FELLOWSHIP PROGRAM
IN CLINICAL IMMUNOLOGY

Department of Microbiology and Immunology
Clinical Immunology Laboratory
Rosalind Franklin University of Medicine and Science
Fellowship Program in Clinical Immunology

American Board of Medical Laboratory Immunology
American Society of Microbiology
Committee on Postgraduate Educational Programs

Site: Rosalind Franklin University of Medicine and Science
North Chicago, Illinois

1. Program Goals:
The objectives of our postdoctoral program are to train individuals to manage and direct a clinical immunology laboratory. The individuals should hold doctoral degrees in immunology and/or medicine and will learn the basics of clinical immunology as well as research and administrative aspects of managing a clinical laboratory. The fellow will complete a two-year program divided between rotations in different clinical laboratory areas, management responsibility for the laboratory, and development of new testing procedures. (The specific objectives for each of the training areas are listed below.)

In general the fellow will become acquainted with all the essentials necessary for the management and operation of a clinical immunology laboratory. The training will include understanding the principles and practice of laboratory procedures, as well as the clinical relevance of individual tests in evaluation and diagnosis of disease. The fellow, through practical and research experience, will become familiar with tests and evaluate the methodologies of testing including quality control and quality assurance.

In addition to becoming proficient with the principles of diagnostic testing, both in specific immunology tests and general areas (chemistry and hematology), the fellow will study personnel management, budget preparation, inspection, and accreditation procedures. The fellow will become involved in preparation and generation of new testing procedures, which will include the composition of procedure manuals as well as users guides.

It is expected that research done during the fellow’s tenure will be published in refereed journals and be presented at national meetings. The fellow will participate in course work such as Essentials of Clinical Reasoning (those portions which involve clinical presentations) and courses in Health Administration offered by RFUMS, and courses in laboratory management offered by the AACC. Finally, the fellow will become responsible for the day to day management of the laboratory.
PROFESSIONAL STAFF OF TRAINING PROGRAM

The fellow will rotate through all areas of the RFUMS Clinical Immunology Lab during the two-year program, under the direction of the following:

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<th>Name</th>
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<tr>
<td>Kenneth D. Beaman, Ph.D., D(ABMLI)</td>
<td>Director Clinical Immunology Laboratory Department of Microbiology/Immunology Rosalind Franklin University of Medicine &amp; Science 3333 Green Bay Road North Chicago, IL 60064</td>
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Responsible for the day to day direction of clinical laboratory activities.
Responsible for the direction of training of medical technologists, graduate and postdoctoral fellows.
Responsible for the direction of independent research.

| Svetlana Dambaeva, M.D., Ph.D., D(ABMLI) | Assistant Director Clinical Immunology Laboratory Department of Microbiology/Immunology Rosalind Franklin University of Medicine & Science 3333 Green Bay Road North Chicago, IL 60064 |

Responsible for the day to day direction of clinical laboratory activities.
Responsible for the direction of training of medical technologists, graduate and postdoctoral fellows.
Responsible for the direction of independent research.

| Alice Gilman-Sachs, Ph.D., S.I., D(ABMLI) | Associate Director Clinical Immunology Lab. Department of Microbiology/Immunology Rosalind Franklin University of Medicine & Science 3333 Green Bay Road North Chicago, IL 60064 |

Responsible for the day to day direction of clinical laboratory activities.
Responsible for the direction of training of medical technologists, graduate and postdoctoral fellows.
Responsible for the direction of independent research.

The administrative activity will be coordinated through Dr. Kenneth Beaman, Director of the laboratory. The financial responsibility for the fellow will be that of the Clinical Immunology Lab of RFUMS/CMS.

2. **Selection of Trainees:** Potential candidates for the program will have a doctorate degree in immunology or medicine and science. Candidates will apply through the form on the CPEP section of the American Society for Microbiology website (https://www.asm.org/index.php/cpep-application/view/form). All applications will be screened to determine that they have the appropriate credentials for the program, i.e. that applicants have doctoral degrees in immunology, medicine or appropriate related field. All acceptable candidates will be asked to submit curriculum vitae plus references for evaluation by members of the selection committee. The selection committee will consist of program director and at least two other members of the training staff. Individuals will be screened and the top candidates as selected by consensus will be asked to present seminars and interview with the committee. After the interviewing process the candidate will be selected by consensus of the committee.
Training

The primary goal of the training program is to prepare the individuals to direct a clinical immunology laboratory. The training will allow the fellow to obtain the skills, knowledge and experience necessary to become a successful medical laboratory immunologist. It is anticipated that upon completion of this course of study, individuals will be able to pass the American Board of Bioanalysis technical supervisor examination. The training will also count as two years of the experience needed for HCLD certification or other equivalent programs. The training will be provided through a variety of techniques, including hands on bench work, interaction with clinicians and course work. The specific objectives of each of the experiences anticipated are described under the objective sections.

The training program involves a series of rotations through the various laboratory sections at the Clinical Immunology Laboratory of the Rosalind Franklin University of Medicine & Science. For procedures not frequently performed at the Clinical Immunology Lab, the fellow will learn through a combination of reading and rotating at other clinical laboratories. In addition to the rotation through the particular laboratory and laboratory sections, courses in Laboratory Administration and Essentials of Clinical Reasoning will be included in the experiences provided. At each of the experiences, combined bench training with data interpretation, administration and consultation services unique to each specific area will be provided. The fellow will work closely with the laboratory director of each of the laboratories or laboratory sections. The fellow will discuss problems, interpretations and administration with these individuals.

At the change of the rotations the fellow will be provided with a variety of laboratory materials as well as references and review articles. At the completion of each rotation the fellow will discuss the relationship of the procedures and the current state of the art. After approximately one year, the fellow will begin to participate in the management and administration of various levels of the laboratory. In addition to courses and the rotations the fellow will be expected to participate in medical grand rounds, clinical immunology seminars and seminars in the Department of Microbiology & Immunology. Finally, it is anticipated that the fellows will attend and present posters and presentations at meetings of the Association of Medical Laboratory Immunologists and other related societies such as the American Society for Microbiology, American Association of Immunologists, American Society for Reproductive Immunology, or American Association for Clinical Chemistry.

It is anticipated that each of the laboratory sections will encompass the time periods listed in the guidelines. It is the aim for this program to tailor each fellow's experience with their own interests and background. It is important that the fellow have a broad training experience.

SPECIFIC AREAS OF TRAINING:

Molecular Biology Techniques: The fellow will learn methodology in molecular biology as it pertains to the clinical immunology laboratory. Each fellow will be able to discuss pertinent results with physicians as it relates to the molecular biology of gene rearrangement and expression with respect to diagnosis. They will become familiar with techniques of Northern
blotting, Southern blotting, restriction fragment length polymorphism (RFLP), and the polymerase chain reaction as well as other methods of gene amplification. The fellow will become familiar with extraction of DNA and RNA from cells and learn to understand the technical aspects of gene amplification, as well as the analysis of PCR products through gel electrophoresis, hybridization, sequence-specific oligonucleotide (SSO) Luminex assays and next-generation sequencing (NGS) techniques. Knowledge of gel electrophoresis and restriction enzyme usage will be taught as well as the usefulness of each of the techniques listed above. The fellow will become familiar with NGS for applications including histocompatibility testing, aneuploidy detection for pre-implantation genetic screening, and gene expression analysis. The utility of PCR in tissue typing as well as detection of infectious diseases will be discussed, and the techniques will be compared with the alternative techniques such as culture and serology.

Histocompatibility Testing: The fellow will be familiar with methods for histocompatibility testing. These will include class I, class II and KIR antigen typing by molecular methods. A fellow will be able to isolate appropriate cells for typing and interpret the results of molecular typing procedures as well as learning about alternative techniques such as microlymphocytotoxicity. The fellow will learn cross matching techniques (both cytotoxicity and flow cytometry techniques) and will be able to compare the utility of these techniques. The fellow will learn additional class II typing methods including HLA typing by RFLP as well as typing with oligonucleotide probes. The fellow will use this information to discuss the rationale for tissue typing and transplantation, to discuss the detection and sensitization of individuals to HLA antigens and their relevance in transplantation, as well as learning about HLA testing for disease association (e.g. Crohn’s disease, rheumatoid arthritis, ankylosing spondylitis). The fellow will be able to discuss the selection of the best donor for transplantation and distinguish between the utility of living related and cadaveric donor transplants. Finally, the fellow will be able to perform blood typing for ABO and Rh antigens.

Information Systems and Equipment: The fellow will be familiar with a variety of information management systems available in the clinical laboratory. The fellows will become familiar with the use of the computers and the management of information. Fellows will obtain a knowledge of the necessary information for patient evaluation. The fellow will be able to discuss quality control and quality assurance necessary for the evaluation and maintenance of information systems as they relate to the clinical laboratory.

Besides the computer information systems, the fellow will be trained to use and understand theory and practicality of the following instruments: Nephelometers, turbidimeters, flow cytometers, electrophoresis equipment, personal computers, spectrophotometers, microscopes, ELISA readers, plate washers, hematology analyzers, coffee makers, thermocyclers, electrophoresis chambers, Luminex instruments, and next-generation sequencing (NGS) instruments. Each instrument will be used as part of a specific rotation, i.e. thermocyclers, electrophoresis, Luminex, and NGS during the molecular biology rotation.

Infectious Disease Serology: The fellow will learn diagnostic criteria for common infectious diseases as defined in the guidelines. They will be able to discuss pertinent results with physicians as it relates to management and diagnosis of infectious disease. Each fellow will become familiar with serological techniques involved including ELISA, agglutination, fluorescent procedures and RIA. The fellow will perform these procedures and evaluate the
methods for testing and utility of the methods. Fellows will understand the techniques and testing for both bacterial and viral infections including ASO, anti-DNAs, anti-hepatitis viruses and anti-HIV assays. In the case of HIV, serologic testing as well as Western blotting and flow cytometry will be utilized in evaluation. Fellows will be presented with specific cases and be able to evaluate each test with respect to the case. The fellow will understand the methods with regard to standardizing serology and quality control. The fellow will be exposed to a variety of populations with specific disease patterns.

It is expected the fellow will become familiar with each of the techniques described and understand all aspects from the principles of basic science through proficiency testing and through the management of specific patients as each relates to a patient population.

**Auto-antibody Testing:** The fellow will become aware of the spectrum of auto-immune diseases and the diagnostic criteria for each of the individual diseases. The fellow will understand the variety of individual tests and understand the different sensitivity and specificity of the tests. The range of testing will include fluorescent antibody testing by microscopy as it relates to antinuclear antibody and anti-cytoplasmic antibody testing, and serologic ELISAs for various autoantibodies such as anti-phospholipid, anti-DNA, anti-histone, anti-Sm/RNP, anti-thyroglobulin and anti-thyroid peroxidase. The fellow will become familiar with frozen tissue antibody techniques, as well as surgical techniques and Western blotting techniques as they relate to each of the auto-immune disease. In serology the fellow will understand the methods to standardize antibody testing and the use of available standard testing materials and proficiency tests. They will work at the bench with technologists involved in each of the testing procedures and will interact with the laboratory director and physicians in the interpretation of the auto-immune tests. The fellow will understand the assays which measure information and know the role of these tests in monitoring immune disease. The fellow will relate the histocompatibility testing in HLA class I and II sera typing with the association of a variety of auto-immune diseases to physicians and aid in interpretation of testing results with patient management and diagnosis. The fellow will understand the principles involved in establishing ranges of testing and the influences of age and sex. They will discuss individual cases with the director and physician, and demonstrate their understanding of the importance of auto-immune testing. The fellow will be familiar with complement and CRP assays and the understanding of how these assays may be used in the diagnosis of auto-immune disease and inflammation.

**Immunodeficiency:** The fellow will understand the laboratory tests for evaluation and determining immune deficiency disease and the proper work up for each. The fellow will use a variety of cellular, serologic and immunophenotyping techniques to be able to detect and categorize individual immunodeficiency and complement deficiency disorders. The fellow will learn techniques for quantitating and assaying lymphocytes, monocytes and granulocytes from individuals with suspected immunodeficiencies. The fellow will understand the role of screening assays for immunoglobulin and complement levels and detection of cellular deficiency. In each case, the fellow will learn to characterize primary and secondary immune deficiency diseases based on humoral, molecular and cellular or functional tests. The fellow will become familiar with the importance of proficiency testing and standardization as they relate to serology and analysis of individual tests. The fellow will gain this information by working at the laboratory bench, evaluating the proficiency testing results and discussing cases and specific populations with the laboratory director and other qualified personnel.
**Flow Cytometry:** The fellow will become familiar with the basic principles of flow cytometry and with the standardization of procedures required for sample preparation, cytometer calibration and data analysis. Fellows will in particular be able to set up protocols, calibrate and compensate flow cytometers and understand basic fundamentals of flow cytometry operation and function. The fellow will learn to prepare various specimens including blood, bone marrow, and lymph nodes, that aid in the diagnosis of leukemias, lymphomas and immunodeficiencies; each fellow will understand the CD nomenclature and their relevance to malignancies and clinical presentations. The fellow will be able to discuss flow cytometry methods and results with physicians and clinicians. The fellow will understand the quantitative assessment of lymphocyte populations in blood and relate this to other patient results for diagnosis and evaluation. The fellow will learn to quantitate CD4 lymphocytes to monitor the status of HIV infected individuals. Finally, the fellow will become experienced with flow cytometry assays for immune cell function (cytotoxicity, cytokine production) as well as cell surface phenotyping.

**Plasma Cell Dyscrasias and Monoclonal Gammopathies:** The fellow will become familiar with assays used for evaluation of immunoglobulin deficiencies and immune gammopathies such as multiple myeloma. The fellow will be familiar with a variety of methods for immunoglobulin analysis including serum protein electrophoresis, serological immunofixation and immunoelectrophoresis techniques. The fellow will become familiar with the utilization of these techniques in a variety of body fluids including serum, urine and CSF samples. The fellow will become acquainted with the various methods for quantitating immunoglobulins and the normal ranges for immunoglobulin levels in various populations. The fellow will become familiar with a variety of proficiency testing and technique procedures in the evaluation of individuals with altered immunoglobulin levels including lymphoid malignancies and immunodeficiencies.

**Allergies:** The fellow will become familiar with the different types of allergy testing available including RAST and RIST. The fellow will understand the importance of immunoglobulin E quantitation and its relationship to the evaluations of allergic disease, and interpretation of the tests and evaluation of the individual patient. The fellow should know both *in vivo* and *in vitro* methods for measuring IgE and allergy specific IgE. Fellow should understand the skin test methods used by allergists as well as the methods for noninvasive tests. The fellow should understand the variety of drugs and specific immune therapies in modulation of allergic disease.

**Public Health Serology:** The fellow will become familiar with the method of epidemiology and infection control and will understand the role of clinical immunology in both prospective and retrospective studies. The fellow will become familiar with the methods of recognition and surveillance as well as control of nosocomial infections. The fellow will learn to relate serological methods to their importance in public health. A focus on sexually transmitted diseases, and in particular, HIV testing and confidentiality, will be included.

**Management and Administration:** One of the important goals for an individual trained in laboratory science is the management and administration of the laboratory. The fellow will be involved in all phases of administration including budget planning and personnel management. Courses in laboratory administration are offered by the medical technology department and are available to fellows as part of their training. The important point in management and administration is quality control and quality assurance guidelines. The fellow will become
familiar with the College of American Pathology as well as CLIA guidelines as they relate to the management of the clinical immunology laboratory. Another important point in laboratory management is laboratory safety. Fellows will attend university safety courses in biosafety, infection control and chemical hygiene, as well as HIPAA training and a course in teamwork and group dynamics. Fellows will have thorough understanding and familiarity with the composition of the laboratory safety manuals, universal precautions, OSHA requirements and biosafety hazards. Special attention to processing blood, serum and tissue specimens; waste management of discarded specimens; and the handling of radioactive materials will be included.

The graduate will become familiar with management principles of personnel, budgeting, work load, space planning as well as hiring and disciplining employees. The fellow will be responsible for the day-to-day direction of the laboratory during the second year of their training, as well as preparing and presenting continuing education seminars for technicians.

The fellow will manage the laboratories associated with the Rosalind Franklin University of Medicine & Science and learn specific laboratory and diagnostic laboratory techniques in the other diagnostic laboratories where rotations will be arranged. The duties of the fellow will include personnel management, scheduling, clinical consultations, quality assurance and quality control both daily and monthly as well as annually. Additional responsibilities will include budgeting and billing, computer documentation and implementation, new procedure development and validation, and ensuring compliance with accrediting/regulatory agencies. New equipment evaluation will also be part of the fellow’s experience during the management portion of the training.

The Clinical Immunology Laboratory at RFUMS/Chicago Medical School has access to all the electronic resources of the medical school library which is located one floor below the laboratory. It also has numerous conference rooms and lecture halls as part of the medical school. Desk space is available in the office adjacent to the clinical laboratory. A PC with personal Internet access will be available for each fellow. Research space is available for the fellow in the research laboratory adjacent to the clinical laboratory.