



## CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

### UMCCTS Undergraduate Clinical Research Internship Program Confirmed Summer 2024 Placement Opportunities

#### **Cancer Research Office**

Principal Investigator: William Walsh, MD

Mentor: Cara Gregoire, RN, BSN, MHA

Location: UMass Chan Medical School-Worcester

The Cancer Research Office supports adult hematology oncology clinical trials. We usually have around 40-50 trials open to accrual with around 10 in the startup/feasibility phase. Our office consists of clinical research nurses and coordinators with various backgrounds who have come together to work toward advancing cancer treatment and prevention efforts. The idea of this project is to provide an overview of a successful clinical research program, as a well-rounded clinical research professional is integral to that program.

As trials tend to move slowly through their lifespan, our plan is to have the intern follow a few different trials through feasibility, protocol review, start up, and enrollment. The intern will be involved in reviewing protocols, participating in feasibility calls/assessments, observing patient care, interactions with sponsors, collection of data, and medical record review. They will attend weekly multi-disciplinary tumor boards and participate in weekly team meetings.

The ideal candidate will be assertive, motivated, genuinely interested in clinical research, and possibly the medical field/nursing, be detail oriented, have some pre-existing medical knowledge, and be interested in oncology. They should have excellent critical thinking skills and an ability to multi-task. They should feel comfortable asking questions.

#### **Clinical Research Center**

Principal Investigator: Katherine Luzuriaga, MD

Mentor: Bethany Trainor, RN, BSN, CCRP; Rafael Fernandes, MS

Location: UMass Chan Medical School-Worcester

The UMass Chan Clinical Research Center (CRC) is dedicated to providing efficient, reliable and high-quality study support for UMass clinical investigators. Interns can expect to work with CRC team members in a variety of capacities on protocols currently being worked:

- Phase 2/3 COVID Infant Vaccine Study with pediatric participants aged 12 weeks to 6 months
- Phase 2/3 Human Growth Hormone studies with pediatric participants with Growth Hormone Deficiency
- Phase 1 Adult EBV Double-Blinded Randomized Vaccine Study
- Phase 1 Adult RSV Double-Blinded Randomized Vaccine Study

The Clinical Research Center is also the home to various clinics that help & treat patients with their respective medical condition, and our department collaborates & assists with other departments with current ongoing trials:

- Dr. Wei-Che Ko's Dermatology Clinic
- Dr. John Harris' Vitiligo Clinic
- Dr. Brenda Wong's Duchenne Muscular Dystrophy Clinic
- The ALS Clinic
- Department of Radiology
- Department of Neurology

This team will provide hands on experience with participants and general research coordination, database management, hands-on lab training, specimen processing, and IRB/regulatory work with mentors. Interns can expect to participate in a developing educational program intended to create strong foundational clinical research knowledge and habits. This is done in tandem with the required Introductory Coordinator Training course. The Clinical Research Center is a busy clinic with many opportunities to observe and get involved in studies and general clinic experiences with potential for follow up phone calls and screening experiences as well.

Candidates must have the ability to work with patients and in a busy clinic, be interested in learning from multiple researchers/Nurses/MDs, and able to work with all age groups.

### **Department of Dermatology**

Principal Investigator: John E. Harris, MD, PhD

Mentor: Celia Hartigan, RN, MPH

Location: UMass Chan Medical School-Worcester with occasional visits to UMass Memorial Medical Center-Hahnemann Campus (2.5 miles away)

We have a very active research group with multiple investigators researching skin conditions such as vitiligo, lupus, contact dermatitis, allergic contact dermatitis, epidermolysis bullosa, hidradenitis suppurativa, mycosis fungoides, and others. Our clinical research team includes investigators, nurses, research fellows, and coordinators.

Interns will learn to screen and enroll subjects, work directly with subjects to complete study visits including vital signs, EKGs, phlebotomy, sample processing, data entry, query resolution, and scheduling next study visits according to the protocol and visit window. They will also maintain the subject research binder and proper documentation. Exposure to regulatory requirements such as IRB submissions is available.

Most research visits occur in the Clinical Research Center, but we also go to the Hahnemann Campus when needed. We see adult and pediatric patients. Research staff attends weekly lab meeting Tuesday mornings, and vitiligo specialty clinic Tuesday afternoons. Other clinics to observe are available if interested.

Interns must be organized, be able to multi-task, pay attention to detail, ask questions, and work collaboratively with multiple investigators.

## **Department of Emergency Medicine**

Principal Investigators: Chad Darling, MD, MSc & Evan Bradley, MD, PhD

Mentor: Jill Anderson, MAT, MPH

Location: UMass Chan Medical School-Worcester

Project 1: Traumatic Intracranial Hemorrhage Risk in Patients Presenting to the Emergency Department After Blunt Head Injury

Project 2: Phase IV Pneumococcal Vaccine Efficacy

Our projects are ideal for a summer intern as they provide opportunities for short-term involvement and have a relatively straightforward research protocol. The projects support learning in the following domains: the basics of IRB submission, research protocols, subject recruitment, data entry (REDCap) and management, preparing brief presentations on project progress, assisting PIs with fundamental data analysis, performing patient follow-up, and training regarding abstract development. In addition, we have a hospital-based prospective clinical trial that can provide a great deal of contact with clinicians, patients, and caregivers. This will allow the intern to better understand the clinical research environment and gain knowledge and skills in clinical trial management. We will also involve the intern in future abstracts or publications that arise from this research. Most importantly, the intern will gain significant experience working within a research team for the summer, including physicians, research assistants, and medical students.

Our current project is an epidemiologic study related to emergency medicine and trauma. An intern interested in public health and trauma research will find our work relevant to their studies. In addition, they will also have an opportunity to be involved in a separate hospital-based clinical trial. They will be collecting biospecimens and can enroll patients as part of this research protocol. They should be comfortable interacting with patients and caregivers. No prior experience with patient interaction is necessary.

## **Department of Medicine**

Principal Investigator: David McManus, MD

Mentor: Edith Mensah Otabil, BA

Location: UMass Chan Medical School-Worcester

Project 1: Risk Underlying Rural Areas Longitudinal Study (RURAL)

Project 2: Integrative Mindfulness-Based Predictive Approach for Chronic low back pain Treatment Study (IMPACT)

We are currently conducting two studies with which our matched intern will be involved. For Project 1, the RURAL study will allow researchers to learn what causes the high burden of heart, lung, blood, and sleep disorders in Kentucky, Alabama, Mississippi and Louisiana and address gaps in knowledge and how to alleviate them. As part of the study, participants will receive a free Fitbit which will be used to collect data related to daily physical activity (e.g., number of steps and heart rate). A smartphone will be used to complete surveys throughout the course of the study.

For Project 2, the IMPACT study will allow researchers to assess whether physical markers (for example: activity, sleep, and heart rate), emotions, and the quality of the relationships in someone's life can help predict how people with long-term back pain will respond to mindfulness treatment. Researchers will utilize a unique machine learning approach to determine the biomarker signature of persons undergoing mindfulness-based stress reduction treatment for their chronic low back pain. As part of the study, participants will receive a smartwatch to collect physical activity, sleep, heart rate data for the entire duration of the study and answer some survey questions. The results of this study may be used to help doctors make better decisions and provide more focused care for people who have chronic pain.

Learning opportunities for interns will include the following:

- Learn about the daily activities of a research coordinator along with different types of clinical research and clinical trials in cardiovascular and digital medicine.
- Gain clinical experience through interaction with study participants.
- Analyze data critically to promote scientific curiosity.
- Gain exposure to the complex interplay of research and patient care.

## **Department of Neurology**

Principal Investigator: Lawrence Hayward, MD, PhD

Mentor: Catherine Douthwright, PhD

Location: UMass Chan Medical School-Worcester

Project 1: Biomarkers in Facioscapulohumeral Muscular Dystrophy (FSHD)

Project 2: Study of the Efficacy and Safety of Losmapimod in Treating Patients with Facioscapulohumeral Muscular Dystrophy

The visiting intern will learn about Facioscapulohumeral Muscular Dystrophy (FSHD), which is a progressive and debilitating neuromuscular disorder. They will learn the process of informed consent and will experience all aspects of a patient's clinical research journey from enrollment to end of study. They will perform clinical assessments, such as vital signs and ECG collection, while working with patients directly. They will also assist with sample processing, learning basic laboratory skills, and will assist with all aspects of data management, from data collection to data entry and query resolution. We have an active phase 3 interventional study as well as an observational biomarker collection study, to allow the intern to gain experience in different types of clinical research. The intern would be working alongside our current research coordinator but must also be organized and be able to work independently.

## **Department of Pediatrics/NICU**

Principal Investigator: Lawrence Rhein, MD, MPH

Mentors: Anjana Bhami Shenoy, MBBS and Heather White, MPH

Location: UMass Memorial Medical Center, Memorial Campus [Note: The first, foundational training week (5/28-6/3) will be held at UMass Chan Medical School-Worcester, 1 ½ miles away.]

Project 1: VIGOR: Virtual Genome Center for Infant Health

Project 2: The Effect of ShotBlocker on Pain in Full Term Infants Undergoing Intramuscular Injection: A Randomized Controlled Trial

Project 3: Apnea, Bradycardia, and Desaturation Events During Infant Bottle Feeding in the Neonatal Intensive Care Unit

In working on Project 1, interns will learn to screen and recruit study subjects, interact with families and clinical staff in the NICU, collect data from the electronic medical record, and present study progress at weekly team meetings. Additionally, they will learn about the IRB process, specifically a multi-site relying study, and assist in preparing regulatory documents for study modifications. Through Project 2, the assigned intern will learn how to screen and consent families, coordinate study procedures with nurses in the newborn nursery, collect and enter data into an electronic data capture, and maintain regulatory documents. Through Project 3, the intern will work with nurses and nutrition specialists in the NICU in an observational, prospective study. This study will primarily be driven by the assigned intern, and the principal investigator and mentor will oversee the project and provide advice at regular intervals. This experience will allow the intern to experience and develop the necessary research skills to conduct their own study.

Additionally, the intern will gain experience working and collaborating with different members that make up a research team and provide infrastructure support. This will include attending physicians, mid-level providers, NICU fellows, nurses, and research team members. Interns also can participate in shadowing, weekly learning opportunities, and conferences going on in the division.

The NICU research team is seeking an organized, motivated individual with good communication skills who is looking to learn more about the daily operations of pediatric clinical trials.

Our offices are located on the Memorial Campus, 119 Belmont St. The intern must have transportation to and from the University Campus for panel presentations.

## **Department of Pediatrics/NICU**

Principal Investigator: Meg Parker, MD, MPH

Mentor: Lindsey Simoncini, MPH, CCRC

Location: UMass Memorial Medical Center, Memorial Campus [Note: The first, foundational training week (5/28-6/3) will be held at UMass Chan Medical School-Worcester, 1 ½ miles away.]

Project 1: Social Determinants of Health Screening and Referral in US NICUs

We are conducting a national study to implement and examine the effectiveness of SDH screening and referral in safety-net NICUs. The roles of the intern(s) would involve assistance with development of

study tools, data collection instruments, and qualitative assessments of NICU teams. This may also involve examining policies and resources to help families connect to resources in states across the US and reviewing tools with actual families. Overall, this would provide exposure to a national social disparities research project and provide foundational skills in health services research conduct.

#### Project 2: Support for Low-Income Mothers of Very Low Birthweight Infants

We are conducting a multicenter randomized controlled trial to examine the impact of financial transfers on maternal caregiving behaviors including breastfeeding and skin-to-skin care in Medicaid-eligible mothers of VLBW infants. The role of the intern in this study would be to assist with screening, recruitment, enrollment, and data collection activities. They would also assist with maintaining the master database for all 4 participating sites and conducting data audits.

Through both of these projects, the intern will be able to contribute to conceptual design of studies, develop and maintain databases, collect and clean data, develop and present abstracts, and interact with diverse families as part of research activities. Additionally, the intern will gain experience working and collaborating with different members that make up a research team and provide infrastructure support. This will include attending physicians, midlevel providers, NICU fellows, nurses, and research team members.

### **Health Informatics and Implementation Science**

Principal Investigator: Ben Gerber, MD, MPH

Mentor: Jessica Wijesundara, MPH, CHES

Location: UMass Chan Medical School-Worcester

The Division of Health Informatics and Implementation Science (HIIS) is seeking an intern interested in population-based research, particularly those involving technology for behavior change. Interest in clinical, consumer, and public health informatics is valued, along with experience in Word, Excel, and PowerPoint. Strong organizational, interpersonal, and written communication skills are necessary.

The intern will work on 3-4 research studies focused on:

1. Training medical residents in weight management counseling.
2. Evaluating continuous glucose monitoring for people with type 2 diabetes.
3. Helping Spanish-speaking patients engage with diabetes self-management training through text messages and digital health training.
4. Studying best practices for clinicians to communicate safety information via text.

Interns will assist with various study tasks, including recruitment and enrollment activities, consenting research participants, data collection, survey administration, assisting with reports, literature reviews, and data organization, and attending project meetings. They will also be able to collaborate with experienced mentors on their own research project using the All of Us Researcher Workbench platform. This includes identifying a research question, literature review, protocol development, data acquisition, management, and statistical consulting through the Quantitative Methods Core when needed.

This internship provides practical experience for individuals interested in population/public health research to learn various research methods, protocols, and topics.

## **Departments of Neurology and Ophthalmology**

Principal Investigator: Kevin E. Houston, OD, MSc, FAAO

Mentors: Kevin Houston, OD, MSc, FAAO and Michelle Manxhari, CRC

Project 1: Head-cancelled virtual reality for rehabilitation of ocular cranial nerve palsies.

Ocular cranial nerve palsies affect 15% of stroke patients with extended hospitalization. Subjects perform 3 tasks in VR: Coin sorting, saccades, and video game play, under 2 conditions: normal view and head cancelled view. We are studying the potentially positive effects of head cancelled viewing by analyzing differences in the extent of eye movements.

Project 2: Magnetic Re-animation of the Eyelid

Severe paralysis of eyelid opening is an uncommon but visually impairing consequence of stroke, severe head trauma, and neuromuscular disease. Current management options act to elevate the lid mechanically, preventing full eye closure. This project involves a clinical trial comparing two new devices for non-invasive restoration of eyelid motility. Outcome measures include comparison of eyelid kinematics measured using artificial intelligence (AI) and machine learning algorithms which attempt to automatically recognize facial features and track the eyelids in video recordings. Interns would be involved in reviewing the automated fitting and correcting errors made by the computer vision engine. Experience with the use of AI and medical device studies would be gained. Interns would work as a member of Dr. Houston's research team which includes neurologists, optometrists, engineers, clinical research coordinators, and project managers. They would attend weekly project meetings where they will be exposed to the workings of a randomized clinical trial.

## **Research Informatics Core**

Principal Investigator: Adrian Zai, MD, PhD, MPH

Mentor: Steven Wong, MS (Precepted by Ugur Celik, MS, PhD Student)

Project: Reducing Infections in post-Surgical Events (RISE) Dashboard Development

Objective: To improve patient care and operational efficiency by providing the infection prevention team with a comprehensive dashboard. This tool will enable real-time monitoring and analysis of SSI data, facilitating prompt and informed decision-making. The project will require collaboration with the infection control and informatics teams to ensure the dashboard meets clinical needs and is integrated into existing workflows.

We are particularly interested in candidates with the following attributes:

- Enthusiastic about UI/UX design, health informatics, clinical IT, and data visualization.
- Familiar with or willing to learn about healthcare data standards and protocols.
- Able to work effectively in a team environment, collaborating with developers, designers, and healthcare professionals.
- Organized and capable of managing multiple aspects of the project, from design to implementation.

- Excellent communicators with the ability to translate technical information into user-friendly formats.
- Creative problem solvers who are proactive in identifying and addressing challenges.
- Highly motivated to learn and passionate about making a difference in healthcare through technology.

### **Eunice Kennedy Shriver Center / Department of Psychiatry**

Principal investigators: Marisa Petruccelli, PsyD, Kyle Frost, PhD, and David Cochran, MD, PhD

Mentor: Lindsey Cincotta

Location: UMass Chan Medical School-Worcester (Eunice Kennedy Shriver Center)

Project 1: MEASURE-ASD (2.5-6 years)

Project 2: PETAL (6 months-24 months)

Project 3: Biomarker ASD (13-17 years)

The visiting intern will gain exposure to several ongoing research studies taking place at the Eunice Kennedy Shriver Center. Research experiences will involve children & adolescents who are typically developing as well as with suspected or diagnosed autism spectrum disorder ranging in ages from 6 months-17 years. The projects include industry-sponsored FDA clinical trials and UMass investigator-initiated studies. Project 1 (MEASURE-ASD) is an FDA clinical trial of an eye-tracking device to be used as a diagnostic aid for evaluating autism in children 2.5-6 years old. Project 2 (PETAL) is an investigator-initiated study of the timing of early intervention for children with high familial likelihood of social communication delays. Project 3 (Biomarker ASD) is a UMass initiated clinical trial to determine the effect of gabapentin on GABA levels in the brain and on social cognition in adolescents with ASD.

Interns will have the opportunity to be exposed to various aspects of the clinical research process, including recruitment and screening, IRB and regulatory documents, electronic data capture, and source documentation. Interns will also learn about the informed consent and clinical assessment process. Interns will also have the opportunity to attend study visits on multiple projects, which may include in-home visits, and clinic-based assessments with children and families (including behavioral assessment and infant EEG). Educational and observational experience of neuroimaging (MRI) will also be provided. Finally, interns will be provided with a variety of didactic materials and experiences to learn more about the intellectual and developmental disabilities populations, and the range of research being conducted at Shriver.

The Eunice Kennedy Shriver Center is seeking an intern who:

- Has strong interpersonal skills and is interested in engaging with children and families.
- Has an interest in working with a neurodiverse population.
- Is interested in pursuing human subjects research.