Advanced Diagnostic Laboratories
Molecular Pathology Fellowship

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H. LEE MOFFITT CANCER CENTER

PATHOLOGY AND LABORATORY MEDICINE

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Advanced Diagnostic Laboratories

H. Lee Moffitt Cancer Center

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Description

The Molecular Pathology Fellowship Program offers a unique opportunity for the trainee to acquire practical experience in cutting edge technologies vital for the successful pursuit of an academic career in pathology. Under the guidance and tutelage of Dr. Theresa Boyle, the Fellow is provided with a background in molecular biology, experience with high level diagnostics, and opportunities to pursue research projects with a variety of investigators covering a broad range of oncological expertise.

As the premier cancer hospital in Florida, H. Lee Moffitt Cancer Center is recognized by the National Cancer Institute (NCI) as a Comprehensive Cancer Institute. Moffitt provides care to over 450,116 outpatients annually, including the largest blood and bone marrow transplant program in the southeast. Laboratory professionals perform over 13,500 needle cytological specimens, and 16 active surgical suites generate over 18,500 solid tumor specimens annually. In addition, anatomic pathologists review over 21,000 referred-in surgical cases, many of which require ancillary high-level diagnostics for complete work-up. The annual volume for internal NGS (Moffitt STAR, Illumina TST170 gene panel) cases is 924.

The Molecular Fellowship Program is centered on patient care, enabling the Fellow to acquire expertise in handling complex and/or time sensitive patient material to inform the management of cancer patients. To that end, the fellow experiences weekly review of external NGS cases for personalized patient care with the Personalized Medicine group, such as reports received from Foundation CDx (N=782), Guardant360 liquid biopsy (N=574), and FoundationOne Heme (N=130) cases. After reviewing basic nucleic acid and protein cellular biology and cancer-associated genetic alterations, the program focuses on the suite of platforms available to detect and categorize these changes. Integral to the curriculum is experience with laboratory management, quality assurance, validation of new tests and techniques, as well as resource allocation and cost-effective practice.

Recognition of the regulatory environment, particularly Clinical Laboratory Improvement Amendments (CLIA), will inform adherence to appropriate standards. Recognition of the economic environment will inform compliance with appropriate coding, billing and reimbursement issues.

At the Moffitt Cancer Center and Research Institute, there is close interaction and cooperation between laboratory professionals and clinical patient management teams. Ultimately, Moffitt places the patient at the center of all decision-making, and expects its faculty, staff and trainees to advocate for quality patient care. The trainee benefits from this exchange by gaining a deeper understanding of the clinical impact of the requested test(s).

Collaborative research is a natural offspring of this close interaction, and the Trainee will be expected to participate in the design, execution and reporting of such investigations. The Program will build on the Fellow's existing specialized knowledge and interest in surgical and/or cytopathology, and can be customized to suit her/his specific ongoing research and clinical interests.

Our MISSION is to contribute to the prevention and cure of cancer through the education of future academic pathologists with an interest in molecular diagnostics.

Our VISION is to transform cancer care through service, science and partnership.

Training Locations

ADVANCED DIAGNOSTIC LABORATORIES (ADL)
The Molecular Pathology Fellowship Rotation is a one year program carried out at the Advanced Diagnostic Laboratories located at the McKinley Campus adjacent to the Moffitt Clinic Building. The ADL Laboratories are state-of-the-art facilities dedicated to the development and implementation of predictive, prognostic and diagnostic molecular biomarker testing that will permit selection of cancer treatments with targeted therapy allowing for the best in personalized medicine. The laboratories contribute to our patient's overall quality of life by facilitating the very best in advanced diagnostic laboratory services. They provide comprehensive CLIA compliant test development for patient care and clinical trial use that is a progressive approach to value-added patient care.

Moffitt Cancer Center is located on the campus of the University of South Florida and is affiliated with the Morsani College of Medicine. Moffitt's Advanced Diagnostic Laboratories are less than one mile south of the main campus. All training will be provided within Moffitt facilities, precluding the necessity of affiliation agreements. The tissue core and the surgical pathology laboratory are located on the first floor of the McKinley campus laboratory building and within the main Moffitt Cancer Center building. The genomics core is centered at the Moffitt Research Center on the Magnolia campus.

Existing Resources for Training

CASE MATERIALS
Moffitt Cancer Center is designated by the National Cancer Institute as a Comprehensive Cancer Center. Annual workload includes approximately 18,500 surgical cases and an additional 10,000 consultations/reviews, as well as 13,500 cytology cases, of which about 900 are consultations or reviews, and about 1700 are fine needle aspirations. The Molecular Pathology of Cancer Fellow will take advantage of many of these cases which are streamed in significant numbers for molecular diagnostics.

RESEARCH RESOURCES
Moffitt is the beneficiary of a P30 Cancer Center Support Grant (CCSG) which includes support for the Cancer Center Shared Resources and Services. These include Flow Cytometry, Molecular Genomics, Proteomics, Analytic Microscopy, Tissue Procurement, Biostatistics and Translational Research.

INTEGRATION WITH OTHER TRAINING PROGRAMS
The Molecular Pathology Fellow will benefit from interacting with other Fellows in several other disciplines, such as Anatomic Pathology, Cytology, and Personalized Medicine Group Fellows. The USF Pathology Residency Program has strong ties to the Moffitt, as residents in the mid to senior level rotate through a variety of clinical services.

MENTORING
Formal mentoring is encouraged, as the Fellow can be assigned to a Program Faculty other than the Program Director for one-on-one interaction on specific topics.

TEACHING RESOURCES
The Fellow is encouraged to participate in the regular teaching sessions of the Pathology department; in addition, numerous scientific sessions, lectures and seminars are available.

EDUCATIONAL OUTCOMES
By the end of the Fellowship the trainee is expected to achieve proficiency in the core competencies of ACGME as they apply to the molecular pathology of cancer: a) Medical knowledge; b) Patient care; c) Professionalism; d) Interpersonal and communication skills; e) Practice-based learning and improvement; and f) Systems based practice. These are detailed below.

Program Goals and Objectives

A - Medical Knowledge:
Upon completion of the molecular pathology laboratory rotation(s), the fellow is expected to apply in depth knowledge of:

1. The basic structure and function of nucleic acids and proteins, and their roles in cellular function.

2. The types of genetic alterations that occur in various conditions including:
    a. Classical Mendelian Disorders.
    b. Disorders associated with copy-number alterations.
    c. Individual variations in drug metabolism.
    d. Hematologic Neoplasms.
    e. Solid Tumors.

3. Articulate the relationship between the nature of these changes and the types of tests used to detect these alterations, the performance of and interpretation of these tests, and their pitfalls.
    a. Multiple PCR-based assays

b. DNA and RNA sequencing (Next Generation sequencing)
c. Pyrosequencing
d. Fluorescence in-situ hybridization (FISH)
e. Chimerism

4. Demonstrate an understanding of various aspects of laboratory management. This includes:
    a. Quality assurance and troubleshooting of the above molecular diagnostic tests;
    b. Validation and evaluation of new assays developed.
    c. Evaluation of instrumentation to perform assays in the laboratory.

B - Patient Care:
Fellows shall apply their acquired knowledge on a continuing basis to patient care.

1. Compare the clinical implications and limitations of the tests performed in the laboratory
2. When appropriate, evaluate essential and accurate patient information (including data from other labs), histopathologic data, immunophenotypic data, and communicate with clinicians as appropriate for relevant information on patient history,
3. Integrate the assembled information to render a diagnosis, prediction, prognosis, or risk assessment.
4. When these tests are inadequate to answer relevant clinical questions, collaborate with the treating physician to identify clinically appropriate tests, laboratories performing such tests, and assist the clinician in interpreting these tests.
5. Engage with health care providers to organize education and consultation services.
6. Recognize which tests have time-critical results that will drive clinical and therapeutic decisions.

C - Professionalism:
During the rotation, fellows must demonstrate a commitment to professional responsibilities, adherence to highest ethical standards, and respect for all. Towards this, they shall:

1. Demonstrate respect and compassion for the patient and a dedication to patient care.
2. Articulate financial and economic systems in which the molecular laboratory operates, including billing, the appropriate use of current procedural terminology codes, diagnostic codes, and health insurance and reimbursement issues.
3. Practice cost-effective health care and resource allocation that does not compromise quality of care.
4. Advocate for quality patient care and contribute to clinician education.
5. Choose the resources, personnel, and health care systems necessary to provide optimal care.

D - Interpersonal and Communication:
During the rotation, fellows must demonstrate interpersonal and communication skills that result in effective information exchange with other health care providers, laboratory personnel, patients, and patients' families.

Towards this end they shall:

1. Exhibit effective working relationships with professional and technical staff, and outside consultants.
2. Communicate effectively with clinicians, at the appropriate level for the information being transmitted; convey and explain test results clearly, precisely, and concisely to physicians in direct conversations, or at conferences; communicate promptly with technical personnel when troubleshooting assays, or when managing the laboratory.
3. Generate written reports of complicated results when issuing reports, for the development and implementation of new laboratory policies and procedures, and for presentation of scientific research data, as appropriate.

E - Practice-based Learning & Improvement:
Fellows shall continuously improve their ability to investigate and evaluate their diagnostic and consultative practices, appraise and assimilate scientific evidence, and improve their patient care practices.

Specifically, they shall:

1. Contribute to the activities of the Association for Molecular Pathology, and other societies.
2. Continuously update their knowledge in sciences and clinical fields related to the tests performed in the Molecular Pathology Laboratory, through literature searches and attendance at conferences.
3. Evaluate validation protocols of tests currently in the laboratory.
4. Participate in new test development and/or validation.

F - Systems-based Practice:
Fellows must critically appraise the larger context and system of health care and the ability to call on system resources to provide molecular genetic pathology services that are of optimal value.

Towards this they shall, where appropriate:

1. Advise clinicians and counselors to ensure that molecular testing performed in the molecular pathology is used and integrated into patient care in an appropriate and cost-efficient manner.
    a. Relate the clinical implications and cost-effectiveness of the tests performed in the molecular pathology laboratory and their implications for patient management.
    b. Judge the appropriateness of potential alternative testing approaches.

2. Frame scientific, legal, and ethical issues relating to molecular testing.
    a. Assess standards and regulations governing laboratory operations including Clinical Laboratory Improvement Amendments (CLIA), and evaluate laboratory compliance with these standards and regulations.
    b. Evaluate the compliance of the laboratory with these standards using the CAP checklists. Develop, in conjunction with the laboratory director, the annual laboratory Quality Improvement Program and present a review of this semi-annually at the departmental QA conference.

3. Outline the impact of laboratory management and activities on other health care professionals, organizations, and society.

4. Articulate the financial and economic systems in which the molecular laboratory operates, including billing, the appropriate use of current procedural terminology codes, diagnostic codes, and health insurance and reimbursement issues.

5. Practice cost-effective health care and resource allocation that does not compromise quality of care.

6. Advocate for quality patient care and contribute to clinician education.

Curriculum Overview

Overview:
The Moffitt Graduate Medical Education office will coordinate general onboarding, around which scheduling of didactic teaching and tours of the physical resources will occur. The Fellow will meet with Dr. Boyle (or designate) upon arrival at Moffitt to review the curriculum.

The program will consist of a continuum of molecular case preview, particularly of the Moffitt STAR next generation sequencing assay, along with weekly interactions with the personalized medicine group to discuss the implications of results for patient care. There will also be an educational series that the fellow will participate in organized into 4 blocks. The fellow will have exposure to core labs, platforms, bioinformatics, multidisciplinary care team, surgical pathology, and the personalized medicine institute. Some of these will simply be tours, such as of the tissue core and digital imaging laboratory; others will include more intensive educational projects, such as with the genomics core.

The first block of three months will incorporate an introduction, laboratory orientation, laboratory safety, quality assurance principles, CAP guidelines, overseen by the Administrative Director of the Advanced Diagnostic Laboratories, Ms. Carolyn Loret de Mola (or designate).

The fellowship director, Dr. Theresa Boyle (or designate), will provide an introduction to research opportunities at the Moffitt Cancer Center. Over the first block, the fellow will select one validation, one research, and one safety project with guidance from the fellowship director. The fellow will be expected to prepare a manuscript describing one of these three projects to be completed by the end of the fellowship year.

The Fellow will maintain a presence and desk space at the Moffitt Advanced Diagnostics laboratory (third floor of the MIOMS building, Suite 312), will engage in a project with the molecular core, tour the tissue core facility, and meet with the faculty members of this program.

During the first two week course of Fellows in the Advanced Diagnostics Laboratories, the molecular fellow will be engaged in teaching the other fellows about NGS preview and participating in this two week course that is offered to other fellows. In October, the fellow will spend dedicated time with Mr. Sean Yoder in the molecular core in conjunction with an introduction to bioinformatics analysis with Dr. Jamie Teer.

The second block will continue to build on the skills learned from the first block and learn various additional techniques and molecular testing used in surgical pathology. During each of these rotations there should be close communication between the Fellow and the respective supervisor to ensure that the learning environment remains optimal. Objectives will be clearly expressed in writing.

An informal mid-rotation assessment by the Program Director, Dr. Boyle, will be conducted in an appropriate manner, with frank immediate feedback, documented in the trainee file promptly. A written assessment of performance will be conducted at the end of each block and documented. Elements of quality assurance (QA), standard operating procedures (SOP), guidelines, informatics, ethical implications and resource utilization should imbue all rotations.

The third block will continue exposure to ancillary techniques and the incorporation of results into clinical decision making. While there may be some flexibility according to the inclinations of individual trainees, the rotations will be scheduled in advance.

The final block will be designated as electives for research and to allow for completion and write up of research project and assay validation as the training period ends.

Description of Educational Series

(Note: This educational series describes educational exposures with some being simply tours or didactic learning sessions, and others with more intensive projects - some, but not all, will be set up as month long rotations. The Fellowship Director will communicate with the Faculty Members and Fellow to determine the set-up and amount of involvement for each educational interaction).

Pyrosequencing	
Supervised by Dr. Qin	MIOMS Building (ADL)
Description: - *Pyrosequencing is a method of DNA sequencing.*	
Goals: - *Relate the role of pyrosequencing in the clinical lab* - *Appraise the effects of results on patient treatment*	
Objectives: - *Report the underlying biochemical mechanism defined by pyrosequencing* - *Analyze the strengths and weaknesses in pyrosequencing* - *Demonstrate reading and interpreting the data generated by pyrosequencing* - *Participate in reporting the results of pyrosequencing*	
Real-time PCR	
Supervised by Dr. Qin	MIOMS Building (ADL)
Description: - *Real-time PCR (RT-PCR) is a method for determining absolute or relative amounts of a target nucleic acid*	
Goals: - *Understand the role of RT- PCR in the clinical lab* - *Understand how the results will affect patient treatment*	
Objectives: - *Report the underlying biochemical mechanism defined by RT- PCR* - *Analyze the strengths and weaknesses in RT- PCR* - *Demonstrate reading and interpreting the data generated by RT- PCR* - *Participate in reporting the results of RT- PCR*	

Sanger Sequencing	
Supervised by Dr. Qin	MIOMS Building (ADL)

Description:

- *Sanger sequencing is a method of DNA sequencing.*

Goals:

- *Understand the role of Sanger sequencing in the clinical lab*
- *Understand how the results will affect patient treatment*

Objectives:

- *Report the underlying biochemical mechanism defined by Sanger sequencing*
- *Analyze the strengths and weaknesses in Sanger sequencing*
- *Demonstrate reading and interpreting the data generated by Sanger sequencing*
- *Participate in reporting the results of Sanger sequencing*

FISH-Fluorescence in situ hybridization	
Supervised by Dr. Liu	MIOMS Building (ADL)

Description:

- *FISH (fluorescent in situ hybridization) is a method for identifying gross chromosomal rearrangements*

Goals:

- *Understand the role of FISH in the clinical lab*
- *Understand how the results will affect patient treatment*

Objectives:

- *Articulate the underlying biochemical mechanism of FISH*
- *Analyze the strengths and weaknesses of using FISH*
- *Demonstrate reading and interpreting the data generated by FISH*
- *Participate in reporting the results of FISH*

Next Generation Sequencing	
Supervised by Dr. Boyle and Dr. Saeed-Vafa	MIOMS Building (ADL)

Description:

- *The next generation sequencing (NGS) provides a method for DNA and RNA sequencing from targeted panels to whole genome.*

Goals:

- *Understand the role of NGS in the clinical lab*
- *Understand how the results will affect patient treatment*

Objectives:

- *Report the underlying biochemical mechanism defined by NGS*
- *Analyze the strengths and weaknesses in NGS*
- *Demonstrate reading and interpreting the data generated by NGS*
- *Participate in reporting the results of NGS*

Validation / Safety / QA Project	
Supervised by Dr. Boyle and Qin	Location: MIOMS Building (ADL)

Description:

- *In the Clinical laboratory, introduction of a new test requires assessment of performance characteristics of the assay and validation of the test by the laboratory.*

Goals:

- *Set up a plan to perform a validation*
- *Create a validation plan*
- *Coordinate wet laboratory work with designated laboratory scientist*

- *Assess the performance characteristics of the test and perform trouble shooting as needed*
- *Write up the final validation*

Objectives:

- *Demonstrate familiarity with established practices and laboratory standards*
- *Analyze and interpret test results and potential variations in that test*
- *Prepare a summary of the validation results for presentation*

Genomics Core

Supervised by Sean Yoder	Location: Moffitt Research Center

Description:

- *The Genomics Core is a non-CLIA laboratory and provides a fee based service for detecting and quantifying DNA and/or RNA molecules on different platforms depending on the goals of a research project.*
- *http://moffittnet.moffitt.org/sites/Research/Operations/MolecularGenomics/Site%20Pages/Overview.aspx*

Goals:

- *Understand how to use the Genomics Core in the clinical lab*

Objectives:

- *Enumerate the different testing platforms available through the Genomics Core*
- *Evaluate the strengths and weaknesses of these platforms*
- *Demonstrate reading and interpreting of data generated by the different platforms in the Genomics Core*

Array-based Platforms

Supervised by Sean Yoder	Location: Moffitt Research Center

Description:

- *The Molecular Genomics Core offers microarray services utilizing arrays and reagents from several vendors, with the ability to interrogate gene expression, methylation patterns, copy number variation, and sequence polymorphisms at a genome-wide level.*

Goals:

- *To understand the strengths and limitations of Affymetrix gene expression arrays*
- *To understand the differences in RNA and DNA-based array technologies*

Objectives:

- *Demonstrate the interpretation and analysis of Affymetrix gene expression data*
- *Analyze and understand the implications of an Affymetrix OncoScan Copy Number Variation data set*
- *Evaluate the strengths and weaknesses of RNA-sequencing vs array-based gene expression data*

Circulating Tumor Cells

Supervised by Dr. Puskas	MIOMS Building (ADL)

Description:

- *The circulating tumor cell platform allows for the detection and quantification of tumor cells in blood.*

Goals:

- *Understand why detecting circulating tumor cells in the clinical lab is relevant*
- *Understand how the results may impact patient treatment*

Objectives:

- *Report the underlying biochemical mechanism defined for detecting circulating tumor cells*
- *Analyze the strength and weaknesses in detection of circulating tumor cells as currently defined*
- *Demonstrate reading and interpreting the data generated for detection of circulating tumor cells*
- *Participate in reporting the results of detection of circulating tumor cells*

NanoString®

Supervised by Dr. Puskas	MIOMS Building (ADL)

Description:

- *The nanoString® platform provides a method to measure the amount of a specific gene at the level of RNA or DNA. This is useful for testing gene expression signatures or genomic DNA amplifications or DNA rearrangements*

Goals:

- *Understand why the levels of gene expression or amplification in the clinical lab are important*
- *Understand how the results may affect patient treatment*

Objectives:

- *Analyze the underlying biochemical mechanism of the NanoString® platform*
- *Evaluate the strengths and weaknesses in using the nanoString® platform*
- *Demonstrate reading and interpreting the data generated from the NanoString® platform*

Digital PCR

Supervised by Dr. Puskas	MIOMS Building (ADL)

Description:

- *Digital PCR provides a method to count the number PCR targets in a sample*

Goals:

- *Understand how digital PCR could be used in the clinical lab*
- *Understand how the results may affect patient treatment*

Objectives:

- *Evaluate the strengths and weaknesses of digital PCR as a technique to evaluate low number of nucleic acid targets*
- *Demonstrate reading and interpreting the data generated by digital PCR and how this information may affect patient treatment*

Bio Informatics

Supervised by Dr. Aik Choon Tan/Jamie Teer	Location: MRC Building

Description:

- *Bioinformatics describes the computer algorithms used to process and interpret biological data, primarily used with NGS and proteomics*

Goals:

- *Understand the role of bioinformatics in the clinical lab*
- *Understand how the results will affect patient treatment*

Objectives:

- *Using NGS as the area of study, evaluate the bioinformatics algorithm currently used in testing patient samples (i.e. the NGS pipeline)*
- *Using NGS, to relate the strengths and weaknesses of the specific NGS pipeline in use*
- *Predict how changes in the NGS method might affect the NGS pipeline*

Total Cancer Care database and resources

Supervised by Dr. Boyle	Location: MIOMS Building (ADL)

Description:

- *Total Cancer Care (TCC) defines Moffitt Cancer Center's approach to treating cancer*
- *http://moffittnet.moffitt.org/sites/TotalCancerCare/Site%20Pages/Overview.aspx*
- *http://moffittnet.moffitt.org/sites/TotalCancerCare/Total%20Cancer%20Care%20Documents/TCC%20Handbook.pdf*

Goals:

- *Understand how TCC drives treating and caring for patients*

Objectives:

- *Reframe the advantages of TCC to clinicians for patient interactions*

Personalized Medicine & Genetic Counseling Services	
Supervised by Christine Walko	Location: MCC Main Building

Description:

- *The purpose of the Personalized Medicine Consult Service is to optimize the treatment of each patient through utilization of all clinically relevant methods of personalization*
- *This rotation will focus on the interpretation of somatic genetic analysis using assays conducted both internally and externally and the translation of these results into patient treatment recommendations*
- *The Consult service reviews all patients with external molecular testing results and internal results when requested*
- *Patients are either reviewed by the smaller consult service members or the Clinical Genomic Action Committee. The latter is a multidisciplinary committee that meets once per month to form consensus recommendations for more complex patient results.*

Goal:

- *To develop expertise in the application of genomic data into standard clinical oncology practice*

Objectives:

- *Critically evaluate clinical data supporting clinical variants and gain appreciation for the variation in amount, quality and applicability of available literature.*
- *Review the available genomic databases and gain proficiency utilizing these databases in relation to patient genomic results, including CBio Portal, COSMIC, CGAC Dashboard, and TCC*
- *Effectively translate results into clinical recommendations that will be presented at the Clinical Genomics Advisory Committee (CGAC), and learn to systematically document recommendations in the patient's medical record*
- *Understand the ethics related to providing both somatic and germline genetic results to patients*

Proteomics	
Supervised by Dr. Koomen	Location: Moffitt Research Center

Description:

- *Proteomics defines the identifying and quantifying proteins is a biological sample*
- *The director of the Proteomics core, John Koomen, will detail the resources provided*
- *http://moffittnet.moffitt.org/sites/Research/Operations/Proteomics/Site%20Pages/Overview.aspx*

Goals:

- *Understand the role that proteomics currently has in the clinical lab*
- *Understand how the results might affect patient treatment*
- *How might proteomics be used in the future in the clinic*

Objectives:

- *Describe the Theory and Practice of Proteomics Platforms (e.g. MALDI MS, LC-MRM)*
- *Analyze the strengths and weaknesses of using proteomics and compare to existing clinical technologies*
- *Articulate the possible roles of proteomics in the clinical lab*
- *Explain how the results might affect patient treatment*
- *Evaluate the potential future clinical use of proteomics*

Administration and Regulatory	
Supervised by Carolyn Loret de Mola	Location: MIOMS Building (ADL)

Description:

- *The functions of the laboratories are governed by laws and regulations from both federal and state branches of government*
- *Moffitt Cancer Center policies maybe more restrictive policies than those described by federal and state organizations*

Goals:

- *Understanding of the federal/state laws and regulations as well as the relevant Moffitt policies*

Recount the information provided in the following links:

- *http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html*
- *http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html*
- *http://floridasclinicallabs.gov/resources/*

Objectives:

- *Recount the information provided in the following links:*
- *http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html*
- *http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html*
- *http://floridasclinicallabs.gov/resources/*

Quality Assurance

Supervised by Carolyn Loret de Mola	Location: MIOMS Building (ADL)

Description:

- *Quality assurance is defined by the policy and procedures to produce accurate clinical test results.*

Goals:

- *Understand the guidelines set forth by clinical laboratory accrediting organizations (CAP) to ensure accurate reporting of test results from patient samples.*

Objectives:

Evaluate the following guidelines:

- *Molecular guidelines: MAS_MOL_04212014.pdf*
- *Flow Cytometry guidelines: MAS_FLO_04212014.pdf*
- *Laboratory common guidelines: MAS_COM_04212014.pdf*
- *Histocompatibility guidelines: MAS_HSC_04212014.pdf*
- *ACMG_Lab_Standards_Next_Generation_Sequencing_Sept2013.pdf*

Hematological Molecular Pathology

Supervised by Dr. Mohammad Hussaini/Dr. Dahui Qin	Location: Pathologist Offices

Description:

- *Hematological Molecular Pathology involves the identification of molecular alterations pertinent for diagnosis, prognosis and therapy in hematological malignancies.*

Goals:

- *Learn about the various laboratory methods used for molecular characterization of hematological specimens*
- *Understand how the results will affect patient treatment*

Objectives:

- *Describe the molecular assays available for molecular analysis of hematological malignancies*
- *Evaluate the control and patient specimen results of molecular testing*
- *State the impact of the molecular result for patient care*

The final block would be designated as an elective or for research, to allow for flexibility as the training period ends.

Additional Educational Opportunities

Laboratory Orientation

Description:

- *To provide an overview of the different assays, platforms and work flow offered by the Advanced Diagnostic Laboratories, that includes Molecular, FISH, HLA and FLOW.*

Goals:

- *Understand the function of the different labs*

Objectives:

- *Compare and contrast various assays, platforms and workflow.*

HLA- Tissue Typing-Dr. Pedro Cano

Description:

- *HLA-tissue typing attempts to match a recipients HLA alleles with those of a donor to minimize the change of rejection*

Goals:

- *Understand the role of detecting HLA alleles for tissue typing in the clinical lab*
- *Understand how the results will affect patient treatment*

Objectives:

- *Explain the underlying biochemical and biological mechanisms defined for HLA tissue typing*
- *Analyze the strength and weaknesses of the different methods for HLA tissue typing*
- *Demonstrate reading and interpreting the data generated for HLA tissue typing*
- *Participate in reporting the results of detection of HLA tissue typing*

Molecular Genetic Consulting

Description:

- *Genetic counseling helps patients understand and cope with their risk for disease before and after molecular testing*
- *Biesecker, B. B. (2001). "Goals of genetic counseling." Clin Genet 60(5): 323-330.*
- *American Board of Medical Genetics and Genomics http://www.abmgg.org/*
- *National Society of Genetic Counselors http://www.nsgc.org/*
- *American Board of Genetic Counseling http://www.abgc.net/*

Goals:

- *Understand the effect of knowing or not knowing a molecular predicted disease risk on a patient and their family members*
- *Understand the best we ways to mitigate knowing or not knowing a predicted molecular disease risk*

Objectives:

- *Appraise the effects of genetic testing on patients and their families*
- *Detail Moffitt Cancer Center guidelines on genetic counseling*
- *Debate the genetic counseling implications of "incidental findings"*

Digital Pathology Supervised by Dr. Daryoush Saeed-Vafa

Description:

- *Digital pathology analyzes both brightfield and fluorescent images via various digital image analysis software environments and machine learning algorithms.*

Goals:

- *Understand the role of digital pathology in the clinical lab*
- *Understand how the results will affect patient treatment*

Objectives:

- *Recount the underlying biochemical mechanism defined for brightfield and fluorescent digital microscopy*
- *Evaluate the strengths and weaknesses of brightfield and fluorescent images in digital pathology*
- *Understand the role of digital image analysis software (HALO) in digital pathology*
- *Demonstrate reading and interpreting the data generated from digital image analysis software environments*
- *Justify the advantages of the digital image analysis in diagnostic and investigational pathology*

Research Project

Description:

- A research project provides an opportunity to critically evaluate a question of importance to pathology or assay development

Goals:

- To understand how research provides evidence based approach to drive medical treatment strategies
- To understand the methods used by research to test a hypothesis and to understand the results

Examples:

- Project 1: Comparison of the quality, quantity and amplification of DNA from matched frozen and formalin fixed tissues. What are the limitations of each source and utility of each source of DNA?
- Project 2: Identify the best method the decalcify tissue with the intent of recovering DNA or RNA for molecular analysis.

Objectives:

- Appraise current literature, available resources and potential impact of potential research projects
- Generate a hypothesis-testing project culminating in publication-worthy data analysis

ELECTIVE OPTIONS

The framework rotation schedule can provide flexibility, particularly in the latter half of the training period; substitution of approved rotations allowing for more detailed study in any of the listed areas is feasible. In addition, additional research rotations may be substituted with the approval of the Program Director. Available surgical pathology rotations at Moffitt include neuropathology, GI pathology, sarcoma pathology or head and neck pathology.

Evaluations

Evaluation of the fellows by the Faculty and Program Director.

Oral Exams

An informal mid-rotation assessment will be implemented by the Program Director based on feedback from faculty the fellow interacts with over the first 2 blocks. The fellow will be formally evaluated on a quarterly basis by the Program Chair, based on the knowledge acquired to date and based on the rotation schedule. Topics covered will include but are not limited to: Workflow and laboratory knowledge, federal and state law regulations, Moffitt Policy, Clinical Laboratory Organization (CAP) Guidelines, PyroSequencing, Sanger Sequencing, RealTime PCR, Next Gen Sequencing, Bioinformatics, Circulating Tumor Cells, Digital Microscopy, Nanostring, and Digital PCR.

360 Degree Evaluation
The fellows will be evaluated through the use of two forms; one is designed for molecular staff/faculty and non-molecular staff/faculty. Evaluations will be requested from faculty members that spend intensive time with the fellow on a monthly basis.

Summative Semi-Annual and Final Evaluations
The Program Director will meet with each fellow semi-annually to discuss performance and provide feedback. An evaluation will be completed for each meeting to provide objective assessment in the six core competencies. An Exit Interview will be completed and the Final Evaluation must include attestation that the fellow is ready for independent practice.

Evaluation of the faculty and the program by the fellows
The fellows will be required to evaluate the faculty and the program by means of an evaluation form at the end of the year. At any time the fellows may make suggestions on improving a given aspect of the program. The evaluations are reviewed by the program director and discussed at the molecular faculty meeting for any issues that may have arisen and needing attention. However, any negative evaluation regarding to individual faculty will be discussed after the fellow's graduation to prevent any fear of retaliation.

Evaluation of the program by the faculty
At the end of the year, a molecular faculty meeting, including the fellows, will be called to discuss the program, after an evaluation form has been completed and collected from the molecular faculty and fellows.

Evaluation of the program director by department chair
At the end of the year, the chair of the Pathology and Cell Biology Department at USF will evaluate the program director giving feedback on the chairs leadership and management of the program. In cases where the Chair of Anatomic Pathology also serves as the chair for the fellowship program a program evaluation will be conducted in lieu of an evaluation by the chair of the program director.

Conferences

Name of Conference	Frequency	Responsible Department	Required
Multidisciplinary Fellows Conference	*1/month*	*Hematology and Medical Oncology through Moffitt GME office*	*YES*
Core Lecture Series Fellow Conference	*Twice Weekly x 2 (July-Aug)*	*Moffitt Graduate Medical Education*	*YES*
Molecular Laboratory Meeting	*1/week*	*Moffitt Laboratory for Advanced Diagnostics*	*YES*
Pathology Department QA Meeting	*1/month*	*MCC*	*YES*

AP Grand Rounds: Updates in Multidisciplinary Oncology	*1/month*	*SRB and/or Virtual*	*YES*
CGAC Community	*1/month*	*Dr. Christine Walko*	*YES*
Personalized Medicine Group Journal Club	*1/month*	*Dr. Christine Walko*	*Yes*
Moffitt Cancer Center Department of Anatomic Pathology Fellows and Residents Weekly Conference	*1/week*	*MCC Anatomic Pathology Dept.*	*Optional*
USF Pathology Resident Lecture Series and Grand Rounds	*1/ week*	*USF Pathology Dept.*	*Optional*
Moffitt Cancer Center Grand Rounds	*1/week*	*Moffitt Cancer Center*	*Optional*

Multidisciplinary Fellows Conference:
Attendance at this conference is mandatory per the Moffitt GME office for fellows. The conference provides training in all aspects of multidisciplinary care of cancer patients and to enhance the integrated treatment approach of the Cancer Center. The conference is designed to address the biology, natural history, diagnosis, and management of cancer, as well as the humanistic, ethical, and professional issues in patient care. The fellows are required to attend without the responsibility of presentation.

Core Lecture Series Fellow Conference:
Attendance at this conference is mandatory for first year fellows rotating at Moffitt Cancer Center. The core curriculum is composed of didactic lectures, interactive case-based teaching sessions concerning the pathophysiology and clinical aspects of hematologic and malignant diseases, journal clubs, state-of-the-art presentations, roundtable discussions, case discussion conferences and tumor boards. Additionally, a number of intensive "mini-courses" have been developed to focus in greater detail on issues important to fellows. The fellows are required to attend without the responsibility of presentation.

Molecular Laboratory Meeting:
Attendance at this lab meeting is mandatory for all molecular fellows. Molecular fellows are required to attend and participate at this meeting.

Pathology Department QA Meeting:
Attendance at this meeting is mandatory for all molecular fellows. Fellows will be assigned and expected to complete a molecular focused safety/QA project. The Molecular Fellow is expected to actively participate at these meetings.

Anatomic Pathology Grand Rounds: Updates in Multidisciplinary Oncology
The fellow is, highly, encouraged to attend these conferences as they are an important supplement to their training. They provide a wide range of topics that assist healthcare professionals to keep up to date on important and evolving processes and procedures which may be outside of their core practice. Grand Rounds present the bigger picture, including the newest research and treatments in an area.

Moffitt Cancer Center Department of Anatomic Pathology Fellows and Residents Weekly Conference: These seminars are held on Monday mornings at 9:00 am.

USF Pathology Resident Lecture Series and Grand Rounds:
Attendees include medical students rotating on pathology, pathology residents, fellows in pathology, visiting scholars and occasionally pathology attendings.

Intradepartmental Anatomic Pathology Slide Review:
Interesting, challenging or problematic cases are discussed among the pathologists.

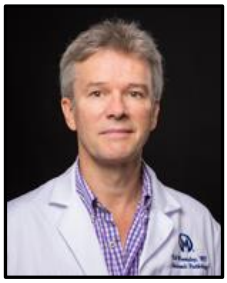
List of Molecular Pathology Faculty and Staff

Bruce Wenig, MD
Chair of Pathology and Program Leader

Lynn Moscinski, MD
CLIA Director of the Advanced Diagnostic Laboratories

Theresa Boyle, MD, PhD, FCAP
Program Director

Mohammad, Hussaini, MD
Associate Program Director



Robert Macaulay, MD, FRCPC
Clinical Competency Committee Chair

Carolyn Loret de Mola MLS (ASCP)^{CM}
Administrative Director of the Advanced Diagnostic Laboratories

Dahui Qin, MD, PhD
Director of the Molecular Laboratory

Christine M. Walko, PharmD, FCCP, BCOP
Personalized Medicine Clinical Service

Daryoush Vafa, MD
Director of the Advanced Analytical and Digital Laboratory

John Koomen, PhD
Director of the Mass-Spectrometry Laboratory

Kenian Liu, PhD
Director of the FISH Laboratory

Pedro Cano, MD
Director of the HLA Laboratory

Aik Choon Tan, PhD
Vice Chair, Biostatistics & Bioinformatics

Jamie Teer, PhD
Biostatistics and Bioinformatics

John Puskas, PhD (ASCP) [CM]
Molecular Scientist

Sean Yoder, MS
Core Facility Manager