



**UNION EUROPEENE DES MÉDECINS SPÉCIALISTES
FEDERATION OF THE SURGICAL SCIENCES
SECTION OF SURGERY/ EUROPEAN BOARD OF SURGERY
DIVISION OF TRANSPLANTATION
EUROPEAN BOARD OF TRANSPLANTATION IMMUNOLOGY**

**EUROPEAN BOARD OF TRANSPLANT IMMUNOLOGY
UEMS-EFI SYLLABUS FOR THE
EUROPEAN SPECIALISATION IN HISTOCOMPATIBILITY &
IMMUNOGENETICS (ESHI) DIPLOMA**

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1. Introduction

A long term aim of the Education Committee of the European Federation for Immunogenetics (EFI) has been to establish a Europe wide mechanism for recognition of high level training and competency in the field of Histocompatibility and Immunogenetics (H&I). As such, a proposal was formulated to the European Union of Medical Specialists (UEMS) to create the European Board of Transplant Immunology (EBTI) within the Division of Transplantation of the UEMS. This body will promote the highest standards of training for transplant immunologists working in the field of H&I. The EBTI will operate as part of the Division of Transplantation under the UEMS Section of Surgery and the European Board of Surgery (EBS). The EBTI will operate in close collaboration with EFI and is a not-for-profit organisation.

Training towards the European Specialisation in Histocompatibility & Immunogenetics (ESHI) Diploma qualification is an in-service training plan for medically or scientifically qualified individuals working in H&I laboratories. It is aimed at Directors/Co-Directors/Heads of laboratories and those who wish to progress to this level.

The aim is to ensure a solid training in the skills necessary to undertake the work of a Director/Co-Director of a clinical H&I laboratory. Applicants will be assessed for eligibility following a period of training and will sit an oral examination. Upon successful completion of the examination the individual will be recognised as being able to form a clinically relevant opinion in H&I related issues based upon an applied, contemporary, scientific understanding. This informed opinion will underpin their ability to give clinically relevant advice in all aspects of H&I.

It is recognised that not all H&I specialists will necessarily experience all areas of H&I in their career and as such a decision has been made to require certain core areas of knowledge of applicants for the ESHI Diploma with the option for assessment against additional modules. All applicants must be able to provide evidence of training in H&I as it relates to supporting clinical solid organ (core Module 1) and/or clinical HSC transplantation (core Module 2). Additionally, applicants may apply to be assessed for their knowledge in H&I relating to disease association studies (Module 3) and transfusion (Module 4). So applicants can apply for up to 4 modules within the ESHI Diploma, with either Module 1 (H&I in solid organ transplantation) or Module 2 (H&I in HSC transplantation) being a mandatory requirement. The resulting Diploma certificate will state which modules have been completed.

Training must take place in clinical H&I laboratories supporting organ and/or haematopoietic stem cell transplantation programmes, disease association testing and blood transfusion services, depending on the modules being applied for. Practical experience at the bench and experience in clinical liaison must be gained in all areas being applied for. Obviously, it may be necessary to receive training in laboratories other than that in which the candidate is employed to receive sufficient breadth of clinical experience. The trainee must show evidence that they have accumulated the advanced clinical, technical, scientific and managerial skills required to direct a diagnostic H&I laboratory.

To undertake i) the training, ii) the application for eligibility and iii) the examination the trainee must:

- ◆ Have the support of the Lab Director.

- ◆ Have an Educational Supervisor who is a current Director or Co-Director of an EFI accredited lab **or** who holds a locally recognised qualification that shows a specialisation in H&I (FRCPath in the UK, Fachimmungenetiker DGI in Germany, Opleidingseisen Medische Immunologie in the Netherlands). Other supervisor qualifications may also be agreed as being suitable by the European Board of Transplant Immunology, in advance of training beginning.
- ◆ Train in a lab which has achieved EFI accreditation at a date prior to the individual's application for the ESHI Diploma examination.

2. Trainee Information

The ESHI Diploma is obtained on Passing Part I (Eligibility) and Part II (Oral Examination).

Part 1: Eligibility

1) The candidate can apply for consideration to take the ESHI oral exam when he/she meets one of the following criteria:

- Science graduates; has completed specialist training in H&I under supervision by a Director/ Co-Director of an EFI accredited lab or under supervision of an individual with a recognised specialist qualification in H&I (see above) during a minimum of 5 years (at least 50% FTE) in post in an EFI accredited H&I lab. N.B the training lab(s) must have been granted EFI accreditation during the period of the candidates training i.e. the lab does not necessarily have to have been EFI accredited for the entire duration of the applicants training.

- Medically qualified candidates; has completed specialist training in H&I under supervision by a Director/ Co-Director of an EFI accredited lab or under supervision of an individual with a recognised specialist qualification in H&I (see above) during a minimum of 3 years (at least 50% FTE) in post in an EFI accredited H&I lab. (Physicians are clinically trained/educated and therefore their understanding and approach towards laboratory test result interpretation includes the clinical outcome which is important in order to put these test results in a clinical context. This explains the difference in minimum time required for training between medically qualified ESHI Diploma candidates and science graduates). N.B the training lab(s) must have been granted EFI accreditation during the period of the candidates training i.e. the lab does not necessarily have to have been EFI accredited for the entire duration of the applicants training.

2) The candidate must also be able to:

- Communicate in the English language

- Submit a training portfolio which demonstrates: 1) continuity and 2) breadth of training covering all aspects of H&I within the modules applied for during their years of training. The candidate's training portfolio must also show a total of 20 credit points (CPs) over the period of their training based on the following system:
 - Attendance at H&I courses (e.g. UK Higher Specialist Training course, Hesperis Course (ESOT), EFI/ASHI/APHIA Summer School) 10 CPs

 - Participation at recognised international transplant/immunology/H&I congress (e.g. Annual EFI/ASHI/APHIA meeting, ESOT, EBMT, etc),
 - Attendance 5 CPs
 - First or last authorship (poster or abstract)+attendance 8 CPs*

 - Participation at recognised national transplant/immunology congress
 - Attendance 3 CPs

- First or last authorship (poster or abstract)+attendance 5 CPs*

*per abstract or poster

- N.B. Attendance of a minimum of two national/international educational transplant/immunology meetings (courses, congresses, symposia) and participation with first or last authorship in at least one (poster or abstract) is mandatory.
- Demonstrate the agreement of the Head of Department and training supervisor for the application to be submitted.

3) The following qualifications and experience, although not mandatory, are considered of great importance and will count in the applicants favour:

- Local professional qualifications e.g. FRCPath in the UK, Fachimmungenetiker DGI in Germany or the Opleidingseisen Medische Immunologie in the Netherlands.
- Higher degree (M.Sc., Ph.D.) in the field of transplantation, transfusion or immunology.
- Publication(s) in peer reviewed journals in the field of transplantation, transfusion or immunology (especially as first or last author).
- Visits to laboratories other than the main training site.

4) The applicant must complete and sign the 'Application for the ESHI Diploma' form which is available on the EFI and EBTI websites.

5) Fees: The amount of 400 Euros must be paid to the European Board of Transplant Immunology of the Division of Transplantation of the UEMS/ EBS.

Please send 400 € eligibility and examination fee to:	
Name of the Bank account:	UEMS / Section of Surgery
Account Number	001-7195551-70
Bank:	BNP Parisbas Fortis, Montagne du Parc3, 1000 Brussels, Belgium
IBAN:	BE60 0017 1955 5170
BIC CODE:	GEBABEBB
Transfer text:	(Honorary Diploma or ESHI Exam) Transplant Immunology, your name

Note: **any Bank transfer fees have to be paid by the applicants.** From this total, 200 Euros allows the candidate to be considered for eligibility. The other 200 Euros are the examination fees and allow the candidate to be examined. If the candidate is not considered eligible for the exam, the 200 Euros for the examination fees will be refunded to them.

6) Applications (including the application form, the completed pages of the syllabus showing training and all other relevant documents should be submitted via e-mail to the

headquarters of the Section of Surgery: office@uemssurg.org and to the Chairman of the Division: j.mytilineos@blutspende.de with one HARD COPY OF ALL DOCUMENTS also sent to:

European Board of Transplant Immunology (EBTI),
ESBQ Transplantation,
c/o Berufsverband der Deutschen Chirurgen
Langenbeck-Virchow-Haus
Luisenstrasse 58/59
D-10117 Berlin
GERMANY

The application will be considered by a sub-committee of the EBTI. The sub-committee will have three members: the Senior or Junior Secretary and two nominated members of the European Board of Transplant Immunology. At least one of the members should not be from the same country as that in which the applicant obtained his/her training in H&I. The applicant will be informed by e-mail on the acceptance or rejection of the application no later than 6 weeks from the date the application was received by the EBTI.

7) If the applicant is successful he/she will be provided with information regarding the date/ time/ venue of the exam.

During an interim period of two years following the creation of the ESHI Diploma (August 2013-end of August 2015), an honorary ESHI Diploma may be awarded to practising, experienced H&I Scientists/Medics upon application if they fulfil one of the following criteria:

a) Director/Co-Director of an EFI accredited laboratory (a copy of the current lab EFI Accreditation certificate must be sent with the application).

b) Holder of UK Fellowship of the Royal College of Pathologists, German Fachimmunogenetiker DGI or Dutch Opleidingseisen Medische Immunologie (A copy of Certificates must be sent) or

c) senior experience in H&I for >10 years.

Applicants for the Honorary Diploma must have experience in either H&I relating to clinical solid organ and/or clinical HSC transplantation. The APPLICATION FOR THE HONORARY EUROPEAN SPECIALISATION IN H&I DIPLOMA is available as a separate form from the EFI and EBTI websites. In these cases, following submission of the Honorary Diploma application form, a current Curriculum Vitae (listing publications), and a fee of 200 Euros, the examination may be waived.

*The application and relevant forms should be sent by email to the headquarters of the Section of Surgery: office@uemssurg.org and to the Chairman of the Division: j.mytilineos@blutspende.de and the amount of 200 Euros must be paid as detailed in 5) above. The decision to waive the examination will be taken by the Executive Committee of the EBTI and will be dependent upon evidence of **experience** as outlined in the ESHI Diploma syllabus.*

Part 2: Oral Examination

The aim of the examination

The examination process will take into account which modules have been applied for and will assess whether trainees working towards specialisation in H&I have acquired the requisite highly specialised scientific knowledge, clinical and laboratory skills and attitudes required to, *inter alia*:

- ◆ Advise on donor/recipient compatibility for transplantation by providing a risk assessment based on H&I factors.
- ◆ Advise on the relevance of HLA type to disease diagnosis and patient management.
- ◆ Provide H&I related advice relevant to the treatment of patients with blood products.
- ◆ Professionally direct a diagnostic H&I laboratory service.

The oral examination will determine whether a candidate has successfully acquired the core body of knowledge and basic skills that underpin the ability to practise H&I at Director/Co-Director level, encompassing fundamental concepts of Histocompatibility, Immunogenetics and the principles of diagnostic and therapeutic H&I. The standard that the candidates will be expected to achieve in the assessment will be commensurate with having completed 5 years in post (at least 50% FTE) for science graduates. For medically qualified candidates, the ESHI exam will normally be taken after a minimum of 3 years training (at least 50% FTE) and specialisation in H&I. Physicians are clinically trained/educated and therefore their understanding and approach towards laboratory test result interpretation includes the clinical outcome which is important in order to put these test results in a clinical context. This explains the difference in minimum time required for training between medically qualified ESHI diploma candidates and science graduates.

The overall purpose of the oral examination is to provide assurance that a candidate who has successfully completed the ESHI training portfolio and has successfully submitted an eligibility application to EBTI is fit to practice at the level of a Director/Co-Director of an EFI accredited laboratory.

Format of the examination

Communication skills are essential for Directors and Co-Directors of H&I laboratories to enable them to offer appropriate clinical advice to their colleagues and to think through the consequences of their advice for patient management. The oral examination will assess these skills, in addition to the candidates' knowledge of the latest developments in the field of H&I, laboratory management and management structures, budgetary control, audit, health and safety at work, quality assurance and training. The oral examination will last for 60-90 minutes and will be undertaken by three-four examiners to ensure coverage of those areas of the syllabus that relate to the modules the candidate has applied for. The candidate will be expected to answer questions on relevant areas of the syllabus, and also to discuss with the examiners two case studies and a scientific paper which will be given to the candidate one hour before the oral examination. The examiners will be made aware of the candidates in advance of the examination and will be asked to declare any conflicts. The candidates will not be made aware of the identity of the examiners prior to the examination.

The examination will be held once or twice a year at the EFI Conference and/or the Autumn EFI Business Meetings depending on demand. Applications for eligibility will need to be received at EBTI at least 3 months prior to the examination date, which will be made known in advance.

The decision of the examining board is final and is not subject to appeal.

The candidate is informed via e-mail regarding the result of the examination no later than a week from the date of the exam.

The successful candidates are awarded the European Specialisation in H&I Diploma and are provided with the relevant Diploma no later than a month from the date of the examination. If a candidate fails they may re-submit for eligibility to be examined again the following year. If the candidate fails twice they will be asked to undertake a period of at least 2 years extra training before re-application.

SYLLABUS FOR TRAINING TOWARDS THE EUROPEAN SPECIALISATION IN H&I (ESHI) DIPLOMA

The candidate must cover those aspects of the following syllabus that relate to the modules that are being applied for. At the start of each of the following sections there is an indication of whether that section is mandatory for all applications or if it only relates to a particular module. It is expected that during the training period, the candidate will gain a full understanding of each component listed, if it is relevant to their application. Evidence should be documented for each area to show how learning has been achieved. Such evidence may include courses which have been attended, lab and/or clinical training that was successfully completed, etc. The name, signature and designation of the trainer must be documented directly on the syllabus document or on a separate sheet which must be attached to support the summarised evidence given on the syllabus.

Upon completion of training, it is expected that the candidate will be able to form a clinically relevant opinion on Histocompatibility and Immunogenetics related issues based upon an applied, contemporary, scientific understanding. This informed opinion will underpin the ability to give clinically relevant advice in all aspects of H&I.

1. Legislation and Regulations (Mandatory for all applicants)

Knows relevant European and Local Statutes, Regulations and Guidance pertaining to:

- a. Transplantation practice
- b. Health and Safety
- c. Biological , chemical and mechanical hazards
- d. Confidentiality
- e. Consent
- f. Specimen handling and transport
- g. Specimen storage and disposal

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

2. Quality Management (Mandatory for all applicants)

Knows the requirements of national and international standards relating to quality management systems, including:

- a. Accreditation
- b. Internal and External Quality Assurance
- c. Quality Control
- d. Introducing new technology / effective change control
- e. Audit
- f. Incident monitoring and root cause analysis
- g. Principles of Good manufacturing Practice

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

3. Laboratory Management (Mandatory for all applicants)

Knows the principles involved and can demonstrate experience in the following:

- a. Budget planning and handling
- b. Recruitment
- c. Disciplinary and grievance procedures
- d. Performance Review
- e. The role of Trade Unions / Partnership working
- f. Communication skills
- g. Leadership Skills
- h. Delivering training
- i. Clinical Governance

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

4. Innate and adaptive immunity (Mandatory for all applicants)

Knows and understands the physiological processes and the clinical relevance of the following in relation to H&I services:

- a. Haemopoiesis in health and disease
- b. The roles of different leukocyte populations
- c. PRRs and PAMPs in innate immunity; TLRs etc
- d. The Complement system
- e. Antigen Presentation and MHC restriction
- f. Structure, function and biological distribution of MHC Antigens
- g. T and B cell activation
- h. Regulatory cell subsets
- i. NK cell activation
- j. Inflammation
- k. The action of immunosuppressive therapies
- l. Autoimmunity

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

5. Transplant immunology (Mandatory for all applicants)

Knows and understands the physiological processes and the clinical relevance of the following in relation to H&I services:

- a. Direct and indirect T cell activation
- b. Role of passenger leukocytes
- c. Immune processes leading to hyperacute, acute, accelerated and chronic allograft rejection
- d. Immune processes leading to GvHD
- e. GvL
- f. Relevance of HLA antibodies in rejection
- g. Non-HLA immunity
- h. Tolerance and regulatory cell populations
- i. NK cells in rejection and GvHD/GvL
- j. Minor histocompatibility antigens
- k. Non inherited maternal antigens (NIMA)

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

6. The Major Histocompatibility Complex (Mandatory for all applicants)

Knows and understands the relevance of the following in relation to H&I services:

- a. International Histocompatibility Workshops
- b. Anthropological studies
- c. The HLA Complex: gene location
- d. HLA gene and protein nomenclature
- e. HLA haplotypes
- f. HLA gene polymorphism
- g. Non-HLA genes in the extended HLA Complex; MIC, HFE, C' (=Complement)

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

7. Relevant techniques in H&I Services (Mandatory for all applicants)

Knows the limitations of the following and can provide clinical interpretation, recommending additional testing where appropriate:

- a. Principles of HLA typing techniques including CDC, SSP, SSO, SBT & NGS (Next Generation Sequencing)
- b. Assays for the detection and definition of HLA-specific antibodies
- c. Techniques employed for donor/recipient cross-matching and assessment of risk at the time of transplant
- d. Omission of the pre-transplant crossmatch
- e. Post-transplant monitoring
- f. Principles involved in the management of a Registry or Cell Bank, including aseptic technique, cell culture, cryopreservation, cataloguing, storage and retrieval.
- g. Cellular assays used within H&I

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

8. Genetics and Molecular Genetics (Mandatory for all applicants)

Knows and understands the principles of the following in relation to H&I:

- a. DNA based technologies used in H&I services
- b. Transcription and translation of genes
- c. Generation of HLA polymorphism
- d. Potential mechanisms underlying HLA and disease associations
- e. Potential mechanisms underlying HLA and pharmacogenetic associations
- f. NK cell receptor gene families

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

9. Biostatistics and Bioinformatics (Mandatory for all applicants)

Can perform basic analyses and advise upon the relevance of statistical analyses including:

- a. Survival analysis
- b. Population genetics
- c. Database Management
- d. International Genetics Databases
- e. Data storage and processing
- f. Epitope prediction

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

10. Clinical Relevance of H&I in solid organ transplantation (Required, unless only applying for core Module 2: H&I in HSC transplantation)

Is experienced with the following aspects of H&I and can provide interpretive advice on the following:

- a. Selection of appropriate donors or recipients for transplantation
- b. Assessment of risk at the time of transplant
- c. Factors influencing transplant outcome
- d. Post-transplant monitoring
- e. Biological variation in requirement for HLA matching in different forms of solid organ transplantation

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

11. Clinical Relevance of H&I in haematopoietic stem cell transplantation (Required, unless only applying for core Module 1: H&I in solid organ transplantation)

Is experienced with the following aspects of H&I and can provide interpretive advice on the following:

- a. Selection of appropriate donors for transplantation
- b. Searching for donors on local and international registries/cord banks
- c. Factors influencing transplant outcome
- d. Post-transplant monitoring
- e. Biological variation in requirement for HLA matching when using different sources of donors for transplantation

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

12. Clinical Relevance of H&I in transfusion (Required if applying for Module 4: H&I in Transfusion)

Is aware of the following aspects of H&I and could provide interpretive advice on the following:

- a. Selection of appropriate donors or recipients for treatment with HLA and/or HPA selected blood products and assessment of risk

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

**13. Clinical Relevance of H&I in disease, cancer and pharmacogenetic testing
(Required if applying for Module 3: H&I in Disease Association)**

Is aware of the following aspects of H&I and could provide interpretive advice on the following:

- a. Clinical relevance of HLA in autoimmune and infectious disease
- b. Clinical relevance of HLA in cancer and immunotherapy
- c. Clinical relevance of HLA in pharmacogenetic testing

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

14. Organ allocation and enhancing donation rates (Required if applying for core Module 1 (H&I in solid organ transplantation))

Knows and understands the principles of the following in relation to H&I:

- a. Deceased donor organ allocation locally and within Europe
- b. Heart beating and non heart beating donation
- c. Opt in and opt out programmes for donation after death
- d. Living donation
- e. Paired exchange schemes
- f. Altruistic donation
- g. Antibody incompatible transplantation

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

15. Research and Development (Mandatory for all applicants)

Understands the principles involved in and can provide documented evidence of experience in the following:

- a. Requirements and Procedures for gaining ethical approval
- b. Research Governance
- c. Good Clinical Practice
- d. Data Analysis
- e. Data Presentation

Evidence	Date	Trainee Signature	Trainer Name, Signature and Designation

Additional Reflective notes (copy as required):

Title:

Reflective notes

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Date	
Signature of Trainee	Name, Signature and Designation of overall Educational supervisor