# **Overview of Program Goals and Objectives**

### **General organization**

The practice of molecular genetic pathology is diverse and continually evolving. As such, a broad and also in-depth background of both basic and clinical molecular diagnostics is required for the successful practitioner. In addition, familiarity with the administrative and management aspects, including regulatory issues and cost analysis of a molecular diagnostic laboratory is important to understand. As part of laboratory and clinical rotations at each of the three core sites, University of Washington (UWMC), Seattle Cancer Care Alliance (SCCA), and Seattle Children's Hospital (SCH), the fellow is expected to master these general goals and objectives pertaining to the location-specific context. In addition, the general duties and responsibilities of the fellow are described in conjunction with an overview of the ACGME core competencies to be assessed.

## Goals and objectives

- 1. Apply understanding of basic molecular biology, including the structural and functional basics of DNA, RNA, mechanisms of inheritance, etc. to each laboratory and clinical rotation for patient care.
- 2. Master the relevant nomenclature and language molecular genetic pathology with an emphasis on accurate description of molecular variation/abnormalities at the DNA, RNA, and protein level for written reports, publications and clinical correspondence
- 3. Apply insight and knowledge of technical aspects of molecular techniques with an emphasis on appreciating the appropriate use for and utility of different diagnostic approaches. These techniques may include PCR, real-time RT-PCR, fragment analysis, allele-refractory mutation amplification, melting-curve analysis, *Invader* technologies, branched DNA techniques, MLPA, SSCP, DGGE, karyotype, FISH/CISH, and other more complex methods (including array CGH and high-throughput sequencing)
- 4. Command an understanding and demonstrate proficiency in navigating bioinformatics resources such as genome browsers (for example, http://genome.ucsc.edu/ or http://uswest.ensembl.org/index.html), (http://www.ncbi.nlm.nih.gov/sites/GeneTests/), gene databases diseasespecific molecular databases (OMIM, NCBI, COSMIC, mycancergenome.org) for acquisition of pertinent patient-specific molecular data, commonly used genetic

software (Mutalyzer, Mutation Surveyor by SoftGenetics, LLC) GeneMapper and Sequence Analysis by Applied Biosystems), and use of websites (such as <a href="http://frodo.wi.mit.edu/primer3/">http://frodo.wi.mit.edu/primer3/</a> ) for assay development

- 5. Participate daily in patient-care activities, observing and/or actively participating in all aspects of the molecular pathology laboratory, including sample preparation, assay performance, data analysis, and report generation in all molecular tests performed by the laboratory
- 6. Develop understanding of strategies behind all molecular assays used in each laboratory, including advantages and disadvantages of methods and instruments
- 7. Understand appropriate management and triage of clinical samples (recognizing for example what an appropriate sample-type is) with an appreciation for cost-effective and evidence-based test utilization
- 8. Integrate knowledge from medical literature and available resources with patientspecific results to generate informative diagnostic reports
- 9. Participate with supervising faculty in the editing of written reports prior to finalization and report
- 10. Communicate to patient care providers to inform and/or discuss results as necessary, and/or present such information in multi-disciplinary conferences where applicable
- 11. Contribute to faculty, staff, resident, fellow education through scholarly activities, journal club presentation, case report, poster and manuscript preparation

# Duties and responsibilities

- 1. Daily participation in the functioning of clinical molecular laboratories
- 2. Communicate with laboratory staff or faculty and correspond with clinicians as necessary to effectively review and sign-out all molecular cases
- 3. Review all pertinent medical literature to develop broad, but in-depth background knowledge
- 4. Participate in laboratory management meetings, including those for quality assurance and personnel management when applicable
- 5. Attend all relevant pathology and clinical conferences and present or be available for consultation regarding molecular data when appropriate; in addition, attend as many relevant molecular seminars as appropriate
- Review quality assurance issues as applicable, including performance of yearly review of SOPs, review CAP proficiency testing of molecular results and CAP checklist for laboratory inspection
- 7. Review, observe and/or perform most if not all techniques and molecular assays performed in each laboratory to develop hands-on experience

- 8. Contribute to the development and validation of at least one novel, molecular diagnostic assay
- 9. Supervise junior residents in conjunction with non-MGP fellows, to residents, commensurate with experience regarding topics of molecular genetic pathology
- 10. Serve as "junior attending", commensurate with experience. This opportunity represents an increase in responsibility and will enable the fellow to gain experience in making decisions in preparation for future independent practice. This does not imply or require institutional credentialing.
- 11. Participate in the education of resident/fellow colleagues, faculty, and technical staff through journal club presentations, preparation of manuscripts and posters, if applicable

The MGP Fellow should meet with the supervising faculty/staff or laboratory director at the <u>start</u> of each site rotation (lab and clinic) to delineate and clarify expectations for each rotation. The MGP Fellow should assume full responsibility and ownership of all molecular cases that pass through the laboratory, as per the supervising faculty/staff and look to develop his/her professional experience according to the ACGME Milestones goals.

### Supervision and evaluation

For each clinical and laboratory rotation, the fellow should inquire with the supervising faculty regarding rotation-specific goals and objectives, and duties at the beginning of the rotation and as outlined at the MGP internal webpage. The fellow will work directly with the staff diagnostician and/or designee, including technical laboratory staff, to fulfill daily patient care duties. The fellows will be required to keep a Logbook of all cases (both clinical and laboratory) with which the fellow is involved to document their experience. This case log must be reviewed by the site/clinic supervisor or supervising clinicians/physicians/staff and submitted to the fellowship director for incorporation into the fellow's portfolio at the mid-year and end-of-year reviews, and is a non-negotiable requirement for successful completion of the program. During and at the end of each rotation, a specific evaluation will be completed by each the supervising faculty member.

# Teaching staff

Appropriate supervising faculty will be indicated as per each specific laboratory and clinical rotation. One or more molecular pathology attending staff members will be on service and available to help answer questions and/or deal with difficult situations. A laboratory technical manager, technical specialist and/or a lead technologist may also be available to help with laboratory administrative and technical issues. The program is designed in such a way that the MGP fellow can assume increasing responsibility over

the course of the training program according to their level of prior experience, education, ability, and knowledge.

### **ACGME Core Competencies**

In each of the clinical and laboratory rotations, the fellow will be evaluated on his/her ability to master the six core competencies of the ACGME, as outlined by the Association for Molecular Pathology Training and Education Committee (see Journal of Molecular Diagnostics, 11(6):497 (2009), manuscript entitled, "*Competency-based education for the molecular genetic pathology fellow: a report of the association for molecular pathology training and education committee*.":

Defineteen		
Patient care	1.	Gather essential patient specific information
	2.	Contact clinicians as needed
	3.	Make informed recommendations based on patient information,
		clinical question, and knowledge of available testing
	4.	Advise providers on the spectrum and clinical appropriateness of
		molecular test for specific clinical issues
	5.	Offer education and consultation services in MGP
	6.	Correspond with providers regarding results of critical assays,
		such as prenatal or diagnostic assays
	7.	Assume progressive patient-care responsibilities
	8.	Prepare and/or review molecular pathology reports prior to
		finalization
Medical knowledge	1.	Demonstrate mastery of science of MGP including nucleic acid
		structure, function, and mutation/variation description as pertinent
		to each rotation
	2.	Demonstrate understanding of pertinent molecular laboratory
		techniques, including theory and practical performance thereof
	3.	Demonstrate basic understanding of principles of laboratory
		management, including QC, QA, test validation, budgeting,
		personnel requirements, regulatory agencies and requirements,
		ethical issues, and laboratory and patient safety
	4.	Understand indicators, clinical implications, methodologies, and
		limitations of molecular testing for a wide-range of disorders
Practice-based	1.	Demonstrate on-going self-education (journal reading and review)
learning and		and involvement in professional societies
improvement	2.	Read, critique, assimilate and apply medical literature to practice

	3. 4. 5.	Develop broad understanding of methods used for molecular testing and process of clinical test development, validation and implementation procedures Demonstrate willingness to educate and instruct others in matters related to molecular genetic pathology, including junior trainees, clinicians and technical staff Demonstrate ability to ask a definable question, search for relevant scientific information, appraise data using principles of evidence-based medicine, and apply results to clinical practice
Interpersonal and	1.	Demonstrate effective working relationships with laboratory
communication		technical staff, departmental faculty and residents, extra-
skills		departmental faculty and staff, and outside consultants
	2.	Show respect and sensitivity toward laboratory technical staff and
	3	Communicate information clearly with molecular team about
	0.	patient history and testing during the review of cases. with an
		increase in comfort level for the information improving over the
		course of the fellowship training
	4.	Develop effective verbal communication skills in the transmission
		of results to health care providers, answering questions
		appropriately as needed
	5.	Develop excellent writing skills to prepare reports and express
		complicated results in a clear manner and in the preparation of
		scholarly results
	6.	Develop presentation skills including selection of appropriate
		presentation materials and visual aids, good oral presentation and
		mannerisms, and ability to effectively answer questions
Professionalism	1.	Demonstrate respect and compassion for the patient
	2.	Fellow must conduct himself/herself with integrity and honor;
		understand ethical issues associated with genetic testing
	3.	Show dependability and punctuality with respect to responsibilities
		and clinical activities
	4.	Respect patient confidentiality and associated regulations, such
	F	as the HIPAA
	Э.	the area of MGP by assuming responsibilities and leadership roles

	6.	Complete all mandatory institutional online courses and tutorial pertaining to professionalism.
Systems-based practice	1. 2.	Integrate and correlate molecular testing results with clinical history and information from other studies such as additional molecular testing, histology, immunohistochemistry, cytogenetics, flow cytometry, FISH, blood smear analysis Provide guidance to clinicians and counselors to ensure that
		molecular testing is used and integrated into patient care in an appropriate and cost-efficient manner
	3.	Use scientific online and print resources on a regular basis to find the latest literature, methods, and clinical research in molecular diagnostics and medical/human genetics
	4.	Be familiar with the scientific, legal and ethical issues involved in molecular genetic testing
	5.	Review requests for send-out tests with attention to cost-effective patient care
	6.	Demonstrate ability to assess, understand, use the resources, personnel, and health care systems necessary to provide optimal care.