

The Jill Roberts Center for Inflammatory Bowel Disease (IBD) is dedicated to the research and treatment of IBD. Our mission is to improve patient care by personalizing therapies for IBD and to discover cures for Crohn's disease and colitis. The JRC is one of the nation's leading multi-disciplinary centers for the diagnosis, comprehensive care and innovative treatment of patients with IBD. We offer integrated clinical services from the New York-Presbyterian Hospital and Weill Cornell Medicine network, including access to world-class surgeons, pediatricians, rheumatologists, and hepatologists. Our goal is to develop novel, safer treatments through "lab to life" research, translating laboratory discoveries into transformative therapies that improve patients' lives.

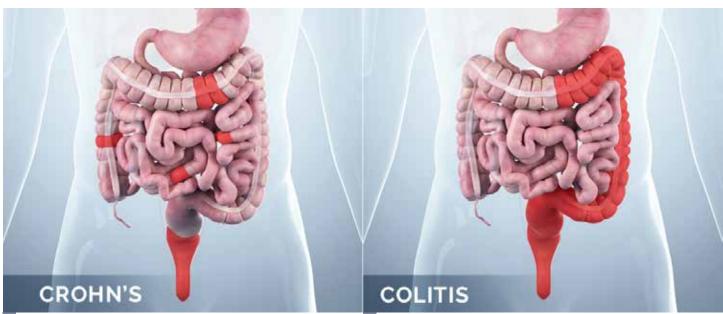


Pictured from left to right: Dr. David Artis, Jill Roberts, Drs. Randy Longman and Ellen Scherl



This year, we sadly lost an invaluable part of the Jill Roberts Center team and our close friend, Jill Roberts, who passed away on March 20, 2020. Jill spent countless hours championing the causes of the Center and Institute that bear her name. She worked daily at the JRC interacting and supporting our patients. She recognized the need for psychosocial support and created a patient support group critical for many of our patients. Jill was passionate about nutrition and helped establish clinical infrastructure to provide nutritional counseling to all JRC patients. Recognizing the critical need for the integration of clinical and basic research to find tomorrow's cures for patients suffering with IBD, Jill established the Jill Roberts Institute for Research in IBD (JRI) to promote synergy between clinical medicine and basic research. Jill had a tremendous impact on our work, our lives, and the lives of our patients. All of us at the JRC and the JRI are privileged to have had the opportunity to work with her and we will continue our efforts to honor her memory.

A BRIEF OVERVIEW OF IBD: CLINICAL SYMPTOMS



Crohn's disease can affect all areas of the digestive tract, from the mouth to the anus

Crohn's Disease may also penetrate through the intestinal wall to involve the connective tissue surrounding the gut.

This may lead to **complications** related to Crohn's disease, such as narrowing of the intestine (known as **stricture**), abscess formation, or the formation of abnormal connections from the bowel to other structures (known as **fistula**).

Other symptoms include:

- Abdominal pain (may be localized, often lower right)
- In some cases: diarrhea, irregular BMs
- Fatigue (2/2 anemia, inflammation)
- Weight loss

Ulcerative colitis (UC) affects the large intestine, or colon.

The inflammation involves the lining of the colon, leading to diarrhea, blood in the stool, abdominal pain, urgency, and weight loss, among other symptoms.

Other symptoms include:

- Rectal bleeding
- Tenesmus, the sensation of needing to have a bowel movement without the ability to do so due to rectal inflammation
- Abdominal cramping
- Weight loss

Above image courtesy of NYP Health Matters online magazine: https://healthmatters.nyp.org/

Extraintestinal manifestations with both Crohn's and UC include **joint pain** in the spine, lower back, and peripheral joints; **inflammation in the eyes** with blurry vision, redness, and/ or eye pain; cold sores in the mouth (aphthous ulcers); **skin rash or ulcer**; kidney stones; and blood clots

A BRIEF OVERVIEW OF IBD: PATHOGENESIS AND TREATMENT

The exact etiology of IBD is unknown but the following factors contribute:

- Genetic/hereditary
- Environmental
 - Diet
 - Stress
- Medications (NSAIDs, Abx)
- Smoking
- Immune-mediated

PATHOGENESIS

The cause of IBD Including both Crohn's Disease and UC is unknown and the genetic features are complex. It is known that family history is the most significant risk factor, however, its inheritance pattern is not as straightforward. Changes in the intestinal microbiome, which is the group of microorganisms and their metabolic products within the intestine, are a hallmark of IBD. These changes have the potential to activate abnormal

immune pathways in patients with a genetic predisposition.

Other potential triggers may include cigarette smoking, use of antibiotics and other medications, dietary additives, gastrointestinal infection, and others. Once the immune system is activated, the body cannot turn off this pro-inflammatory circuit. Therefore, the immune system becomes unable to perform its protective function and the dysregulated immune activation leads to ongoing inflammation.

Patients with IBD develop and manifest symptoms at any age, from infancy until your 80s and 90s. It is most common in the teens and 20s, but unlike many diseases with a genetic predisposition, it may also emerge many decades after birth.

TREATMENT

While Crohn's disease and UC are chronic diseases with no known cures, there are several effective treatment options. After completing laboratory, imaging, and endoscopic evaluations to determine whether a patient is experiencing mild-to-moderate versus moderate-to-severe disease activity, medical therapeutics may then be discussed and initiated.

Depending on the degree of severity, there are four basic categories of medications that may be used to help induce remission, prevent flare-ups, and ultimately improve one's quality of life. Those include aminosalicylates (a class of drugs used to reduce inflammation in the lining of the intestine), corticosteroids (often known as steroids), immune modulators (a class of drugs that helps activate normal immune function), and biologic therapies.

Ultimately, the goal is to avoid long-term steroid use and to maintain remission with effective anti-inflammatory therapies.

A Brief Overview of IBD was sourced from NYP Health Matters online journal from the interview with Dr. Dana Lukin, entitled "Crohn's vs. Colitis: What's the Difference?" and from JRC Registered Dietitian Ryan Warren

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Baseline Clearance of Infliximab Is Associated With Requirement for Colectomy in Patients With Acute Severe Ulcerative Colitis

Robert Battat "-L.", Amy Hemperly "-", Stephanie Truong ", Natalie Whitmire", Brigid S. Boland ", Parambir S. Dulai ", Ariela K. Holmer", Nghia H. Nguyen ", Siddharth Singh ", Niels Vande Casteele ", William J. Sandborn " & R.

Available online 26 April 2020





Original Research

ull Report: Chinical—Allimentary Trica

Development and Validation of a Test to Monitor Endoscopic Activity in Patients With Crohn's Disease Based on Serum Levels of Proteins

Geert D'Haems ¹* * ¹⁸ M. Orlaith Kelly ⁷* *, Robert Battat ³* *, Mark S. Silverberg ⁴, David Laharie ³, Edouard Louis ⁴, Edouardo Savarido ⁶, Giorgia Bodini ⁸, Andres Yarur ⁸, Brigid S. Boland ³, Waqqas Afif ³⁹, Xiao-jum U. ¹¹, Michael Hale ¹¹, Jessica Ho ¹³, Venkateswariu Kondragunta ¹¹, Benjamin Huang ¹¹, Crystal Kuy ¹¹, Lauren Okada ¹¹ ... Parambir S. Dulai ²* ¹.

Dulai ²* ¹.

Volume 158, Issue 3, February 2020, Pages 515-526.e10

Baseline Disease Activity and Steroid Therapy Stratify Risk of COVID-19 in Patients with Inflammatory Bowel Disease

Dana J. Lukin 1,1 $X_1 \boxtimes A_1$ Anand Kumar 1,n Kaveh Hajifathalian 2,n Reem Z. Sharaiha 3 . Ellen J. Scheri 1,2 Randy S. Longman 1,2 3 JRC Study Group 4 , the WCM-GI Study Group 5

Received 10 May 2020, Revised 20 May 2020, Accepted 23 May 2020, Available online 29 May 2020.





Escalation of Immunosuppressive Therapy for Inflammatory Bowel Disease Is Not Associated With Adverse Outcomes After Infection With Clostridium difficile

Dana J Lukin, MD, PhD, Garrett Lawlor, MD, David P Hudesman, MD, Laura Durbin, MPH, Jordan E Axelrad, MD, MPH, Monica Passi, MD, Kimberly Cavaliere, MD, Elliot Coburn, MD, Michelle Loftus, DO, Henry Jen, MD ... Show more

Inflammatory Bowel Diseases, Volume 25, Issue 4, April 2019, Pages 775–781, https://doi.org/10.1093/ibd/izy308

Published: 12 October 2018 Article history +

Article

Expansion of Bacteriophages Is Linked to Aggravated Intestinal Inflammation and Colitis

Lusha Gogokhia ^{1, 2}, Kate Buhrke ¹, Rickesha Bell ¹, Brenden Hoffman ¹, D. Garrett Brown ¹, Christin Hanke-Gogokhia ¹, Nadim J. Ajami ¹, Matthew C. Wong ¹, Arevik Ghazaryan ¹, John F. Valentine ¹, Nathan Porter ², Eric Martens ⁴, Ryan O'Connell ¹, Vinita Jacob ², Ellen Scherl ², Carl Crawford ², W. Zac Stephens ³, Sherwood R. Casjens ¹, Randy S. Longman ³, June L. Round ^{1, 5} & IS

Volume 25, Issue 2, 13 February 2019, Pages 285-299.e8





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Microbiota-Induced TNF-like Ligand 1A Drives Group 3 Innate Lymphoid Cell-Mediated Barrier Protection and Intestinal T Cell Activation during Colitis

Jim G. Castellanos ¹, Vsola Woo ¹, Monica Viladomiu ¹, Gregory Putzel ¹, Svertana Lima ¹, Gretchen E. Diehl ², Andrew R. Marderstein ¹, Jorge Gandara ¹, Alexendar R. Perez ², David R. Withers ³, Stephan R. Targan ⁶, David Q. Shih ⁸, Ellen J. Scherl ⁵, Randy S. Longman ¹, ¹, ², ², ²8

Volume 49, Issue 6, 18 December 2018, Pages 1077-1089.e5

CONSORTIUM LEADERSHIP:



SMART-IBD: Stratifying Medication And Refractory to Therapy IBD. PI: Longman



IBD-ReMEdY: Research, Mentorship, Education in NY. Director of Research, Lukin



VICTORY Consortium: Site Leadership, Lukin



New York Crohn's and Colitis Organization (NYCCO): Executive Council, Scherl



IBD Qorus

Crohn's and Colitis
Foundation: Site Leadership, Lukin

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JRC TRAINEES

Rockefeller Clinical Scholar, Fuchs Lab, Rockefeller University

DR. RACHEL NIEC

NIH T32, 3rd year Fellow, Brady Lab, Rockefeller University

DR. CHARLES BUFFIE DR. WASEEM AHMED

Advanced IBD Fellow 2020-2021

JRC PILOT AWARD PROGRAM, Initiated in 2020 SCHERL-ROBERTS VISITING FELLOW IN IBD Geert D'Haens 2019 Stephen Schreiber 2020

> Top Template design by Freepik; Bottom Template design by BiZkettE1 / Freepik

Kenneth

Kenneth Rainin Foundation. Synergy Award: Cell-free DNA as a diagnostic for Crohn's disease (Pl: Longman)

Kenneth Rainin Foundation: Time-restricted feeding as a treatment for Crohn's Kenneth Rainin disease (PI: Lukin)

Helmsley Foundation: HELMSLEY Anti-phage antibodies in stratifying Crohn's disease diagnosis and treatment response (MPI: June Round (Utah), Ben Larman (JHU), Randy Longman (Cornell)). Weill Cornell Medicine Jill Roberts Center for Inflammatory Bowel Disease

NOTABLE GRANTS

NIH/NIDDK Ro1: Microbiome in Crohn's Spondyloarthritis (PI: Longman)



NIH/NIDDK Ro1: Role for TL1A in Innate Immunity of Crohn's disease (PI: Longman)



Crohn's and Colitis Foundation. Litwin Pioneer Award: The role for fiber in efficacy of FMT for UC (PI: Longman)



Fund for the Future. Weill Cornell DOM: Career Development Award (PI: Battat)



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INTERLOCKING PARTS: PARTNERSHIP WITH JILL ROBERTS INSTITUTE FOR IBD

- The Jill Roberts Institute IBD Live Cell Bank
- ◆ The Jill Roberts Institute: Microbiome Core Lab
- Scientific Advisory Board

Credits:

Content creation / management: Jennifer Conrad

Design: Jennifer Conrad*

*=except where credited otherwise



JRC PHYSICIANS

The JRC offers seven dedicated IBD-focused gastroenterologists for patient care. In addition, there is a full time dietitian and peer support groups to provide a holistic approach to patient care and service. Our clinical team includes an Advanced IBD Fellow, who provides a critical bridge for translational research.



Randy Longman, MD, PhD

Dr. Longman is the **Director of the Jill Roberts Center for Inflammatory Bowel Disease at Weill Cornell Medicine.** He is a gastroenterologist and a mucosal immunologist focused on the care of patients with IBD. He has expertise in evaluating and treating patients with extra-intestinal manifestations of IBD with a particular focus on joint inflammation or spondyloarthritis associated with IBD. His research focuses on defining the cellular and molecular mechanisms underlying host-microbiota interactions in IBD. Dr. Longman's work has been published in leading scientific journals and he has received awards from the NIH, Crohn's and Colitis Foundation, NY Crohn's Foundation, Kenneth Rainin Foundation, Charina Foundation, and Irma T. Hirschl Trust for this work.



Ellen Scherl, MD

Dr. Scherl established the IBD Center at NY Presbyterian Hospital / Weill Cornell Medicine in 2002 and became the **Founding Director of the Jill Roberts Center for IBD** in 2006. Under her direction, JRC has experienced exciting growth. Dr. Scherl, who is the Jill Roberts Professor in Clinical Medicine at Weill Cornell, is an internationally renowned expert in treating patients with ulcerative colitis and Crohn's disease. She has been published extensively, and is a principal investigator on multiple clinical trials. As she searches for an IBD cure, Dr. Scherl's commitment to patient care is the driving force of JRC.



Dana Lukin, MD

Dr. Dana Lukin is an Associate Professor of Clinical Medicine and the Clinical Director of Translational Research for the Jill Roberts Center. He has a focus on the clinical management of complex and treatment-refractory inflammatory bowel disease and is actively involved in the clinical trials program at the center. His research interests include real world experience with new and emerging IBD therapies, biomarker development and validation, and clinical research in IBD. Dr. Lukin serves as the Director of the Advanced Fellowship Program in IBD. He is the co-chair of the Crohn's and Colitis Foundation New York Chapter Medical Advisory Committee and is actively involved in IBD patient and medical educational initiatives.



Vinita Jacob, MD

Dr. Jacob joined JRC in July 2008. She is an Assistant Professor of Clinical Medicine and **the Director of Interdisciplinary Education**. She has given frequent presentations on women's IBD issues, particularly concerning IBD-related fertility issues and the safety of IBD medications during pregnancy. Dr. Jacob is an investigator on multiple clinical trials and an author of numerous published papers concerning IBD.



Robert Burakoff, MD, MPH

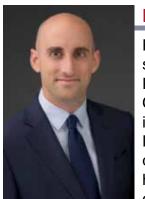
Dr. Burakoff is Professor of Medicine at Weill Cornell Medical College. An outstanding clinician and accomplished researcher, Dr. Robert Burakoff has particular expertise in inflammatory bowel disease. Dr. Burakoff's translational research seeks to identify biological markers to differentiate Crohn's disease from Ulcerative colitis, as well as determine disease severity and response to therapy.

In 2011, the Crohn's and Colitis Foundation of America (CCFA) honored him as Humanitarian of the year for his care of patients with IBD. He is a founding Editor and former Co-Editor-in-Chief of *Inflammatory Bowel Diseases*, the first journal devoted to the study of basic and clinical science in IBD, and recently served as Editor-in-Chief of *Scientific American Medicine*.



Meira Abramowitz, MD

Dr. Abramowitz joined JRC in July 2015 as an Assistant Professor of Medicine. She is the primary co-investigator on several projects characterizing IBD in the Afro-Caribbean population, and has presented her work at several national meetings.



Robert J. Battat, MD

Robert J. Battat, M.D. is an expert in Inflammatory Bowel Disease specializing in Crohn's Disease and Ulcerative Colitis. He is an Attending Physician at the NewYork-Presbyterian Hospital/Weill Cornell Medical Center and the Jill Roberts Center for Inflammatory Bowel Disease. Dr. Battat is a physician-scientist with a major interest in personalized medicine in Inflammatory Bowel Disease and has extensively published scientific articles on this topic. Dr. Battat is a reviewer for over a dozen scientific journals and has lectured on Inflammatory Bowel Disease at national and international conferences.



Clinical Nutritionist Ryan Warren, MS, RDN, CDN

Ryan specializes in providing evidence- and practice-based nutrition education and counseling for patients with a variety of complex gastro-intestinal conditions, including Crohn's disease, ulcerative colitis, irritable bowel syndrome (IBS), small intestinal bacterial overgrowth (SIBO), diverticulosis, diverticulitis, constipation, diarrhea, and gastroesophageal reflux (GERD). Aside from her work in clinical care, she is also actively involved in nutrition-focused clinical research at Weill Cornell and serves as a preceptor and mentor for graduate-level nutrition students in training.



Advanced IBD Fellow Anand Kumar, MD, IBD Fellow

Dr. Kumar is the IBD Fellow at the Weill Cornell Medicine- Jill Roberts Center for Inflammatory Bowel Disease. Dr. Kumar received his medical degree at India's top ranked Armed Forces Medical College. Subsequently, he worked as a medical officer at the Singapore General Hospital, Singapore and later as a research affiliate at Purdue University. He completed Internal Medicine residency and Chief residency at Albert Einstein College of Medicine-Montefiore Medical Center and subsequently worked as an attending physician at Montefiore Medical Center. He is passionate about providing excellent, compassionate care to hospitalized patients and teaching residents and aims to develop a career in gastroenterology and hepatology research with a focus on IBD.



JRC NURSES AND STAFF

NURSE PRACTITIONERS



Helene Brodsky

INFUSION NURSES

Ashley Monteau Joany Casiano Evelyn Kuo

PRACTICE MANAGER

Toni Marrow

PRACTICE SPECIALIST

Keshia Holder

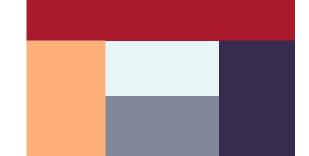


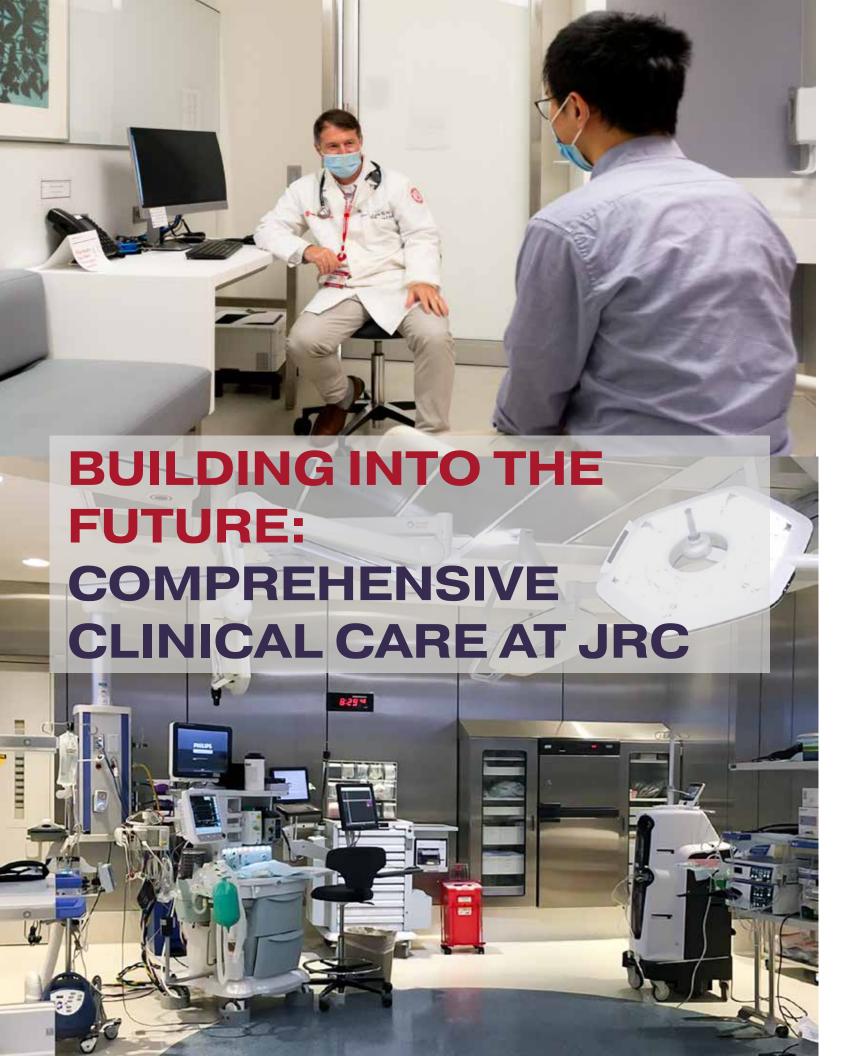
Colleen Wickham



Ann Shum







THE TRANSFORMING POWER OF SPACE: JRC AT DAVID H. KOCH CENTER

On April 30, 2018, the state-of-the-art **David H. Koch Center (DHK)**, part of New York Presbyterian Hospital and Weill Cornell Medicine, opened for patient care. Soon after, **the Jill Roberts Center relocated to the 9th floor of this building**, and the transition has dramatically improved our patient care. The DHK Center provides 18 generously sized exam rooms and a dedicated JRC Infusion Suite with 15 chairs to adequately manage the increasing volume of patients for whom we provide care. Additionally, there are 11 endoscopy suites located on the 8th floor and Radiology is located on the 7th floor to facilitate complex care.

Another important feature of the new space is that our exam rooms are located in close proximity to our colleagues in colorectal surgery. This proximity streamlines management and coordination of complex IBD referrals and ultimately improves IBD care.

This new space also enables us to achieve our translational research mission of life-to-lab. Our clinical research offices are embedded in the clinical exam space and we have established onsite processing facilities for all of our research needs. **This innovative space has transformed the JRC!**



JRC INFUSION SUITE

Two different views of the JRC Infusion Suite. Above photo: Panorama view of the suite and bottom left photo: A closer view of a chair station bay in the suite A critical part of the JRC is our unique site of service infusion center. Equipped with 15 chairs, patients are able to receive high level infusion therapy coupled with their physician visit. This is a critical part of IBD care to personalize treatment plans on an ongoing basis to improve overall outcomes. The on-site infusion center also offers our refractory IBD patients access to various novel therapies through clinical trials. Our infusion center is staffed by two full-time

PHARMACEUTICAL TRIALS



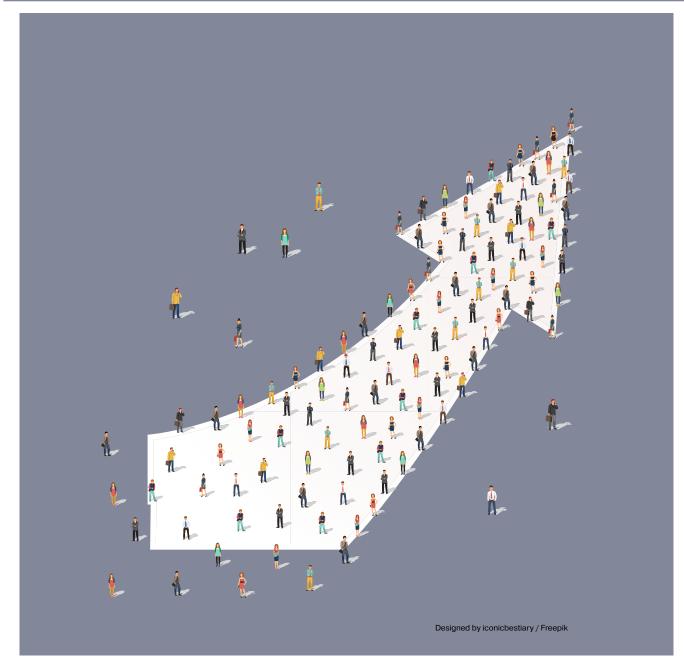
As one of the IBD leading centers in the US, the JRC has many refractory IBD patients who are non-responsive to commercially available medicines. These patients are referred to us from around the nation. The JRC partners with pharmaceutical companies to provide patients with leading edge medical therapies. Our pharmaceutical trial program is one of the largest programs in the world. This program aims to quickly provide patients with alternative medical therapies that are not readily available on the market. Having access to these cutting-edge therapies earlier before widespread distribution provides the pace that for some

Additionally, our clinicians who participate in clinical trials gain expertise with novel therapies and become familiar with the medication and its side effects even before it is F.D.A. approved. In quest for new treatments to serve all of our patients, the JRC believes in the strength of numbers and is pleased to partner with pharmaceutical trials to provide new opportunities in patient treatment. For further information, please visit: https://jillrobertsibdcenter.weillcornell.org/research

-and-clinical-trials/clinical-trials

patients is critical.

EXPANDING NETWORKS: OUR MULTI-DISCIPLINARY APPROACH TO IBD



In the newly constructed David H. Koch Center, the Jill Roberts Center now has physical proximity to colorectal surgical unit, allowing for the new possibility of having the surgeon, physician and patient in the same room to discuss either options or surgical procedures. The physical proximity allows the patient to be an active participant in decisions about their health. This collaboration created an opening to address gaps in patient care as the JRC looks to further develop multi-disciplinary care with the goal for a patient to be able to see two physicians simultaneously during one visit.

Given the multitude of extraintestinal manifestations caused by IBD including inflammation of the joints and skin, mulitdisciplinary partnership is critical for comprehensive IBD care. To address this, we have established a close collaboration with Drs. Lisa Mandl and Sergio Schwartzman, who are rheumatologists at the Hospital for Special Surgery (HSS), for treating patients with joint manifestations. This collaboration facilitates patient evaluation, care, and research. Our aim is to broaden this approach to include colleagues in dermatology, infectious disease, obstetrics, and endocrinology to provide comprehensive IBD care at the highest level.

We envision this bridge building through active participation with colleagues in other disciplines and education. We have established monthly surgical conferences where surgeons and physicians can present and discuss complex patient management strategies. The JRC started an educational series with both IBD and rheumatology fellows that increases communications between physicians. The next phase of growth continues with an educational basis, both internally with seminars but also externally with patient awareness. Drs. Longman and Scherl serve as key opinion leaders working on content for the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) to raise awareness of extra intestinal manifestations. Our aim is to build a paradigm for IBD specialty care at the JRC that will improve patient outcomes and serve as a model throughout the world.



Current JRC Collaborators – **Left:** Dr. Longman with Dr. Fabrizio Michelassi, the Chairman of Surgery at Weill Cornell Medicine and a Colorectal Surgeon. **Right:** Dr. Lisa Mandl, a rheumatologist at the Hospital for Special Surgery (HSS)



STRENGTHING THE WHOLE BODY: NUTRITION SUPPORT



Image designed by Freepi

"We cannot truly treat the patient without addressing their diet, nutritional status and feelings about food and how food impacts their disease and reported outcomes. Food and nutrition have to be incorporated into our therapeutic algorithms in order to optimize our IBD strategies."

-Dr. Ellen Scherl

Nutrition and diet can play a significant role in affecting inflammatory bowel disease. Some dietary patterns can help fight chronic inflammation whereas others can exacerbate chronic inflammation. Because IBD is a chronic inflammatory condition, diet should be considered an essential component in overall patient care.

Every patient who sees one of the clinical doctors at the Jill Roberts Center has an opportunity to have a complimentary nutrition consultation with **Registered Dietitian Nutritionist Ryan Warren**. While not every patient decides to use this service, Ryan sees on average 25 patients during the week. Some patients meet with Ryan once, establishing basic dietary guidelines while others meet with her on an ongoing basis. Counseling skills are part of the dietitian's training because food is often connected to deeper psychological issues. Oftentimes, patients have restrictions on their diet and eating because many foods can exacerbate IBD symptoms. For this reason, some may develop disordered eating patterns. Many IBD patients experience weight loss thus creating a desire to gain weight as a frequent goal. IBD patients also face the

risk of malnutrition due to malabsorption as possible side effects from medications and general symptoms such as nausea, diarrhea and abdominal pain, all of which may cause a decrease in appetite.

In her sessions, Ryan explains that each patient is typically made aware of her **GENERAL GUIDELINES**, which are:

- 1) Eat real, whole foods
- 2) Limit or avoid added sugar, artificial sweeteners and unrecognizable food additives
- 3) Work to identify personal food triggers
- 4) Adhere to eating behavior guidelines, which include slow mindful eating and thorough chewing
- 5) Focus on adequate hydration.

Beyond that, *every patient's session is as unique as their fingerprint*. Ryan's approach emphasizes the ways a patient can use food for nourishment and health rather than restriction of foods, unless warranted. Ryan customizes her expertise into a combination of listening and guidance, offering possible diets that address the foods that can cause inflammation in order to avoid triggers, creating meal plans and handouts, but most importantly, seeing the patient holistically. Ryan reviews with her patients more than just what they are eating but also how they are eating, their stress levels, how much and what kinds of exercise they get, and whether or not patients are also interested in integrative approaches. Many utilize the services of the Integrative Health Center, also located in the David H. Koch Center for acupuncture, stress management and other mindful based services.

Ryan has seen significant results in her patients as their conditions change and improve not only due to her individualized patient plans but also from her general recommendations. Sometimes, if medically appropriate, the only treatment plan will be dietary modifications and these cases can turn out quite well.

Food and nutrition are powerful tools for our bodies. Healthy eating leads to a healthy gut microbiota, which plays a significant role in general gut health. Healthy, anti-inflammatory

diets also promote better overall health and higher quality of life for IBD patients because of fewer flare ups or unwanted symptoms from trigger and pro-inflammatory foods. Nutrition is a key component of the holistic care that the Jill Roberts Center is dedicated to providing for their patients.



General Goals of the "Perfect" Diet

- **◆ To promote healing**
- To help medications work as effectively/efficiently as possible, if applicable
- **→ To maintain the integrity of the gut** microbiota
- **◆** To correct and prevent nutrient deficiencies
- To improve symptoms and overall quality of life

Currently, the JRC's registered dietitian, Ryan Warren, serves as the preceptor for the James J. Peters VA Medical Center (JJPVAMC) Interns. The JJPVAMC Dietetic Internship program is a year-long program, where students complete 35 weeks in various areas of medical and social service specialties.

The current pandemic has affected the internship program and its activities. **Before COVID19**, a critical piece of the internship involved patient interaction.

Normally, during the 3-week rotation:

- the **first week** is mostly observation as interns spend clinical hours observing Ryan provide counseling to her patients
- followed by the interns starting the interview process with patients in week two
- in week three, interns have the opportunity to counsel patients on their own (with Ryan supervising the consultation)

GI is a complex and niche rotation so there is no expectation that the interns will have the facts right away. In addition to the patient contact, the interns complete webinars, readings, and and various assignments, including:

- creating patient-friendly handouts
- a blog post activity, where they select a nutritionally relevant GI topic, then review and analyze research on the topic and finally put it into familiar language for patients in the style of a blog post article
- Interns may also provide customized meal planning for individual patients.

Interns have the opportunity to observe endoscopic procedures with Dr. Scherl so that they have the chance to see firsthand the GI anatomy that they need to understand in order to work with complex GI patients. Dr. Scherl is very interactive, both in terms of teaching and asking the interns questions. Another procedure that the interns help to facilitate with supervision is the hydrogen breath testing for Small Intestinal Bacterial Overgrowth (SIBO), lactose intolerance or fructose

intolerance. Patients drink a formula and then breathe into the machine at different points over 3 hours. Samples are analyzed for production of hydrogen and methane gases, which may in some cases indicate small intestinal bacterial overgrowth or fructose and lactose intolerances. Interns learn how to read and interpret these results.

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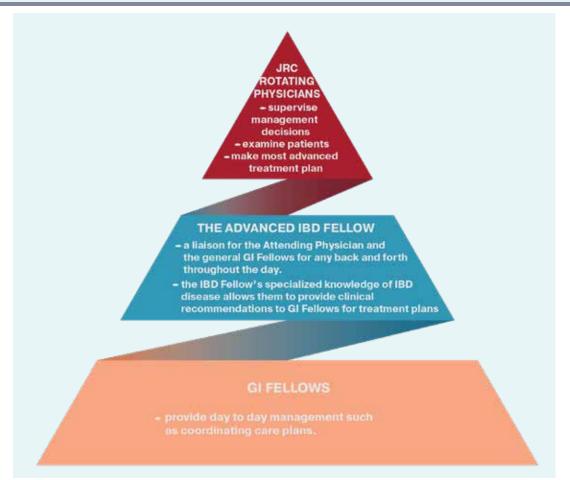
In the initial period of COVID 19, it was not possible for interns to participate as volunteers in Telehealth visits, but this will hopefully change for the next class of dietetic interns starting in August 2020. In this period of remote learning, the focus was more research based and the patient contact portion was provided through a case study based on an actual JRC patient that Ryan has counseled.

Research is a critical component of the internship, as GI is both a complex and evolving field. Ryan and her interns devote time to research in order to answer issues that arise in patient visits and to keep abreast of the latest developments for patient care.



JRC Registered Dietitian Ryan Warren

INPATIENT IBD SERVICE



The Inpatient IBD Service is critical for coordinating complex IBD care for our JRC and WMC IBD patients and facilitates care coordination with our surgical colleagues. **Started in Fall 2019**, this initiative arose due to the gap between outpatient care and recommendations and the inpatient treatment plans. The patients that we refer to inpatient care are patients that we know very well. We feel the options we have to offer them are specialized for the complexity of their illness. Therefore, **Drs. Lukin and Longman structured the service to be a collaborative effort between the GI Fellows, the Advanced IBD Fellow and rotating IBD Attending Physicians. We wanted to make sure the patient and Fellow experience were first and foremost. Drs. Lukin and Longman created an ongoing dialogue with the management of the GI fellowship, Dr. Carl V. Crawford and Dr. David Wan, in order to made sure that the Inpatient IBD Service would fit in with GI Fellows workflow and also provide them with additional education. The new service allows JRC Attending Physicians to be a point person for other specialists such as surgery and radiology to communicate higher level management decisions that are very critical to ensuring positive outcomes for the patient.**

The service itself is a three-layer care plan. At the top layer, there is the rotating IBD Attending Physician. Drs Battat, Jacob, Longman, Lukin and Scherl share this role and rotate by the week to supervise management decisions, examine patients, and make most advanced treatment plan. This service allows for an uniform educational experience

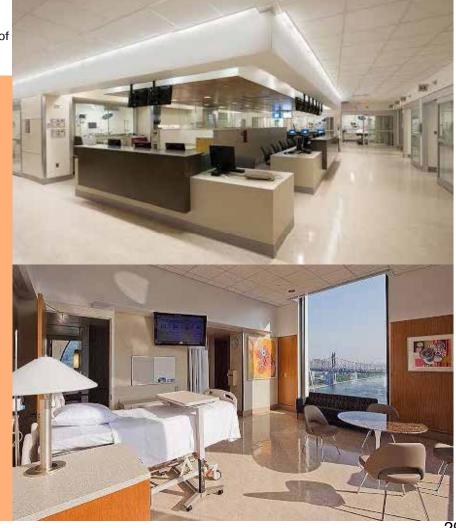
for the Fellows as well as much a more consistent patient care experience. The Advance IBD Fellow is a liaison for the Attending Physician and the general GI Fellows for any back and forth throughout the day. Because of the IBD Fellow's specialized knowledge of IBD disease, they provide clinical recommendations to GI Fellows for treatment plans that minimize unnecessary risks to the patient. The general GI Fellows provide day to day management such as coordinating care plans.

Our involvement in the inpatient setting was created to minimize frequent issues with our patient population such as unnecessary exposure to CAT scans and using steroids for prolonged periods of time. We also offer tailored medical decision making with regard to past medications that the patient have been on with the goal to reduce the need for surgery and complications, and towards potential adverse effects of medical therapies that are commonly used in the hospital. We offer different and novel ways to provide patient care beyond algorithm approach for what they are being admitted. Most importantly, patients have a support system in the hospital and the next level care that only Weill Cornell can offer them. Finally, we can coordinate returning into the outpatient world to make sure our patients have a safe plan to go forward if there are lines or medications needed to be managed, or if there is a need for biologic medications, we are therefore able to schedule those patients without them falling through the cracks. The coordination of a three-layer care team provides the specialization, continuity of patient care, and ultimately provides safety and security for the patients, which fulfills our goals for this service.

Two views: Inpatient nurse station and an inpatient room at New York Presbyterian Hospital; Images courtesy of NYP

GOALS:

- Proactively manage our patients care
- Patients benefit from experienced IBD angle to minimize frequent issues arising in inpatient setting and tailored decisions about medications
- Reducing need for surgery and complications
- Facilitate comprehensive and collaborative decision making to improve outcomes
- Follow up outpatient continuity care



OPTIMIZE VACCINE AVAILABILITY



Designed by Freepik

A critical quality metric currently being emphasized in GI and IBD Societies is **optimizing vaccination for immunosuppressed patients because they are at a higher risk of developing illness.** JRC physicians discuss vaccines during office visits and they counsel the patient appropriately to ensure their vaccine record is current and complete. The physicians will be able to provide vaccines in the Center or have a nearby location on the Weill Cornell campus where patients can easily receive their vaccines and have a follow up to ensure the vaccines were completed.

To determine the impact of vaccines on our patients with IBD, the JRC has partnered with IBD Qorus, an initiative through the Crohn's and Colitis Foundation to improve the quality and care for IBD patients. Lead by Dr. Lukin at Weill Cornell, IBD Qorus involves nationwide participation from physicians reporting their quality metrics and receiving feedback on their levels of care. We will utilize IBD Qorus to ensure we are meeting nationwide standards. Optimized vaccine access is one part of providing the highest level of comprehensive patient care and an important aspect of keeping patients healthy.

NURTURING THE MIND: PSYCHOLOGICAL SUPPORT FOR IBD



Designed by prostooleh / Freepile

For IBD patients, many obstacles arise in daily functioning that most people never have to consider. Some patients have to plan their lives around bathroom access, which in New York City, can be very difficult. The basic necessity of eating can become a careful decision. As with anyone living with a chronic illness, there are ups and downs with symptoms and treatments. This challenge can be complicated by both financial and practical difficulties associated with the required medical care and treatment. Addressing this psychosocial element of IBD care is a major goal of our Center.

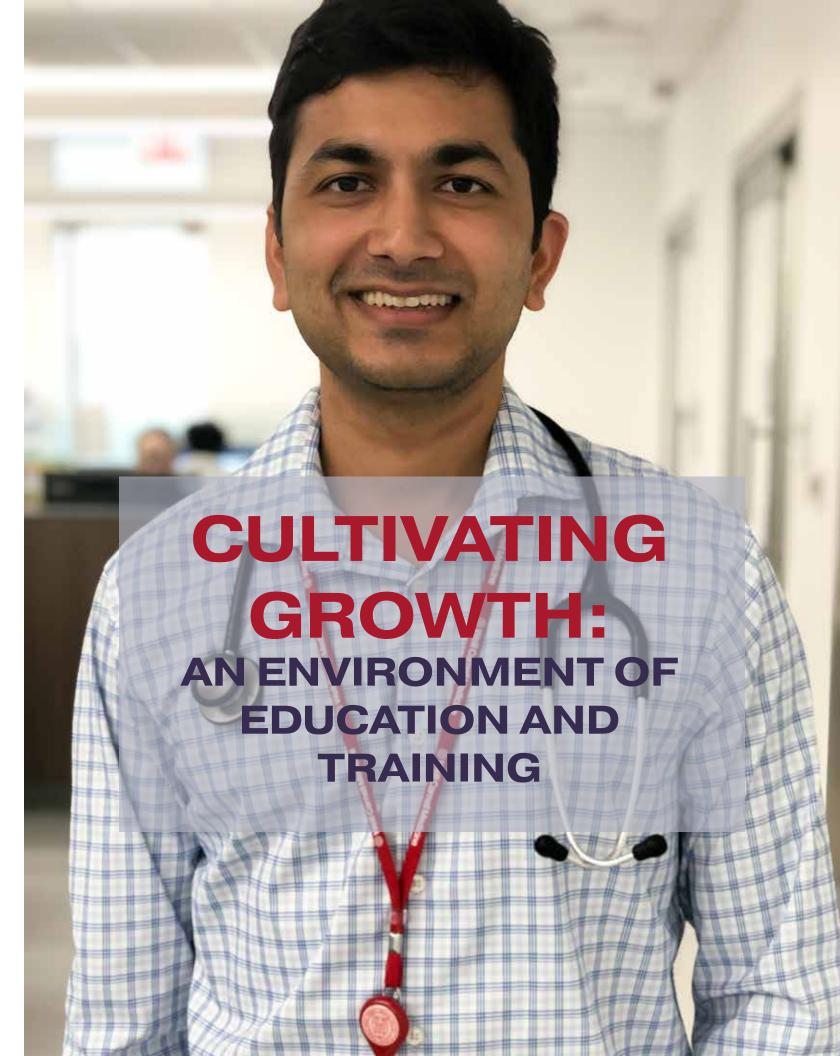
In the history of the JRC, it is important to highlight the fact that **Jill Roberts was a trailblazer and proponent of offering psychological support to patients.** In fact, Jill

Roberts personally supervised and helped to initiate a patient support group that many of the JRC patients utilized. She established rotating speakers for the support group that consisted of all the JRC doctors, who would speak at the support group about their area of expertise in IBD.

Currently, the JRC collaborates with the Center for Advanced Digestive Care (CADC) at Weill Cornell to provide social work support for JRC patients. Additionally, JRC Registered Dietitian Ryan Warren provides a counseling component to her services. In 2019, there was a social work intern who provided vitally needed psychological patient care. As our center grows, we have realized the need for expanding the psychological services for patients. We are working on innovative ways to support our belief in providing a critical and seamless link between the patient and psychological care.







ADVANCED IBD FELLOWSHIP PROGRAM

In 2019, the Advanced Fellowship in IBD program at the Jill Roberts Center was created under the leadership of program director, Dr. Dana Lukin. The curriculum was developed to provide state-of-the-art clinical and research training in IBD and incorporates pivotal elements of several previously established fellowship programs in order to ensure all the landmarks and guidelines for the trainee are reached. This competitive program was designed for candidates seeking a dynamic and comprehensive one-year immersion at a leading academic IBD center. The goal of the one-year multidisciplinary fellowship is to prepare the advanced fellow for independent practice as a gastroenterologist specializing in the care of patients with IBD. The fellowship is split between clinical exposure (60%) and research (40%). Clinically, the fellow's activities are focused on knowledge of inpatient and outpatient management of both average risk and complicated IBD, completing rotations with the JRC clinical faculty, including our clinical dietitian, in an outpatient setting as well as our collaborators in colorectal surgery, pathology, radiology, and pediatric IBD. In addition, the IBD Fellow serves a critical role in leading the inpatient IBD service under the supervision of JRC physicians.



Dr. Anand Kumar is the 2019-2020 JRC Advanced Inflammatory Bowel Disease (IBD) Fellow. His first spark of interest in Gastroenterology (GI) started during his medical school as he was intrigued learning about the pathophysiology of the gastrointestinal system. Subsequently, he has had rich clinical and academic experiences in the related fields while working in Singapore and subsequently at Indiana University under the mentorship of Dr. Naga Chalasani. He then completed his internal medicine residency and chief residency from the Montefiore Medical Center and joined there as an academic hospitalist. During these years, his passion for GI grew stronger. He came to appreciate the challenges of diagnosing and treating complex IBD cases with diverse presentations. Dr. Kumar was fascinated by the multidisciplinary perspective that an IBD specialist must perfect, and in doing so, the tremendous research opportunities the field offers.

Dr. Kumar enjoyed working with an expert group of gastroenterologists focusing on IBD patient care during his rotations. Because of the specialization of care provided at the JRC, it is an **exceptional training setting for multidisciplinary care of complex IBD cases** both in the outpatient and inpatient settings.

- The Advanced IBD fellowship helps our fellows hone the diagnostic art of making accurate diagnosis of IBD, staging disease activity as well as severity and making shared decisions with JRC Clinicians regarding treatment. The opportunity to rotate with affiliated specialists has also been an essential component of his multi-dimensional IBD training.
- IBD Fellows learn to interpret complex clinical, laboratory, endoscopic and imaging data for making individualized therapeutic decisions.
- The IBD Fellow serves a critical role in leading the inpatient IBD service under the supervision of JRC physicians. The IBD Fellow, working with the rotating IBD attending clinician acts as a liaison and teacher to the GI Fellows as part of the JRC Inpatient IBD Service at New York Presbyterian Hospital. Because of the IBD Fellow's specialized knowledge of IBD disease, they provide clinical recommendations to GI Fellows, working under the Department of Medicine, for treatment plans that minimize unnecessary risks to the patient. The Advanced Fellow also coordinates the monthly multi-disciplinary clinical correlation conference and is involved in a monthly IBD conference for the GI Fellows.
- These fellows have the opportunity to have rotation with colorectal surgeons specializing in IBD-specific surgeries, pediatric IBD gastroenterologists and radiology as part of JRC's emphasis on multi-dimensional IBD training.

Dr. Kumar has worked closely with his mentor and program director, Dr. Dana Lukin on several research projects that include

Evaluation of ethnic and racial variations in IBD phenotype and healthcare delivery and the effects of substance abuse and depression on IBD outcomes and presented their research at national meetings including the American College of Gastroenterology, Digestive Disease Week and Advances in IBD.

The research program is designed to provide the fellow with a solid foundation in research methods, the logistics of conducting clinical research, study design, and a skill set aimed at performing independent research. The aim is for the fellow to experience all stages of at least one meaningful research project from conception to presentation at a national meeting and subsequent manuscript preparation and publication. During his advanced fellowship year, Dr. Kumar has used his protected academic time to play a lead role in multiple studies including:

- Analysis of the impact of co-morbid heart failure in patients with IBD, published in the European Journal of Gastroenterology and Hepatology and an investigation of the impact of diabetes mellitus on IBD, which is submitted for publication.
- Assessment of the real-world use of Tofacitinib (a medication used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis) in Crohn's colitis, presented at Crohn's and Colitis Congress 2020.
- Evaluation of patient attitudes toward biologic medication discontinuation adminstered through a patient survey. This evaluation was presented at Digestive Disease Week 2020.
- Under the expert mentorship of the JRC Director, Dr. Randy Longman, he published his first review article on Crohn's disease associated spondyloarthritis in the Journal of Gastroenterology.
- Dr. Kumar is currently evaluating the risk and characterization of COVID-19 in the IBD patient cohort. This study was recently published in the journal, Gastroenterology.

Dr. Kumar aims to become an accomplished gastroenterologist who specializes in delivering comprehensive care to IBD patients and is committed to advancement of the field through research and teaching. As he has been accepted into a three-year GI Fellowship at Lenox Hill Hospital, Dr. Kumar is closer to reaching his goal of becoming a well-rounded Gastroenterologist. The JRC both gained from his contributions and provided him an opportunity to learn and grow into a specialized role. With the success of the advanced fellowship in its first year, the JRC is looking forward to continuing to develop the program into a premier training program in IBD.



GI GRAND ROUNDS *SPONSORED BY JRC*

One training module is the GI Grand Rounds, sponsored by the JILL ROBERTS CENTER FOR IBD, Division for Gastroenterology and Hepatology and the Weill Cornell Continuing Education program. The objectives of these courses are improved patient care through physicians learning new content that is relevant to their medical practice. In 2019, the following guest lectures provided the content for GI Grand Rounds.

How do we target therapy for IBD?

Maria T. Abreu, MD

Martin Kalser Chair in GI, Vice Chair of Research,
Dir Crohn's & Colitis Center, Prof of Med, Microbiology &
Immunology
University of Miami Miller School of Medicine
Thursday, January 10, 2019
7:30-8:30 am
1305 York Avenue, 2nd Floor, Room C



THE 2019 ELLEN SCHERL-JILL ROBERTS VISITING PROFESSOR

Inflammatory Bowel Disease: How a Multidimensional Approach will Lead to Better Outcomes for our Patients

Geert D'Haens, MD, PhD, AGAF

Dir of IBD Clinical Research, Vice Dir of Trainning Prog & Med Dir European Cln Operations
University of Amsterdam, AmsterdamUMC, AMC & Robarts Clinical Trials Inc
Thursday, February 14, 2019
1305 York Avenue, 2nd Floor, Room C





From left to right: Drs. Ellen Scherl, Geert D'Haens and Jill Roberts at the presentation of the 2019 Scherl-Roberts Visiting Professor Award



From left to right: Jill Roberts, Drs. Ellen Scherl and Stefan Schreiber at the presentation of the 2020 Scherl-Roberts Visiting Professor Award



Can the gut microbiome be changed to modify risk for infection?

Daniel Freedberg, MD, MS

Assistant Professor of Medicine and Epidemiology Columbia University/Mailman School of Public Health Thursday, September 26, 2019 7:30-8:30 am 413 East 69th Street, 2nd FL, Rm BB 204-C



****CO-SPONSORED BY THE JRC***** The role of interpersonal gut microbiome variation in IBD

Jeremiah Faith, PhD

Associate Professor Precision Immunology Institute, Institute for Data Science & Genomic Technology, ISMMS Thursday, December 5, 2019 7:30-8:30 am 1305 York Avenue, 2nd FL Room B



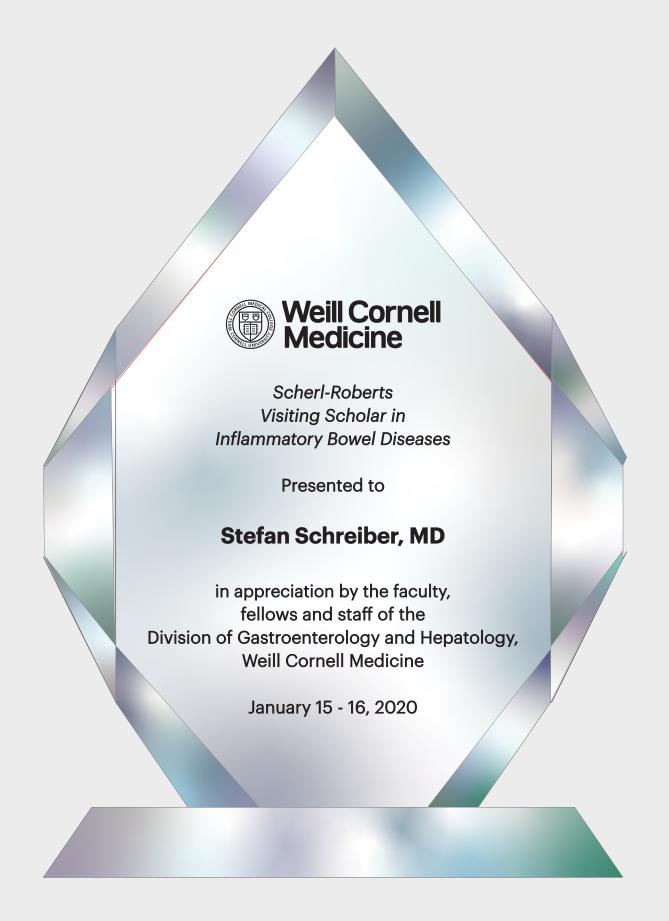
THE 2020 ELLEN SCHERL-JILL ROBERTS VISITING PROFESSOR

Tryptophan Metabolism as a Therapeutic Target for Chronic Inflammatory Diseases

Stefan Schreiber, MD

Clinic Director, Department of Internal Medicine I University Hospital Schleswig-Holstein (UKSH), Kiel, Germany Director, Institute of Molecular Biology, Kiel University, Germany Wednesday, January 15, 2020 Uris Auditorium





THE JILL ROBERTS CENTER PILOT AWARDS FOR RESEARCH IN INFLAMMATORY BOWEL DISEASE

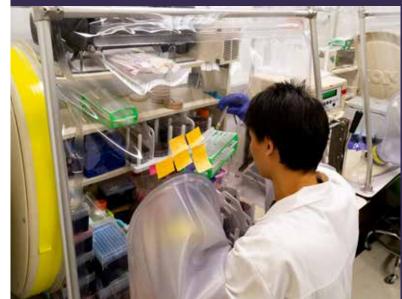
The Jill Roberts Center (JRC) is excited to announce the availability of grant funds for pilot and feasibility projects in the area of inflammatory bowel disease (IBD) research. These awards are supported by the Jill Roberts IBD Research Fund in memory of Jill Roberts and her commitment to advancing the science and research related to IBD. Awards will be for approximately \$25,000 for a period of one year, renewable for an additional year.

The external scientific advisory board of the JRC will evaluate the proposals. The board is seeking high-risk, high-reward research that is needed in basic, translational, and clinical science to further our understanding of the pathogenesis and / or support paradigm shifting changes in IBD care. The Jill Roberts Center Pilot Awards are open to new investigators without current or past NIH research support who are seeking to obtain preliminary data to establish an IBD research program. Proposals from established, funded investigators with no previous work in IBD-related areas

but who wish to test the applicability of their expertise to an IBD-related problem will be given careful consideration.









Photos in laboratory by Jennifer Conrac

This award also seeks to support established investigators in IBD-related areas who wish to test the feasibility of a new or innovative idea, which constitutes a significant departure from their funded research and/or initiates a new collaboration. Finally, trainees who are recipients of an NRSA individual award (F32) or are supported by an institutional training grant (T32) are eligible if they are in their last year of training, have had at least one year of research laboratory experience, and have suitable expertise and independence to design and carry out the planned experiments are also strongly encouraged to apply with their project proposals.

IBD remains a major health problem impacting our community. This new research funding initiative expands the network of the JRC to include the award investigators as part of our partnership for gaining more knowledge and expertise about IBD that ultimately lead to advances in patient care.

LAB TO LIFE:
TRANSLATIONAL
RESEARCH AT THE
JILL ROBERTS
CENTER



JRC TRANSLATIONAL RESEARCH TEAM



Fatiha Chabouni, MD, Clinical Research Manager

Dr. Chabouni joined the Jill Roberts Center (JRC) in 2007 and has played a vital role in expanding the clinical research program. She obtained her medical degree at Algiers Medical School and practiced at the Tizi-Ouzou Hospital for 8 years as a general practitioner.

As JRC's Research Associate and Clinical Trials Program Manager, she has assisted in initiating and managing over 80 pharmaceutical clinical trials and 50 investigator-initiated trials. Dr. Chabouni currently oversees the day-to-day activities for 40 trials and is the main contact for patient research participation. She also manages clinical trials billing and compliance.



Monisha Ravisetti, Clinical Research Assistant

Monisha Ravisetti currently holds a position at the Jill Roberts Center for Inflammatory Bowel Disease as a Clinical Research Assistant working on our clinical trials and our observational analyses. She received her degree from New York University with a major in Philosophy and minors in Physics and Chemistry. During her undergraduate years, she worked at NYU Langone, primarily on microbiome research, and at the NYU Neuroscience and Education Lab, studying the mechanisms of and correlations between topics of mental health. Upon graduating, she delved into clinical work at Mount Sinai which supported efforts to bring greater precision to Emergency Medicine through practice-pattern studies. Monisha reconciles her backgrounds in Philosophy, Psychology, and Basic Science by working alongside our patient population enrolled in research studies in both a holistic and an evidence-based manner.



Stevie Yang, Clinical Research Assistant

Stevie Yang joined the Jill Roberts Center for Inflammatory Bowel Disease as a clinical research assistant in July 2018. She assists in heading all sponsor-initiated clinical research trials with a focus on coordinating patient visits, data management, and site monitor support. She is also engaged in investigator-initiated research, including the PRIME quality improvement initiative and investigating the safety of IBD biologic therapy during pregnancy.

Stevie received a Bachelor of Arts degree in Molecular Biology and a minor in Global Health from Princeton University. As an underclassmen, she interned at the University of Massachusetts Medical School and helped analyze RNA interference strategies for Huntington's disease treatment. At Princeton, she pursued her senior thesis research exploring the dynamic shape of the pathogenic bacterium Vibrio cholerae and its larger implications.



Lucia Duenas-Bianchi, Translational Research Assistant

Lucía is a Translational Research Assistant working on our SMART, MINDFUL and Time-Restricted Feeding studies. At the JRC, Lucía is responsible for the recruitment and management of research conducted by the Longman Lab. Originally from Perú, she earned her undergraduate degree in Global Public Health/ Chemistry at New York University. In conjunction with her studies at NYU, she worked in a public health lab studying intimate partner violence and at Columbia Medical Center studying the innervation in the oral cavities of mice. After graduation, Lucia worked as a clinical coordinator in a neurology practice before joining us at the JRC. Lucia applies her experiences in both macro and micro health sciences to guide the way she performs research.



Gabriela Funez-dePagnier, Translational Research Assistant

Gabby Funez-dePagnier joined the Jill Roberts Center for IBD in January 2019 as a translational research assistant. She assists in the recruitment, development, and management of Dr. Longman's translational research, specifically the SMART-IBD observational study and the FMT/psyllium fiber clinical trial. For these investigator-initiated studies she obtains patient's consent and clinical data, processes biological specimens, conducts data management, and coordinates with the Weill Cornell IRB and the U.S. FDA.

She completed her Bachelor of Science degree in Biology and Public Health/ Community Medicine at Tufts University. While an undergraduate, she conducted research on nerve regeneration and angiogenesis in a diabetic mouse model at the Vaccine and Immunotherapy Center (VIC) at Massachusetts General Hospital. After graduation, she first joined Weill Cornell as a research technician studying drug resistance in Kelch-13 mutant malarial parasites and sexual differentiation in P. Falciparum malaria.



Pictured left to right in front row: Lucia Duenas-Bianchi, Monisha Ravisetti, Tanvi Mahabre, Drs. Ellen Scherl and Fatiha Chabouni, Stevie Yang, Gabriela FunezdePagnier
Pictured left to right in back row: Drs. Dana Lukin and Robert Battat, IBD Fellow Anand Kumar, and Brian Krichevsky (JCTO)

SMART IBD: STRATIFYING MEDICATION RESPONSE AND REFRACTORY TO THERAPY IBD

SMART IBD is a major research initiative to understand why some people respond to medications and others do not. This initiative created at the Jill Roberts Center in 2019 provides longitudinal clinical information accompanied by biological specimens from all patients initiating biologic or small molecule therapy at the Center. One of the goals of this database is to identify key clinical and biologic markers of response to therapy. Biologic markers will include immune phenotyping, metagenomic, and metabolomic targets associated with clinical response. Results from this initiative will provide a critical resource for improving our effective use of medical therapy to treat IBD.

Funding for this initiative generously provided by:







Active IBD (Pre-therapy)

The JRC translational team defines and collects:

- Clinical phenotype
- Disease Activity
- Biological samples (blood, fecal, +/mucosal biopsy)



Post-induction (10-16 weeks)

The JRC translational team monitors and collects:

- Disease activity
- Biological samples(blood, fecal, +/mucosal biopsy)



One year follow up

The JRC translational team reports and collects:

- Disease activity
- Biological samples (blood, fecal, +/mucosal biopsy)

CAN DIET IMPACT IBD?: TIME RESTRICTED EATING IN CROHN'S DISEASE



Funding for this pilot study generously provided by:



Images provided by Freepik; Design concept and layout by Jennifer Conrad

Ms. Jill Roberts was actively engaged in the daily activities of the Jill Roberts Center and a strong proponent for the role of nutrition in IBD. In November 2018, Ms. Roberts approached the Center registered dietitians (RD), Colleen Webb and Ryan Warren, and the JRC clinical team to create a research study centered on nutrition. After discussing several potential nutritional interventions, the team, including the RD's and Drs. Ellen Scherl, Amy Tsou, Randy Longman, and Dana Lukin, decided to proceed with a pilot study on time restricted eating. This method of eating has been shown to be an effective method to improve metabolic function in a variety of diseases, including diabetes and obesity. Time restricted feeding has also been shown to decrease inflammation and alter immune function in animal models. However, there have been no studies with time restricted eating to date for IBD. Working collaboratively, the dietitians and physicians developed a grant proposal which was funded by the Kenneth Rainin Foundation. The study has been approved by the IRB and will resume active enrollment with the re-opening plans of Weill Cornell Medical College.

Various nutritional interventions and diets have garnered interest from physicians and the patient community for the treatment of Crohn's disease. However, the only currently effective dietary therapy recommended for the treatment of active Crohn's disease is Exclusive Enteral Nutrition (EEN), a formula-based diet aimed at bowel rest. The principle behind this diet is to avoid stimulation of the gut since food antigens stimulate the mucosal immune system, allowing time for bowel damage to heal. However, this diet requires a prolonged period without the consumption of a standard diet and is therefore poorly tolerated within the adult population.

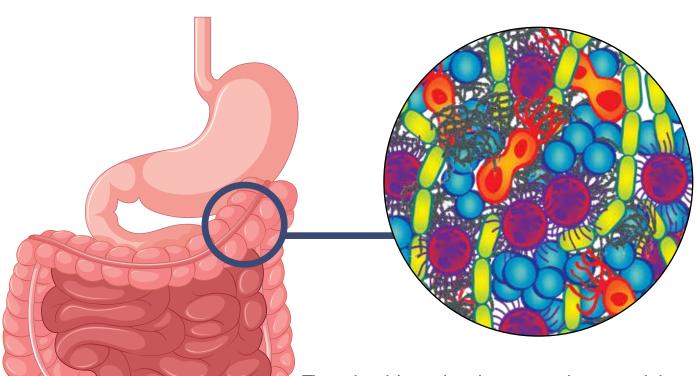
The study at the Jill Roberts Center is designed for patients over the age of 18 with Crohn's Disease to restrict their eating to an 8-hour daily window and to fast for the other 16 hours in the 24-hour cycle over a four-week period. The study seeks to enroll 20 patients over the course of one year to assess the feasibility, rates of dietary adherence, and effects of time restricted feeding on clinical and biochemical aspects of disease activity, with the goal of informing larger, randomized, prospective studies. This study will assess changes in clinical disease activity, biochemical markers of active disease, longitudinal changes in the fecal microbiota, and changes in immune cells following a four-week study period.

THE STUDY BREAKDOWN:

- Adult patients with mild-to-moderate Crohn's disease on stable medical therapy will be eligible for participation. Baseline demographic, disease activity, and body composition data will be assessed.
- Stool samples will be collected at baseline longitudinally during the four-week study period to assess changes in microbiota composition
- Fed- and fasting baseline blood samples will be compared to longitudinally collected samples to assess biochemical markers of Crohn's disease activity as well as to assess immune cell phenotypes using CyTOF, a specialized type of flow cytometry used in immune profiling of lymphocytes from the peripheral (circulating) blood.
- Each patient will also be evaluated longitudinally with a body mass/composition scanner (InBody) to assess body mass and composition changes.
- Drs. Robert Battat and Carolyn Newberry are also part of the study team, providing clinical visits with patients and aiding in research design.
- JRC Registered Dietitian Nutritionist Ryan Warren will provide patient support, reviewing the dietary intervention and patient food logs over the course of the fourweek time restricted eating diet. The patients will enter their food logs into a secure Redcap database, using an app.

Many medications and therapies that alleviate symptoms for IBD patients are also associated with potential for adverse effects and cost. Finding complimentary treatment options through diet may help offer new possibilities for treatment and symptom management in patients with Crohn's disease. Time restricted eating may thereby provide an adjunctive treatment attractive to patients which will allow for a more personal approach to disease management.

GUT MICROBIOME IN IBD RESEARCH AND TREATMENT

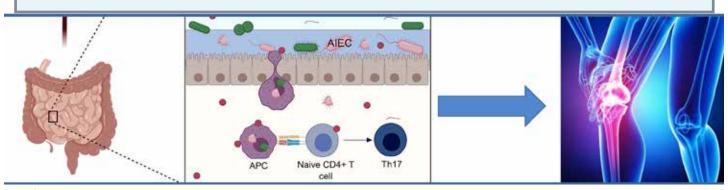


The microbiome has become a buzzword that is seen and heard throughout media and everyday conversation. Intestinal bacteria outnumber our human cells by 10 to 1 with 300 times the number of genes in the human genome; however the role for the microbiome in the underlying etiology of IBD remains an intense focus of our research.

Do markers exist in the IBD microbiome that can guide IBD diagnosis and guide safer more effective therapy?

Are there functional diagnostics that can assess the impact of the gut microbiome on systemic immunity?

DEFINING A ROLE FOR MICROBIOTA IN IBD-ASSOCIATED SPONDYLOARTHRITIS (SPA)



Connecting the gut and joints. Research from Dr. Longman and colleagues have shown that inflammation in the intestine can lead to immune cell activation in circulating cells and subsequent joint inflamation.

IBD is not limited to the intestine but can occur throughout the body affecting eyes, mouth, liver, kidneys, skin and circulation. The most common extraintestinal manifestations (EIM) occur in the musculoskeletal and dermatologic systems. Our current focus is IBD-associated peripheral spondyloarthritis (SpA), which includes both axial spinal inflammation and peripheral joint manifestations of synovitis, dactylitis, and enthesitis, Peripheral manifestations alone carry a prevalence of 20% in Crohn's Disease (CD) and 10% in ulcerative colitis (UC), predominantly affecting joints of the lower limbs.

Presently, there are no diagnostic biomarkers for SpA as test results are seronegative and

there are no visible markers with radiography. There is a clinical need for diagnostic and therapeutic approaches for early and effective therapeutic intervention.

Our current avenues of research focus on definining clinical, immunologic, and microbial biomarkers of IBD-associated joint inflammation. In collaboration with a team of rheumatologists at HSS, we aim to define clinical and radiographic guidelines for assessment in IBD associated spondyloarthritis.

Axial or lower spinal pain is a symptom of SpA.

Image created by kipargeter@Freepik

THE GUT MICROBIOME AND IMMUNE PHENOTYPE OF CROHN'S SPONDYLOARTHRITIS

The Longman Lab, part of the Jill Roberts Institute for Research in IBD recently discovered the expansion of certain bacteria called Adherent-Invasive E. coli in IBD-patients with spondyloarthritis. This microbial biomarker correlated with patient reported disease active index called BASDAI that uses a 0-10 scale measuring pain, discomfort and fatigue that pertain to the five major symptoms of this disease. In mouse model experiments, the Adherent-invasive E. coli isolates induced T helper 17 cell (TH17) mucosal immunity, leading to more severe colitis or inflammatory arthritis. The findings from this study have identified clinical and microbial biomarkers now used at the JRC to track disease and help select medical therapy.



The Longman Lab at the 2019 NYC IBD Day. Pictured left to right: Dr. Randy Longman, Silvia Pires, Maeva Metz, Monica Villadomiu Pujol, and Svetlana Ferreira Lima

This study lead to the questions:

Are there functional diagnostics that can assess the impact of the gut microbiome on systemic immunity?

Can we identify patients that can be treated effectively with current medications?

Can we develop new medications to treat CD SpA?

NEW DIAGNOSTIC AND THERAPEUTIC STRATEGIES FOR CD-SpA

Based on our previous work, follow up studies are underway to define the practical impact of these findings on IBD care.

Our current approaches include:

A.Novel Therapies: Develop novel small molecule inhibitors of key metabolic pathways in AIEC induction of Th17

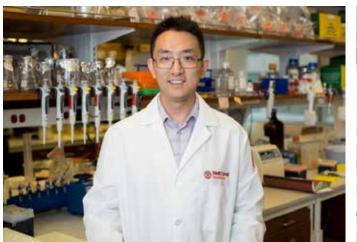
B.More Effective Use of Therapy: Longitudinal characterization of CD-SpA response to sulfasalazine, a disease-modifying drug, to characterize microbial biomarkers of response

C.Improving Diagnostics: Establish novel, non-invasive methods to characterize gut microbiome translocation as a diagnostic for CD SpA

NOVEL THERAPIES: TARGETING METABOLIC CAPACITY OF CD-SPA MICROBES TO REGULATE MUCOSAL IMMUNITY

There are two research teams focused on further pinpointing genetics involved in microbial disease and subsequent treatment. **The Longman Lab in collaboration with the Guo Lab**, at the Jill Roberts Institute are working on *Defining microbial metabolites required for T cell activation*. **The Longman Lab is also collaborating with colleague Dr. Ken Simpson**, who works at Cornell University on the Ithaca campus on *Develop small molecules inhibitors of bacterial metabolism to treat inflammation*.

Dr. Chun-Jun Guo at the Jill Roberts Institute



Dr. Ken Simpson at Cornell University, Ithaca, NY



CAN WE CHANGE THE MICROBIOME?: FECAL MICROBIOTA TRANSPLANTATION FOR ULCERATIVE COLITIS

Fecal microbiota transplant (FMT) is the process of transferring fecal bacteria from a healthy donor to a recipient. FMT has grown in use and acceptance as it is highly effective for the treatment of recurrent C. difficile colitis.

Efficacy in patients with IBD remains under investigation and the FDA requires an IND (Investigational New Drug) application for investigational use to treat patients using FMT.

In 2017, our JRC team led by Drs. Jacob, Scherl, and Longman evaluated the safety and efficacy of two-donor FMT via colonoscopy for the treatment of UC.

At week 4 after the transplant, patients were assessed for response, remission, and mucosal healing. Of the 20 patients enrolled in this study, 7 patients (35%) achieved a clinical response by week 4. Three patients (15%) were in remission at week 4 and 2 of these patients (10%) achieved mucosal healing. Three patients (15%) required escalation of care. No serious adverse events were observed.

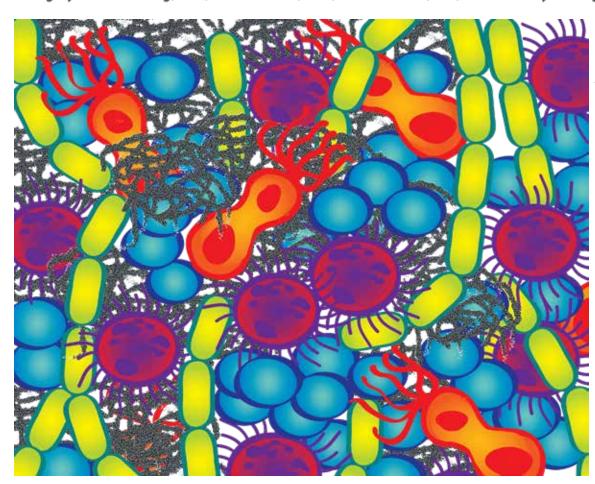
The microbiome analysis revealed the limited diversity of these patients pre-FMT was significantly increased by the high diversity 2 donor sample FMT. Post-transplant, the patient microbiome more closely resembled the donor FMP than their

pre-transplant sample in both those who responded to treatment and those who did not respond. Noticeably, donor composition correlated with clinical response. Additionally, mucosal CD4 T-cell (white blood cells) analysis revealed a reduction in both Th1 (Th1 helper cells lead to an increased cell-mediated response, typically against intracellular bacteria and protozoa) and regulatory T-cells post-FMT.

Drs. Jacob, Scherl and Longman were able to conclude that high-diversity, 2-donor FMP delivery by colonoscopy seems safe and effective in increasing fecal microbial diversity in patients with active ulcerative colitis. Donor composition correlated with clinical response. Further analysis and research of the microbiome to define and characterize the immunological parameters may provide insight into factors influencing clinical outcome.

Single Delivery of High-Diversity Fecal Microbiota Preparation by Colonoscopy Is Safe and Effective in Increasing Microbial Diversity in Active Ulcerative Colitis

Vinita Jacob, MD,* † Carl Crawford, MD,† Shirley Cohen-Mekelburg, MD,† Monica Viladomiu, PhD,†,‡ Gregory G. Putzel, PhD,‡ Yecheskel Schneider, MD,† Fatiha Chabouni, MD,* † Sarah O'Neil, PA,† Brian Bosworth, MD,§ Viola Woo, BS,†,‡ Nadim J. Ajami, PhD,¶ Joseph F. Petrosino, PhD,¶ Ylaine Gerardin, PhD,¶ Zain Kassam, MD, MPH,¶,** Mark Smith, PhD,¶,** Iliyan D. Iliev, PhD,‡ Gregory F. Sonnenberg, PhD,†,‡ David Artis, PhD,†,‡ Ellen Scherl, MD,*,† and Randy S. Longman, MD, PhD*,†,‡

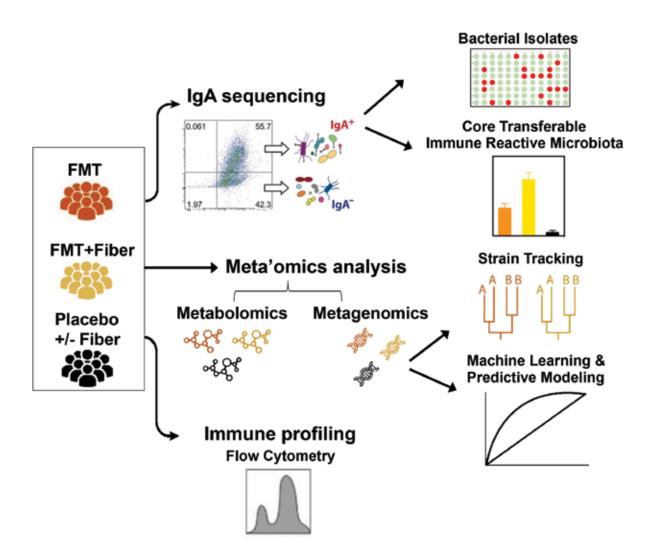


representation of gut bacteria microbiome; Illustrations on 56 & 57 by Jennifer Conrad

CAN WE CHANGE THE MICROBIOME TO TREAT IBD?: MINDFUL STUDY

Brief Summary:

A double-blind, randomized, placebo-controlled clinical trial examining the efficacy and safety of Fecal Microbiota Transplantation (FMT) and high fiber supplementation in patients with active mild to moderate Ulcerative Colitis (UC). All enrolled subjects will provide serological, stool and mucosal specimen at each clinic visit to help further define the alterations in microbial profiles and immune cell function in response to psyllium fiber after FMT treatment.



Study Type: Interventional (Clinical Trial) **Estimated Enrollment:** 135 participants **Actual Study Start Date:** January 31, 2020

Estimated Primary Completion Date: January 2023 **Estimated Study Completion Date:** January 2025

Sponsor: Weill Medical College of Cornell University

Collaborator: Crohn's and Colitis Foundation **Principal Investigator:** Randy Longman, MD, PhD

Weill Cornell Medicine

Sub-Investigator: Dana Lukin, MD, PhD **Sub-Investigator:** Carl Crawford, MD **Sub-Investigator:** Ellen Scherl, MD

Detailed Description:

This is a randomized, double-blind, placebo-controlled clinical trial with the following treatment assignments:

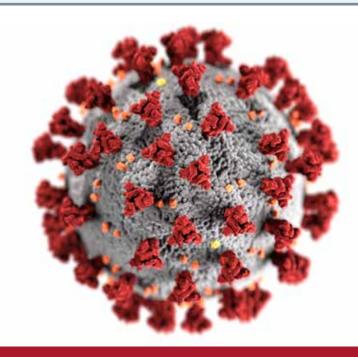
- 1. Investigational FMT (one-time)
- 2. Investigational FMT (one-time) + Psyllium (2x/day for 4 weeks)
- 3. Placebo FMT (one-time) + open label FMT (one-time) +/- Psyllium (2x/day for 4 weeks) a. Subjects in this group will be unblinded after the completion of their week 8 evaluation by flexible sigmoidoscopy and will consequently be given open label FMT.

Subjects will receive the investigational or placebo FMT treatment only if they meet all inclusion and exclusion criteria during the week 0 screening colonoscopy. Subjects will receive a follow-up phone call or return for a clinic visit every 2 weeks post-FMT until week 12. At week 8 post-FMT, all subjects will be evaluated by flexible sigmoidoscopy in the clinic. Stool and blood samples will be collected from subjects at week 0 prior to FMT, week 4 post-FMT, and week 8 post-FMT. Mucosal biopsies will also be taken during the initial colonoscopy at week 0 and during the follow-up flexible sigmoidoscopy at week 8. Subjects randomized into the placebo cohort will receive open-label investigational FMT by flexible sigmoidoscopy at the week 8 clinic visit (after week 8 endpoint data are collected). These subjects will return 4 weeks later at week 12 for a clinic visit. All subjects will be contacted for follow-up phone calls every subsequent 6 months for the next year. ClinicalTrials.gov Identifier: NCT03998488

Funding for this study generously provided by:



COVID-19 AND IBD



Representation of the COVID19 from the Centers for Disease Control and Prevention (CDC) Telemdicine graphic designed by studiogstock / Freepik; Testing graphic designed by stories / Freepik

In March 2019, New York City emerged as the epicenter of the worldwide pandemic of COVID-19. As our hospital struggled to provide care for thousands of patients infected with SARS-CoV2, physicians at the JRC led the charge to counsel IBD patients and research the impact of this novel coronavirus on patients with IBD, particularly those taking immunosuppressive medications.



ONSITE MANAGEMENT

During the pandemic, the JRC and the infusion center remained open to care for patients with IBD. We instituted strict screening guidelines and provided appropriate PPE for providers and patients. We increased testing capacity to ensure that all patients entering the infusion suite were negative for SARS-CoV2. These changes allowed us to provide continued essential care and medication for our patients.



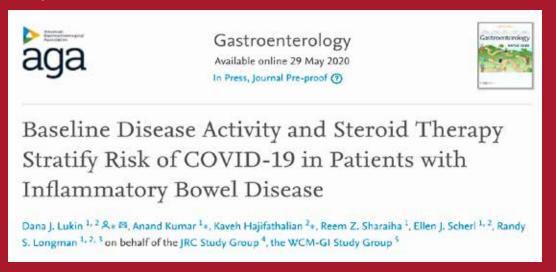
TELEMEDICINE

While telemedicine existed prior to the pandemic, we greatly expanded our capacity for telemedicine.

Nearly all of our routine visits were converted to telemedicine and over 50% remain. This resource allowed us to provide high-level IBD specialty care while minimizing risk of exposure and strategically coordinating in-person care encounters. We anticipate that telemedicine will remain a strong component of our practice in the future.

COVID-19 AND IBD RESEARCH

At the center of the epidemic, we cared for hundreds of patients with IBD and COVID-19. Leading the way to understand the impact of COVID-19 in IBD, we evaluate outcomes of these patients recently published in *Gastroenterology*. Our findings show that patients with IBD, and particularly those maintained on immunosuppressive medications, were not at increased risk of getting COVID-19 or having more severe symptoms. In fact, patients with higher disease activity or those requiring prednisone to control their disease had worse outcomes. These findings support our guidelines to continue maintenance medications and help to provide critical guidance to our patients during this pandemic.



Jill Roberts Center for Inflammatory Bowel Disease Jill Roberts
Institute for
Research in
Inflammatory
Bowel
Disease

INTERLOCKING PARTS: PARTNERSHIP WITH JILL ROBERTS INSTITUTE FOR RESEARCH IN IBD

One of the most important partnerships that the Jill Roberts Center for IBD (JRC) shares is with the Jill Roberts Institute for Research in IBD (JRI). Mrs. Jill Roberts, who generously provided a way for these entities to thrive, believed in the necessity of both outstanding clinical care and research for tomorrow's cures. Initiatives and research bind the Center and the Institute together. Dr. Randy Longman, who serves as both the Director and clinician in the JRC and additionally is the Principal Investigator of a laboratory in the JRI, serves as a link to facilitate cooperative projects. Two initiatives of this working partnership are the Jill Roberts Institute IBD Live Cell Bank and the Microbiome Core at JRI.

THE JILL ROBERTS INSTITUTE IBD LIVE CELL BANK







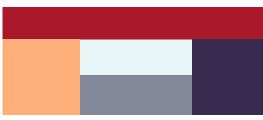


Pictured left to right: Drs. Ellen Scherl, Gregory Sonnenberg, David Artis, and Randy Longman established the JRI Live Cell Bank

First established in 2015, the Jill Roberts IBD Live Cell Bank has grown into a rich research tool. The JRI Clinical Coordinator selects and screens patients for potential donors who are interested in contributing their samples to the Live Cell Bank. Once a patient agrees to be a donor, the Clinical Coordinator consents and interviews them to get their complete clinical history and disease active scores. This critical information is entered into REDCap – a Web-based, secure, study-specific, queriable database – maintained by the CTSC. The patient samples stored include peripheral blood and cryopreserved peripheral blood mononuclear cells(PBMCs), biopsy tissues from the Intestinal epithelium for transcriptome and proteomic analysis and live cryopreserved immune cells from lamina propria for functional studies. Stool samples are also

collected for microbiome analysis – viral, fungal and bacterial. Currently the Live Cell Bank includes samples from 2,000 consented patients.

The Live Cell Bank provides a critical resource for translational research. This queriable resource allows investigators to rapidly test the clinical applications of emerging basic research and serves as a invaluable resource for clinical characterization of our cohorts.





Artis Lab Manager Mei-Yi Zheng and Artis Research Technician Sreehaas Digumarthi process IBD Live Cell Bank Samples

MICROBIOME CORE AT THE JILL ROBERTS INSTITUTE



Another critical link between the JRI and JRC is the JRI Microbiome Core, which provides services and support for translational studies Established in June 2018, the JRI Microbiome Core developed from a need in the laboratories for microbiome characterization. Jorge Gandara, the Microbiome Research Service Manager, used his previous experience and expertise in sample sequencing to streamline the process using and developing the core resource at the JRI. The JRI Microbiome Core serves entire Weill Cornell community but also has a wide customer base including Stoneybrook University, Memorial Sloan Kettering Cancer Center, Rockefeller University, and Cornell University at Ithaca. While Jorge manages the Microbiome Core, he is supported by JRI's Bioinformatician Dr. Greg Putzel, who provides additional data analysis for customers if needed and Drs. David Artis, Iliyan Iliev, and Randy Longman serve as faculty oversight. The Microbiome Core serves as a critical resource for translational microbiome research at the JRC and Weill Cornell Medicine.

JRC SCIENTIFIC ADVISORY BOARD

The JRC Scientific Advisory Board is a new initiative to establish the future planning of the Center from a scientific perspective to serve patients with the most promising developments in the field of IBD Care. The Advisory Board members were selected for their exemplary record as both clinicians and researchers in IBD care. The 2020 inaugural meeting was conducted virtually, but in future years the Advisory Board meeting will coincide with a half day symposium highlighting translational and clinical IBD research at Weill Cornell.



Dr. Adam Cheifetz

Dr. Cheifetz is Director of the Center for Inflammatory Bowel Disease at Beth Israel Deaconess Medical Center and Professor of Medicine at Harvard Medical School. He is Director of the Harvard Medical School Gastroenterology Clerkship Elective and Assistant Director of the Advanced Fellowship in Inflammatory Bowel Disease at Beth Israel Deaconess Medical Center.



Dr. Miguel Regueiro

Dr. Regueiro is currently the Chair of the Department of Gastroenter-ology, Hepatology, and Nutrition, and Vice Chair of the Digestive Disease and Surgery Institute at Cleveland Clinic in Ohio. He serves as Medical Co-Chair of Digestive Disease and Surgical Institute Research Governance committee and is Professor of Medicine at the Lerner College of Medicine, Cleveland Clinic. He also holds the Pier C. and Renee A. Borra Family Endowed Chair in Gastroenterology and Hepatology, Digestive Disease and Surgery Institute.



Dr. Scott Snapper

Dr. Snapper is a physician-scientist with a passion both for patient care as well as research focusing on under-standing the role of the immune system in inflammatory bowel diseases and immunodeficiencies. Dr. Snapper is the Wolpow Family Chair and Director of the Center for Inflammatory Bowel Disease at Boston Children's Hospital. In January 2020, Dr. Snapper became the Chief of the Division of Gastroenterology, Hepatology and Nutrition.



JILL ROBERTS

Center for Inflammatory Bowel Disease





