies approved by ASHI is as follows:

b. World Education Services: www.wes.org
c. Educational Credential Evaluators: www.ece.org
d. International Consultants of Delaware: www.icdel.com
f. Any agencies recognized by the National Association of Credential Evaluation Services (NACES) https://www.naces.org/members

iii. Directors of non-ASHI Accredited Laboratories

Directors of non-ASHI Accredited Laboratories may want ACHI 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, as their training may be outside of an ASHI accredited laboratory and need special review:

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/ACHI Portfolio Committee criteria

iv. Board Certification Requirements

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.

*International new director candidates: 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. For International applicants from countries that don’t require Board certification, they can be evaluated provided they have been assuming a full laboratory director position for at least 2 years and otherwise meet all other applicable requirements. Approval of directors without Board certification will be restricted to the country they are practicing in and will be designated Associates of ACHI.

As of August, 2011, all US HHS-approved boards are accepted. Including board certification from passing the Diplomate exam, requirements detailed below

New director candidates must be board certified before they submit the portfolio of cases. This will be made clear to all DITs in the initial registration email. Candidates will not be sent the green light email from the portfolio committee until board certification requirements are met.

If board certification is obtained through the ACHI’s Diplomate exam, the candidate is registered to become a Fellow of the American College of Histocompatibility & Immunogenetics. If board certification is obtained through one of the other HHS approved board exams, the candidate is registered to become an Affiliate of the American College of Histocompatibility & Immunogenetics.

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.

v. Diplomate Examination Requirements
The Diplomate exam is one option to meet the Board certification requirement, detailed above. The ACHI Credentials Committee will present this option to all DIT candidates at the time of initial registration.

Procedures:

- Examination: Each applicant for certification who has been found eligible for examination shall submit to and satisfactorily pass such examination within three (3) years of approval of the original application. If more than three (3) years has elapsed, a candidate is required to provide evidence of additional training that is acceptable to the ACHI Board before submitting an application a second time.
• Failing the Exam & Re-examination: An applicant who fails the examination may apply for re-
examination. There shall be no limitation to the number of times an applicant may be examined
if the applicant meets current requirements.
• Passing the Exam: Applicants who have completed the examination process will receive written
notification of their passing and will be issued certificates. Passing the exam qualifies them as a
diplomate of the ABHI. This individual can NOT yet direct an ASHI-accredited laboratory until the
portfolio & oral interview processes are successfully completed.
• Continuing Certification: Certified individuals will be issued certificates for a three year period
and must be recertified at three year intervals in order to maintain active certification status
with the ACHI. Recertification shall be either by re-examination or by accumulation of credits for
approved continuing education and professional activities.

vi. Evaluation of Training/Experience:
• The ACHI Credentials Evaluation Committee 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
Credentials Evaluation Committee. As of January 1, 2013, training for candidates in the United
States 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 below "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 unique and unusual circumstances, the Credentials Evaluation Committee may forward
materials to the ACHI Board for consultation and review.

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 Clinical / Anatomical 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.
- Laboratory experience should be acquired preferably in an ASHI accredited facility. Alternatively, laboratory experience may be acquired in a setting where an appropriate range of procedures is performed under competent direction, either in a clinical service laboratory or a basic research laboratory utilizing multiple procedures common to the discipline.
- Basic immunology and genetics training can be obtained in many educational settings. Specialized training in histocompatibility and immunogenetics can be obtained at ASHI approved or sponsored programs and workshops or other programs offered by other organizations.
- Applications. Each application for certification shall be signed by the applicant, notarized and filed with the Dean of the Credentials Committee; and shall be accompanied by such fee as prescribed by the College.
- Denial of application & appeals procedure: Any member of the College or an applicant may appeal a decision on the qualifications of an applicant to participate in the examination process to the Judiciary Committee within thirty (30) days of notification of the application’s rejection. Additional evidence must then be submitted for admittance to the examination procedure. The majority decision of the Judiciary Committee shall prevail.

vii. Outcomes

- **ASSOCIATE:** When an individual passes the 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 they
pass the portfolio process, and oral interview they become an Affiliate of the American College of Histocompatibility & Immunogenetics.

- **FELLOW:** When an individual passes the 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 Registrar on how to reapply, with further training requested as needed.

**Grandfathering**

1. Individuals who are ASHI-DTRC approved directors and ABHI certified Diplomates prior to October 31, 2020 are automatically recognized as Fellows of the American College of Histocompatibility & Immunogenetics. A certificate stating such Fellowship will be issued to individuals as requested at no cost.

2. Individuals who are ASHI-DTRC approved directors prior to October 31, 2020 but are board certified through another HHS approved organization (e.g. AP/CP, ABMLI, ABB) or international directors without board certification are automatically recognized as Affiliates of the American College of Histocompatibility & Immunogenetics. A certificate stating such Affiliation will be issued to individuals as requested for $100 fee.
B.  Technologist Certification through the ACHI

Certified Histocompatibility Specialist (CHS) requirements

Certification as a Histocompatibility Specialist may be granted or issued by the American College of Histocompatibility and Immunogenetics to qualified individuals on recommendation of the ACHI Credentialing Committee and College.

Applicants for this examination must meet the following qualifications: a) possess a baccalaureate degree in chemical, physical, biological or clinical laboratory science from an accredited college or university or possess a baccalaureate degree with at least 24 semester hours of science courses that include-- (i) Six semester hours of chemistry; (ii) Six semester hours of biology; and (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination and b) have at least five (5) years of notarized, documented relevant full-time work experience, in a laboratory which is approved by the Society or one in which the laboratory director meets the standards of the Society for an accredited laboratory, and c) have notarized written verification of histocompatibility work experience in the form of a letter from the laboratory director which states the length of time in histocompatibility testing, details of the work performed, a brief description of the procedures used and the director's signature. This experience must be completed within 10 years of the application date and prior to the end of the month in which the exam is administered.

Option for a sponsorship program: Individuals lacking work experience in an approved laboratory or one in which the director does not meet standards of the Society for director, may fulfill the requirement by sponsorship. Written recommendations from two qualified sponsors, to include CHS or directors (with whom they have had a working or collaborative relationship during the working experience being submitted for eligibility consideration) shall be submitted with the application. Directors must be ABHI certified or the director of a laboratory accredited by ASHI, UNOS, EFI (European Federation for Immunogenetics), APHIA) or BSHI (British Society for Histocompatibility and Immunogenetics) or an equivalent accrediting body. The recommendations must be detailed letters attesting to the applicant's qualifications to sit for the exam. Sponsors must have direct knowledge of the applicant's experience and expertise.

Certified Histocompatibility Technologist (CHT) requirements:

Certification as a Histocompatibility Technologist may be granted or issued by the American College of Histocompatibility and Immunogenetics to qualified individuals on recommendation of the ACHI Credentialing Committee and College. Applicants for this examination must meet the following qualifications: a) possess a baccalaureate degree in chemical, physical, biological or clinical laboratory science from an accredited college or university or possess a baccalaureate degree with at least 24 semester hours of science courses that include-- (i) Six semester hours of chemistry; (ii) Six semester hours of biology; and (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology
in any combination and b) have at least one (1) year of notarized, documented relevant full-time work experience in a laboratory which is approved by the Society or one in which the laboratory director meets the standards of the Society for an accredited laboratory. Time requirements to sit for the exam will include through the end of the month in which the exam is administered. This experience must be completed within 5 years of the application date and prior to the end of the month in which the exam is administered.

Option for a sponsorship program: Individuals lacking work experience in an approved laboratory or one in which the director does not meet standards of the Society for director, may fulfill the requirement by sponsorship. Written recommendations from two qualified sponsors, to include CHS or directors (with whom they have had a working or collaborative relationship during the working experience being submitted for eligibility consideration) shall be submitted with the application. Directors must be ABHI certified or the director of an ASHI, UNOS, EFI (European Federation for Immunogenetics), APHIA) or BSHI (British Society for Histocompatibility and Immunogenetics) accredited laboratory. The recommendations must be detailed letters attesting to the applicant's qualifications to sit for the exam. Sponsors must have direct knowledge of the applicant's experience and expertise.

**Certified Histocompatibility Associate (CHA) requirements**

Certification as a Histocompatibility Associate may be granted or issued by the American College of Histocompatibility and Immunogenetics to qualified individuals on recommendation of the Credentialing committee and ACHI Board. Applicants for this examination must meet the following qualifications: a) completed 24 semester hours of science courses from an accredited college or university that include--(i) Six semester hours of chemistry; (ii) Six semester hours of biology; and (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination and b) have at least two (2) years of notarized, documented relevant full-time work experience in a laboratory which is approved by the Society or one in which the laboratory director meets the standards of the Society for an accredited laboratory. Time requirements to sit for the exam will include through the end of the month in which the exam is administered. This experience must be completed within 5 years of the application date and prior to the end of the month in which the exam is administered.

Option for a sponsorship program: Individuals lacking work experience in an approved laboratory or one in which the director does not meet standards of the Society for director, may fulfill the requirement by sponsorship. Written recommendations from two qualified sponsors, to include CHS or directors (with whom they have had a working or collaborative relationship during the working experience being submitted for eligibility consideration) shall be submitted with the application. Directors must be ABHI certified or the director of an ASHI, UNOS, EFI (European Federation for Immunogenetics), APHIA or BSHI (British Society for Histocompatibility and Immunogenetics) accredited laboratory. The recommendations must be detailed letters attesting to the applicant's qualifications to sit for the exam. Sponsors must have direct knowledge of the applicant's experience and expertise.
APPENDIX 1
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 Registrar 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.
APPENDIX 2

Portfolio Committee (former ASHI-DTRC) Operations Manual

*add document here later to save space

APPENDIX 3

Fellowship Program Guidelines

*add document here later to save space