

The Innovator

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Growing gastrointestinal (GI) research program at Baystate

Gastrointestinal (GI) research is a burgeoning field in western Massachusetts. Currently, Baystate Health has 12 GI physicians, three advanced providers, and six GI fellows and residents. Dr. Rohit Singhanian, Director of Clinical Research (Department of Gastroenterology) at Baystate Medical Center, believes GI research has a great future at Baystate. His primary goal is to create an outpatient inflammatory bowel disease (IBD) clinic that serves patients with Crohn's disease and Ulcerative Colitis through care and therapy.

"We want to improve the care of our GI patients and provide access to investigational therapies," said Dr. Singhanian. "We are collaborating with our GI physicians at Baystate to identify how we can improve care for our patients." This includes three major funded official programs so far:

1. YELLOWSTONE trial – Phase 3, Multicenter, Randomized, Double Blinded, Placebo-Controlled Study of Oral Ozanimod as Induction Therapy, Maintenance Therapy and Open-Label Extension For Moderately to Severely Active Crohn's

Disease. (Sponsor: Celgene, now Bristol Meyers Squibb Inc.)

2. QUASAR Trial: A Study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis Protocol CNTO1959UCO3001.

(Sponsor: Janssen Research and Development)

3. Alliance for IBD (All4IBD): A Digital IBD network for Inflammatory Bowel Disease with a goal to improve outcomes for patients through digital patient engagement – to enhance patient-provider



Rohit Singhanian, MD, MS, FACP, AGAF



Judith Pride, RN, MSHS, CCRP, CIP

engagement, provide patient education, perform remote patient monitoring, and support integrated patient care using the Rx.Health IBD Digital Medicine Toolkit that can

be "prescribed" directly to patient smartphones. (Sponsored by Roche and Rx.Health)

Other recent efforts to aid GI patients are through

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Clinical Trials Unit (CTU) introduces Clinical Trial Specialist

The CTO is pleased to welcome Viorika Nelson, DNP, FNP-C, Clinical Trial Specialist. The Clinical Trial Specialist (CTS) is responsible for assisting the PIs in directing the care of subjects enrolled in clinical trials and has a significant role in the conduct of research. Dr. Nelson will work collaboratively with the PIs and other health care team members such as a sub-investigator on various clinical trials. She is working at the new

Clinical Trials Unit, located at 80 Wason Avenue in Springfield.

"There is a vast need for this role," said Judy Pride, Judith Pride, RN, MSHS, CCRP, CIP, Program Director of the Clinical Trials Office. "The CTU is located offsite from the main Baystate campus and 3300 Main Street. Our investigators have competing responsibilities, which makes it more difficult to attend each participant study visit. The CTS will

be available to complete required study activities in the absence of the PI."

Dr. Nelson will assist with physical exams, reviewing lab results, monitoring patients, consenting study participants, and various protocol required study assessments. She began working for Baystate in 2001 as a registered nurse on the surgical floor. Since then, she has held other roles in cardiology, psychiatry, and substance abuse as a NP. On top

of this, she has a diverse background and is multi-lingual in English, Romanian, and Russian. She has always had an interest in teaching and/or research and is excited to be the first to take on this new role.

"[I am learning that] there are lots of protocols, ensuring safety for the patients, confidentiality for the patients, and the ins and outs of the different trials," explained Dr. Nelson.

"I think she will be a great addition to our



Viorika Nelson, DNP, FNP-C, is the new Clinical Trial Specialist at 80 Wason Avenue.

team. It is important to have a diverse team to help contribute to diverse

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What is nursing research? And why is it so important?

Nursing is often described as an art. Within that art, the layperson may see it as a series of tasks: checking in with patients, ensuring they get their medications, and more. As with other practice professions, nursing, is in fact, quite heavily based in science and research. Sometimes this gets lost because of the past perceptions of nursing as a task-oriented profession. In 2020, the Year of the Nurse and Midwife, we celebrated the birth of the first known nurse scientist: Florence Nightingale. Her theories still provide the foundation for much of nursing practice.

Nursing research seeks to evaluate nursing practice and test theories and models of nursing practice to find answers

to questions relating to nursing interventions, education, workforce trends, and healthcare delivery with a goal of providing the foundation for evidence-based solutions.

Melissa O'Malley Tuomi, PHD, RN, CPHQ is the Director of Professional Practice, Nursing Quality, and Research at Baystate Medical Center and an Assistant Professor at UMass Medical Graduate School of Nursing (GSN). She leads the newly-established Center for Nursing Excellence and Innovation, which oversees nursing practice, professional development, and research and also serves as a bridge between the Baystate Institutional Review Board (IRB) and nurses and



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students. Her favored research method to teach is "qualitative descriptive," an inductive and subjective process used throughout healthcare to capture data through interviews, focus groups, observations, or

documents to explore the "lived [human] experience" of the phenomenon being studied. The method takes an emic stance to provide rich description through the eyes of the participant. Data obtained through this method is rigorously reviewed to ensure trustworthiness and provides the foundation for more complex quantitative analysis and, in Dr. Tuomi's case, instrument development to measure the effect of our work on outcomes.

"Nursing research is only about 170 years old, and many of our interventions still need to be studied," said Dr. Tuomi. "What we are trying to do is to apply existing research methods to answer burning questions in

nursing practice. The way I describe this to nurses is: 'what is the thing you often wonder about or find frustrating in practice?'"

While many nurses are intrigued by research, some find themselves frustrated with the process.

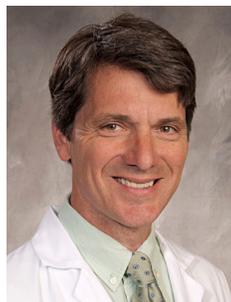
"A bachelor's degree alone doesn't prepare you for research entirely, but it provides a solid start. In the 2011 IOM report 'The Future of Nursing: Leading Change, Advancing Health,' Dr. Don Berwick posits that nurses are well poised to lead improvement based on their education," explained Dr. Tuomi. "The practice of nursing research requires advanced training in methods and knowledge of human rights and etc. We are building a

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COVID therapies after a year of research efforts - Mark Tidswell, MD

I am fortunate to work in the Critical Care research program at Baystate. We have been funded by the NIH for the past twenty years as a center in a US network for a Lung Injury research. Last year, this NIH network was ideally poised to carry out research on severe COVID-19. We now run several Federal operation warp speed trials to evaluate new therapies, and we conduct CDC surveillance work. The pace of COVID-19 research is rapid. Almost as quickly as a new therapy is available, it is added

to one of our trials. Dr. Jay S. Steingrub oversees this research at Baystate, Brigham and Women's Hospital, Maine Medical Center, and University of Florida Health. Under his direction, the staff of the Critical Care research program are constantly at work and have enrolled hundreds of subjects here at Baystate. The effort requires late nights and weekends and is helping to find better treatments for patients with COVID-19. We have expanded our work to patients on the ward as well as in the ICU. The



Mark Tidswell, MD

research team includes Lesley DeSouza, Sherrill Thornton-Thompson, Cynthia Kardos, RN, Sarah Romain, RN, and Lori-Ann

Kozikowski, RN, all of whom have worked hard through the surges of COVID-19. We also have support from the Baystate Clinical Trial Office: Scott Ouellette, Andres Santana, and others.

Last year Anthony Fauci said "you're not just going to pull a vaccine out of your pocket", because we usually expect vaccine development to take many years. Yet, not even a year later, millions of people in the US have been vaccinated. We also have new therapies proven to be effective to treat COVID-19.

The astonishing and rapid progress in research is due to international collaboration, public funding, attention to safety, and the incredible effort of clinical researchers. It is also a tribute to the courage of people who volunteer as research subjects.

Although this past year has been difficult, I am grateful to work with a research group at Baystate that contributes to the worldwide goal of finding solutions to COVID-19. Hopefully these efforts will speed up our return to normal.

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the COVID-19 registry with Dr. Mihaela Stefan, as well as several resident projects submitted for publication or as posters (with a Presidential Poster Award from the American College of Gastroenterology's annual meeting in 2020).

Clinical Trials for GI

"We're planning on opening our first GI studies

in 2021, beginning with Crohn's Disease (Yellowstone) and Ulcerative Colitis (Quasar)," said Judith Pride, RN, MSHS, CCRC, CRP, CIP, Program Director of the Baystate Clinical Trials Office (CTO). "The CTO will be instrumental in the conduct of the trials by providing study coordination, regulatory services, helping enroll patients and complete study visits." The

studies were planned to launch in 2020 but were delayed due to the impact of COVID-19. Mrs. Pride added "we have hired a Clinical Trial Specialist (AP) position to assist our investigators fulfill day to day study activities. The Clinical Trial Specialist joined our team in March."

"Obviously, these efforts could not have been initiated without the blessings,

guidance, and mentorship of Dr. Ira Schmelkin (Division Chief, GI), Dr. Abraham Thomas (Chair, Department of Medicine), Dr. Peter Friedmann, Dr. Jay Steingrub, Dr. David J. Desilets, and the entire team of Baystate Gastroenterology," added Dr. Singhania. "Through these efforts, we have been able to distinguish Baystate on the forefront of GI care."

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enrollment in our clinical trials." added Mrs. Pride.

Fun facts: Dr. Nelson loves her rescue dog (German Shepherd-Lab mix), her family, and her husband, who is a physical therapist at Baystate. She enjoys hiking and biking and being outdoors.

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team of mentors with this advanced training to support nurses looking to become more involved in conducting research to answer their own questions.”

The National Institute of Nursing Research (NINR), part of the National Institutes of Health (NIH), defines nursing research as “developing knowledge to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, and enhance end-of-life and palliative care.”

“Nurses don’t always realize that they are ‘scientists at work’ [Berwick, 2011] but all day long we are asking questions and answering them with data in a systematic way. For example, you’re applying existing knowledge to test a hypothesis every time you assess someone with low blood pressure and increase their IV fluids as opposed

to giving medication. I teach students that the nursing process (Assess, Diagnose, Plan, Intervene, Evaluate) is similar to improvement methods and the scientific process,” added Dr. Tuomi.

Research and quality improvement go hand-in-hand.

“An important part of our care is spending uninterrupted time at the bedside listening to patients,” said Dr. Tuomi. “From their stories, we learn so much about the social context of their illness and patient experience and can gain insight into ways to help them heal or transition to the next step in their care. I want to bring methods like this to more of our nurses so they realize that research isn’t a big, scary thing; it’s grounded in a key function of nursing: observing. There are some nurses that love research, and we want to foster that.”

Each year, Dr. Tuomi and her team present “Art of Innovation.” This event

celebrates research and improvement in nursing and presents an opportunity for nurses to showcase their work and learn about ways to become involved. She and Dr. Paulette Seymour-Route, PhD, RN, the Nurse Scientist at BMC, are currently conducting an instrument development study to assess the impact of certain job characteristics on nurses’ job satisfaction.

This year (2021), Dr. Tuomi and her team are hoping to launch a mentorship program and work with nurses interested in asking questions about what they do.

“Healthcare is changing, and nurses need to be equal partners with other healthcare professions in leading change. One goal of the BMC Center of Nursing Excellence and Innovation is to help retain nurses by better understanding the work that they do and how that influences their perception of nursing.”

Kudos

C3PO study on convalescent plasma treatment for COVID-19 recognized by NIH

With the C3PO outpatient convalescent plasma study ending, Baystate has distinguished itself as one of the top enrollers for this NIH funded multicenter clinical trial coordinated through the SIREN network. The trial was stopped in early 2021 for futility of detecting a difference in the primary outcome. Led by Howard Smithline, MD and the C3PO team. Well done!

Daniel Skiest, MD published in New England Journal of Medicine

Congratulations to Dr. Dan Skiest, Professor of Medicine, on co-authoring the *New England Journal of Medicine* publication “Tocilizumab

in Hospitalized Patients with Severe Covid-19 Pneumonia.”

Dr. Bill Soares earns Honorable Mention for Best Overall Abstract from the American Society of Addiction Medicine (ASAM)

William Soares MD’s recent abstract, “A Qualitative Study of Addiction Treatment State Legislation in Emergency Departments,” has been selected to receive the ASAM Abstract Submission Award Honorable Mention: Best Overall. This recognition is presented to the primary author of a very high scoring submitted abstract in that award category. Dr. Soares will present this abstract at the ASAM Virtual Conference 2021. Congratulations!

News from Tufts CTSI

THE 23RD ANNUAL CLINICAL AND TRANSLATIONAL SCIENCE GRADUATE PROGRAM SYMPOSIUM IS FRIDAY, MAY 7

Interested in cutting-edge research conducted by the next generation of investigators? Join us for the 23rd Annual Clinical and Translational Science (CTS) Graduate Program Symposium on Friday, May 7, 9:00AM-1:00PM, via Zoom. This event will feature presentations and posters by CTS Graduate Program students, as well as a keynote address by Robert W. Yeh,

MD, MSc, MBA, Director of the Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology at the Beth Israel Deaconess Medical Center, and Associate Professor of Medicine at Harvard Medical School. Learn more at tuftsctsi.org/events/23rd-annual-clinical-and-translational-science-graduate-program-symposium.

MENTOR TRAINING FOR JUNIOR AND SENIOR FACULTY

Want to have more effective mentor/mentee relationships? Join

Tufts CTSI this spring for training opportunities for faculty members with mentees preparing for research careers in biomedical, behavioral, clinical, and social sciences. Junior and senior faculty are invited to apply to attend Mentor Training on Monday, May 17 or Monday, May 24, 1:00-3:00PM. Apply at tufts.qualtrics.com/jfe/form/SV_bqttGsyvfh1aEv4 by May 12.

Please contact Amy West to register or with any questions at awest@tuftsmedicalcenter.org.

Clinical trials unit planned for Baystate Franklin Medical Center

The Office of Research plans to develop a Clinical Trials Unit at Baystate Franklin Medical Center. Space has been identified and plans are in the initial phase. New developments



will be announced throughout the year.

Did you know? Clinical Trials Day is May 20

Clinical Trials Day falls on May 20 every year. It is a national day to recognize clinical trials staff, researchers, and the history of clinical trials. It is also a day to bring awareness to clinical trials and pursuing clinical research as a career option.

Baystate Health has dozens of researchers and research staff who explore the unknown every day, moving scientific and

medical explorations forward.

“We would like to use Clinical Trials day to thank all of our researchers and clinical trials staff,” said Judith Pride, RN, MSHS, CCRC, CCRP, CIP, Program Director of the Clinical Trials Office (CTO) at Baystate Health.

Learn more about the history of Clinical Trials Day at clinicaltrialsday.org/about.



All aboard the patient transport vehicle!

(Left) Drs. Peter Vieira and Peter Friedmann take the CTU’s patient transport vehicle out for a spin. The vehicle will take patients from other main campus buildings to the CTU at 80 Wason Ave.

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We are interested in ensuring that Baystate employees and patients (and their families) are aware of the important research that goes on at Baystate and how it contributes to better patient care. The Innovator welcomes feedback and story ideas. Contact Allison Billeter at allison.billeter@baystatehealth.org to submit yours.

Compliance Corner with Jennifer Pacheco, MPH, CIM, CIP

CIS Clinical Trial Alerts

Beginning April 2, 2021, CIS alert request forms are required with each new sponsored clinical trial submission to the IRB. In an effort to close gaps identified in the organizations Clinical Trial remediation overseen by the Board of Trustees Audit and Compliance Committee, we must also require current projects to update and maintain CIS alerts with linked patient participants.

Studies without an active CIS alert have been identified. Sola Odesina, HRPP Education and Compliance Specialist, will provide research teams with a list of projects that currently do not have a CIS Alert and answer any questions they have on the form or process.

The Florence eBinder Suite is Live!

Baystate's new eBinder suite went live March 15, 2021. All funded

projects and all internally supported projects requiring an expedited or full board IRB review will require use of the system. To date several training sessions have been offered to assist users in becoming acquainted with the system. Research teams were provided a link to training but if you need us to resend please email us at HumanResearch@Baystatehealth.org.

The system is designed

as a digital version of the regulatory paper binder that enables our teams to organize, store, e-sign, and track research documents for those on-site and remote. It will also assist with sponsor remote monitor visits; allow the study team to access documents between research locations.

Please call 413-794-3458 or email Jennifer.Pacheco@baystatehealth.org if you have questions.



Jennifer Pacheco, MPH, CIM, CIP

News from UMass CCTS



TRAINING OPPORTUNITIES TO AUGMENT LEARNING (TOTAL)

The DL&I Incubator team is pleased to announce the launch of Training Opportunities To Augment Learning (TOTAL), a digital app that allows biomedical trainees to attend career and professional development events held at Boston University and eight Boston-based partner institutions. Learn more at digital.bu.edu/total-qa.



PROJECTS IN PROCESS SEMINAR SERIES (PIPSS)

Virtual event on Fridays, through June 11, 11:00 AM - 12:00 PM. The series will feature presentations from our TL1, Millennium, MSCI and KL2 scholars on their various research projects. Contact Melissa Corash at Melissa.BrewerCorash@umassmed.edu for further details.

Meet the Researcher



Corina Schoen, MD

Name: Corina N. Schoen, MD

Title/Academic Rank: Assistant Professor Obstetrics and Gynecology

Department: Ob-Gyn, Division of Maternal Fetal Medicine

Number of years at Baystate: 4

What research training do you have? I was fortunate enough to do fellowship at a place where the faculty were very active researchers. There was mentorship throughout my 3 years of subspecialty training in clinical trial development and meta-analyses, with additional graduate level courses to supplement this training.

What got you interested in research overall? I never thought I would be doing what I do today. I very much went into Maternal Fetal Medicine for the clinical practice, but my mentor in fellowship made research so

accessible and fun, and this is the same excitement I try and pass along to the residents I mentor now.

What is your area of research?

Labor, labor induction, preeclampsia, and preterm labor.

Do you have any awards? I

am currently receiving funding through the RPAP for a single arm observational trial looking at induction of labor at term to reduce the cesarean delivery rate for women with obesity. I am also awaiting comments for an RO1 submitted with Yale to assess the prematurity and fetal growth restriction risk associated with marijuana use during pregnancy.

What do you like most about your job? I love the variety in my work. I

get to teach residents every day, and for the select few who are preparing for fellowship I get to serve as a close mentor, and this often persists well after graduation. Clinically my work is extremely rewarding, and my best days are those where I can provide reassurance to women with the most complicated pregnancies. I find my research is applicable to many of the patients I treat, and instituting practice-changing management based on my research trials conducted at Baystate has fueled my drive to keep going.

What do you do to unwind

outside of work? Biking to get ice cream with my husband and four children, attempting to bake (often unsuccessfully), gardening, and playing piano.

Notable Recent Published Papers

Contact Baystate's Health Science Library for more information at libraryinfo.bhs.org/home

Bhat AG, Farah M, Szalai H, Lagu T, Lindenaue PK, Visintainer P, Pack QR. Evaluation of the American Association of Cardiovascular and Pulmonary Rehabilitation Exercise Risk Stratification Classification Tool Without Exercise Testing. *J Cardiopulm Rehabil Prev.* 2021 Feb 11. doi: 10.1097/HCR.0000000000000584. Epub ahead of print.

Zhou Y, O'Donovan B, Beqari J, Aluidor R. Retroperitoneal Necrosis as a Rare Complication After Celiac Plexus Block. *Cureus.* 2021 Feb 6;13(2):e13169. doi: 10.7759/cureus.13169.

Wormser GP, McKenna D, Shaffer KD, Silverman JH, Scavarda C, Visintainer P. Evaluation of selected variables to determine if any had predictive value for, or correlated with, residual symptoms at approximately 12 months after diagnosis and treatment of early Lyme disease. *Diagn Microbiol Infect Dis.* 2021 Feb 12;100(3):115348. doi:

10.1016/j.diagmicrobio.2021.115348. Epub ahead of print.

Schoenfeld EM, Poronsky KE, Westafer LM, DiFronzo BM, Visintainer P, Scales CD, Hess EP, Lindenaue PK. Feasibility and efficacy of a decision aid for emergency department patients with suspected ureterolithiasis: protocol for an adaptive randomized controlled trial. *Trials.* 2021 Mar 10;22(1):201. doi: 10.1186/s13063-021-05140-9.

Westafer LM, Bond C, Milne W. Diagnostic Testing Differences Between Advanced Practice Providers and Physicians. *Acad Emerg Med.* 2021 Mar 15. doi: 10.1111/acem.14247. Epub ahead of print.

Artenstein AW. A half-century of meningococcal vaccines. *Vaccine.* 2021 Mar 19;S0264-410X(21)00292-9. doi: 10.1016/j.vaccine.2021.03.024. Epub ahead of print.