

UNC CENTER FOR
**FUNCTIONAL GI &
MOTILITY DISORDERS**

ANNUAL REPORT 2007

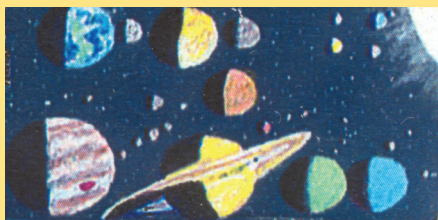
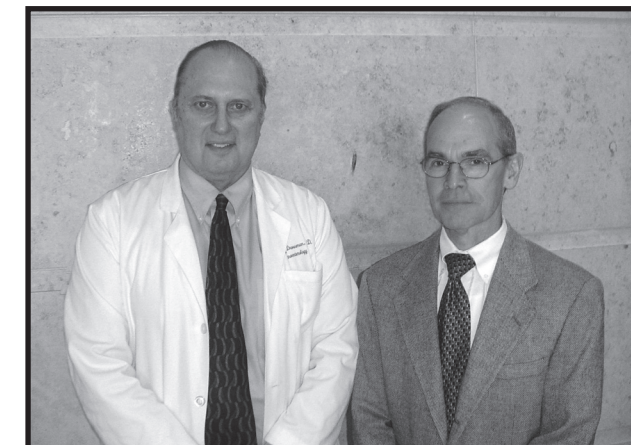


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Cover



Cover art for this annual report was provided by Robert Johnson, whose interest in and support for the Center are greatly appreciated. The artwork was arranged by Jennifer Peterson.

DEAR READER

Welcome to the "2007 Annual Report – UNC Center for Functional GI & Motility Disorders." The yearly process of gathering and presenting information about the Center is an opportunity to reflect on our accomplishments and to thank everyone for their contributions to the Center – faculty, clinicians, investigators, staff, directors and advisors, collaborators, research funding agencies, individual donors, foundations, and corporate sponsors. This report is about all of us and we hope it conveys our gratitude as well as celebrating the year's accomplishments.

The Center is in the fourth year of a five-year grant from the National Institutes of Health (NIH) to foster interdisciplinary research on interactions between the mind and body in health and disease. This \$4.4 million grant established a Gastrointestinal Biopsychosocial Research Program within our Center, which is focused on the causes and treatment of functional GI and motility disorders. This broad-based NIH initiative has evolved from growing evidence that interdisciplinary research -- which integrates the study of social, behavioral, psychological and biological factors -- holds particular promise in understanding the origins of disease and promoting health. Our Center was the first to advocate a biopsychosocial approach to the study and treatment of functional GI and motility disorders. In addition to activities funded through the "mind-body infrastructure grant," our annual report chronicles other significant activities and accomplishments, including these important milestones:

- 47 articles in peer reviewed journals, 19 books chapters, 18 published abstracts
- \$3.4 million in new research grants and contracts – 10% from NIH, 42% from pharmaceutical companies, and 48% from other sources (foundations, UNC School of Medicine Office of the Dean)
- \$4.2 million in overall support for research activities -- 57% NIH, 28% pharmaceutical, and 15% other
- hosting Research Day 2007
- three additional seed grants awarded
- continued generous support from individual donors, foundations, and educational grants from corporate sponsors.

There is always more to share than we include in the annual report. We invite our readers to visit the Center's website at www.med.unc.edu/ibs for further details.

With gratitude,



Douglas A. Drossman, MD
Co-Director
Professor of Medicine and Psychiatry



William E. Whitehead, PhD
Co-Director
Professor of Medicine and
Adjunct Professor of OBGYN

HIGHLIGHTS OF 2007

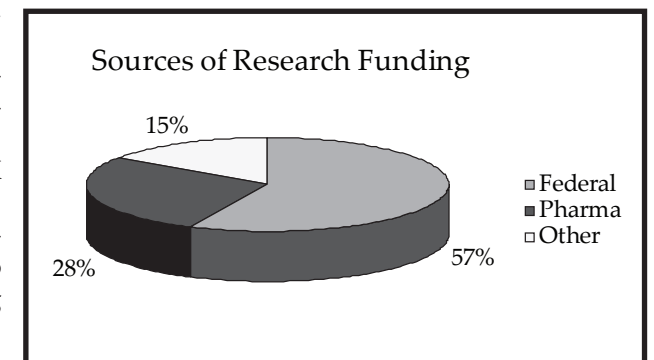
Mind-Body Infrastructure Grant

- ♦ Infrastructure Grant Advisory Board of UNC leaders held its annual meeting on April 20, 2007
- ♦ Scientific Advisory Board of leading experts in functional GI and motility disorders held its annual meeting on September 28, 2007
- ♦ Research Day 2007: Gastrointestinal Biopsychosocial Research at UNC was hosted by the Center on the campus of the UNC School of Medicine on September 28-29, 2007

Awards, Appointments, Special Honors

- ♦ **Doug Drossman, MD**
 - was appointed to the editorial boards of *Psychology*, *Health and Medicine* and *World Journal of Gastroenterology*
 - received the 2007 AGA Mentors Research Scholars Award
 - was listed as "Top Gastroenterologist" in Men's Health Magazine (April 2007) and listed in "Best Doctors in America"
 - served as Chair of the IFFGD 7th International Symposium on Functional GI Disorders
 - Selected for chapter as Best Gastroenterology Practice in: "Inside the Minds: The Art and Science of Gastroenterology" (Aspatore Press 2007)
 - Member of the Institute of Medicine Committee on Gulf War and Health: Physiologic, Psychologic and Psychosocial Effects of Deployment Related Stress, National Academy of Sciences
- ♦ **Steve Heymen, PhD**
 - completed his PhD in Psychology and was promoted to Assistant Professor of Medicine
 - served as guest editor for *Diseases of the Colon and Rectum and Gastroenterology*
- ♦ **Temitope O. Keku, PhD**
 - appointed Adjunct Associate Professor, Dept. of Nutrition, UNC School of Public Health
 - served on NCI special emphasis grant review panels
- ♦ **Ryan Madanick, MD** was selected for the UNC Teaching Scholars Program (2007-2008)
- ♦ **Doug Morgan, MD, MPH**
 - awarded a 3-year grant from UNC (Investments for the Future Initiative) to initiate a bilingual multi-specialty clinic for adult Latinos clinical care, research and teaching
 - awarded an NIH Mentored Clinical Research Scholar Award (KO7 CA125588) to study gastric cancer epidemiology in Latin America
 - served on the Consensus Committees for the International Conference on Capsule Endoscopy and the Gastroenterology Advisory Summit
 - recipient of ASGE Capsule Endoscopy Research Award, 2006-2007
- ♦ **Yehuda Ringel, MD**
 - joined the editorial boards for the *Journal of Clinical Gastroenterology* and the *World Journal of Gastroenterology*
 - recruited Ian Carroll, PhD, microbiologist to work on translational research projects

- ♦ **Yolanda Scarlett, MD** was appointed to the AGA Education and Training Committee
- ♦ **Nicholas Shaheen, MD**
 - served as Vice Chair, Clinical Practice, AGA
 - served as Chair, National Research Committee, ACG
 - served as President, North Carolina Society of Gastroenterology
- ♦ Both **Dr. Keku** and **Dr. Scarlett** served as mentors for the Second Annual AGA-Abbott Immunology Investing in the Future Program: Promoting Diversity in GI Training (Digestive Diseases Week, Washington DC, May 2007)
- ♦ **Miranda Van Tilburg, PhD**
 - received the IFFGD 2007 Research Excellence award for Junior Investigator in Pediatrics
 - received a scholarship to attend the NICHD summer school research institute in applied and adolescent development
- ♦ **Stephan Weinland, PhD**
 - passed his North Carolina and National EPPP Psychology Licensure exams
 - received a travel award to attend the 2007 Functional Brain Gut Research Group (FBG) Young Investigators Forum
- ♦ **Bill Whitehead, PhD**
 - collaborated with the Division of Gastroenterology and Hepatology to establish a Pelvic Floor Biofeedback Clinic (Steve Heymen, PhD, Director)
 - appointed to NIH Study Section: Behavioral Medicine, Interventions and Outcomes
 - awarded a bridge grant from NIDDK (RO1 DK31369-215)
 - awarded a 3-year grant from UNC (Investments for the Future Initiative) to develop and test an approach to treating fecal incontinence in the community



Educational Grants

- ♦ The S&R Foundation and Sucampo Pharmaceuticals are two sponsors of the Center who have continued to provide valued support for our clinical services, research initiatives, patient and public educational efforts, and programs to train researchers and clinicians.
- ♦ We also greatly appreciate receiving educational grants in 2007 from Takeda Pharmaceuticals and The Procter & Gamble Company (P&G), as well as Prometheus Pharmaceuticals, Microbia Pharmaceuticals, AstraZeneca Pharmaceuticals, and Novartis Pharmaceuticals.

ABOUT THE CENTER

The UNC Center for Functional GI & Motility Disorders was established in 1994 by its Co-Directors – Douglas A. Drossman, MD and William E. Whitehead, PhD – as a “center of excellence” within the Division of Gastroenterology and Hepatology, School of Medicine, University of North Carolina at Chapel Hill. Over the years, the Center has evolved into a multidisciplinary patient care, research, training, and public education initiative with an annual budget of over \$2 million and a base of more than 30 faculty, investigators and staff, in addition to visiting and collaborating scholars.

Mission

The mission of the UNC Center for Functional GI and Motility Disorders is to advance the biopsychosocial understanding and care of patients with functional gastrointestinal and motility disorders through patient care, research, training and education.

Goals of the Center

To achieve its mission, the Center is committed to the following goals:

- **Patient Care** – To offer state-of-the-art evaluation and treatment for the full range of functional GI and motility disorders.
- **Research**–To conduct studies on the physiological and psychosocial mechanisms underlying functional GI and motility disorders, their impact on quality of life and health outcomes, and their treatment.
- **Training** – To provide multidisciplinary training and education in clinical and research skills, with an emphasis on patient-centered care and advanced research methods.
- **Public Education**–To provide helpful and up-to-date information, through seminars and workshops as well as printed materials, videos and the internet.

Core Activities of the Center

The integration of **patient care** by gastroenterologists, physician assistants and psychologists in our Functional GI Clinic with state-of-the-art Motility Services places the Center at the forefront of patient evaluation and treatment for functional GI and motility disorders. The Center functions as a tertiary treatment center and receives referrals from gastroenterologists throughout the United States and around the world.

The Center’s unique **research** program provides opportunities for Center faculty, investigators and collaborators to develop and pursue new areas of research in the field of FGIDs. Center associates have developed innovative technologies, such as Internet-based questionnaire research and a network of collaborators at other institutions across the United States and around the world. Through their leadership roles and activities in other organizations – such as The Rome Foundation, Functional Brain-Gut Research Group (FBG), International Foundation for Functional Gastrointestinal Disorders (IFFGD), and AGA Motility Nerve-Gut Interactions Section – the Center’s co-directors play a significant role in defining the research agenda for the entire field of functional GI and motility disorders.

The Center has an excellent program for **training** postdoctoral fellows as well as individualized and highly specific learning opportunities for advanced scholars, physicians and scientists who visit the Center for a couple of days, a week or two, or even longer periods of time. The Center has also created a preceptorship for pharmaceutical representatives (primarily medical liaisons), to provide a thorough grounding in the epidemiology, pathophysiology, diagnosis, and treatment of FGIDs, as well as training in the interpersonal aspects of working with patients and communicating with physicians.

The Center’s **education** programs target patients and their family and friends, health care professionals at all levels, and the public at large. The Center promotes increased awareness and understanding of FGIDs through symposia, printed materials, videos, and its website www.med.unc.edu/ibs.

CO-DIRECTORS

Douglas Drossman, MD Professor of Medicine and Psychiatry



Dr. Drossman is Professor of Medicine and Psychiatry (UNC School of Medicine, Division of Gastroenterology & Hepatology) and Co-Director of the UNC Center for Functional GI & Motility Disorders. He has had a long-standing interest in the research and evaluation of difficult to diagnose and treat GI disorders. He established a program of research in functional GI disorders at UNC more than 25 years ago and

has published more than 400 books, articles and abstracts relating to epidemiology, psychosocial and quality of life assessment, design of treatment trials, and outcomes of research in GI disorders. He has also published two books, a GI procedures manual, and a textbook on Functional GI Disorders (Rome I, Rome II and Rome III). In addition, he serves on six editorial boards in medicine, gastroenterology and psychosomatic medicine, was associate editor of *Gastroenterology* and GI section editor of the Merck manual, and is currently editor of *Digestive Health Matters* published by IFFGD as well as the newsletter of the Functional Brain-Gut Research Group.

Dr. Drossman received his MD degree from Albert Einstein College of Medicine in 1970, and completed his medical residency at the University of North Carolina School of Medicine and New York University-Bellevue Medical Center. After his residency, he sub-specialized in psychosocial (psychosomatic) medicine at the University of Rochester School of Medicine under the mentorship of Dr. George Engel from 1975 to 1976 and in gastroenterology at the University of North Carolina in from 1976 to 1978.

Dr. Drossman has been involved in several national and international activities which include President of the Rome Foundation and Scientific Director and member of the Board of the International Foundation for Functional GI Disorders (IFFGD). He is a past president of the American Psychosomatic Society, immediate past Chair of the AGA Council on Motility and Nerve-Gut Interactions, and Founder/Past President of the Functional Brain-Gut Research Group of AGA. He is an AGA Fellow and serves on the AGA Media Committee, AGA Nominating Committee, and the AGA Research Awards Panel. Dr. Drossman is a Fellow of the American College of Physicians and a Master of the American College of Gastroenterology. He is a member of the Institute of Medicine of the National Academy of Sciences Committee on Gulf War and Health: Physiologic, Psychologic and Psychosocial Effects of Deployment Related Stress. He has been an Ad Hoc Advisory Board member of the NIH National Center for Complementary and Alternative Medicine (NCCAM), and is currently serving on the NIH (NIIDK) National Commission on Digestive Diseases Functional GI and Motility Disorders Working Group.

William E. Whitehead, PhD Professor of Medicine and Adjunct Professor of OBGYN



Dr. Whitehead is Co-Director of the UNC Center for Functional GI & Motility Disorders. He was recruited to UNC in 1993 to direct the Gastrointestinal Motility Program, and in 1994 he and Dr. Drossman founded the Center for Functional GI and Motility Disorders. He has been involved in research on functional gastrointestinal disorders for 40 years and is recognized internationally for his research and teaching on constipation, fecal

incontinence, and irritable bowel syndrome (IBS). His current research interests are the heterogeneity of IBS (the concept that IBS is not one disorder but a collection of different disorders with distinct etiologies and treatments), psychosocial factors that affect visceral pain sensitivity in IBS, comorbidity of IBS with other disorders, and the biofeedback treatment and medical management of fecal incontinence and constipation.

In 1999, Dr. Whitehead also joined the UNC Division of Urogynecology as an adjunct faculty member to help develop a fellowship program in Urogynecology and Reconstructive Pelvic Floor Surgery. He teaches surgery fellows in this fellowship program and heads a monthly case conference attended by the urogynecology faculty and fellows and the GI motility team. Dr. Whitehead collaborates with several faculty in Gynecology in research on the role of obstetrical injury in the etiology of fecal incontinence, behavioral treatments for incontinence, and the role of reproductive hormones in IBS.

Dr. Whitehead received his PhD from the University of Chicago in clinical psychology and physiology in 1973 and did his dissertation research on the biofeedback conditioning of gastric acid secretion. After graduation, he joined the faculty of the Department of Psychiatry, University of Cincinnati College of Medicine, and worked for seven years in the psychosomatic service where he began his research on visceral perception and IBS. In 1979, after a year as a visiting scientist at the Gerontology Research Center of the National Institute on Aging (NIA), Dr. Whitehead was recruited to the Department of Psychiatry at the Johns Hopkins University School of Medicine and established a 15-year collaboration with Dr. Marvin Schuster, which included co-authorship of the text, *Gastrointestinal Disorders: Behavioral and Physiological Basis for Treatment* (Academic Press, 1985). He was chief of the Gastrointestinal Physiology Laboratory at the Bayview Medical Center, where he continued to evolve his research on IBS and began research programs on the biofeedback treatment of fecal incontinence and on the understanding and treatment of rumination syndrome and failure to thrive.

D. DROSSMAN, CONT.

As Medical Director of the UNC Center for Functional GI & Motility Disorders, Dr. Drossman sees patients in the Functional GI Clinic. He also precepts GI fellows and visiting gastroenterologists to develop their clinical skills in patient care and communication. He facilitates the learning of medical faculty and fellows, psychiatry residents and medical students with regard to the biopsychosocial care of patients with functional GI disorders. In 2004, Dr. Drossman received the AGA Distinguished Educator Award, recognizing an individual for achievements as an outstanding educator over a lifelong career.

Dr. Drossman's educational and clinical interests in the psychosocial/behavioral aspects of patient care have led to the development of a series of videotapes to teach physicians and other healthcare professionals how to conduct an effective patient interview, carry out a psychosocial assessment, and enhance patient-doctor communication. He has taught numerous US and international workshops on this topic and was chair of the ACG Physician-Patient Relations Committee from 1994-1996. He is also a charter fellow of the American Academy on Physicians and Patients, a consortium of doctors teaching these skills to medical school faculty. In 2007, he received the AGA Mentors Research Scholar Award.

Dr. Drossman has an active research program that relates to the clinical, epidemiological, psychosocial, and treatment aspects of irritable bowel syndrome and the functional GI disorders. He has held several NIH grants totaling \$10 million, including a multi-center treatment trial of functional bowel disorders with cognitive behavioral therapy and antidepressants in addition to several pharmaceutical trials of new investigative agents for IBS. He has developed and validated several assessment and quality of life measures that are used worldwide for clinical research. Recently, he is studying brain imaging (fMRI) in functional bowel disorders to determine if reported changes in the brain are associated with pain and stress, and are responsive to treatment. He also consults with pharmaceutical companies and government agencies regarding treatment trials. In 1999, Dr. Drossman received the Janssen Award for Clinical Research in Digestive Diseases. In 2003, he received the Research Scientist Award for Clinical Research presented by the Functional Brain-Gut Research Group (FBG) during Digestive Diseases Week. That year, he also received the American Psychosomatic Society's President's Award. In 2005, Dr. Drossman received the AGA/Miles and Shirley Fiterman Foundation Joseph B. Kirsner Award in Clinical Research in Gastroenterology.

In addition to his clinical care, research and teaching responsibilities associated with the UNC School of Medicine and the Center for Functional GI & Motility Disorders, Dr. Drossman has numerous involvements with leading national and international organizations:

- Chair of the Executive Committee (since 1989) and President (since 2003) of the Rome Foundation
- Editor of *Rome III: The Functional Gastrointestinal Disorders*, 3rd edition, published in 2006

W. WHITEHEAD, CONT.

Dr. Whitehead is a career investigator who has been continuously funded by NIH since 1977. He was supported by a National Institute of Mental Health (NIMH) research scientist award for 22 years and has received research support from NIDDK, NICHD, NIA, NINR, and NIMH. His 35 RO1 grants have included studies of (1) the causes and treatment of fecal incontinence in special populations such as spina bifida and elderly, (2) the causes and treatment of constipation, (3) treatment of rumination syndrome in developmentally disabled children, (4) the role of visceral perception in IBS, (5) comorbidity of IBS with other disorders, and (6) psychological and behavioral treatment of IBS. He has published over 250 journal articles, books, and book chapters and more than 225 abstracts on these topics. In 2002 he and Dr. Drossman were awarded an NIH Mind-Body Infrastructure grant (R24 DK67674) to provide core support for an expansion of the Center's research program in functional GI and motility disorders.

Twenty-four research fellows, both psychologists and physicians, have completed predoctoral or postdoctoral training in Dr. Whitehead's laboratory. Nineteen of these alumni are in academic positions, one is still in medical school, two are in private practice (gastroenterologists), and the jobs of two are unknown. Dr. Whitehead also organizes and participates in preceptorships and CME courses on a regular basis, in the U.S. and internationally.

In 1990, Dr. Whitehead joined the board of the Rome Foundation (then known as the Multinational Working Team Project to Develop Diagnostic Criteria for Functional Gastrointestinal Disorders). He chaired the Rome I working team on Anorectal Disorders in 1990-1994, the Rome II working team on Anorectal Disorders in 1995-2000, and co-chaired the working team on Design of Treatment Trials from 2001-2006. He also chaired the International Resource Committee for the Rome Foundation and led a multisite study to validate the Rome III diagnostic questionnaire in 2006. Other awards and leadership positions in national and international organizations are as follows:

- Co-founder and past chair of Functional Brain-Gut Research Group (FBG) special interest section within the American Gastroenterological Association (AGA)
- Head of the steering committee and chair of two multidisciplinary conferences on fecal incontinence sponsored by the International Foundation for Functional Gastrointestinal Disorders (IFFGD)
- Associate Editor of *Gastroenterology*, the official journal of the American Gastroenterology Association (AGA), from 2001-2006
- Organized an international conference on the design of treatment trials for functional GI disorders
- Co-chair of the fecal incontinence subcommittee for the International Consultation on Incontinence
- Member of the Planning Committee for the NIH State of the Science Conference on the Prevention of Fecal and Urinary Incontinence 2006-2007.
- Advisory Board for the General Clinical Research Center (GCRC) at the UNC School of Medicine
- FBG (Functional Brain-Gut Research Group) Research Scientist Award for Clinical Research in 1999

D. DROSSMAN, CONT.

- Editor of *Understanding the Irritable Gut: The Functional GI Disorders* authored by W. Grant Thompson and sponsored by the Rome Foundation
- Member of the Board of Directors, Chair of the Scientific Advisory Board, and Chair of the Awards Committee of the International Foundation for Functional GI Disorders (IFFGD)
- Co-Chair and Chair of the Motility and Nerve-Gut Interactions Section of the AGA Council from 2001 to 2005
- Founder and past chair of the Functional Brain-Gut Research Group (FBG) special interest section within the American Gastroenterological Association (AGA)
- Chair of the Digestive Health Initiative on Functional GI Disorders sponsored by the American Digestive Health Foundation in 1999-2000
- Functional Brain-Gut Research Group Research Scientist Award -- 2001
- Past-president of the American Psychosomatic Society
- Fellow of the American College of Physicians (ACP)
- Master of the American College of Gastroenterology (MACG)
- Charter fellow of the American Academy of Physician and Patient
- Janssen Award for Clinical Research in Digestive Diseases -- 1999
- Associate Editor of *Gastroenterology*, the official journal of the AGA, from 2001 to 2006
- Author of the AGA Clinical Teaching Project on IBS (1997) and the AGA Gastroenterology Teaching Project on IBS (2nd edition, 2003)
- Editor of the *Manual of GI Procedures* (now in its fourth edition)
- On the board of the medical website Medscape Gastroenterology
- Gastroenterology Section editor of the Merck Manual 1990-2005
- Member of the Institute of Medicine Committee on Gulf War and Health: Physiologic, Psychologic and Psychosocial Effects of Deployment Related Stress
- Member of the NIDDK (NIH) National Commission on Digestive Diseases Subcommittee on Functional GI & Motility Disorders

Dr. Drossman is considered a world authority in the field of functional GI disorders and physician-patient communication. He presents at numerous national and international meetings throughout the year.

W. WHITEHEAD, CONT.

- IFFGD Award for Research Excellence in 2003
- Janssen Award for Outstanding Research in Gastroenterology in 2004.
- Fellow of both the American College of Gastroenterology and the American Gastroenterological Association
- Member NIH Behavioral Medicine Study Section

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- Donald Patrick, PhD – University of Washington, Seattle, WA
- Holly Richter, MD – University of Alabama at Birmingham, AL
- Des Runyan, MD, DrPH – Department of Social Medicine and Robert Wood Johnson Clinical Scholars Program, University of NC at Chapel Hill, Chapel Hill, NC
- R. Balfour Sartor, MD – Division of Gastroenterology & Hepatology, UNC School of Medicine, Chapel Hill, NC
- Max Schmulson, MD – Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico
- Naomi Spence, PhD – Carolina Population Center, University of NC at Chapel Hill, Chapel Hill, NC
- Ami Sperber, MD – Beer-Sheva University, Tel Aviv, Israel
- John Steege, MD – Advanced Laparoscopy Div., Dept. of OBGYN, UNC School of Medicine, Chapel Hill, NC
- Nicholas Talley, MD, MPH – Mayo Clinic, Jacksonville FL
- Brenda Toner, PhD, CPsy – Centre for Addiction & Mental Health, University of Toronto, Ontario, Canada
- Ashook Tuteja, MD – University of Utah, Salt Lake City, UT
- Martin Ulshen, MD – Dept. of Pediatrics, Duke University Medical Center, Durham, NC
- Anthony Visco, MD – Chief, Urogynecology, Duke University School of Medicine, Durham, NC
- Michael Von Korff, PhD -- Group Health Cooperative of Puget Sound, Seattle, WA
- Lynn Walker, PhD – Adolescent Medicine & Behavioral Science, Vanderbilt Univ. Medical Center, Nashville, TN
- Eric Westman, MD – Duke University Medical Center, Durham, NC
- Peter Whorwell, MD – University of South Manchester, Manchester, UK
- Nader Youssef, MD – Goryeb Medical Center at Atlantic Health, Morristown, NJ
- Adam Zolotor, MD MPH -- Family Medicine, University of NC at Chapel Hill, Chapel Hill, NC

PATIENT CARE

One of the four goals of the Center is to provide state-of-the-art evaluation and treatment for a full range of functional gastrointestinal and motility disorders (FGIDs).

Patients come from throughout North Carolina, the United States, and other countries to benefit from the Center's unique biopsychosocial approach to understanding and treating FGIDs.

Functional GI and Motility Disorders Clinic

Established and directed by Dr. Douglas Drossman, the Functional GI and Motility Disorders Clinic at UNC Hospitals is the premier site, both nationally and internationally, for referral of patients with functional GI and motility disorders (FGID). The clinic's unique multi-disciplinary, patient-centered approach integrates medical, physiological and psychological factors in the evaluation, understanding and treatment of patients with these disorders. The clinic also serves as a leading tertiary referral site for patients who have difficult-to-diagnose illnesses or challenging disease/disorder management issues. The clinic's services and educational activities have expanded over the last few years with the addition to Dr. Yehuda Ringel as a faculty member at UNC. Dr. Ringel's clinic is a referral service for patients with functional upper GI symptoms (e.g., dyspepsia, non-cardiac chest pain, chronic nausea, vomiting) and/or complicated motility disorders (e.g., gastroparesis, chronic intestinal pseudo-obstruction, intractable constipation), in addition to IBS and other functional bowel disorders. Other FGID Clinic staff include Christine B. Dalton, PA-C; Lynn Eckert, PA; Danielle Maier, PA-C, MA PAS; Charles K. Burnett, PhD, DrPH; and Stephan Weinland, PhD.

On Wednesday afternoons, the clinic is also staffed with a Fellow (gastroenterologist in training), who is supervised by Dr. Drossman or Dr. Ringel. The Center's clinical personnel are also routinely involved with consulting on patients at UNC Hospitals with severe functional GI or motility disorders and with physicians who call for advice regarding their patients. The clinic often has visiting gastroenterologists and trainees from other states and countries who are interested in learning more about the clinical approach, diagnosis and treatment of FGID patients. They also learn how to improve their interviewing and patient skills (see Visiting Scholars).



Back row: Dr. Stephan Weinland, Dr. Douglas Drossman, Eric Dedert, Dr. Spencer Dorn
Front row: Linda Miller, Chris Dalton, Lynn Eckert, Dr. Madhusudan Grover

A new service now being provided to the Functional GI and Motility clinic is the electrogastrogram (EGG). This clinical and research tool provides information on the electrical activity of the stomach and is helpful for evaluating patients with nausea, dyspepsia, vomiting and other functional GI and motility disorders that involve the stomach.

Clinical Case Conference: An important part of improving patient care is the Clinical Case Conference, held every Thursday morning in the FGID Clinic. Clinicians have the opportunity to present difficult cases and exchange ideas regarding patient evaluation and treatment. Participants in the Clinical Case Conference address the physical, social and psychological factors that are relevant to a specific case, utilizing the group's overall expertise to maximize the impact on patient care. This weekly forum also provides a learning opportunity for resident fellows, investigators, and others interested in the clinical aspects of caring for patients with functional GI and motility disorders.

GI Motility Program

The GI Motility Program at UNC Hospitals was established by Dr. Whitehead. Diagnostic evaluations and clinical care are now managed by Dr. Yolanda Scarlett (Medical Director), Dr. Yehuda Ringel, and Danielle Maier, PA, for lower GI motility disorders, and Dr. Nicholas Shaheen (Medical Director), Dr. Doug Morgan and Dr. Ryan Madanick for swallowing disorders and ambulatory pH testing. Sheila Crawford, RN, is the head nurse for the UNC Hospitals GI Motility Lab, and Jennifer Williams, RN, also performs diagnostic testing in the Laboratory.

Patients with GI motility disorders may be seen initially in the Functional GI and Motility Disorders Clinic (see above), or they may be referred directly to the medical staff of the GI Motility Lab if referring physicians anticipate that diagnostic motility testing or biofeedback training will be needed. Diagnostic motility tests may be scheduled directly by outside physicians, but a medical consultation from one of the clinicians affiliated with the GI Motility Lab is recommended. The following services are provided by the GI Motility Lab:

- ♦ Diagnostic anorectal motility tests for fecal incontinence, constipation or rectal pain
- ♦ Ambulatory pH and impedance testing
- ♦ Esophageal motility testing
- ♦ Hydrogen breath tests for small bowel bacterial overgrowth and carbohydrate malabsorption
- ♦ Breath tests for *H. pylori* infection

Pelvic Floor Biofeedback Clinic: A state of the art pelvic floor biofeedback clinic is directed by Steve Heymen, PhD. Appropriate referrals for this clinic are patients with fecal incontinence or dyssynergic defecation (a form of constipation in which the patient has difficulty emptying the rectum). Angel Moore, NA, assists Dr. Heymen in this clinic.

Pelvic Floor Disorders Conference: The Pelvic Floor Disorders Case Conference is held monthly and is central to the training, patient care and research objectives of the GI Motility Service. The format for the conference is a discussion of cases that have been seen by the gastroenterology and urogynecology services, focusing on cases that present complex decision making about patient care or important teaching points. There is also discussion of whether certain patients are appropriate for referral to one of the ongoing research studies at the Center. The conference also provides an opportunity for updates on new publications, research conferences, and new research initiatives.

Psychological Services

♦ Charles K. Burnett, PhD, DrPH, Clinical Associate Professor of Medicine, and Stephan Weinland, PhD, Instructor of Medicine, provide psychological services to the Functional GI & Motility Disorders Clinic. Patients are referred to the two psychologists through the Center and by outside physicians. When the medical evaluation of a patient visiting the FGID Clinic suggests that psychological evaluation and/or

treatment that could include pain management or psychological treatments would be beneficial, Drs. Burnett or Weinland or a psychology intern working with them is brought into the patient's overall care as part of our multi-disciplinary team approach. Drs. Burnett and Weinland specialize in the treatment of patients with chronic gastrointestinal illnesses, using one or more of the following techniques or therapies, in collaboration with the patient's other health care providers:

- ♦ **Stress Management:** Stress management therapy seeks to help a person understand the role of stress in his/her life and how it relates to the person's FGID symptoms. It also seeks to provide the patient with a variety of ways for dealing with stressful events in ways that minimize their impact on the person's FGID symptoms and quality of life.
- ♦ **Cognitive Behavioral Therapy (CBT):** CBT focuses on the interrelationship between a patient's thoughts (cognitions), actions (behaviors) and feelings (affect), and the role they play in their FGID symptoms. A common example is to beat the "vicious cycle" that occurs when chronic severe symptoms lead to psychological distress which, in turn, worsens the symptoms. By understanding and focusing on the psychological components of the "brain-gut axis", changes can be made in how a patient thinks, acts and feels about his/her GI difficulties, and thereby help reduce the frequency and intensity of FGID symptoms.
- ♦ **Relaxation Therapy:** Relaxation therapies to reduce a person's current state of physical and psychological activation include progressive muscle relaxation (PMR), autogenic training, breath regulation, and meditation. With these techniques, a person can learn how to "turn down the volume" on their GI symptoms by becoming more calm and relaxed about them.
- ♦ **Hypnosis:** Hypnosis or hypnotherapy is a set of techniques designed to help a person focus their attention and concentration in more positive directions. This can be accomplished with the help of a therapist or by oneself (self-hypnosis). It creates a very deep state of relaxation and imagining through which the patient is open to ideas or concepts that may help him/her manage certain problems, such as FGID symptoms.

RESEARCH

An important goal of the Center is to conduct research studies on the physiological and psychosocial mechanisms underlying functional GI and motility disorders, their impact on quality of life and health outcomes, and their treatment.

The Center has developed a broad portfolio of research on the mechanisms of functional GI and motility disorders, as well as their psychosocial correlates, health outcomes, and treatment. The Center's Co-Directors have a long history of research support from the National Institutes of Health (NIH), pharmaceutical companies, and other sources. Other Center investigators have established their own independent research programs and funding. The research activities of faculty and investigators associated with the Center are supported through a variety of grants and contracts – 57% from the National Institutes of Health (NIH), 28% from pharmaceutical companies, and 15% from foundations and other sources. In 2007, funding support for Center research activities was increased by an additional \$3.4 million in grants and contracts. New grants awarded by NIH in calendar year 2007 include:

- ♦ RO1 DK31369-21S1 (Whitehead, PI) – Bridge funding for a grant titled *Psychophysiology of IBS*, that has been funded by the NIDDKD since 1984 and is up for renewal. Bridge funding was provided to extend the current grant by 4 months while a new application is being prepared.
- ♦ RO1 DK074730-01A (Cotton, PI; Drossman, Co-PI) *Evaluating Predictors and Interventions in*



Dr. Whitehead and his research collaborators: (L to R) Lenore Keck, Jane Tucker, Dr. Steve Heymen, Dr. Miranda van Tilburg, Dr. Oli Palsson, Marsha Turner, Dr. William Whitehead

Sphincter of Oddi Dysfunction (EPISOD). Aim: To assess the effectiveness of endoscopic sphincterotomy in adult patients with sphincter oddi dysfunction.

- ♦ RO1 HD050345-01A (Levy, PI; Whitehead, Co-I) – This grant titled *Psychosocial Intervention for Children with IBD*, is based at the University of Washington. The study tests a cognitive behavioral stress management intervention in a new population of children with ulcerative colitis or Crohn's disease. This collaborative project is part of the Center's Research Network.

Mind-Body Infrastructure Grant

NIH Center: *Gastrointestinal Biopsychosocial Research Program*

In 2004, the Center was awarded a grant (R24 DK067674) from NIH to foster interdisciplinary research on interactions between the mind and body in health and disease, with a specific focus on the causes and treatment of functional GI and motility disorders. The five-year, \$4.45 million grant established a Gastrointestinal Biopsychosocial Research Program within the Center. The Center's Co-Directors--Drs. Whitehead and Drossman--are Co-PIs for this grant. An Infrastructure Grant Advisory Board of leaders from within the UNC School of Medicine and School of Public Health as well as a Scientific Advisory Board of leading national and international experts in functional GI and motility provide advice to the Center on ways to make the best possible use of the infrastructure grant.

This multi-year "infrastructure grant" is being used to build on the Center's longstanding record of NIH-funded research in mind-body interactions and to carry out longer-term collaborations with other disciplines in health and medicine at UNC and with other institutions throughout the US and other countries. Examples of mind-body research at the Center include studies on the role of stress, abuse history and other psychosocial factors in IBS and their outcomes; brain imaging to assess the association between psychological factors and central pain regulation; hereditary and learned-behavior aspects of IBS and recurrent abdominal pain (RAP); the effects of reproductive hormones on IBS; and the tendency of IBS to co-exist with other disorders. Center researchers have also studied the effectiveness of treatment strategies that combine cognitive behavior therapy (CBT), hypnosis, antidepressants, and/or patient education with medications for IBS; biofeedback combined with medical management for fecal incontinence and constipation; and complimentary and alternative medicine techniques such as Mindfulness Meditation.

The Center's research programs are multidisciplinary, involving collaborations between gastroenterologists, psychologists, neuroradiologists, psychiatrists, physician assistants, and nurses. Within UNC at Chapel Hill, collaborators came from the departments of Medicine, Psychology, Psychiatry, Surgery and Gynecology, as well as the schools of Dentistry and Public Health. Research at the Center has included studies on the pathophysiology and treatment of such prevalent functional GI disorders as IBS, functional dyspepsia, functional abdominal pain, fecal incontinence, and constipation. These disorders greatly impair quality of life and result in aggregate annual health care costs in the United States exceeding \$25 billion.



Dr. Drossman and his research collaborators: (L to R) Dr. J.B.Hu, Dr. Spencer Dorn, Carolyn Morris, Dr. Jane Leserman, Dr. Douglas Drossman, Chris Dalton, Dr. Stephan Weinland, Shannon Adams, Dr. Madhu Grover

Research Resources

♦ Research Administration Core

The purposes of the Research Administration Core are to provide (1) a central resource for recruiting research subjects, (2) assistance with the recruitment of Hispanic and other minority research subjects, and (3) a team of research coordinators.

♦ Research Network Core

In addition to collaborations with investigators in a variety of disciplines at UNC, the Center has an ever-expanding Research Network of collaborating institutions outside UNC for large-scale, multi-center studies. These strategic alliances have been developed to take advantage of the specialized skills and expertise of investigators at other sites and to increase the pool of research subjects participating in Center studies. The Research Network has benefited from the development of new technologies for web-based data acquisition/sharing and research subject recruitment, as well as a growing library of FGID-related scannable and Internet-based questionnaires in different languages. The purposes of the Research Network Core are to (1) provide administrative support from the UNC Center for funded research collaborations; (2) provide data management for multi-center studies; and (3) provide Center investigators with research-ready sites with proven abilities, both nationally and internationally, to facilitate the funding of large-scale, multi-center studies.

♦ Biometry Core

The primary purposes of the Biometry Core are to provide (1) consultation and advice on experimental design and statistical analysis; (2) data entry and data management for selected projects; and (3) data analysis for selected projects. Other capabilities of this

core are: (4) developing questionnaire booklets for research studies; (5) developing data management and quality assurance procedures and manuals; (6) developing data management programs; (7) coding, entering and cleaning data; (8) developing random assignment schemes for clinical trials; (9) overseeing the production of reports for data and safety monitoring boards and for regulatory agencies; and (10) assisting investigators in analyzing their data and developing research reports for publication.

♦ Data Acquisition & Technology Applications (DATA) Core

The DATA Core provides researchers with sophisticated data acquisition and data-sharing methodologies, data management, and archiving of research data to facilitate the conduct of large studies (especially multi-site studies) by our UNC research team and our national and international Research Network collaborators. Capabilities of this core include (1) creating and scanning of machine-readable questionnaires, (2) internet surveys, (3) programs and websites for managing multi-site studies, (4) secure server for multi-site studies, (5) PDA-based symptom surveys, and (6) automated telephone data entry.

♦ Education & Dissemination Core

The goals of the Education & Dissemination Core are to (1) meet the educational needs of patients and the general public, (2) educate health care providers in the diagnosis and treatment of functional GI and motility disorders, (3) disseminate research findings

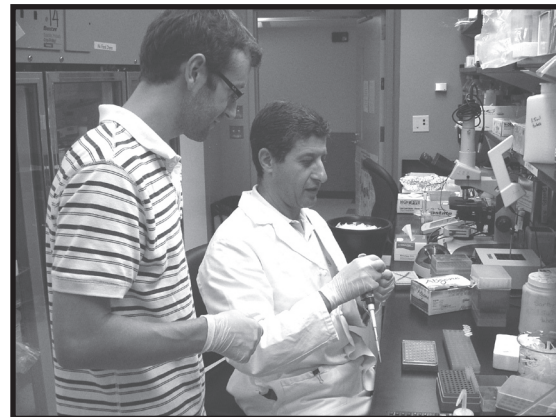
to professional and lay audiences, and (4) utilize the internet for the recruitment of research study subjects and for the conduct of internet-based surveys and other research projects.

♦ **Seed Grant Core**

The NIH infrastructure grant provides funding for a Seed Grant Program (SGP) to support up to three pilot projects each fiscal year (each for \$37,500 in direct costs). The goals of the SGP are to encourage and develop new investigators by providing (1) funds to collect the pilot data essential to successful NIH applications, and (2) mentoring in grant writing as well as the conduct of a research project. Research seed grants are awarded to new investigators for studies related to functional GI and motility disorders under the following eligibility criteria:

- ♦ The Seed Grant Program is open to any investigator at UNC (whether a member of the Center or not) and to any investigator within the Research Network associated with the Center.
- ♦ Investigators who have already received NIH support as a principal investigator are not eligible for Seed Grant funds. The only exception to this restriction is PIs who have received only conference or educational grants from NIH; these PIs are not yet considered experienced in securing NIH research grants.
- ♦ Proposals that are extensions of already-funded grants are also not eligible for SGP funds.
- ♦ All proposals must identify a senior research mentor for the proposed project, and include a letter of support from the mentor agreeing to provide supervision and semiannual reports.

The application process is modeled on the one used by NIH, using the NIH form with a Center cover page and page restrictions. Nicholas Talley, MD, Chief of Medicine at the Mayo Clinic in Jacksonville, FL, serves as chair of an ad hoc Seed Grant Selection Committee. This committee consists of Dr. Talley along with one or more other investigators selected by him who (1) have the expertise to evaluate the scientific merit of a particular proposal, (2) are not affiliated with the UNC Center, and (3) have no conflict of interest with respect to the applicant. The application review process is also modeled on the one used at NIH, using the following guidelines: (a) significance of the research question and strength of the research plan; (b) feasibility (availability of subjects and other resources); (c) training and other qualifications of the applicant; (d) plans for mentoring; (e) plans for using the grant to prepare for the submission of an NIH project grant; and (f) relevance

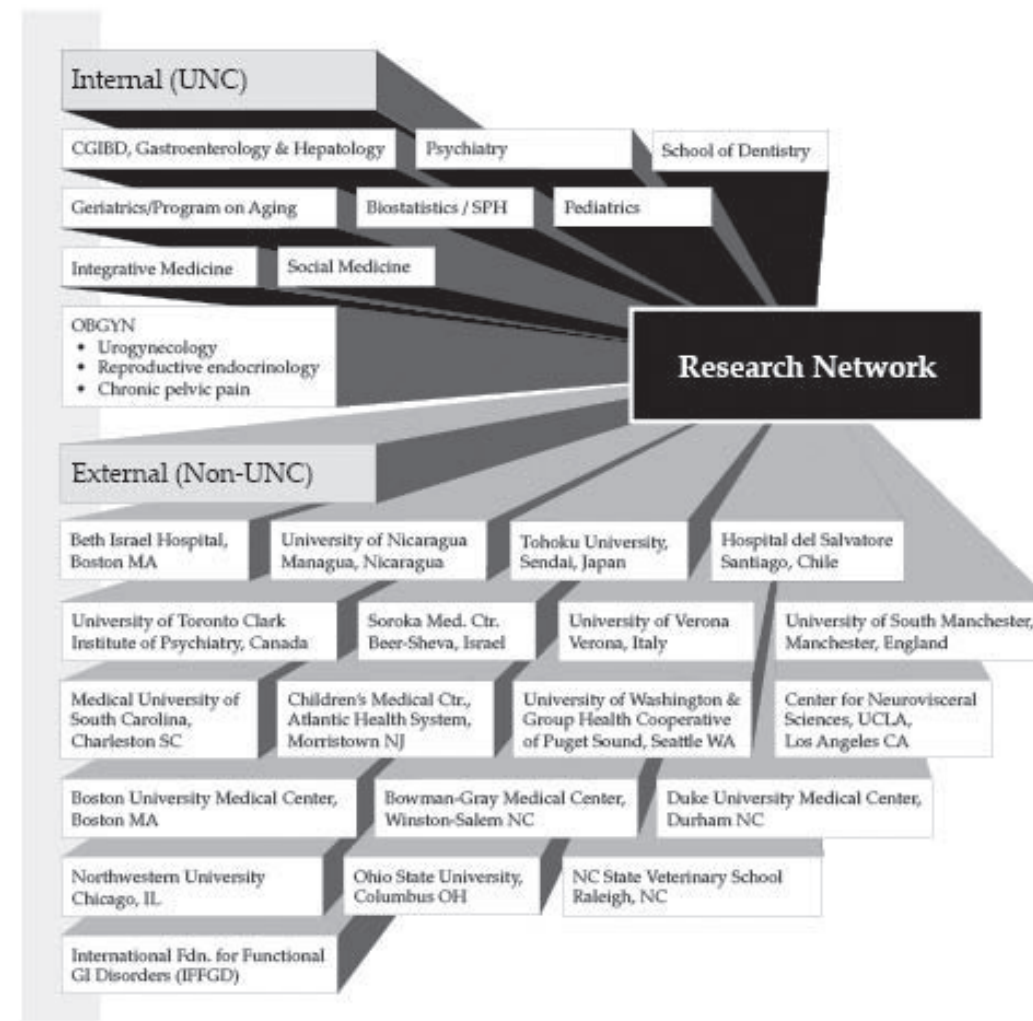


Ian Carroll, PhD, and Yehuda Ringel, MD

to functional gastrointestinal or motility disorders. Support is not provided for pharmaceutical or device trials (ineligible).

As of the end of 2007, the following seed grants have been awarded:

- ♦ Miranda Van Tilburg, PhD -- *Development of a Standardized Hypnotherapy for Chronic Abdominal Pain in Children*
- ♦ Denesh Chitkara, MD -- *Functional abdominal complaints from childhood to adulthood: evaluation of early environmental influences using a population based birth cohort*
- ♦ Yehuda Ringel, MD -- *The association between intestinal microflora and mucosal inflammation and immune activation in patients with IBS – a pilot study*
- ♦ Kimberly A. Brownley, PhD – *Endogenous ghrelin and gastric emptying in patients with functional dyspepsia*
- ♦ Michael Jones, MD – *Stigma in irritable bowel syndrome: development of a condition-specific measure and relationship to quality of life*
- ♦ Susan A. Gaylord, PhD – *Mindfulness for irritable bowel syndrome*
- ♦ Sumei Liu, MD – *Stress, enteric corticotrophin-releasing factor (CRF), and colon dysfunction*
- ♦ Martina Puzanovova, MD – *Autonomic reactivity in response to laboratory induced mental stressor in children with IBS*
- ♦ Nader N. Youssef, MD – *Feasibility and efficacy of a school nurse guided imagery program for children with recurrent abdominal pain: a pilot study.*



2007 SEED GRANT AWARDS



Deniz Zolnoun, MD, MPH



Miranda van Tilburg, PhD



Ian Carroll, PhD

RESEARCH DAY 2007:

Gastrointestinal Biopsychosocial Research at UNC
September 28-29, 2007

In October 2004, the UNC Center for Functional GI & Motility Disorders was awarded a grant (R24 DK067674) from the National Institutes of Health (NIH) to foster interdisciplinary research on interactions between the mind and body in health and disease, with a specific focus on the causes and treatment of functional gastrointestinal disorders. As part of this NIH grant, the Center hosted the third annual Research Day on September 28-29, 2007, on the campus of the University of North Carolina at Chapel Hill.

The program for this non-CME symposium was focused on six areas of research: (1) Brain-Gut Axis, (2) Gut Physiology, (3) Pelvic Floor (4) Pediatric Functional GI Disorders, (5) Complementary and Alternative Medicine Treatments, and (6) Psychosocial Assessment. The format was presentations on the state-of-the-art in each of these areas by visiting senior scientists, followed by overviews of on-going studies involving UNC faculty and investigators. A booklet summarizing all presentations is available on the Center's website at www.med.unc.edu/ibs.

Research Day 2007 was held this year in association with the UCLA Center for Neurovisceral Sciences and Women's Health (CNS) and the UNC Center for Gastrointestinal Biology & Disease (CGIBD), UNC Division of Gastroenterology & Hepatology. We greatly appreciate the educational grants from Sucampo Pharmaceuticals, S&R Foundation, Takeda Pharmaceuticals, Microbia Pharmaceuticals, Novartis Pharmaceuticals, The Procter & Gamble Company, and AstraZeneca Pharmaceuticals that provided additional support for this event.

TOPIC: Brain-Gut Axis

♦ **Emeran Mayer, MD**
State of the Art: *New directions in brain imaging*
Professor, Depts. of Medicine, Physiology, Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine, UCLA; Director, UCLA Center for Neurovisceral



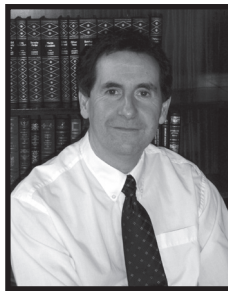
Sciences & Women's Health (CNS/WH), UCLA Division of Digestive Diseases; Chair, UCLA Collaborative Centers for Integrative Medicine; Los Angeles, CA

♦ **Douglas A. Drossman, MD** -- *Brain imaging: effects of IBS and abuse history*
Professor of Medicine & Psychiatry, UNC School of Medicine, Co-Director, UNC Center for Functional GI & Motility Disorders, Chapel Hill, NC

♦ **Steve Heymen, PhD** -- *CNS modulation of somatic pain in IBS: diffuse noxious inhibitory control*
Assistant Professor of Medicine, UNC School of Medicine, Chapel Hill, NC

TOPIC: Gut Physiology

♦ **Peter Whorwell, MD** --
State of the Art: *Probiotics*
Professor of Gastroenterology, Academic Dept. of Medicine, Education and Research Centre, Wyhenshawe Hospital, West Didsbury; Manchester, England



♦ **Yehuda Ringel, MD** -- *Intestinal microflora in IBS*
Assistant Professor of Medicine, UNC School of Medicine, Chapel Hill, NC

♦ **Madhusudan Grover, MD** -- *Small intestine bacterial overgrowth and irritable bowel syndrome*
PGY-2 Internal Medicine, School of Medicine, Michigan State University; East Lansing, Michigan

♦ **William E. Whitehead, PhD** -- *Genetics of IBS*
Professor of Medicine & Adjunct Professor of OBGYN, UNC School of Medicine
Co-Director, UNC Center for Functional GI & Motility Disorders, Chapel Hill, NC

TOPIC: Pelvic Floor

- ♦ **Steve Heymen, PhD** -- *Biofeedback treatment of fecal incontinence*
Assistant Professor of Medicine, UNC School of Medicine, Chapel Hill, NC
- ♦ **Yolanda Scarlett, MD** -- *Education and medical management of fecal incontinence*
Assistant Professor of Medicine, UNC School of Medicine, Chapel Hill, NC
- ♦ **Jane Leserman, PhD** -- *Health status and abuse/trauma history in chronic pelvic pain*
Professor of Medicine & Psychiatry, UNC School of Medicine, Chapel Hill, NC


TOPIC: Pediatric Functional GI Disorders

- ♦ **Rona Levy, PhD** -- *Update on cognitive behavior therapy for functional abdominal pain and proposed study of CBT for inflammatory bowel disease in children*
Professor, School of Social Work, University of Washington, Seattle, WA
- 
- ♦ **Miranda Van Tilburg, PhD** -- *Home based guided imagery to treat functional abdominal pain*
Assistant Professor of Medicine, UNC School of Medicine, Chapel Hill, NC
 - ♦ **Denesh Chitkara, MD** -- *Recollection of childhood abdominal pain in adults with functional gastrointestinal disorders*
Assistant Professor of Pediatrics, UNC School of Medicine, Chapel Hill, NC

TOPIC: Complementary and Alternative Medicine Treatment

- ♦ **Susan Gaylord, PhD** -- *Mindfulness meditation treatment for IBS*
Assistant Professor of Physical Medicine & Rehabilitation, UNC School of Medicine, Chapel Hill, NC
- ♦ **Miranda Van Tilburg, PhD** -- *Ginger for IBS: a new treatment alternative?*
Assistant Professor of Medicine, UNC School of Medicine, Chapel Hill, NC

TOPIC: Psychosocial Assessment

- ♦ **Bruce Naliboff, PhD**
-- State of the Art: *Development of the Visceral Sensitivity Index*
Professor, UCLA Dept. of Psychiatry & Biobehavioral Sciences, David Geffen School of Medicine, UCLA; Co-Director-Human Research, UCLA Center for Neurovisceral Sciences & Women's Health (CNS/WH), UCLA Division of Digestive Diseases; Los Angeles, CA
- 
- ♦ **Olafur Palsson, PsyD** -- *Investigating the role of comorbidity in IBS*
Associate Professor of Medicine, UNC School of Medicine, Chapel Hill, NC
 - ♦ **Spencer Dorn, MD, MPH** -- *Biopsychosocial predictors of health status in celiac disease*
Clinical Fellow in Digestive Diseases, UNC School of Medicine, Chapel Hill, NC
 - ♦ **Steve Weinland, PhD** -- *Ecological Momentary Assessment*
Instructor of Medicine, UNC School of Medicine, Chapel Hill, NC
 - ♦ **Madhusudan Grover, MD** -- *The use of atypical antipsychotic quetiapine for refractory functional GI disorders*
PGY-2 Internal Medicine, School of Medicine, Michigan State University, East Lansing, Michigan

2007 RESEARCH GRANTS, CONTRACTS AND AWARDS

The following research-supporting grants, contracts and awards were active in calendar year 2007.

NIH and other Federally-Supported Studies

| | |
|--|-----------------------------|
| UO1 DK074739-01A1 (Cotton, PI; Drossman, UNC-PI) | 9/15/07-06/30/12 |
| NIDDKD | \$119,620 (UNC subcontract) |
| <i>Evaluating Predictors and Interventions in Sphincter of Oddi Dysfunction (EPISOD).</i> | |
| Aim: To assess the effectiveness of endoscopic sphincterotomy in adult patients with sphincter oddi dysfunction. | |
| KO7 CA125588-0111 (Morgan, PI) | 09/01/07-08/30/12 |
| NIH NCI | \$375,000 |
| <i>Mentored Clinical Research Scholar Award – Gastric Cancer Epidemiology in Central America</i> | |
| Aim: To investigate host genetic, bacterial and nutritional risk factors for gastric cancer in a high-incidence population. | |
| R24 DK067674 (Whitehead and Drossman, co-PIs) | 7/1/04-6/30/09 |
| NIDDKD | \$4,450,000 |
| Infrastructure grant titled <i>Gastrointestinal Biopsychosocial Research Center</i> , submitted in response to RFA OB-03-004, Mind-Body Interactions and Health: Research in Infrastructure Program. | |
| Aims: The goals of the grant are (1) to establish a network of collaborators within UNC and between the UNC Center and other sites nationally and internationally to carry out research on functional gastrointestinal and motility disorders, (2) to provide support for investigations through core resources (biostatistics, data acquisition technology, subject recruitment, project management), and (3) to recruit and train new investigators in this field. | |
| K23 (Ringel, PI) | 10/01/06-11/01/11 |
| NIDDK | \$632,595 |
| <i>The Role of Intestinal Inflammation in the Pathophysiology or Irritable Bowel Syndrome</i> | |
| Aims: (1) To compare sub-clinical mucosal inflammation between patients with diarrhea predominant IBS (IBS-D) and controls. (2) To compare clinically accessible biomarkers for sub-clinical intestinal inflammation with alterations in mucosal immune function in patients with IBS. (3) To investigate whether alterations in intestinal inflammatory cytokines are associated with alterations in relevant intestinal physiology. | |

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| RO1 DK31369 (Whitehead, PI) | 12/1/02-11/31/08 |
| NIDDKD | \$1,714,897 \$128,480 (bridge funding 07-08) |
| <i>Psychophysiology of IBS</i> | |
| Aims: The aim of the current grant was to test the heterogeneity hypothesis, i.e., the hypothesis that IBS is not a single disease entity but instead represents a cluster of distinct etiologies for common bowel symptoms. We recruited 280 IBS patients and 60 healthy controls, assessed all major physiological and psychological mechanisms proposed for IBS, and then used the statistical method of cluster analysis to identify distinct subgroups. We found four subtypes of IBS: pain-predominant, psychologically-distressed, constipation-predominant, and diarrhea-predominant. In the next five-year cycle (currently under review) we will test additional IBS patients and healthy controls and will investigate genetic polymorphisms and environmental exposures that contribute to the development of these four subtypes of IBS. | |
| FRN 63138 (Toner, PI; Drossman, Co-PI) | 09/01/05-08/31/10 |
| Canadian Institute of Health Research (CIHR) | \$230,426 (UNC subcontract) |
| <i>Multicenter Trial of Combined Cognitive Behavioral Therapy and Antidepressant Treatment in Functional Bowel Disorders</i> | |
| Aims: The primary aim of this study is to compare the outcome of combined treatment of CBT and desipramine against single treatment (CBT or desipramine) among patients with moderate or severe functional bowel disorder. Secondary aims are (1) to identify demographic, symptomatic, physiological and psychosocial predictors of improvement; (2) to determine the relationship of GI physiology to abdominal pain and association with psychosocial variables; and (3) to determine whether treatment effects are mediated by changes in GI physiology and whether the effects are independent of psychosocial variables. The study assessment will be done at the University of Toronto, and data management and analysis will be coordinated at UNC. | |
| 3R24DK067674-03 (Miranda Van Tilburg, PI) | 9/1/06-8/31/08 |
| NIDDK | \$202,939 |
| <i>Supplement to Gastrointestinal Biopsychosocial Research Center (R24 DK67674 NIDDK)</i> | |
| Aims: To test the effectiveness of home based Guided Imagery to treat chronic abdominal pain of functional origin. | |

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|--|-----------------------------|
| RO1 HD050345 (Levy, PI; Whitehead, PI for subcontract) | 07/01/07-06/30/11 |
| NICH & NIDDKD | \$171,341 (UNC subcontract) |
| <i>Psychosocial Intervention in Children with IBD</i> | |
| Aim: A randomized controlled trial comparing social learning and cognitive behavior therapy (SLCBT) to an education and support condition (ES) for the treatment of inflammatory bowel disease in children. The goal is to reduce the severity and frequency of exacerbations of IBD in children. | |
| RO1 HD36069 (Levy, PI; Whitehead, PI for subcontract) | 04/01/99-03/31/08 |
| NICH & NIDDKD | \$203,510 (UNC subcontract) |
| <i>Intergenerational Transmission of Illness Behavior</i> | |
| Aims of initial grant: (1) To assess the ways parents respond to their children's somatic complaints and to assess the relationship of parental reinforcement and modeling to various measures of illness behavior in their children. (2) To determine whether the effects of modeling and reinforcement are independent of the psychosocial variables of family stress, competence, and parent and child psychological symptoms. Aims of competitive renewal funded 4/03-3/08: To carry out a prospective clinical trial to treat recurrent abdominal pain in children. The treatment model was based on findings from the initial grant. | |
| R21 AT3619 (Susan Gaylord, PI) | 10/01/06-09/30/09 |
| NICAM | \$250,000 |
| <i>Mindfulness Treatment of Irritable Bowel Syndrome</i> | |
| Aims: This is a pilot study to test the feasibility and design parameters for a randomized clinical trial to evaluate the efficacy of Mindfulness Based Stress Reduction, in comparison to a patient support group control, for the treatment of irritable bowel syndrome. A secondary aim is to evaluate the mechanism responsible for any treatment effects. | |
| Investments in the Future Initiative (Whitehead) | 07/01/07-06/30/10 |
| UNC School of Medicine | \$580,000 |
| <i>Transferring Scientific Discoveries in GI Motility Disorders from the Laboratory to Community Practitioners: Treating Fecal Incontinence and Constipation in the Frail Elderly and Women</i> | |
| Investments for the Future Initiative (Morgan) | 07/01/07-06/30/10 |
| UNC School of Medicine | \$900,000 |
| <i>Initiation of a Bilingual Multispecialty Clinic for Adult Latinos for Clinical Care, Research and Teaching</i> | |

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| Rome Foundation (Morgan, PI) | 07/01/06-12/31/08 |
| Rome Foundation for the Functional Gastrointestinal Disorders | |
| <i>Multinational Spanish Translation and Validation of the Rome III Diagnostic Questionnaire in Latin America. Consortium: UNC, Mexico, Nicaragua, Chile</i> | |

Research Contracts and Clinical Trials with Pharmaceutical Companies

Center investigators had research contracts with pharmaceutical companies for broad investigations of outcome measures, or to study the safety and efficacy of various drugs or medical devices through clinical trials.

Investigator Initiated Studies

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|---|-------------------|
| CHTF919EUS54 (Whitehead, PI) | 01/01/06-12/31/08 |
| Novartis Pharmaceuticals | |
| <i>CONQUEST Study: Impact of chronic constipation on health care costs and quality of life</i> | |
| Aims: Carry out a large survey of a health maintenance organization comparing clinic consulters with chronic constipation, patients with chronic constipation who have not consulted physicians, patients with constipation-predominant IBS, and healthy controls. The survey population totals 1700 individuals. | |
| 07-031L (Drossman, PI, Weiland Co-PI) | 04/01/07-01/31/09 |
| Takeda Pharmaceuticals | |
| <i>A proposal to evaluate time-specific relationships between variables of pain, stress, and bloating in the onset of IBS diarrhea and constipation symptoms using Ecological Momentary Assessment (EMA)</i> | |
| 07-004L (Whitehead, PI) | 04/01/07-06/30/10 |
| Takeda Pharmaceuticals | |
| <i>(Drug) effects on visceral pain sensitivity</i> | |
| Aims: To test the hypothesis that Lupiprostone decreases pain sensitivity as measured by a barostat. | |
| 07-005L (Whitehead, PI) | 03/01/08-06/30/10 |
| Takeda Pharmaceuticals | |
| <i>Development of a Questionnaire to Measure Hypervigilance for Visceral Pain</i> | |
| Aims: To develop and validate a questionnaire used to identify patients who are hypervigilant for noxious visceral sensations and who show a lower threshold for reporting pain. | |

Other Research Support and Awards

PUBLIC EDUCATION & INFORMATION

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|---|-------------------|
| Unnumbered (Whitehead, PI) | 07/30/07-06/30/08 |
| McNeill | |
| <i>Secondary Prevention of Fecal Incontinence through diagnostic screening and conservative management with education and medications to normalize stool consistency.</i> | |
| Aim: Develop a training DVD for providers/patients to be used in the fecal incontinence treatment program. | |

Pharmaceutical Contracts

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| IRUSQUET0448 (Drossman, PI, Weinland Co-PI) | 11/19/07-11/30/10 |
| AstraZeneca | |
| <i>An open label study of Quetiapine for the treatment of refractory functional bowel disorders</i> | |

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| XXXX-07-010 (Drossman, PI) | 01/15/08-01/14/09 |
| Dynogen | |
| <i>A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Effectiveness of (drug) in Female Patients with Irritable Bowel Syndrome with Constipation</i> | |

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|---|-------------------|
| AGIXX-007 (Drossman, PI) | 01/15/08-01/14/09 |
| AGI Therapeutics Research Ltd. | |
| <i>An Open-Label, Roll-Over Safety Study of (drug) in the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D)</i> | |

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| AGIXX-007 (Drossman, PI) | 11/15/07-11/14/08 |
| AGI Therapeutics Research Ltd. | |
| <i>A Randomized, Double-Blind, Placebo-Controlled Study of (drug) in the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D)</i> | |

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| MCP 103-202 (Drossman, PI) | 06/01/07-07/30/08 |
| Microbia | |
| <i>A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Range-Finding, Parallel-Design, Phase 2 Trial of (Drug) Administered to Patients with Irritable Bowel Syndrome</i> | |

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|---|-------------------|
| MCP 103-201 (Drossman, PI) | 03/20/07-08/31/08 |
| Microbia | |
| <i>A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Range-Finding, Parallel-Group, Phase 2 Trial of (Drug) to Patients with Chronic Constipation</i> | |

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| 203818-008-00 (Drossman, PI) | 03/29/07-2/28/09 |
| Allergan | |
| <i>A Multicenter, Multi-Dose, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Safety and Effectiveness of (drug) for the Relief of Irritable Bowel Syndrome</i> | |

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| TRN-002-20 (Drossman, PI) | 08/21/06-08/20/07 |
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| Trine Pharmaceuticals | |
| <i>A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of (Drug) for the Symptomatic Treatment of Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D) in Females</i> | |

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| TD-5108 (Drossman and Dalton, Co-PI) | 11/01/06-10/31/07 |
| Theravance | |
| <i>A Randomized, Placebo-Controlled, Double-Blind Study of (Drug) for the Treatment of Chronic Constipation</i> | |

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| ASMP2003 (Drossman, PI) | 06/15/06-06/14/09 |
| Tioga | |
| <i>A 12-Week, Randomized, Double-Blind, Dose-Ranging, Placebo-Controlled Study of (Drug) in Subjects with Irritable Bowel Syndrome</i> | |

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|---|-------------------|
| 0211-SIB-05S1 (Drossman, PI) | 10/25/05-10/24/12 |
| Sucampo Pharmaceuticals | |
| An Open Label Study of (Drug) for Constipation-Predominant Irritable Bowel Syndrome | |

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| SPI/0211SIB-0432 (Drossman, PI) | 07/05/05-7/304/08 |
| Sucampo Pharmaceuticals | |
| <i>A 12-Week, Multicenter, Double-Blind, Randomized Efficacy and Safety Study of (Drug) in Subjects with Constipation-Predominant Irritable Bowel Syndrome (Phase III)</i> | |

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|---|-------------------|
| (Ringel, PI) | 07/01/05-06/30/07 |
| GlaxoSmithKline/GSK | |
| <i>Genetic Surrogate Markers for Irritable Bowel Syndrome Susceptibility, Co-Morbidity and Disease Characterization</i> | |

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| (Ringel, PI) | 03/15/06-12/31/07 |
| Salix Pharmaceuticals | |
| <i>A phase 2, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of three different doses (275, 550 and 1100 mg) of Rifaximin administered BID for either two or four weeks in the treatment of patients with diarrhea-predominant Irritable Bowel Syndrome</i> | |

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| (Ringel, PI) | 07/01/05-06/30/08 |
| Danisco USA Inc. | |
| <i>Clinical Efficacy of Probiotic Bacteria in Patients with IBS, Functional Diarrhea, or Functional Bloating</i> | |

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| (Ringel, PI) | 01/01/07-12/31/08 |
| General Mills | |
| <i>Clinical Efficacy of (Drug) in Subjects with Functional Gastrointestinal Symptoms</i> | |

A fourth goal of the Center is to provide helpful up-to-date information for patients and the public through seminars and workshops as well as printed materials, videos and the Internet.

The Center's educational activities for patients and the larger public include symposia, printed materials and publications, videos, and the website www.med.unc.edu/ibs. These activities are supported through donations from individuals and educational grants from corporate sponsors.

The Center's website at www.med.unc.edu/ibs has evolved as a leading on-line resource for information on IBS and other functional GI and motility disorders for patients, health care providers and scientists, and the public at large. Our website averages 20,000 to 40,000 visitors per month. Content is updated on a regular basis, and new technologies and approaches are expanding the website's utility as a vehicle to recruit subjects for research studies and conduct Internet-based surveys.

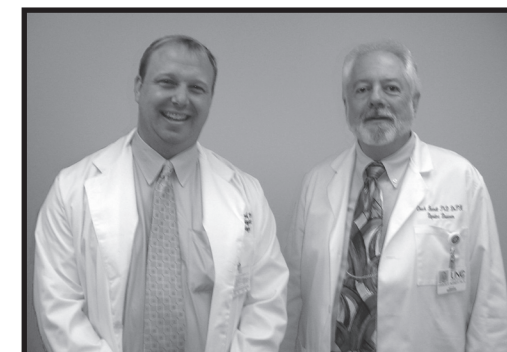
In addition to the website, patients and the larger public have access to helpful information through the Center's patient education brochures and videos. Center brochures are available on topics such as Irritable Bowel Syndrome (IBS), Fecal Incontinence, How to Talk with Your Physician, Constipation, The Use of Antidepressants in the Treatment of

IBS, Psychological Services, Why see a psychologist when the diagnosis is IBS, Narcotic Bowel, and Bowel Retraining.

Center videos (many on-line at www.med.unc.edu/ibs) are available on topics such as "Living with IBS," "IBS - Transforming Your Life Through IBS Management" (Winner of Communicator Award), "Biopsychosocial Approach to IBS: Improving the Physician-Patient Relationship" (Winner of 1997 AMA International Film Festival), AGA Clinical Teaching Project, Third Annual Symposium on Functional GI & Motility Disorders, and video clips from the Cutting Edge Series. A new documentary video titled "Doctor, I Have These Symptoms", produced by Bella Communications, provides information on IBS through the eyes of several patients seen at our Center (winner of 2005 Communicator Award).

The Center's newsletter - **Digest** - contains articles and news items on new treatments, research findings, updates on GI conferences, announcements of events and Center activities, and recognition for Center supporters and sponsors. It is available on-line at www.med.unc.edu/ibs and hard copies are distributed through the Center's extensive mailing list, at various events, and upon request.

Patient symposia are hosted every other year. The last one was July 15, 2006 and the next one is scheduled for August 23, 2008.



Psychological Services: Dr. Stephan Weinland and Dr. Charles Burnett



Motility Lab: Scott Winners, Sheila Crawford, Dr. Yolanda Scarlett, Kate Enron

TRAINING

Another goal of the Center is to provide multidisciplinary training and education in clinical and research skills, with an emphasis on patient-centered care and advanced research methods.

This goal is implemented through a Visiting Scholars Program (short stays by guest faculty), Visiting Scientist Program (more extended stays by guest faculty), training at the pre-doctoral or postdoctoral level, and regularly scheduled seminars (also see Patient Care). The Center has developed educational materials (videos, brochures) for health professionals, and is involved with events providing continuing medical education (CME) credits. Readers are encouraged to visit the Center's website to see our professional educational materials in the "Training" area of the website, including a growing list of on-line publications and videos.

Visiting Scholars Program

The Visiting Scholars Program provides an opportunity for faculty, investigators and clinicians from other institutions to visit the Center for a short stay of a couple of days or several weeks. By hosting visitors from around the US and the world, the Center benefits from a unique opportunity to share and exchange ideas on treatments for functional GI and motility patients, confer on research studies, and build collaboration networks for future projects. For the duration of their stay at the Center, visiting scholars have access to expert psychologists, gastroenterologists and physiologists, providing a wide variety of opportunities to learn vital skills and techniques in the treatment and research of functional GI and motility disorders. Visiting scholars also have the chance to observe patient care, participate in research meetings and teaching conferences (CME), and expand their training experience by meeting with other faculty within the Division of Gastroenterology and Hepatology and elsewhere at UNC. Visiting Scholars in 2007 included:

- ♦ **Tom Abell, MD** (Division of Digestive Diseases, University of Mississippi Medical Center, Jackson MS) – January 25-26, March 12-13
- ♦ **Lynn Walker, PhD** (Professor of Pediatrics, Director, Division of Adolescent Medicine and Behavioral Science, Vanderbilt Children's Hospital) – March 15-16
- ♦ **Eamonn Quigley, MD** (National University of Ireland Cork, Cork, Ireland) – March 22

- ♦ **Kathleen Moore, PhD** (NIH Office of the Ombudsman, Washington DC) – April 18-20
- ♦ **Madhusudan Grover, MD** (PGY-2 Internal Medicine, Michigan State University, Ann Arbor MI) – May 29 – July 27
- ♦ **Paulo Leandro, MD, MA** (Santa Casa BH, Belo Horizonte, Brazil) – May 7-18
- ♦ **Ching-Liang ("Tony") Lu, MD** (Div. of Gastroenterology, Taipei Veterans General Hospital and National Yang-Ming University, Taipei, Taiwan)) – July 16-27
- ♦ **Maria Tomekova** (PhD student, Psychology, Faculty of Philosophy, Trnava University, Trnava, Slovakia) – September 1 – November 30
- ♦ **Sharon Jedel, PhD** (Psychologist, Div. of Gastroenterology, Rush University Medical Center, Chicago IL) – November 26-30

Visiting Scientists Program

The Center's Visiting Scientist Program hosts faculty and investigators from other institutions for extended stays of one or two years, during which they participate as visiting faculty in the research projects of Center investigators. The Center accepts visiting scientists at all levels of their career and provides them with the flexibility to tailor their experience at the Center to their own needs and interests. Visiting scientists are normally supported by their own institutions or grant agencies but, under exceptional circumstances, they may be supported by the Center. Visiting scientists are expected to lecture or make presentations and, in this way, to bring new skills and knowledge to the Center's resident clinicians and investigators. They carry out and publish studies related to functional GI and motility disorders, and are invited to write articles for the Center's quarterly Digest that are representative of their particular clinical care or academic interests.



Madhusudan Grover



Maria Tomekova

Pre-doctoral Training Program

The Center is able to provide pre-doctoral research and/or clinical training to a limited number of trainees through its Pre-doctoral Training Program. These are usually one-year fellowships and are normally supported by grant agencies external to the Center. The first of these fellows was Catherine Forneris, who subsequently completed her PhD in clinical psychology and is now on the faculty of the UNC Department of Psychiatry. Another pre-doctoral fellow was Neeta Venepalli, a third year medical student when she completed a Doris Duke Fellowship. Her training involved all stages of developing and completing a clinical research study -- literature review and proposal preparation, recruitment and interviewing of research subjects, analysis of the data, and writing and publishing the manuscript. Her topic was families of children with recurrent abdominal pain (RAP). She has now completed her MD degree and accepted an internship and residency training at Northwestern University, Evanston, Illinois.

Postdoctoral Training Program

The Center hosts postdoctoral fellows on an ongoing basis. Postdoctoral fellows typically stay for one or two years and receive mentored research training while participating in research projects with senior investigators in the Center. They may receive stipends from one of the two training grants awarded through the Division of Gastroenterology and Hepatology or from extramural grants.

Seminars

In the Patient Care section of this annual report, we have already described the Clinical Case Conference and the Anorectal Motility Case Conference. In addition, the Evening Seminar on Clinical and Psychosocial Skills developed by Dr. Drossman is a unique program in clinical skills development based on a biopsychosocial patient-centered approach to understanding and treating patients with functional GI disorders (FGIDs). This program evolved from the work of Drs. George Engel and Karl Rogers. Dr. Drossman's patient interview and educational facilitation style is highly regarded, and professionals in medicine and allied health fields visit the Center

to learn these techniques while participating in the care of patients. Dr. Drossman began a monthly evening seminar for health care professionals that has included faculty and residents in Medicine and Psychiatry and, more recently, GI fellows. This seminar features interactive learning methods, including videotaped discussions, role playing, small group learning, and live interviews with patients. The seminar is unique in its participatory style, and the methods have been presented at national meetings and described in professional journals and magazines.

PUBLICATIONS IN 2007

47 journal articles/commentaries/editorials, 19 books or book chapters, and 18 abstracts written by Center faculty and investigators were published or accepted for publication in 2007.

Articles, commentaries, editorials

- Bradley CS, Nygaard I, Brown MB, Gutman RE, Kenton KS, Whitehead WE, Goode PS, Wren PA, Ghetti C, Weber AM; Pelvic Floor Disorders Network. Bowel symptoms in women one year after sacrocolpopexy. *American Journal of Obstetrics & Gynecology*, in press.
- Bradley CS, Richter HE, Gutman RE, Brown MB, Whitehead WE, Fine PM, Hakim C, Harford F, Weber AM; Pelvic Floor Disorders Network. Risk factors for sonographic internal anal sphincter gaps 6-12 months after delivery complicated by anal sphincter tear. *American Journal of Obstetrics & Gynecology* 2007 Sep;197(3):310.e1-5.
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- Dorn SD, Palsson OS, Thiwan SM, Clark WC, Kanazawa M, van Tilburg MAL, Drossman DA, Scarlett Y, Levy RL, Ringel Y, Crowell MD, Olden KW, Whitehead WE. Increased colonic pain sensitivity in irritable bowel syndrome is the result of an increased tendency to report pain rather than increased neurosensory sensitivity. *Gut* 2007;56:1202-1209.
- Dorn SD, Ringel Y. Lubiprostone: Easing the Strain of Constipation? *Gastroenterology* 2008;134(1):355-7.
- Drossman D, Morris CB, Hu Y, Toner BB, Diamant N, Whitehead WE, Dalton CB, Leserman J, Patrick DL, Bangdiwala SI. Characterization of health related quality of life (HRQOL) for patients with functional bowel disorder (FBD) and its response to treatment. *American Journal of Gastroenterology* 2007;102:1442-1453.
- Drossman DA. Commentary on chronic constipation. *Primary Care Quarterly* 2007;11:44-45.
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- Morgan DR. Hispanic-Latino digestive health. *AGA Perspectives, American Gastroenterological Association*. 2007;3(1):8-9.
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Books, chapters

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2. Drossman DA. Introduction: A doctor's view. In: *Thompson WG, Understanding the irritable gut (an interpretation of Rome III: The functional gastrointestinal disorders)*. 2008.
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FACULTY, CLINICIANS, INVESTIGATORS AND STAFF

Co-Directors

The Co-Directors are profiled in greater detail earlier in this report.

Douglas A. Drossman, Co-Director

Professor of Medicine and Psychiatry

As Medical Director for the Functional GI & Motility Disorders Clinic, Dr. Drossman works closely with the clinicians described in Patient Care section of this annual report. In addition, his research team includes: Shrikant Bangdiwala, PhD; Jane Leserman, PhD; Stephan Weinland, PhD; Christine Dalton, PA-C; J.B. Hu, PhD; Carolyn Morris, MPH; Kim Meyer, CRC; Ann Selph; Shannon Adams; Jane Hankins, MAT; Syed Thiwan, MD, and Spencer Dorn, MD, MPH.

William E. Whitehead, Co-Director

Professor of Medicine and Adjunct Professor of OBGYN

Dr. Whitehead's research Team includes: Yolanda Scarlett, MD; Olafur Palsson, PsyD; Miranda Van Tilburg, PhD; Steve Heymen, PhD; Motoyori Kanazawa, MD, PhD (Tohoku University, Sendai, Japan); Syed Thiwan, MD; Spencer Dorn, MD; Marsha Turner, MS Ed; Lenore Keck, RN; Jane Tucker, RN. Collaborators include Yehuda Ringel, MD, Temitope Keku, PhD, William Maixner, DDS, and Luda Diatchenko, MD.

Faculty, Clinicians and Investigators

Shrikant I. Bangdiwala, PhD

Research Professor in Biostatistics, Director of Biometry Core

Dr. Bangdiwala has extensive experience in the design, conduct and analysis of multi-center studies, having worked on clinical trials in congestive heart failure, cardiovascular risk factors, functional bowel disease, and cancer prevention. Dr. Bangdiwala also has extensive experience as a member of various data and safety monitoring boards for studies in ophthalmology, HIV/AIDS, and cardiology. He collaborates with investigators at the Center on several studies, including research on brain imaging of IBS patients with and without a history of abuse and a comparative study of cognitive behavioral and anti-depressant treatment. Dr. Bangdiwala's role in these projects includes helping with research design, developing statistical analytical strategies, overseeing data management and statistical analyses, and paper preparation.

Charles K. Burnett, PhD, DrPH

Clinical Associate Professor of Medicine, Director of Psychological Services

Dr. Burnett has been associated with the Center since 1993 and has a long-standing interest in psychological

treatments specifically for patients with functional GI and motility disorders. Patients are referred to him through the Center, the FGID Clinic, and by outside physicians. He specializes in treatment of patients with chronic illnesses, using cognitive behavioral therapy (CBT), pain management techniques, stress management, biofeedback, and hypnosis. Dr. Burnett also precepts psychology interns and mentors visiting professors, and participates in the Center's training programs through the weekly clinical case conference and evening seminars.

Ian Carroll, PhD

Microbiologist

Dr. Carroll is a molecular microbiologist and his research investigates the role of the gut flora in intestinal disorders such as Irritable Bowel Syndrome (IBS). He obtained a bachelor's degree in biotechnology from Dublin City University in Ireland and continued his research career in molecular microbiology at Trinity College Dublin where he obtained his PhD. He then moved to the United States, where he carried out his postdoctoral research in the genetics department at UNC-CH studying anti-inflammatory effects of probiotic microorganisms in Inflammatory Bowel Disease (IBD). Dr. Carroll is working with Dr. Ringel on several projects investigating the role of probiotics in functional bowel disorders.

Christine B. Dalton, PA-C

Physician Assistant

Ms. Dalton has been a Physician Assistant (PA) in the Functional GI & Motility Disorders Clinic for 12 years. She spends most of her time in patient care or in research. In the Clinic, she often sees the patient first and then collaborates with Dr. Drossman in the patient's ongoing care. She handles most of the telephone calls from patients, including medication management, addressing symptom concerns, and other matters. Her primary clinical interests include the management of treatment-resistant patients and the care of patients who have experienced chronic GI symptoms for many years with little or no relief or understanding of their conditions. Her research interests include new treatment options, secondary symptoms, effective patient education and successful patient-provider communications.

Spencer Dorn, MD, MPH

Clinical Fellow in Gastroenterology & Hepatology

Spencer Dorn joined the Center in 2005 as a National Institutes of Health Post-Doctoral Research Fellow in Digestive Diseases Epidemiology. He is currently completing a clinical fellowship in Gastroenterology and Hepatology and continues to pursue research on the pathophysiology, diagnosis and management of functional GI disorders. His research interests also include health services for chronic digestive disorders. A native of New York, Dr. Dorn received his undergraduate degree, with highest distinction, from the University of Michigan; his medical degree, summa cum laude, from SUNY at Brooklyn College of Medicine; and a Masters in Public Health from the University of North Carolina at Chapel

Hill. Dr. Dorn completed his internal medicine training at Brigham and Women's Hospital, where he was a clinical fellow at Harvard Medical School.

Steve Heymen, PhD

Assistant Professor of Medicine, Director of Biofeedback Services

Dr. Heymen is a Fellow of the Biofeedback Certification Institute of America and has provided biofeedback therapy for more than 20 years. He is the project manager for an NIH-funded study of the efficacy of behavioral treatments for fecal incontinence and constipation. He recently completed his dissertation for a PhD in Biological Psychology through the UNC Department of Psychology.

Temitope O. Keku, PhD

Research Associate Professor of Medicine

Adjunct Associate Professor, Dept. of Nutrition, UNC School of Public Health

Dr. Keku carries out translational research that combines basic science with epidemiology to gain a better understanding of the etiology and pathogenesis of GI diseases. Her research focus is in the area of gene-environment interactions and molecular epidemiology of colorectal cancer. She is also involved in studies evaluating the role of intestinal microflora in GI diseases, particularly colorectal cancer, IBS and IBD. Dr. Keku collaborates with Drs. Whitehead, Ringel and Morgan on the contributions of genetic polymorphisms to irritable bowel syndrome (IBS). She is also a co-investigator on the GI SPORE Project 1 and the Diet and Health Studies (DHS). Dr. Keku has undergraduate and Masters degrees from the University of Jos, Nigeria. She has an MSPH in Parasitology & Laboratory Practice and a PhD in Epidemiology from the UNC School of Public Health. Dr. Keku's research team includes: Xiang Jun Shen PhD (Post-Doctoral Research Associate), Paul Wilson, PhD (Research Associate), Janie Peacock, BS (Research Technician), and Katharine Thompson, BS (Research Technician III).

Jane Leserman, PhD

Professor of Psychiatry and Medicine

Dr. Leserman is a medical sociologist with an extensive research background in behavioral and psychosomatic medicine, the effects of stress on the immune system, issues related to women's health, and quantitative research methods. Her research has examined the long-term physical and mental health effects of sexual and physical abuse among women with GI disorders and pelvic pain. She collaborates with Dr. Drossman and other Center investigators on several studies, including research on brain imaging among IBS patients with and without an abuse history and a study comparing behavioral and antidepressant treatment. Dr. Leserman's role in these projects includes helping with research design, psychosocial measurement, planning and performing data analyses, and paper preparation.

Ryan Madanick, MD

Assistant Professor of Medicine

Center for Esophageal Diseases and Swallowing
Dr. Madanick attended the University of Miami in the Honors Program in Medicine, where he earned both

his undergraduate and medical degrees. He completed his residency in Internal Medicine at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania, where he was awarded Intern of the Year and Outstanding Teaching Resident. He returned to Miami for his subspecialty fellowship in gastroenterology at Jackson Memorial Hospital/University of Miami Medical Center. After completing his fellowship, he stayed on the faculty at the University of Miami until he moved to UNC in November 2006. He is board certified in Internal Medicine and Gastroenterology. His clinical and research interests include refractory gastroesophageal reflux disease, extraesophageal reflux disease, eosinophilic esophagitis and esophageal motility disorders.

Danielle Maier, PA-C, MA PAS

Physician Assistant

Mrs. Maier is a Physician Assistant in the Functional GI & Motility Disorders Clinic. She sees patients on her own as well as with Drs. Ringel and Scarlett. She has completed intensive training in the biopsychosocial care of patients, and assists in interpreting studies in the UNC motility lab. She has completed her Masters degree in Physician Assistant studies, and is currently involved in several research studies with Dr. Yehuda Ringel. She is a PA graduate of the Wake Forest School of Medicine, where she graduated with high honors.

Douglas R. Morgan, MD, MPH

Assistant Professor of Medicine; Director, Center for Latino Digestive Health

Dr. Morgan attended Dartmouth College and received his medical degree from Case Western Reserve University. He completed his postgraduate training in Internal Medicine and Gastroenterology at the University of California, San Francisco. He also earned a Masters in Public Health in Epidemiology at the University of California, Berkeley. Dr. Morgan has been a UNC faculty member for the past four years and is a member of the UNC Center for Esophageal Diseases, with a focus on gastric disorders, including Functional Dyspepsia and H. Pylori. He also directs the Capsule Endoscopy program at UNC. Dr. Morgan is Director of the Center for Latino Digestive Health at UNC, with clinical and research initiatives in Central America and North Carolina. He has extensive experience in Latin America and with the Latino population. He is a former Peace Corps engineer, having designed rural electrification systems in Honduras. In medical school, he served as US Public Health Service COSTEP volunteer at Migrant Farm worker clinics in the Rio Grande Valley. His research interests include the epidemiology of FGIDs in the Latino population, gastric cancer epidemiology, and Latino digestive health. Active functional GI research protocols include a large population-based FGID epidemiology collaboration with the University of Nicaragua, with funding from the Rome Committees. He also directs a gastric cancer epidemiology initiative in Honduras, with a focus on host genetic and dietary factors. Dr. Morgan receives research funding from the NIH through the Mentored Scholars Program, as well as from foundations and industry. He was a recipient of the American College of Gastroenterology's Governor's Award for Excellence in Clinical Research in October 2004. His research team includes Paris Heidt (Program Manager).

Olafur S. Palsson, PsyD*Associate Professor of Medicine*

Dr. Palsson is a Clinical Psychologist who did his postdoctoral training at the UNC Center in 1994-1996, and then established and directed a behavioral medicine program at Eastern Virginia Medical School. He returned to the UNC Center in 2001 and has continued to develop his research interests in functional GI and motility disorders, which include investigation of various psychological and physiological aspects and influences on GI functioning and symptoms, questionnaire development to improve research on functional GI disorders, and hypnosis treatment for IBS. Dr. Palsson was the Guest Editor of the January 2006 special issue on IBS and Hypnosis for the International Journal of Clinical Hypnosis, and Course Director for a UNC School of Medicine three-day CME program on "Hypnosis Treatment for Functional Gastrointestinal Disorders" in November of 2004. Dr. Palsson has extensive experience in internet programming and is the Center's Director of Data Technology. He has developed innovative methodologies for collecting and processing clinical data in a confidential and secure manner through the Internet, and has played a lead role in several large internet-mediated studies.

Yehuda Ringel, MD*Assistant Professor of Medicine; Director, Probiotic Bacteria & Microflora Research Program*

Dr. Ringel received his medical degree at the Technion - The Israeli Institute of Technology. He completed his training in Internal Medicine and Gastroenterology at Tel-Aviv Medical Center, and earned a Masters degree in Internal Medicine from Tel-Aviv University, where he served as a faculty member until coming to the United States. He completed a postdoctoral research fellowship at the UNC Center under the mentorship of Drs. Drossman and Whitehead and has been a faculty member at UNC for the past five years. Dr. Ringel is experienced in the theories and methodologies involved in research related to functional GI disorders, including the design and conduct of clinical trials, use of advanced GI physiology and motility research techniques, validating psychosocial research tools, and functional brain imaging. He has expanded the Center's research and educational activities in GI tract sensation (e.g., visceral hypersensitivity) focused on physiological and psychological mechanisms in functional GI disorders. Dr. Drossman and he are leading a brain imaging project, which is looking at the role of the central nervous system in intestinal sensation and functional GI disorders using advanced imaging techniques with positron emission tomography (PET) and functional MRI (fMRI). Dr. Ringel is also investigating the effect of various physiological (intestinal smooth muscle tone/compliance, autonomic nervous system activity) and psychosocial (history of abuse) factors in upper and lower GI tract sensation, and he is involved in the design, evaluation and conduct of clinical trials evaluating new drugs and treatment approaches for functional GI disorders. Over the last two years, Dr. Ringel has developed an independent interdisciplinary translational research project investigating the role of intestinal bacteria, inflammation and genetics in the pathophysiology of IBS. In this project, he is collaborating with other investigators at UNC, including Drs. Balfour Sartor and Young-Hyo Chang, as well as Dr. Todd Klaenhammer from the NCSU

Departments of Microbiology, Genetics, and Food Science. Other areas of research interest include: (1) epidemiology of FGIDs, (2) mechanism of GI physiological responses to pain, and (3) design and evaluation of clinical trials. Dr. Ringel mentors medical students, residents and fellows on various research and writing projects. Dr. Ringel's research work has been recognized through the awards he has received, including: AGA/Solvay Award for Clinical Research in IBS/Motility awarded by the Foundation for Digestive Health and Nutrition; ACG Junior Faculty Development Award; and the Young Investigator Award of the Functional Brain-Gut Research Group (FBG). In 2005, he received a K-12 award for a project entitled "The Role of Intestinal Inflammation in the Pathophysiology of Functional GI Disorders". He has also received a UNC Center seed grant for a project entitled "The association between intestinal microflora and mucosal inflammation and immune activation in patients with IBS—a pilot study". And, in 2006, he received a K23 award from NIDDK for a project titled "The Role of Intestinal Inflammation in the Pathophysiology of Irritable Bowel Syndrome".

Yolanda Scarlett, MD*Assistant Professor of Medicine, Medical Director-GI Motility Service*

Dr. Scarlett oversees the operations of UNC's GI Motility Service. She also trains gastroenterology and urogynecology fellows in diagnostic motility testing, and leads a monthly case conference on anorectal disorders. Her primary area of clinical and research interest is anorectal motility disorders.

Nicholas J. Shaheen, MD, MPH*Associate Professor of Medicine and Epidemiology; Director of the Center for Esophageal Diseases and Swallowing*

Nicholas Shaheen is Associate Professor of Medicine and Epidemiology at the UNC School of Medicine and UNC School of Public Health, and Director of the UNC Center for Esophageal Diseases and Swallowing. He attended college at Harvard University and earned his medical degree at the University of Chicago, Pritzker School of Medicine, where he fulfilled his internship and residency requirements. He completed his clinical fellowship training at UNC, where he also earned his Masters degree at the School of Public Health. He then completed a National Institutes of Health fellowship in Epidemiology. For the past seven years, he has been a faculty member at UNC. His research interest is in the epidemiology and management of esophageal diseases. He is the author of numerous journal articles and book chapters related to reflux disease, motility disorders, Barrett's esophagus, and esophageal cancer. He is currently on the editorial board of *Gastroenterology* and *Evidence-Based Gastroenterology*, and is a reviewer for numerous journals. Dr. Shaheen receives research funding from the National Institutes of Health as well as multiple private foundations and corporations to pursue clinical and translational research in esophageal diseases. He is a member of several professional societies, including the American Gastroenterological Association, the American Society of Gastrointestinal Endoscopy, the American Medical Society, and the North Carolina Medical Society. He is a Fellow of the American College of Gastroenterology and the American College of Physicians. Dr. Shaheen's research team includes: Ryan Madanick, MD; Melissa

Brennan, RN (Study Coordinator); Paris Heidt (Study Coordinator); Stephanie Bright (Study Coordinator); and Nicole Cheng, PA.

Syed Thiwan, MD*Clinical Fellow in Gastroenterology and Hepatology*

Dr. Thiwan obtained his medical degree from India and came to the US for further training. He practiced Internal Medicine for a non-profit health care clinic near Charlotte, NC, before coming to UNC to specialize in Gastroenterology. After finishing two years of post-doctoral training under Dr. Whitehead, he started his GI Fellowship training in 2005. Dr. Thiwan is a co-investigator in Dr. Whitehead's study of the psychophysiology of IBS, looking at the possibility of different etiopathologic groupings among IBS patients. Dr. Thiwan has also developed and validated a questionnaire that measures the intensity of bloating, along with Dr. Palsson and Dr. Whitehead. Data from this study and on symptom reporting by patients on Tricyclic antidepressants were presented at DDW 2005. His interests are the pathophysiology and treatment of functional GI disorders, EUS, and atypical GERD.

Miranda Van Tilburg, PhD*Assistant Professor of Medicine*

Dr. van Tilburg is an assistant professor of medicine in the Division of Gastroenterology and Hepatology. She received her Master's degree in Economic Psychology and her PhD in Health Psychology at Tilburg University, The Netherlands. In 2001, she completed a three-year postdoctoral fellowship in Endocrinology and Medical Psychology at Duke University Medical Center. In 2002, Dr. van Tilburg joined the UNC Center for Functional GI & Motility Disorders on a part time basis. After securing an NIH supplement to promote re-entry into the biomedical sciences she resumed full time work in November 2006. She has an interest in pediatric functional GI disorders, especially Functional Abdominal Pain (FAP). Compared to adults, children's functional GI disorders have received little attention and Dr. van Tilburg has worked hard to expand the Center's research activities in this area. She collaborates with pediatric gastroenterologists at the University of North Carolina, Duke University Medical Center and Goryeb Children's Hospital in New Jersey. Her main research focus is on how to effectively involve parents and children in their own care. She has developed a home-based Guided Imagery treatment for FAP that children can use with only minimal guidance from their physician. The treatment is delivered by CDs and DVDs -- eliminating the need for a trained therapist -- which makes this type of treatment more widely available to children. The home-based program has been very successful in reducing abdominal pain and disability in children and has been well accepted by children, parents and clinicians. Dr van Tilburg was the first seed grant recipient of the Center for this work and subsequently secured additional NIH funding. In addition, her work focuses on the role of abuse in unexplained gastrointestinal symptoms in children. She recently received a second seed grant award to study the role of abuse and depression in suicidal ideation among adolescents who suffer from chronic abdominal pain. Dr van Tilburg is also interested in parental perceptions of functional gastrointestinal disorders and how this affects

medical consultation seeking. For her work she has been awarded the 2007 Pediatric Junior Investigator Award of the International Foundation for Functional Gastrointestinal Disorders (IFFGD).

Stephan Weinland, PhD*Instructor of Medicine*

Dr. Weinland is an Instructor in the Division of Gastroenterology and Hepatology in the School of Medicine, University of North Carolina at Chapel Hill. He joined the UNC Center for Functional GI & Motility Disorders in October 2006 after completing his post doctoral residency working for the National Health Service in the United Kingdom. Dr. Weinland is a Clinical Psychologist with a specialization in behavioral medicine. He received his PhD from the Illinois Institute of Technology and completed his clinical residency at the Miami VA Medical Center. Past research has involved the development of a revised Medication Quantification Scale for Opioid Medication and an Item Response Theory based analysis of the McGill Pain Questionnaire. Current research interests involve conducting ecological momentary assessment of functional bowel disorders and the role of diary data in assessment of symptoms. Dr. Weinland will be working with patients and physicians in the functional GI clinic as well as conducting research with the Center.

Other Center Staff

Shannon Adams, BA – Ms. Adams joined the Center in January 2007 as Dr. Drossman's IBS Social Research Administrator. She is involved with the coordination of Dr. Drossman's clinical and research activities in addition to serving as administrative coordinator for the Biometry Core. She assists with publications, drug study budgets, and external contracts. Her undergraduate studies were in Psychology and Economics, and she is currently working on an MBA, with plans to graduate in December 2008. She has been working in health care for the past ten years, but this is her first position in a research setting.

Jennifer Boos, BS – Ms. Boos has been a Study Coordinator for Drs. Ringel and Drossman. She graduated from UNC at Chapel Hill in May 2006 with a BS in Biology and a minor in Social and Economic Justice. Her research background is in toxicology and oncology with the National Institute of Environmental Health Sciences. She will be leaving the Center in August 2008 to pursue a Physician Assistant degree at Duke University.

Gae Caudill – Ms. Caudill is a part-time administrative assistant and data entry technician. She maintains the Center's computerized database, responds to requests for information, mails the Center's newsletter and annual report, and assists with a variety of duties associated with Center meetings and events. She also designs scannable questionnaires, scans survey data, and performs quality/accuracy checks on survey data.

Sheila Crawford, RN - Ms. Crawford is the charge nurse for UNC Hospitals GI Motility Lab. She is responsible for performing diagnostic motility tests for pediatrics

and adults, as well as biofeedback for pediatric patients. She also provides training in the lab for GI and surgery fellows.

Mark Duncan - Mark Duncan joined the Center in 2007, splitting his time between the Center for Gastrointestinal Biology & Disease (75% of time) and the Center for Functional Gastrointestinal & Motility Disorders (25%). His primary responsibilities with the Center are coding dynamic, database-driven web applications, surveys and forms and maintaining the REGISTRY database of potential research study subjects.

Lynn Eckert, PA - Ms. Eckert is a Physician Assistant working with Dr. Drossman as well as seeing patients on her own in the Functional GI & Motility Disorders Clinic. She evaluates patients in the clinic, performs a history and physical examination, formulates a differential diagnosis, and creates a diagnostic and treatment plan appropriate for the patient. Ms. Eckert has worked in all areas of gastroenterology and received her PA training at Duke University School of Medicine. She has a BA in Clinical Nutrition from UNC at Greensboro and has experience and interest in research.

Jane Hankins, MAT - Jane Hankins is the study coordinator for Dr. Drossman's clinical trials group working on the Atkins and the ElectroGastrogram (EGG) studies. She also assists Kim Meyer with clinical trials.

Yuming J.B. Hu, MA, PhD - Dr. Hu is Assistant Director of the Biometry Core and is involved with data management and analysis of Dr. Drossman's NIH treatment trial of functional bowel disorders (FBD). His data management responsibilities also includes the UNC pilot study of functional MRI of FBD, the Center's master database of FBD patients, the IBS patient education (PEQ) study with Boston University, the Celiac study with Columbia University, and the new 5-year combined drug and CBT treatment trial of FBD at the University of Toronto.

Lenore Keck, RN - Ms. Keck is a Research Nurse with Dr. Whitehead's group. She participates in all stages of clinical research studies, including study subject recruitment and screening, administering psychological and physiological tests, and data management.

Sarah McGee, BA - Ms. McGee is Administrative Assistant to Drs. Whitehead, Ringel and Morgan. She has a BA in Public Policy from the University of North Carolina at Chapel Hill.

Kim Meyer, CCRC - Ms. Meyer is Dr. Drossman's Project Director for clinical trials. Her primary research interests include the use of pharmaceuticals to treat constipation-predominant IBS, diarrhea-predominant IBS, and chronic constipation.

Linda Miller, AD Computer Information Systems - Ms. Miller is the IBS/Functional Bowel Clinic Scheduling Coordinator. She has an AD in Computer Information Systems, a diploma in Software Applications, and has completed the Medical Coding Certification Program (ICD-9, CPT-4) at Durham Tech. In the evening, she attends NC Central University and is completing a BA in Public Administration.

Carolyn Morris, MPH - Ms. Morris is the Biostatistician for Dr. Drossman's research group and the Biometry Core. She has been primarily involved with performing

statistical analyses on data from the seven-year multi-center NIH study of treatment in FBD, but she also assists with analyses of data sets for other Center studies.

Kirsten Nyrop, MACT - Ms. Nyrop is the Center Coordinator. Her responsibilities include editor/writer for the Center's website and publications, fundraising, marketing/press relations, and organizational development. She is also Administrator of the Center's NIH Mind-Body Infrastructure Grant. Ms. Nyrop is enrolled part-time in the PhD program at the UNC School of Social Work, where her research interest is medical care of the elderly.

Moneika Owens, BA - Ms. Owens joined the Center as Dr. Drossman's research assistant for clinical trials. She is a recent graduate of UNC (BA in Sociology) and has been a work study student at the Center for several years. She plans to apply for medical school in the near future.

Jennifer Peterson, MA - Ms. Peterson is the Media Coordinator for the Center. She graduated from the University of Northern Iowa with a bachelor's degree in Public Relations and a master's degree in Communications and Training Technology.

Ann Selph - Ms. Selph is research administrator to Dr. Drossman. She has 25 years of UNC experience in various capacities that include grants management, accounting, and administrative support. She has completed her associate in arts degree from Central Carolina Community College and continues to take classes through Continuing Studies at UNC Chapel Hill.

Jane Tucker, RN - Ms. Tucker is a Research Nurse with Dr. Whitehead's group. For the Center's biofeedback study, she performs anorectal motility testing and administers questionnaires to the study participants. Her other responsibilities include barostat procedures, lab procedures, recruiting/screening as well as scheduling participants for the studies. She works closely with the research pharmacy if studies require medication and monitors the participant's response to the medication. And, she works closely with the Principal Investigators of each study and keeps them abreast of any concerns.

Marsha Turner, MS - Ms. Turner is the Research Coordinator for Dr. Whitehead's research program. She is involved with the planning and preparation of new projects in the program, including NIH grant submissions and industry-sponsored outcomes research. She assists with all aspects of current studies and is responsible for correspondence with the Biomedical IRB and General Clinical Research Center, both at UNC. Ms. Turner also coordinates activities within the research network of the Gastrointestinal Biopsychosocial Research Center, a network of national and international collaborating institutions.

Sarah Van Heusen, MSHA - Ms. Van Heusen is Dr. Ringel's research project director focusing on studies in IBS, probiotic bacteria and intestinal microflora. She previously worked for the Carolina Population Center, where she was a project coordinator on the Pregnancy, Infection and Nutrition Study for over four years. She has a bachelor's degree in Psychology and master's degree in Health Services Administration, and has experience as a project coordinator in biomedical research, epidemiology and social research.

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