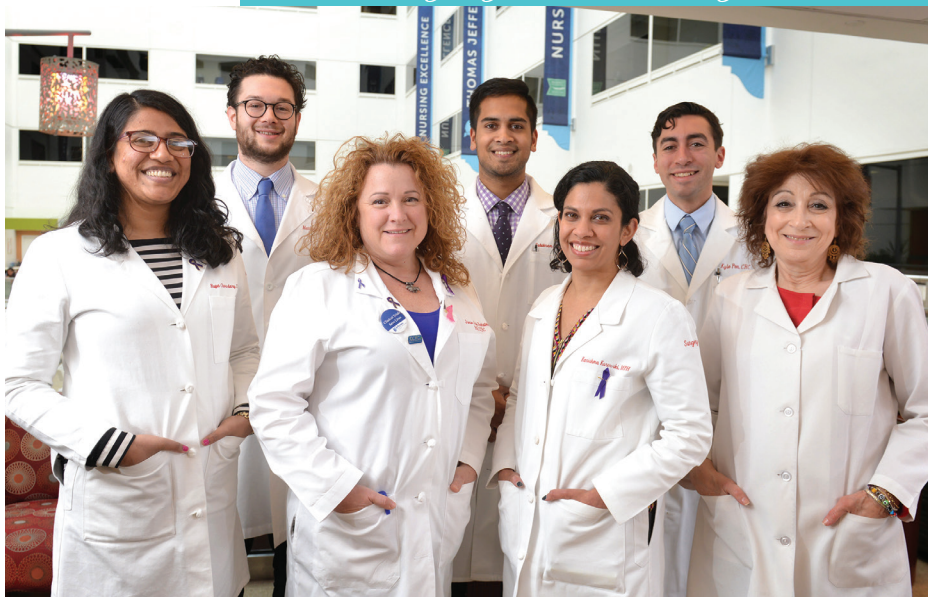


Changing Lives Through Research



Clinical Research Team members Rupa Chowdary, Matthew Isenberg, MSW, Jamie Jay Rothstein, RN, CCRC, CCRP, Subikram "Raaj" Chandra, Karishma Kurowski, MPH, Kyle Peer, and Dee Rinaldi manage the administrative and regulatory aspects of all clinical trials in the Department of Surgery.

Clinical Research Team Supports Over 100 Diverse, Complex Trials

Faculty in the Department of Surgery are currently leading or participating in more than 100 clinical trials. Each has a distinct protocol and requires management of numerous components – from patient recruitment and informed consent to electronic data entry and management of subject care throughout the trial. All of these activities must comply with regulations imposed by the Food & Drug Administration (FDA), National Institute of Health (NIH) Collaborative Institutional Training Initiative (CITI) and Health Insurance Portability and Accountability Act (HIPAA), which require the protection of Personal Health Information.

"As just one example, we're supporting Dr. Adam Berger with a Phase 2 international multi-center trial of a compound that could function as a personalized vaccine therapy for melanoma patients," Rothstein says. The team is working with Dr. Berger on nine other trials, including the INTEGRATE study, which is following patients with cutaneous melanoma who have had the DecisionDx-Melanoma gene expression assay performed.

Additionally, the team is coordinating with Dr. Melissa Lazar on a clinical trial for patients diagnosed with breast cancer. The goal: to determine if standard of care lumpectomy (SOC)

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To navigate those complexities, the Department relies on the Clinical Research Team, led by Jamie Jay Rothstein, RN, CCRC, CCRP. The team is supporting a wide variety of clinical trials that are open and accruing patients in the following specialties: bariatric, cardiothoracic, colorectal, pancreatic, transplant, trauma and vascular surgery.

or SOC lumpectomy along with use of a MarginProbe® device offers greater safety and effectiveness. The device is designed to help surgeons quickly achieve "clean margins" by identifying cancerous (malignant) tissue in the surrounding tissue of the tumor in real time, rather than waiting for an assessment from the pathologist.

With more than 25 combined years of experience, Dominique Viccharelli and Milagros "Milly" Yax have made helping others the focus of their careers. Before joining the Department of Surgery, Yax worked as a medical assistant, most recently with Jefferson Internal Medicine in Voorhees, NJ. Since becoming Clinical Coordinator in Surgery last November, she no longer checks patients' vitals or assists physicians with exams – but she's found a new way to make a difference. Yax is responsible for assisting patients of Harish Lavu, MD, FACS, and Jordan M. Winter, MD, FACS, who both specialize in pancreatic cancer surgery.

Since 2009 Viccharelli has provided the same service for the patients of Charles J. Yeo, MD, FACS, the Samuel D. Gross Professor and Chair of Surgery and Co-Director of the Jefferson Pancreas, Biliary and Related Cancer Center. As Clinical Coordinators, they each serve as their patients' primary point of contact – from scheduling the initial appointment and navigating diagnostic tests and referrals through treatment and follow-up.

"I enjoy taking care of our patients from beginning to end," Yax says. "They get to know me, and we build a relationship. They know they can come to me with questions or concerns. I think it makes a huge difference for them to have my email address and direct phone number versus talking to someone different every time they call. It's much more personalized."

In addition, Viccharelli provides administrative support for the Jefferson Pancreas Tumor Registry (JPTR), which collects information from pancreatic cancer

Meet the Team

Rothstein's team now includes six Clinical Research Coordinators (CRCs) and a Clinical Research Specialist.

Matthew Isenberg, MSW, CRC II, joined the team in 2013. He identified, screened, interviewed and recruited eligible patients for the Department's

highest-accruing trial studying a pancreatic cancer vaccine from NewLink Genetics. He is now the lead coordinator on this trial.

Karishma Kurowski, MPH, CRC II, joined the team in 2014. She is skilled in navigating protocols, collecting data, and obtaining informed consent, including educating subjects about clinical protocols, required therapies



Milagros "Milly" Yax and Dominique Viccharelli

patients and family members who enroll in the study. The registry, established in 2008, now has well over 500 people enrolled: 65% have sporadic (non-hereditary pancreatic) cancers, 14% have familial (hereditary) pancreatic cancers, 14% are non-affected family members and 7% have closely related conditions. All registrants are asked to complete an extensive questionnaire. The Registry is directed by Theresa P. Yeo, PhD, and Harish Lavu, MD.

"I know it's a lot of paperwork, but it's so important for our patients and their families to complete it," Viccharelli says. "The data is invaluable in helping us study the disease, so we can understand not only the genetic components but also potential environmental and occupational risk factors."

For more information about the JPTR or to download questionnaires, please visit Jefferson.edu/Pancreasregistry

and procedures, and answering subject questions.

Rupa Chowdary and Subikram "Raaj" Chandra are each lead CRCs for their own trials and are responsible for many activities – from preparing for subject visits and completing source documentation to entering data into the Electronic Data Capture system promptly after each visit. Another key responsibility: the time-consuming task of reporting adverse events (AEs) and serious adverse events (SAEs) per FDA guidelines.

Other members of the team include Kyle Peer, who joined last year as a Clinical Research Specialist and Dee Rinaldi, CRC II, who joined the team in April.

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