2022 Summer OSEL Regulatory Research Experience (SORRE) Announcement

The Office of Science and Engineering Laboratories (OSEL) at the FDA Center for Device and Radiological Health (CDRH) accelerates patient access to innovative, safe and effective medical devices through best-in-the-world regulatory science. We are composed of scientists and engineers who have a broad diversity of expertise from microbiology, chemistry, physics, data science to artificial intelligence and machine learning.

The SORRE Program is hosted by the OSEL Diversity, Equity, Inclusion, & Belonging Council (DEI&B) to increase underrepresented students to perform regulatory science research at the U.S. Food and Drug Administration (FDA).

The program has several paid and unpaid opportunities for students to engage in OSEL's Regulatory Science Research Programs, which consist of a variety of research projects primarily focused on laboratory research of medical devices.

The OSEL Regulatory Science Project Catalog below describes opportunities available for the 2022 Summer program. Please read each project description as you will need to select your top three.

Open Date: January 18th, 2022
Close Date: February 18th, 2022

ELIGIBILITY

- Be currently enrolled in an accredited college or university and interested in a future career in STEM (science, technology, engineering, or math). Current High school students are also eligible to apply.
- Applicants must be able to meet applicable security requirements of the agency, which include completion of a background check. Completion of a background check requires individuals to have resided for a minimum of three of the past five years within the United States.

PROGRAM BENEFITS

- Explore future career opportunities in a regulatory science environment
- Working closely with a mentor in regulatory science research
- Cohort participants have the opportunity to:
    - meet as a group periodically throughout the program to develop and refine professional skills, practice science/technical oral and written communication, & build support networks
    - attend informal virtual lunches with the FDA Fellows Association (FFA) group to network with other FDA Fellows
    - attend the Summer Seminar Series hosted by the FFA to become familiar with the multi-disciplinary research at the FDA across all its Centers

HOW TO APPLY TO 2022 SORRE

Please submit one PDF document (in this order; cover letter & CV) to OSEL_DEI@fda.hhs.gov.

- The one-page Cover Letter could include:
  - Background about yourself
  - How does research interest or motivates you?
  - List of your top three projects and why; from the catalog below
- IMPORTANT: Due to COVID-19, the 2022 SORRE may be a remote experience and the projects may change
- If you have any questions, please contact us at OSEL_DEI@fda.hhs.gov.

The OSEL Regulatory Science Project Catalog

SUMMER 2022

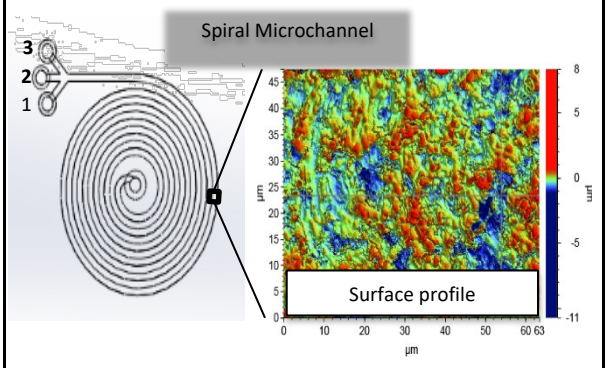
Office of Science Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

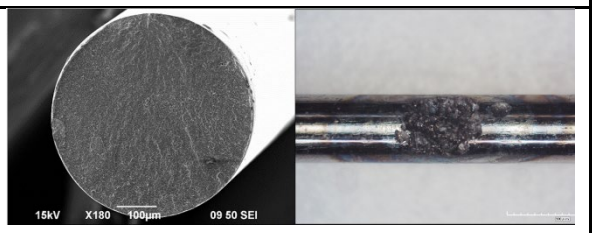
This catalog was put together to provide details for the current summer research opportunities offered in OSEL.

Division of Applied Mechanics (DAM)

The Division of Applied Mechanics DAM) within CDRH's Office of Science and Engineering Laboratories (OSEL) identifies and uses applied mechanics to investigate interactions between the human body and medical devices or radiation-emitting products.

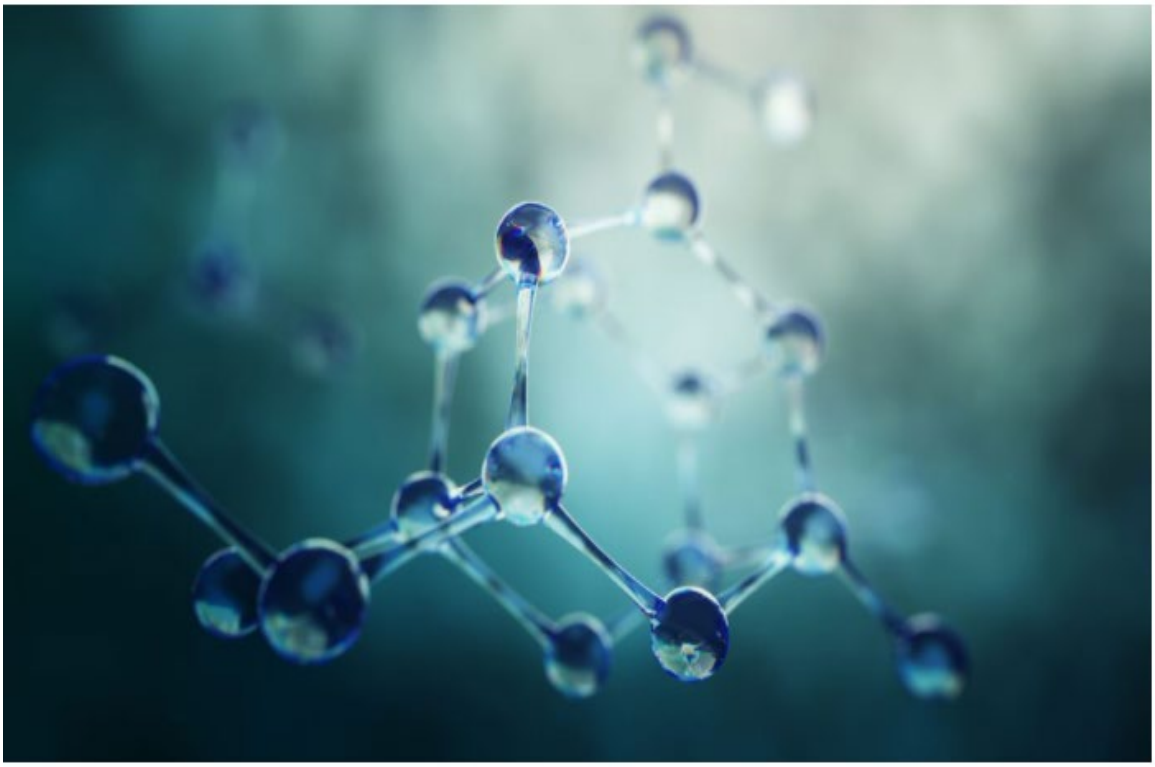
Develop Methodologies for Evaluating Blood Damage caused by Medical Devices U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Applied Mechanics **Mentor**: Megan Jamiolkowski, PhD	**Project Description:** Complications related to blood damage can occur in patients using blood-contacting medical devices such as catheters, ventricular assist devices, artificial heart valves, and extracorporeal circulation systems. The goal of this project is to develop bench test methods to better characterize blood damage (e.g., red blood cell damage, platelet activation, and blood clot formation) associated with medical devices and blood-contacting materials**.**
Position Requirements: Internship position for a student to work full-time for 10-13 weeks in the Blood Damage Assessment Lab on hemocompatibility research during the summer of 2022. This internship will require working with animal and human blood in biological safety hoods. A completed Hepatitis B vaccination record is required before starting the position. The position is open to college students studying in STEM majors, preferably with laboratory experience in bioengineering, biology, or chemistry. Due to the time-sensitive nature of blood experiments, the intern should be able to work on a flexible schedule (sometimes need to stay late on blood experiment days to finish experiments).	**Results:** This project will aid in the development of FDA testing guidelines and international standards for characterizing device-induced blood damage. During this research project, the intern will receive broad biomedical research training in various aspects of engineering and biological testing. The major tasks assigned to the intern will be to: 1) develop different engineering models for simulating physiologic blood flow through medical devices; 2) perform benchtop experiments using human and animal blood and characterize the extent of blood damage using various laboratory techniques such as spectrophotometry, microscopy, hematological analysis, and platelet activation assays; and 3) analyze experimental results, perform statistical analyses, and summarize the test data.

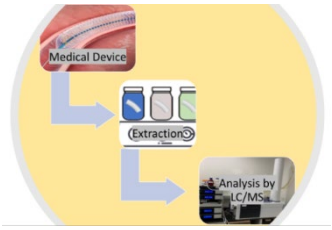
Study of fabrication methods used in microfluidics U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Applied Mechanics **Mentor**: Luke Herbertson, PhD	**Project Description:** This project aims to study the impact of different fabrication methods and materials options used for manufacturing microfluidic medical devices. The first step is to conduct market research, as well as gauge the academic and regulatory landscapes, to understand the trends in materials used and fabrication methods needed to produce current and emerging microfluidics-based medical devices. Micro-channels will then be designed using CAD software and fabricated in-house by the intern to study the flow phenomena in a representative channel design. Commercially available microfluidic systems will also be studied in this context to understand the effect of channel properties (surface roughness, material compatibility, hydrophobicity, geometrical features, and size) on fluid flow through small channels. The goal of this research is to provide FDA with a better understanding of the benefits and limitations of using different fabrication and processing techniques for manufacturing microfluidic diagnostic devices.
Specifically, the role of the intern will be to: • Understand different fabrication processes used in microfluidics and their advantages and disadvantages • Learn fabrication techniques like soft-lithography and micro-machining • Implement the principles of fluid mechanics to the micro-scale to understand different flow phenomena • Gain wet lab experience by performing bench testing of microfluidic medical devices • Use statistical analyses to quantify similarities and differences in device performance	

Improving the assessment of fatigue and corrosion performance of implantable metals U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Applied Mechanics **Mentor**: Jason Weaver, Ph.D.	**Goal of the Project:** This project's goals can be broadly classified into two areas- fatigue and corrosion. For the fatigue portion of the project, the goal is to improve fatigue testing of implantable nitinol devices by characterizing the Fatigue-to-Fracture (FtF) testing methodology and by better understanding factors affecting fatigue life. For the corrosion portion of the project, the goal is to improve corrosion susceptibility test methods and better understand how medical device implantation affects the local and systemic immune response.
Role of the Student: During this appointment, the participant will learn how to conduct fatigue tests with a rotary bend wire fatigue testing machine. They will learn how to use an optical microscope to evaluate important characteristics of fractured surfaces. They will additionally learn how to conduct cyclic potentiodynamic polarization corrosion testing on small metallic implants.	

The Division of Biology, Chemistry, and Materials Science (DBCMS)

The Division of Biology, Chemistry, and Materials Science (DBCMS) within CDRH's Office of Science and Engineering Laboratories (OSEL) comprises wide-ranging expertise to address a host of issues stemming from molecular-level interactions between the human body and medical devices or radiation-emitting products.



Advancing Chemical Characterization of Medical Devices U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, The Division of Biology, Chemistry, and Materials Science **Mentor**: Berk Oktem, Ph.D. DABT	**Goal of the Project:** Development of tissue-specific simulated extraction conditions that are relevant across a range of matrix materials and extractables of interest. 
Role of the Student: Student will participate on the preparation of samples, development of specific testing conditions, analysis using a diverse set of analytical chemist methods and processing of data.	**Description:** This highly visible project is designed to do an extractable study where true body fluids -starting with blood- will be closely studied with target specific methods that are tolerant to highly cluttered samples, as in the case with body fluids. This will enable measurement of extraction power of the body fluids and enable piecewise characterization of the body fluid extraction power by synthetically recreating those components and verifying the extraction power. with state-of-the-art analytical techniques such as Liquid chromatography/ mass spectrometry (LC/MS). Methods developed in this project will be included in CDRH tools catalog which will help to assess the safety and effectiveness of a medical device.

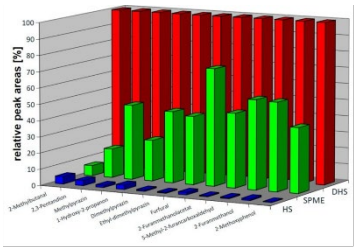
Program: Advancing Chemical Characterization of Medical Devices

U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, The Division of Biology, Chemistry, and Materials Science

Mentor:
Samanthi Wickramasekara Ph.D.

Goal of the Project:

Development of standardized medical device sample processing methods to meet requirements of analytical thresholds in regulatory standards



Relative quantification of commonly found volatiles using different analysis methods; HS-head space ; SPME-solid phase microextraction; DHS- dynamic head space

Role of the Student:
Student will participate on the preparation of samples, development of specific testing conditions, analysis using a diverse set of analytical chemistry methods and processing of data.

Description:

Project is designed to evaluate the impact of extract processing techniques on recovery of representative compounds. Various sample extraction and chemical analysis methods will be tested. The student trainee will get hands on experience in different extraction/processing methodologies such as solid phase extraction (SPE), Liquid-liquid extraction (LLE), Solid phase micro extraction (SPME), Dynamic head space (DHS) along with state-of-the-art analytical techniques such as gas chromatography / mass spectrometry (GC/MS), Liquid chromatography/ mass spectrometry (LC/MS). Methods developed in this project will be included in CDRH tools catalog which will help to assess the safety and effectiveness of a medical device.

Program: Advancing Next Generation Sterilization Modalities for Medical Devices U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, The Division of Biology, Chemistry, and Materials Science **Mentor**: Jon Weeks, Ph.D.	**Goal of the Project:** Development of a multi-dimensional risk assessment tool to assess risks associated with changes in medical device sterilants. This project will begin by assessing the risks associated with changes from ethylene oxide to vaporized hydrogen peroxide. The larger goal is to develop a framework that can be used to assess risks associated with changes from ethylene oxide to other gaseous sterilants or radiation-based sterilization.
Role of the Student: Student will participate in a robust literature review of materials compatibility with vaporized hydrogen peroxide. They will assess peer-reviewed literature, FDA guidance documents, and relevant guidance and standards from international and national standards organizations.	**Description:** This highly visible project is aimed to assist medical device manufacturers to assess the risks associated with sterilant changes in an effort to reduce the industry's over reliance on ethylene oxide. The comprehensive literature will compile the existing body of evidence while future research (including research collaboration agreements) will fill holes. Together this information will be developed into a CDRH regulatory science tool and will be added to the CDRH tools catalog to which will help to assess the safety and effectiveness of a medical device.

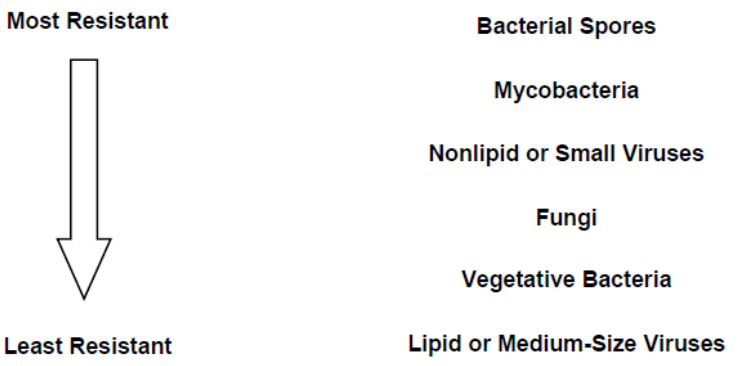
Program: Advancing Next Generation Sterilization Modalities for Medical Devices

U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, The Division of Biology, Chemistry, and Materials Science

Mentor: Jon Weeks, Ph.D.

Goal of the Project:

Development of microbiological tool to assess the hierarchy of resistance of microorganisms to sterilants.

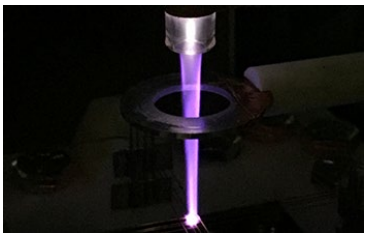


Modified from Favero, M.S. and Bond, W.W., Chemical Disinfection of Medical and Surgical Materials. In: Disinfection, Sterilization, and Preservation, 5th Ed Phila: Lippincott Williams & Wilkins 2001: 881-917.

Role of the Student:
Student will participate in selection of microorganisms for resistance testing. They will learn microbiological test methods and data analysis.

Description:

This highly visible project is aimed to amass a collection of microorganisms to be used for microbiological testing for the development of novel sterilants. Standard and developed microbicidal testing methods will be used to assess the resistances of the microorganisms. Data will be used to characterize the hierarchy of resistances and a platform for other alternative sterilants. The outputs from this project will be included in the CDRH tools catalog which will help to assess the safety and effectiveness of sterilants used to process medical devices.

Program: Emergency Preparedness, Decontamination of PPE (Personal Protective Equipment) Using Cold Plasma and Other Modalities U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, The Division of Biology, Chemistry, and Materials Science **Mentors**: Steven Wood, PhD Enusha Karunasena, PhD	**Goal of the Project:** These findings may inform a framework (a regulatory science tool) for how the FDA assesses new decontamination technologies for single-to-multi-use PPE.  https://www.nsf.gov/discoveries/disc_summ.jsp?cntn_id=300669&org=NSF&from=news
Role of the Student: The student will be trained in the proper use of the cold plasma device to assist in the execution of the PPE decontamination assays. The student will also be coached in presenting the research to the Infection Control research group at the end of the summer internship.	**Description:** This project is a collaboration between FDA and George Washington University. As the medical device ecosystem seeks to develop and regulate innovative technologies for decontamination, this project will examine the ability of cold plasma to inactivate virus particles on PPE materials, as well as the effect of the plasma on the material itself. Cold Plasma is not as harsh as typical decontamination modalities and might therefore serve as a good model to develop a framework for decontamination modalities to be used on PPE that is normally designed for single use, but in emergency/pandemic situations, may need to be used multiple times.

Division of Biomedical Physics

The Division of Biomedical Physics (DBP) participates in the Center's mission of protecting and promoting public health by identifying and investigating the biophysical interactions between medical devices and the human body.

Assessing Wearable ECG Analysis Algorithms During Noise and Motion Conditions

OSEL Program: Patient Monitoring and Control
Division of Biomedical Physics

Mentor: Christopher Scully, PhD

Goal of the Project

Patient monitoring devices that continuously process physiologic signals can be subject to poor performance due to noise and motion artifacts recorded in the signals. Our team has developed a method to improve the assessment of ECG analysis algorithms during noise and motion conditions. We will be performing a clinical study to collect ECG data on human subjects for validating our method. We are looking for a student to help with data analysis and processing of physiologic signals recorded during the clinical study.

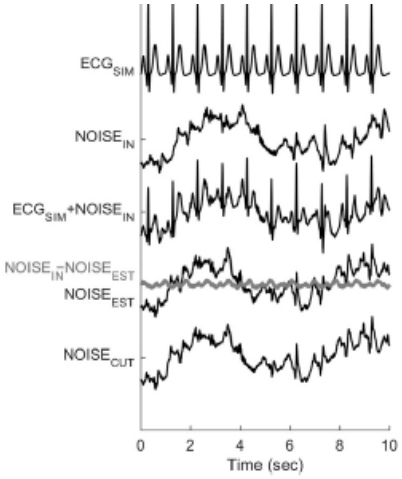
Role of the Student:

- Apply signal processing techniques to characterize cardiovascular signals (electrocardiographs)
- Develop and verify new software routines using high level programming languages (e.g., Matlab, Python) for processing physiologic signals
- Perform statistical analyses and present results to a team of biomedical scientists
- Draft reports detailing the methods applied and results of work over the project period

Expectations with the Project:

- Contribute to a project developing a regulatory science tool for improving the development of novel wearable ECG devices
- Lead to the public availability of software code for implementing a method to characterize arrhythmia analysis algorithm performance during noise and motion conditions
- Gain experience with cardiovascular signal analysis, physiologic signal algorithm development, software development, data analysis and presentation

Example of Estimating ECG Signal Noise for Device Testing (Galeotti and Scully, Journal of Electrocardiography, 2018)



OPH Ophthalmology

Image analysis of microglia morphology as a tool for rapid detection of neurotoxic compounds

Mentor: Ethan Cohen, PhD

Microscopy/physiology.

DEI&B candidate would help with microglia cobalt toxicity experiments, process counts on microglia. Pharmacology.

Learn about retinal anatomy and function.

Time Lapse confocal microscopy.

3 months

Also, Haohua Qian NEI/NIH

Joseph Hanig OTR/CDER

Specific Aims

Identify the ion selectivity of the constitutively active divalent cation channels causing microglia filopodia activation.

(Co2+, Cd2+, Ni2+)

Pharmacologically identify the Co2+ channel mechanism causing retinal damage and the retinal cell types injured. Use known mixed cation channel blockers. L-type calcium channel antagonists /nimodipine., AMPA/KA receptor, NBQX, Is ATP released (Pannexin probenacid,)?

Determine how the retinal structure is altered by real-time OCT of the retina in the presence of cobalt.

Measure how the retinal layers are altered by Co2+ and does swelling of the layer correlate with local microglia activation- i.e., hairs/contraction.

1. **Objective**: Determine the pharmacology of the constitutively active channels in the retina that are permeable to cobalt and cadmium causing rapid retinal toxicity. Unlike the many hours needed to activate TLR4, HIF1alpha, or metallothionine, Co2+ and Cd2+ cause unusually rapid retinal toxicity on the order of minutes. These channels may play role in joint implant retinopathy.

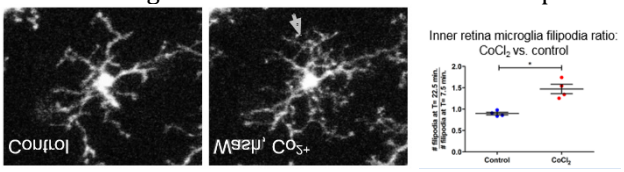
2. **Expected Outcomes**

Identify the divalent ion selectivity of the damage mechanism causing microglia activation.

Identify the ion channel pathway causing retinal damage and the retinal cell types injured. Is ATP released?

Determine how the retinal structure is altered by real-time OCT of the retina in the presence of cobalt.

Concept: Use normal CX3CR1 EGFP+ transgenic mice where microglia are labeled with fluorescent report



er proteins.

Method: Confocal microscopy, optical coherence microscopy.

Time-lapse confocal microscopy of eyecup/isolated mouse retina microglia to divalent metal ions like Co2+.

Filopodia process counts vs exposure time.

Pharmacological blockers of potential ATP release pathways, Probenacid blocker of ATP-activated Pannexin channel.

Optical coherence microscopy to compare swelling the confocal microglial activation.

Chronic Effects of Cardiac Contractility Modulation Stimulation in 3D Human Engineered Heart Tissues

OSEL Program: Cardiovascular Electrophysiology

Mentor: T.K. Feaster Ph.D.

Goal of the Project:

- Evaluate mechanisms of safety and efficacy of Cardiac Contractility Modulation (CCM) medical devices.
- Extend our previous studies of acute effects of CCM on 2D hiPSC-CMs, to chronic CCM assessment in 3D human Engineered Heart Tissues (EHTs)
- Accelerate key cardiovascular program charter effort and enhance existing project goals.
- Previously we demonstrated and quantified the acute effects of clinical CCM parameters on 2D hiPSC-CM function in vitro (Feaster et al. 2021). Next, in this DEIB project, we will elucidate the chronic effects (e.g., Days) of CCM on 3D hiPSC-CM function, mitochondrial activity, structure and molecular profile to determine which model best recapitulates the clinical CCM response.

Role of the Student:

- Learn human induced pluripotent stem cell derived cardiomyocytes (hiPSC-CMs) handling and culture techniques.
- Generate human 3D EHTs.
- Perform literature review.
- Learn how to evaluate cardiac functional readouts (i.e., Electrophysiology, Calcium Handling and Contractility).
- Learn how the scientific method is applied to regulatory science.
- Learn data analysis, report generation and present data to a regulatory scientist and engineers.

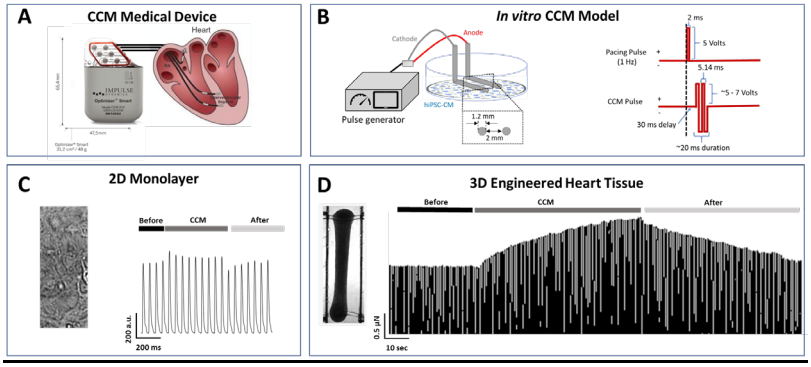
Expectations with the Project:

- Contribute to the development of an in *vitro* human iPSC-CM Cardiac Contractility Modulation Regulatory Assessment Tool.
- Gain regulatory science experience and develop skills to evaluate human cardiac function at the bench.
- Contribute to CCM peer- reviewed publication

Acute effects of CCM on hiPSC-CM Contractility: (CCM Project, PI: Feaster and Blinova, 2021)

- hiPSC- CMs respond to acute clinical CCM stimulation
- CCM stimulation enhances contraction and relatxation rate
- CCM effects are in part mediated by β-adrenergic signaling
- CCM increases calcium sensitivity

CCM enhances contractility in 2D and 3D hiPSC-CM models:



References:

Feaster et al. 2015, doi: 10.1161/CIRCRESAHA.115.307580

Blinova et al. 2017, doi: 10.1093/toxsci/kfw200

Blinova et al. 2018, doi: 10.1016/j.celrep.2018.08.079

Gintant et al. 2020, doi: 10.1016/j.yrtph.2020.104756

Feaster et al. 2021, doi: 10.14814/phy2.15085

Evaluation of Mathematical Models of Respiratory Systems under Instructed Breathing Patterns

OSEL Program: Patient Monitoring and Control
Division of Biomedical Physics

Mentor: Ramin Bighamian, PhD

Goal of the Project

Physiological closed loop controlled (PCLC) medical devices can encounter many modes of failure and instability. In silico assessment of a single PCLC or multiple interactive PCLC medical devices is a vital step toward evaluation of their performance under normal and worst-case conditions. PCLC devices for critical care such as ventilators and fluid management are being developed. Our team has developed mathematical models for closed-loop fluid management. However, mathematical models of respiratory system remained to be investigated. We are collecting respiratory physiological data from healthy subjects under different breathing tasks. We are looking for a student to help us investigate existing mathematical models of respiratory systems using the collected data.

Role of the Student:

- Perform literature review
- Identify most relevant mathematical models of respiratory system
- Apply signal processing techniques to characterize collected respiratory signals
- Implement physiological models using high level programming languages (Matlab, Python)
- Perform systems-level model assessment to identify aspects to be improved/refined within each model
- Draft reports and present results to a team of biomedical scientists

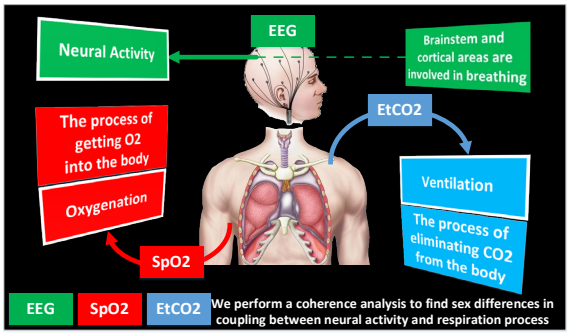
Expectations with the Project:

- Contribute to enhance, develop, and validate mathematical models of respiratory systems
- Contribute to a project developing a regulatory science tool for in silico assessment of PCLC respiratory management.
- Gain experience with respiratory signal analysis, model/software development, data analysis and presentation

Different Patterns of Breathing Tasks for Data Collection: (OWH project, PI: Bighamian, 2021)

- Normal breathing (baseline)
- Inspiratory breath hold
- Fast breathing
- Deep breathing

Other Physiological Variables to Be Collected:



Developing a hemodynamic platform for testing pulse contour cardiac output Algorithms

OSEL Program: Patient Monitoring and Control
Division of Biomedical Physics

Mentor: Masoud Farahmand, PhD

Goal of the Project

Performance testing of a new cardiac output monitoring device typically involves clinical studies comparing the device to a reference method. This inhibits rapid iteration of new device designs, limiting innovation that can lead to improved performance. We are taking a regulatory science approach to develop complementary and alternative bench performance testing for new hemodynamic monitoring devices to better understand how they perform and to potentially reduce clinical testing requirements. The student will help our team with bench testing, data collection and analysis.

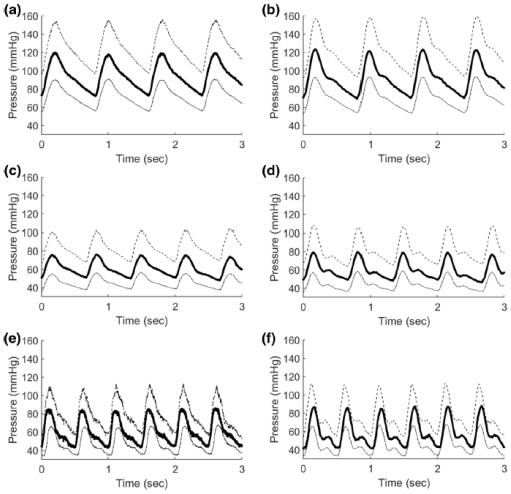
Role of the Student:

- Develop, design, prototype, and evaluate testing platforms including physiological pressure signal simulators, and mock flow loops
- Optimize our custom programs in Matlab for data acquisition and instrumentation
- Apply signal processing techniques to analyze, extract, optimize, and automat data cleaning and feature selection to extract relevant information from large pressure and flow time series
- Participate in redesign a previously developed flow loop platform for integration with blood oxygenation tuning system and phantoms
- Draft reports and present to teams of scientists, and engineers

Expectations with the Project:

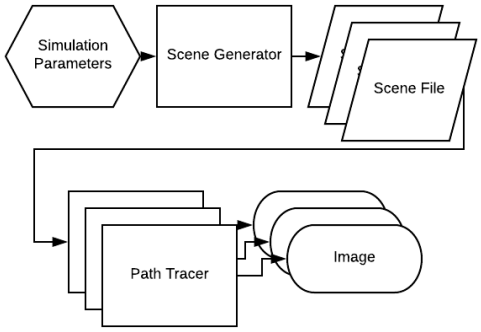
- Participate in the development of regulatory tools for testing advanced hemodynamic monitoring systems
- Contribute to peer-reviewed publication
- Gain experience with physiologic signal processing, instrumentation and data acquisition

Example of Pressure waveforms generated by the flow loop (Packy, Farahmand, Scully; Cardiovascular *Engineering and Technology*, 2021)

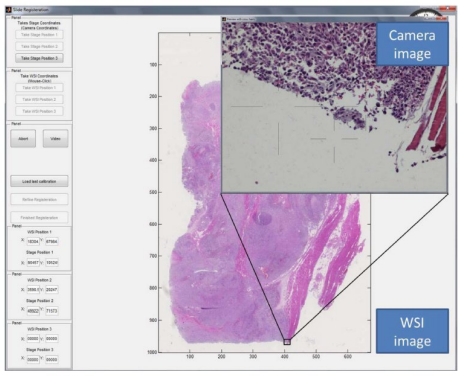


The Division of Imaging, Diagnostics and Software Reliability (DIDSR)

The Division of Imaging, Diagnostics, and Software Reliability (DIDSR) within CDRH's Office of Science and Engineering Laboratories (OSEL) develops methods for evaluating the image quality of emerging imaging systems; develops methods for characterizing new medical image display devices; evaluates the dose reduction potential of new image reconstruction methods, and assesses the performance of Artificial Intelligence and Machine Learning algorithms. DIDSR also develops state-of-the-art methods for the design of clinical trials involving imaging devices and the evaluation of resulting trial data to enable more efficient and effective utilization of imaging data and more powerful clinical studies.

Develop photorealistic in silico imaging of skin in support of algorithmic decision making for medical diagnostic devices. U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Imaging, Diagnostics and Software Reliability **Mentor**: Aldo Badano, PhD	**Goal of the Project:** An internship is available in DIDSR/OSEL/CDRH/FDA to develop photorealistic in silico imaging of skin in support of algorithmic decision making for medical diagnostic devices. This work includes using physically based rendering tools (e.g., mitsuba2) coupled with pipeline scripting for large scale simulation in a high-performance computing cluster and inclusion of state-of-the-art 3D lesion models.
Role of the Student: This work includes using physically based rendering tools (e.g., mitsuba2) coupled with pipeline scripting for large scale simulation in a high-performance computing cluster and inclusion of state-of-the-art 3D lesion models.	

Multi-class evaluation metrics for evaluation of medical devices U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Imaging, Diagnostics and Software Reliability **Mentor**: Kenny Cha, PhD	**Goal of the Project:** Survey and evaluation of metrics used for multi-class evaluation to identify those that could potentially be used to evaluate a medical device
Role of the Student: The student will conduct a survey on multi-class metrics and work to characterize those metrics to understand their strengths and weaknesses.	**Example of multi-class medical device application area for skin lesion classification** 

High Throughput Truthing (HTT) of pathologist annotations as a reference standard for validating artificial intelligence in digital pathology U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Imaging, Diagnostics and Software Reliability **Mentor**: Brandon Gallas, PhD	**Goal of the Project:** The MDDT qualified data would be available to any algorithm developer to be used to validate their algorithm performance in a submission to the FDA/CDRH. In collaboration with internal and external subject matter experts, the project will develop data-collection and data-analysis methods and tools.
Role of the Student: • During the research appointment, the fellow will learn how to communicate professionally and effectively with an interdisciplinary collaborative team. • They will apply statistical and data science tools, such as git and R, for pre-processing of data and data analysis • The student will learn how to work with web applications, and application programming interfaces to modularize code for data collection • As part of the team, the participant will have the opportunity to learn about statistical measures of variance and intra-/inter-reader reliability, and how to implement them with custom-build software packages.	 Figure 3. Screen shot of the registration interface including the real-time microscope field of view as seen with the mounted camera ("Preview with cross hairs" window).

Develop spectral small-angle x-ray scattering (sSAXS) system and method for estimating brain amyloid burden in Alzheimer's disease (AD). sSAXS imaging system is based on capturing the sSAXS signature of amyloid plaques per scanned location using a polychromatic x-ray beam, a spectroscopic photon-counting detector, and a 3-axis motorized sample stage. U.S. Food & Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Division of Imaging, Diagnostics and Software Reliability **Mentor**: Eshan Dahal	**Goal of the Project:** The fellow will be part of a project that will develop spectral small-angle x-ray scattering (sSAXS) system and method for estimating brain amyloid burden in Alzheimer's disease (AD). sSAXS imaging system is based on capturing the SAXS signature of amyloid plaques per scanned location using a polychromatic x-ray beam, a spectroscopic photon-counting detector, and a 3-axis motorized sample stage. Towards this effort, the fellow will assist in automating sSAXS measurements using LabView and test the 2D and 3D imaging capability of the prototype for estimating amyloid burden in the brain.
Role of the Student: • The participant will gain experience with LabView programming to control and automate imaging experiments in a prototype x-ray system. • The participant will learn to perform experimental measurements to characterize a newly designed sSAXS imaging system. • The participant will learn about imaging methods for amyloid burden estimation in Alzheimer's disease.