Clinical Trials Office (CTO) launched

Clinical trials research is integral to Baystate Health’s identity. It offers state-of-the-art treatments to our patients in western Massachusetts. It enables Baystate Health to collaborate with pharmaceutical and device manufacturers that are creating the next generation of therapeutic interventions. In addition, clinical trials research promotes both the quality and diversity of faculty through academic engagement, enhances the recruitment and retention of skilled professionals by creating an atmosphere of scholarly inquiry, and raises the local, regional and national stature of the institution.

According to clinicaltrials.gov, a clinical trial, by definition, “involves research using human volunteers (participants) that is intended to add to medical knowledge. Participants receive specific interventions (like drugs, devices, or procedures) according to the research plan or protocol created by the investigators.” Such studies are essential to advance evidence-based medical practice. However, the regulatory and operational demands of clinical trials have magnified in recent decades. To meet these challenges, the Office of Research launched the new Baystate Health Clinical Trials Office (CTO) in September 2018.

“Young the tremendous expense of health care, all sectors in our society have a vested interest in finding better strategies of patient evaluation and treatment,” says Jay Steingrub, MD, Director of the new Clinical Trials Office. “Such important efforts need to encompass the biological sciences, epidemiology, use of new technologies and other health care related resources. Research is critical to the future of health care; without supporting research we are left with a myopic acceptance of the current therapeutic and diagnostic limitations for our patients.”

BUILDING THE CLINICAL TRIALS OFFICE

After over a year of planning, the CTO has been set up to provide new infrastructure for clinical trials at Baystate Health. The goal is to advance Baystate’s capabilities to participate in industry-sponsored clinical trials. The initial approach is to concentrate on those services most sought after by industry and by our own faculty. These include such elements as a single point of contact, improved contracting efficiency, an up-to-date investigator database, appropriate facilities for company monitors, and assistance with planning and executing studies, including nurse coordinator services.

“The CTO is expanding its role to include the development of patient recruitment services, training and educational programs for nurse coordinators and research assistants and physician investigators and eventually the development of a satellite site network at Baystate Franklin Medical Center,” says Steingrub. “Perhaps the most unique aspiration for the CTO is comprehensiveness. The goal of the CTO is to provide one-stop shopping in that all the resources required for conducting a clinical trial at Baystate are available within the CTO team.”

Everyday activities of the CTO rely on coordinating the activities of the entire team within the Office of Research, including Sponsored Programs Administration and the Human Research Protection Program. This collaboration will make sponsor interactions with Baystate efficient and effective. It will also reduce the usual start up barriers facing new investigators who want to become involved in the clinical trials process.

“More than anything else, it’s the ease of working with a group that is dedicated to the same goals; that is timely, accurate and reliable completion of important clinical trials,” adds Steingrub. “This is our mission: for the CTO to support the effective, efficient and reliable evaluation of new pharmaceuticals, and medical devices in collaboration with sponsoring organizations, including industry and government.”

Lori Kozikowski, RN, BSN, CTO Program Director, shares Jay Steingrub, MD, Director of the Center for Clinical Trials and Translational Investigation, and Lori-Ann Kozikowski, RN, BSN, CTO Program Director.

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THE FUTURE OF CLINICAL TRIALS AT BAYSTATE

The Baystate CTO links to researchers and patients at other institutions and in other communities as well. "The CTO has created an avenue for not only our external subjects, but also for UMass Amherst and UMass Worcester scientists to better align with our doctors and researchers here at Baystate," Steingrub adds. "Through our research, many of our discoveries are able to be shared with the clinical population." "It’s all about addressing the needs of the population," says Kozikowski. "When people are sick, they want options. They don’t want to have to go to Boston or Hartford for the care they are looking for. If research is available to people, they’re willing to listen and make a choice."

Clinical research is central to Baystate’s mission of demonstrating how medical advances can and should be applied to improve human health. "We at Baystate have recognized that to ensure our continued involvement in such activity we must change the way we do business with industry sponsors," concludes Steingrub. "It is the CTO’s firm belief that clinical research in general, and industry sponsored trials in particular; belong at our academic medical center. To date, industry reactions to our CTO services have been enthusiastic."

The CTO team looks forward to partnering with clinicians, scientists, staff, patients and families to expand opportunities for clinical trials and thus advance the state of caring at Baystate Health.

FOR MORE INFORMATION: If you are interested in learning more or participating in a clinical trial at Baystate, visit www.baystatehealth.org/patients/learn-about-clinical-trials.

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A Hello from the [New] Editor

Hi everyone,

For those of you who don’t know me, my name is Allison Litera (most people call me Allie). I am the Digital Content Analyst for the Offices of Faculty Affairs and Research here at UMMS-Baystate. I have been part of the team since October 2018 and am thrilled to be bringing back The Innovator as the writer, editor, and designer of this quarterly publication.

I’ve been a resident of the Pioneer Valley my entire life. I graduated from the Hartford Art School in 2012 with a BFA in illustration and an art history minor. I’m an all-around creative person. When I’m not working full time, I am a freelance caricature artist, crafter, writer, and photographer.

Since I do not come from a medical background myself, it is my hope to help make The Innovator accessible and easily understood by the everyday reader – someone who might not necessarily be a medical professional or researcher. The medical world fascinates me and I am eager to learn more about it every day.

I look forward to keeping you all in the loop about the great research happening throughout the Baystate Health system. If you have any story ideas for The Innovator, please feel free to send me an email at allison.litera@baystatehealth.org. We would be happy to consider your ideas!

Until next time,

Allie

Jennifer Pacheco, MPH, CIM, CIP promoted to Chief Research Compliance Officer

Jennifer Pacheco, MPH, CIM, CIP was promoted to Director, Healthcare Research Compliance and Chief Research Compliance Officer for Baystate Health, effective October 2018. Pacheco joined Baystate’s Human Research Protection Program (HRPP) in 2006. Promoted to HRPP Director in 2013, she has guided the institution and its research teams in meeting ethical principles and regulatory requirements for research. Under her leadership, our HRPP implemented process improvements for our IRBs that have greatly reduced administrative burden and time-to-approval, and passed brilliantly two rounds of accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Pacheco’s new role as Director of Healthcare Research Compliance and Chief Research Compliance Officer gives her a platform to educate people about research in public, in the hospital, and for medical professionals. It also gives a clear, centralized institutional voice to research compliance issues. In her new role leading the research compliance program, Ms. Pacheco will have matured reporting to the Chief Research Officer and to the Chief Compliance & Privacy Officer. She will continue to oversee administration of the HRPP, and collaborate with relevant departments in ensuring adherence to research billing compliance and research conflict of interest policies. Her goals are to make the research regulatory personnel approachable and available to field any questions or concerns; minimize risks to research subjects, employees, and the institution; advance new standards of research practice; and improve efficiency in review and monitoring to lower the burdens associated with healthcare research.

“When people think of research compliance, they may get a little intimidated,” she explains, “but we are here to help. We want get you where you need to be, and still get you where you’re looking to go.”

If you have any questions about research compliance or human research protection at Baystate Health, call (413) 794-3458 or email jennifer.pacheco@baystatehealth.org.
As an academic health system, Baystate Health performs research at all of its hospitals as part of its focus on advancing care. For example, research has been growing at Baystate Franklin Medical Center in Greenfield, MA. Here we highlight a couple of the latest projects occurring there.

SPEECH PATHOLOGY RESEARCH WITH AMANDA BERNHARD, MA, CCC-SLP

Parkinson’s disease can cause problems with speech in up to 90% of patients who have it. Amanda Bernhard, MA, CCC-SLP, is leading research at BFMC comparing the effects of rehabilitation exercises vs. a worn device to combat the communication challenges presented by Parkinson’s. The program that Bernhard offers at BFMC is called LSVT LOUD (LSVT stands for “Lee Silverman Voice Treatment”). Research supporting the effectiveness of this program dates back to the late 1980s. The intensive treatment is used globally to help patients with Parkinson’s disease regain normalcy to their speech. The research project is hosted at the University of Massachusetts Amherst and is headed up by Dr. Kelly Richardson. The funding is provided by the National Institutes of Health (NIH).

“LSVT LOUD teaches, through various phonation and speech exercises, how to use a louder voice,” explains Bernhard. “It improves respiratory strength, vocal volume and quality, speech clarity, and swallowing function.” Most of Bernhard’s patients have many “success moments” that they share with her. One woman told Bernhard that completing the LSVT program “restored her confidence” and that she felt she was able to make her voice heard again. Another felt so empowered by the LSVT program that she felt inspired to create a singing group for individuals with Parkinson’s at a local exercise center. A gentleman Bernhard is working with at the moment said that his daughter, upon hearing his louder voice over the phone, told him “you sound like you did two or three years ago, your old voice is back!”

The other treatment option used in the research study is a device called a SpeechVive; a hearing aid-type apparatus fitted to and worn by an individual, just like a hearing aid. When the individual speaks, the SpeechVive turns on and projects a babbling noise into the background. This sound encourages the wearer to speak louder. The SpeechVive was developed and invented within the past couple years by Jessica Huber, PhD, of Purdue University. According to purdue.edu, “The SpeechVive capitalizes on the Lombard effect. This is the reflex that causes us to speak louder, clearer, and slower in the presence of background noise. All adults demonstrate this response. People with Parkinson’s disease have difficulty with speech loudness, clarity, and rate. The SpeechVive has the potential to improve all three domains via the Lombard effect.”

“It is a newer device with not a lot of research yet to back up its effectiveness, but that’s what we’re hoping this study helps discover,” informs Bernhard. “It seems like it could be an excellent tool for the right patient.”

The study will follow 12 participants in each treatment group, and documentation of the level of each participant’s vocal volume and respiratory support will be measured to see how effective each method is and to compare the results of the two groups. “If I can help by contributing to the research that assists this population, I will be delighted. It is such a joy working with these individuals,” adds Bernhard.

“With Parkinson’s patients in particular, so many of them have amazing things to say and unfortunately feel unheard most of the time. Giving them a safe, fun space to work on their conversation abilities is a great part of my job. I love that the LSVT program is so empowering.”

Ultimately, Bernhard is excited to help her patients express their true voices again.

For more information, contact Amanda Bernhard, MA, CCC-SLP at Amanda.Bernhard@baystatehealth.org or (413) 773-2411.

RURAL NEW ENGLAND HEALTH STUDY WITH PETER FRIEDMANN, MD, MPH, DFASAM, FACP, PRINCIPAL INVESTIGATOR

Researchers at UMMS-Baystate are conducting a study funded by the National Institute on Drug Abuse (NIDA), Centers for Disease Control and Prevention (CDC), Substance Abuse Mental Health Services Administration (SAMHSA) and the Appalachian Regional Commission to better understand the opioid epidemic and the availability of health services in rural communities in New England.

“In New England’s rural areas,” says Dr. Peter Friedmann, Principal Investigator, “the epidemic of opioid use disorder (OUD) and its related sequelae of overdose, HIV, hepatitis C virus (HCV), sexually transmitted infections (STIs) and other infectious comorbidities present the most substantial challenges to public health and health care in decades.”

Baystate is one of only eight institutions throughout the U.S. that received funding to participate in what has become the National Rural Opioid Initiative. The research team is based at BFMC but is working in locations throughout the Interstate 91 corridor from Greenfield all the way up north to the Canadian border.

“We are looking for people who use painkillers or non-medically inject any type of drugs,” says Randall Hoskinson, Project Director for the study. Study participants complete a survey that asks a broad range of questions about the individual’s experiences with substance use, their ability or – as is often the case – their inability to access different services, stigma, and their social network. They are also tested for HIV, Hepatitis C, and syphilis using rapid tests. Blood samples are collected from those who test positive for viral genetics analysis conducted through Massachusetts General Hospital and the CDC. The UMMS-Baystate Research team and partners at Dartmouth and Tufts will use survey responses and blood test results to map opioid use and the spread of infectious disease throughout the region.

“This information will be compared with what is available in terms of substance use treatment, harm reduction (e.g. needle exchanges and naloxone distribution), health services, and infectious disease specialty care,” adds Hoskinson. The data collected will help create a better, more accessible system of care and resources for persons with substance use disorders in order to reduce overdose deaths and the spread of infectious diseases.

But first, the team must collect the data. To begin recruiting participants, study staff goes out into the community and talk to people walking down the street, or stopping into a gas station or convenience store. “We start up a general conversation,” explains Julie Kingsbury, Clinical Research Coordinator. “We target people who we think might be eligible for this study, or to see if they may know someone who... (Continued on page 4)

(Continued from page 3) is.” Respondent Driven Sampling (RDS) is utilized for recruitment. RDS is a referral-based system that is used to find members of hard-to-reach or hidden populations. Participants are given coupons to distribute to other people they know who use drugs and are given an incentive for successful referrals of peers that take part in the study.

“We with this research, we are learning from people who know firsthand what it’s like to use opioids and inject drugs and live in a rural area, something that has been looked at very little in the past,” adds Elyse Bianchet, Research Assistant. Breaking the stigma surrounding addiction is a goal as well.

“People can be afraid to admit that they use. They may be afraid that we have something to do with the law. We stress that this is 100% confidential,” assures Kingsbury. Along with confidentiality, what the team values most is treating participants with respect, dignity, and compassion without judgement.

“We reassure them that their drug use doesn’t define them, and we always make sure we appreciate their time and input and that their time and input is extremely valuable,” adds Bianchet. “Many people who use drugs do so because they have experienced a lot of trauma. Living in active addiction is an ordeal in itself. Someone injecting heroin every day is not having fun. It’s a lonely, painful, difficult place.” Thus, the majority of participants are enthusiastic that the study is taking place because they want to help make the situation better for others across New England.

“They know this is important work, and they are eager and proud to be a part of it,” adds Eric Romo, a MD-PhD student at UMass-Worcester outside of BFMC’s Research Offices.

community of drug users as a whole.

“All in all, we will never be sure of how many people use opioids,” concludes Kingsbury. “There’s a whole population that doesn’t want to be known.”

For more information on the Rural New England Health Study, or to find out how to participate, contact Julie Kingsbury at Julie. Kingsbury@baystatehealth.org or (413) 773-4422.


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