Essentials and Guidelines

Of an Accredited Postgraduate Fellowship Program in Medical Laboratory Immunology

ESTABLISHED BY

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1. PREAMBLE

The *Essentials* of approved postgraduate fellowship programs in medical laboratory immunology have been established by the Committee on Postgraduate Educational Programs (CPEP), to which the American Society for Microbiology has delegated responsibility to perform the duties and make the decisions concerning accreditation of training programs in this field. The *Essentials* represent the minimum requirements for CPEP-accredited educational programs. The present document has been developed and revised after extensive review by medical laboratory immunologists and other health professionals. Advice and suggestions were solicited from a broad range of individuals. The *Essentials* are adopted by the American Society for Microbiology, upon the recommendation of CPEP.

1.1. Purpose

The purpose of CPEP is to promote and encourage excellence in the training of medical laboratory immunologists through the approval of postgraduate programs that can meet these *Essentials*. Ultimately, the goal is to improve the quality of clinical immunology laboratory services (diagnostic, educational, consultative, and investigative) in health-related fields and, thus, contribute to the health and welfare of the public. CPEP assesses each program's compliance with the *Essentials* through review of its application, by on-site evaluations, and by the monitoring of annual reports from approved programs. Copies of these *Essentials* are available to the public and are provided to Fellows who enter CPEP-approved programs.

1.2. Objective

Essentials are a statement of policy and, as such, constitute minimum standards of quality in educational programs that are recognized by CPEP accreditation. These *Essentials* and accompanying guidelines are intended to assist clinical immunology programs in meeting and exceeding minimum standards in the design and conduct of sound educational programs. These *Essentials* represent policies which must be carried out. Strict adherence to the *Essentials* is mandatory. Guidelines present pathways toward fulfilling the *Essentials*. Guidelines usually represent one of many ways to satisfy an *Essential* and, therefore, strict adherence to

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instruction. In such instances, it may be desirable to have an institution that provides a significant portion of the instruction to be listed as a co-sponsor of the program.

Sponsors may recognize the contribution of collaborating institutions by requesting CPEP to issue appropriate certificates recognizing the collaboration.

2.1.4. Certification – *Essentials*

The sponsoring and collaborating institutions must be accredited, certified, or licensed as required by existing laws or accepted practice by recognized agencies or be otherwise acceptable to CPEP.

ASM members shall treat others equitably and respectfully without regard to race, color, ethnicity, religion, national origin, sex, age, marital status, sexual orientation, gender identity or expression, family responsibilities, genetic information, disability, political affiliation, or any other personal characteristic protected from discrimination or harassment by law.

2.1.5. Responsibilities of the Sponsor and Affiliate Institution – *Essentials*

Responsibilities of the sponsor and each affiliate/collaborating institution for program administration, instruction, supervision, and documentation must be clearly described in written documents and made available for distribution and inspection.

2.2. Curriculum

2.2.1. Program Length – *Essentials*

The length of the program is 24 months.

2.2.1.1. Guidelines

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- Immunoglobulin analysis and lymphocyte malignancies
- Soluble markers
- Public health serology
- Molecular diagnostics
- Quality management
- Laboratory safety
- Laboratory management
- Laboratory regulations
- Instrumentation and automation
- Participation in sign-outs, communication, on-call services, and clinical consultation
- Research and teaching methodologies

In order for Fellows to acquire the knowledge and skills of a medical laboratory immunologist, appropriate instruction must be made available through bench training and experience, on-call responsibilities, clinical consultations, clinical conferences, hospital rounds, workshops, organized courses, self-instruction materials, and administrative training. Ample diagnostic material (quantity and variety) must be available, with concomitant opportunity for the Fellow to learn how to correlate laboratory information with patient care and/or public health needs. Emphasis must be placed on laboratory diagnostic practice and clinical experience.

2.2.2.1. Guidelines

While it is CPEP policy that curriculum contents and instructional methods are the prerogative of the sponsoring institutions, CPEP offers the accompanying guidelines to assist the programs in developing sound and appropriate instruction that will enable the Fellow to attain the program objectives.

component. The modular objectives should also help the faculty to organize content, learning experiences, and performance evaluations for various portions of the program.

If the parent institution cannot provide adequate training in certain areas, arrangements must be made for the Fellows to learn the material at other institutions and through supervised independent study.

The Fellows should have the opportunity to become acquainted with "new" immunological problems, epidemics of national or global concern, and major effects or trends in health care and maintenance. Aspects of other laboratory disciplines, such as pathology, molecular pathology, hematology, clinical chemistry, histology, microbiology, and virology, should be an intrinsic component of the basic program in the context of discussions about specific disease processes.

Additional training should be provided in research but should not be so extensive as to preclude or preempt satisfactory completion of other essential rotations and aspects of the program. Although research and publication are encouraged, it should be understood that this is not primarily a research training program.

Opportunity for attendance and presentation at ASM, AMLI or other nationally recognized conferences/ meetings in clinical/public health science should be provided/supported unless extenuating circumstances (ex. pandemic, health of the trainee, FMLA, etc) prevent this. Programs should clearly state the availability of conference funds and expectations for conference attendance so that such information can be easily accessible for all trainees. If attendance at national meetings is not feasible, programs should support local and regional conference opportunities for trainees.

2.2.3. Knowledge to be Gained from Specialty Area Training

2.2.3.1. Specimen Collection, Processing, Proper Handling to Maintain Stability – *Essentials*

The Fellows must know and understand the proper collection of specimens for the detection of cells, antibodies, complement, or other components and must be able to discriminate which specimens are appropriate for testing. Universal precautions must be observed in all phases of collection and handling and when packaging and shipping Division 6.2 materials DOT and IATA regulations must be followed.

2.2.3.1.1. Guidelines

The Fellow should be familiar with transport devices and conditions for preserving the quality of the specimen. The Fellow should be familiar with the Department of Transportation (DOT) guidelines for packing and shipping infectious substances.

The Fellow should understand the use and content of the Laboratory Test Catalog/Handbook and be able to assist clinicians in the selection of appropriate tests.

The Fellow should be able to determine if a shipment classifies as a Category A, Category B or Exempt Human Specimen and define the packaging and shipping requirements associated

testing methods, and multiplex liquid bead-based assays. The Fellow must know the application and interpretation of antibody and antigen detection tests for common bacterial, fungal, parasitic, and viral infections. The Fellow must understand and be able to articulate the statistical methods needed to evaluate serologic assays including sensitivity, specificity, positive predictive value, negative predictive value, estimations of variance, and accuracy etc.

2.2.3.2.1. Guidelines

1. The Fellow should know the established diagnostic criteria (if established) for both common and emerging infectious diseases.

2. The Fellow should understand the advantages and limitations of the serology of infectious diseases and how the aforementioned statistical parameters can be influenced by disease prevalence and host factors, e.g., age, sex, and immune status, and by co-morbidities, e.g., HIV, HBV, and EBV.

3. The Fellow should be familiar with current testing algorithms as defined by the CDC for commonly tested for STDs and epidemiologically important infections like HIV, Lyme disease, syphilis, etc.

4. The Fellow should understand the methods used to standardize infectious disease serology testing and know the source (CAP, API, ASHI) of available proficiency testing materials.

5. The Fellow should understand the principles involved in the establishment of normal ranges of

The Fellow must know the background principles, techniques, and methods of flow cytometry, monoclonal antibodies, and immunofluorescence and their use in the phenotyping of lymphocytes and the white cell elements of the bone marrow, peripheral blood, tissue biopsies such as lymph nodes, and body fluids. The Fellow must be familiar with the surface and intracellular antigen markers which help to categorize hematological malignancies and those which define the developmental stages and functional role of white blood cell and lymphocyte subsets.

2.2.3.5.1. Guidelines

1. The Fellow should know the basic principles of flow cytometry and be familiar with standardized procedures required to correctly analyze and interpret flow cytometry data. The Fellow must understand instrument calibration, compensation, gating, bitmaps, and statistical data analysis.

2. The Fellow must be familiar with flow cytometric assay optimization including FMO and single stain control utilization as well as signal to noise, antibody, and control titration methods

3. The Fellow should understand the requirements for proper collection, transportation, handling, and processing of specimens for flow cytometry testing.

4. The Fellow should be familiar with the variety of CD surface and intracellular antigens that define and are routinely used to categorize and differentiate lymphocytes and bone marrow derived cells.

5. The Fellow should be familiar with the hematological malignancies and their clinical presentations. The Fellow should be able to integrate information from surface and intracellular antigen testing of leukemia and lymphoma cells with clinical and pathological data to arrive at a final diagnostic category of malignancy. This may require that the Fellow work closely with a hematopathologist who has more data and benefits from the morphological aspects of the case.

6. The Fellow should understand the basis for the quantitative assessment of lymphocyte subsets in the peripheral blood. The Fellow should be familiar with the effects that malignancies, infectious diseases, and autoimmune diseases have on the phenotypic and functional characteristics of peripheral blood lymphocytes.

7. The Fellow should be familiar with the guidelines that have been defined by the CLSI and CDC for lymphocyte phenotyping in peripheral blood and by the CLSI for leukemia phenotyping. The

The Fellow must have a basic knowledge of the Major Histocompatibility Complex genes and proteins and their role in the immune system. In addition, the Fellow must be familiar with non-MHC genes and

9. The Fellow should know the immunologic effects of chemotherapeutic and immunosuppressive agents used for transplantation and for control of rejection episodes and possible interference of these agents with test methods.

10. The Fellow should be competent in immunogenetics testing for non-transplant clinical purposes, such as blood/products transfusion support, disease associations, vaccine eligibility, pharmacogenetics, and personalized medicine.

2.2.3.7. Hypersensitivity and Cytokine Release Analysis – *Essentials*

The Fellow must understand the immunologic pathways which lead to type 1 hypersensitivity reactions and cytokine release syndrome. The Fellow must know the available laboratory assays which can be used to monitor the likelihood of allergic reactions to a variety of allergic substances. The Fellow must be familiar with the inflammatory mediators of allergic reactions and the modalities of the clinically available therapies.

2.2.3.7.1. Guidelines

1. The Fellow should know the basis for the IgE mediated allergic response at both the cellular and molecular level. The Fellow should be familiar with the mechanism of IgE crosslinking, intracellular stimulation pathways, and methods of granule release for basophils and mast cells. The Fellow should know the various mediators of inflammation and their pathologic effects.

2. The Fellow should know the *in vivo* skin test methods used by allergists and understand the immunologic response which leads to the positive skin test response in allergic individuals.

3. The Fellow should know the *in vitro* methods for measuring levels of IgE and allergen and component-specific IgE and their interpw3(gE)2.6 (a)4.25 Ii 0.2 (ua)4.211.048 0 Td[(T)2.5 (he)4.2 04.2 (ve)4.2 (l)

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The Fellow must know the theory and technical methods of protein electrophoresis, nephelometry, immunoelectrophoresis, immunofixation, capillary electrophoresis, and immunosubtraction for quantitation of immunoglobulins and immunoglobulin subclasses and the analysis of light chain clonality. The Fellow must understand the spectrum of clinical lymphoid malignancy diseases where monoclonal immunoglobulins are detected.

2.2.3.8.1. Guidelines

1. The Fellow should be able to integrate immunoglobulin quantitations, electrophoresis, immunoelectrophoresis, and immunofixation testing to determine immunoglobulin clonality for patients' serum, urine, body fluid, and CSF samples.

2. The Fellow should understand the analysis of CSF and serum immunoglobulin and albumin to determine the local oligoclonal synthesis of IgG in the CSF.

3. The Fellow should be familiar with the clinical presentations of the various lymphoid and hematologic malignancies and the clinical and laboratory diagnostic criteria for this group of der) Tc.2 (sm)-.2 (tm)-8(r) Tc.2 (sm)-8(r.)-2.80 Tc 0 Tw ( )Tj4 Td[(T)2.EMC /LBodyET/MCID 16 >>B1930.006 q0 T

- Recognition, surveillance and control of healthcare-associated infections.

2. The Fellow should be familiar with transmission risks associated with specific types of healthcare settings (e.g., hospitals and ICU) and transmission risks associated with specific patient populations (e.g., immunocompromised and cystic fibrosis patients).

3. The Fellow should learn the serologic and molecular methods that help determine the causes of epidemiologically important infections.

4. The Fellow should be able to provide professional educational assistance to other clinical/diagnostic immunology laboratories throughout the state and where applicable to the general public.

5. The Fellow should be familiar with the following public health laboratory methods:

    - Sexually transmitted diseases testing
    - Rabies virus detection
    - Public health screening for diagnosis or immune status
    - HIV Testing and confidentiality
    - Vector-borne disease testing such as arboviruses

2.2.3.11. Molecular Diagnostics – *Essentials*

The Fellow must be familiar with the theory, application of, and limitations of molecular techniques such as:

- Nucleic acid extraction
- Use of [illegible]

4.

The Fellow must be familiar with the theory and practice of laboratory safety that includes local, state, and federal regulations, and the design and implementation of a program that protects the health and safety of all laboratory employees. The Fellow must be familiar with laboratory and hospital safety committees.

- Developing job descriptions
- Developing interviewing skills, and evaluating candidate qualifications
- Evaluating competency of laboratory personnel
- Understanding CE requirements for employee credentialing

The Fellow must be competent in aspects of laboratory fiscal management, including:

- Allocating staff and resources
- Justifying new and existing staff positions
- Reimbursement coding systems
- Developing and monitoring laboratory budget
- Developing fee structure for laboratory services including research testing
- Developing laboratory cost containment measures and cost analysis
- Evaluating existing and new testing procedures considering cost/benefit criteria
- Negotiating contracts for laboratory equipment, service contracts, and facilities

2.2.3.14.1. Guidelines

1. The Fellow should assume responsibility for direction of a section of the laboratory for a 3-6 month period as an acting assistant laboratory director and participate in the on call program for the clinical immunology laboratory.

2. The Fellow should participate in the annual budget planning process, e.g., by preparing a cost analysis of a piece of capital equipment or justification for a new technologist position.

3. The Fellow, whenever possible, should sit in on personnel actions, including interviewing performance appraisals and disciplinary actions. The Fellow should understand the importance of being a good team player.
   4.
4. The Fellow should take management training courses that are available. Many institutions provide courses which help develop supervisory skills. Fellows are encouraged to participate. If management courses are not off4.2 (nd)12 (t-h)]TJ[(he)4.2 pf gopas cC -12nicaC -12n006 Tc -0.006 Tw -076 Tw

wage and hours laws. The Fellow should understand the legal aspects of human resource management (e.g. FMLA and ADA) and information management (e.g. HIPAA and FOIA).

9. The Fellow should be familiar with the provision of clinical immunology services to clients outside of the Fellow's laboratory/setting/hospital (e.g. customer service; bringing in new/outside business; establishing a small or satellite laboratory at another site; how services differ among community hospital, academic, commercial/reference, Veterans Administration, and local/state public health laboratories).

2.2.3.15. Laboratory Regulations – *Essentials*

The Fellow must describe the major requirements of private and governmental (federal and local) agencies that accredit, certify or license clinical laboratories, or that have standards regarding

The Fellow must understand the application and utilization of:

1. Automated or semi-automated systems for analyte detection
2. Computerized information systems for recording, analyzing and reporting laboratory data
3. Hospital information system and how it communicates with the laboratory information system (LIS)
4. Computers and software which provide management, quality control and safety functions
5. Advantages, disadvantages, and regulations associated with auto -result, -verification, and -release
6. Appropriate test utilization (e.g. cost effectiveness, operations, and clinical benefits)
7. The Fellow must be familiar with at least one contemporary laboratory information system

2.2.3.16.1 Guidelines

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2.2.3.18. Research and Teaching Methodologies – *Essentials*

The Fellow must develop a protocol and describe the research methodology, controls and statistical considerations to test a hypothesis proposed as an answer to a basic or applied research problem in immunology. The research methodology may also be applicable to development and regulatory requirements for laboratory-developed tests.

2.2.3.18.1. Guidelines

1. Fellows should be encouraged to attend and participate in local, regional and national scientific meetings where research data is submitted for presentation. The program should assist Fellows to the extent possible in funding for meeting attendance.

2. The Fellow should learn the use of basic analytical tools for laboratory assays such as ROC curves and basic statistical methods.

3. The Fellow should understand the basic parameters used to establish expected/normal ranges and predictive value analysis.

4. The Fellow should participate in preparing Institutional Review Board (IRB) proposal and take courses in CITI and IRB training.

5. Fellows should be encouraged to interact with other clinical diagnostic trainees to learn about emerging technologies, such as, mass spectrometry or next generation sequencing that are evolving in clinical immunology.

2.2.4. Length of Time Fellows Must Spend in Specialty Training Areas – Essentials and Guidelines

The table below lists the amount of time a Fellow spends in each of the major training areas during a two-year program. The minimum *Essential* or requirement times are intended for individuals who enter a program with little or no previous experience in clinical immunology and represent the time needed to achieve the objectives stated in the *Essentials*. The ranges of time or guidelines for each area provide flexibility which may be necessary due to prior experience of the Fellow. Essentiaow4.4 21 Tf 0 Tc 0 T265 1 Tf 0 Tc 0

Essentials and Guidelines for Length of Time in Major Training Areas

a written document in advance of the rotation, detailing time spent on different activities and learning objectives.

Program dire

Program officials should have time to fulfill the administrative and educational duties of the program. Adequate clerical and other support staff should be available.

2.3.3. Program Director Responsibilities – *Essentials*

The program director must be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. In this activity, the program director must cooperate and collaborate fully with the program and instructional officials at the parent and collaborating institutions. The program director shall be responsible for ensuring that appropriate evaluation instruments are developed and applied regularly and consistently and that appropriate records of all Fellows in the program are maintained.

2.3.3.1. Guidelines

The program director shall assume ultimate responsibility for the didactic instruction, laboratory experience, and clinical phase of the program. Although other officials at the sponsoring and collaborating institutions should be delegated specific responsibilities, it is the program director's responsibility that all phases of the program are appropriate and successful in meeting program goals and objectives.

2.3.4. Program Director Qualifications – *Essentials*

The program director must be (a) a medical laboratory immunologist who holds a responsible leadership position in the sponsoring institution and (b) certified (with active status) as a Diplomate by the American Board of Medical Laboratory Immunology (ABMLI) or other CLIA-recognized board that is immunologically focused and acceptable to CPEP. The program director must be engaged full time in immunological work (diagnostic, research, teaching, program administration) at the sponsoring institution.

2.3.5. Assistant or Deputy Program Director Qualifications – *Essentials*

If the program has a designated assistant or deputy program director, they must be certified by a CLIA-recognized board that is immunologically focused and acceptable to CPEP and the certification must be active. The assistant or deputy program director(s) must have appropriate credentials that are acceptable for faculty appointments at the sponsoring and/or collaborating institutions.

2.3.6. Instructional Staff

2.3.6.1. General Qualifications – *Essentials*

All instructional staff must be qualified through academic preparation, experience, and appointment to effectively teach the subjects assigned.

2.3.6.1.1. Guidelines

The breadth or competency of the staff of the sponsoring and/or collaborating institutions should be such that all areas of medical laboratory immunology can be covered satisfactorily to meet the objectives of the program. In addition to physicians and scientists who are immunologists, the staff may include specialists in management and education as well as physicians with interest and expertise

2.3.6.2. Program Officials – *Essentials*

In addition to the program director, the program officials of the sponsoring and/or collaborating institutions must include at least two doctoral level, full-time staff members with expertise and interest in clinical immunology. These people do not have to be part of the clinical immunology laboratory staff.

2.3.6.2.1. Guidelines

Fields of competence of additional program officials should supplement rather than duplicate those of the program director

2.3.6.3. Technical and Clinical Personnel – *Essentials*

The program director must be assisted by sufficient professional, technical, and clinical personnel to permit the laboratory to carry out all of the responsibilities in service, teaching, consultation and research in an efficient and effective manner.

2.3.6.3.1. Guidelines

The technical personnel should be certified by appropriate agencies (e.g., The National Registry of Certified Microbiologists, Board of Certification [ASCP], National Registry of Clinical Chemistry), or be eligible for such certification.

2.3.7. Financial Resources – *Essentials*

The financial resources of the sponsoring institution must be such that continued operation of the educational program is assured for completion of the program by current and newly accepted Fellows.

2.3.7.1. Guidelines

In addition to adequate budgetary support for the teaching and diagnostic operations of the laboratory, adequate stipend support for Fellows should be provided.

2.3.8. Physical Resources – *Essentials*

Adequate laboratories, classrooms, office space, computer resources, and other facilities must be provided.

2.3.8.1. Guidelines

The laboratories should have sufficient space to accommodate both the staff and Fellows without interfering with the regular activities of the laboratory. A separate office/laboratory area for Fellows is desirable.

2.3.9. Equipment and Supplies – *Essentials*

Appropriate, modern equipment and supplies in sufficient quantity must be provided.

2.3.9.1. Guidelines

Institutions lacking state-of-the-art automated instruments and computer facilities should make Fellows aware of such technology by having them rotate through other institutions and/or attend lectures and workshops dealing with these subject areas. Adequate instructional materials should be available,

including clinical materials that are not available on a regular basis. Programs sculd prt videert nic-1.193o-5.4 (a)]TJ0 (ic)-

2.4.3.1. Guidelines

The participating program is also advised to provide fellows with stipends equivalent to other

2.4.7. Appeal Mechanism – *Essentials*

In the event a Fellow has a grievance with the program, an appropriate appeal mechanism must be available and made known to the Fellow.

2.4.7.1. Guidelines

Every attempt should be made to resolve the Fellows' complaints and concerns within the department or within the institution. A more formal appeal mechanism is available through CPEP. Details of this process are described in the