



UNC Center for
Functional GI
& Motility
Disorders

Annual Report
2005

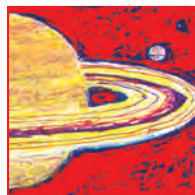
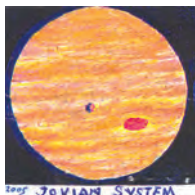
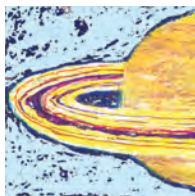
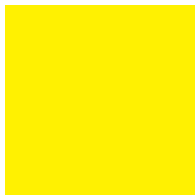
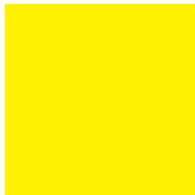
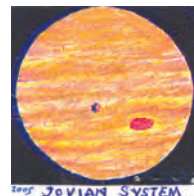
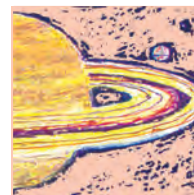
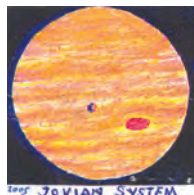
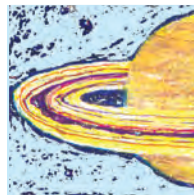
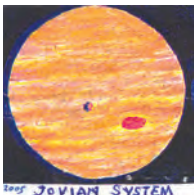



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Cover art for this annual report was provided by Robert Johnson, whose interest in and support for the Center are greatly appreciated. The artwork was arranged by John Herr.

Dear Reader

Welcome to the “2005 Annual Report – UNC Center for Functional GI & Motility Disorders.” The yearly process of gathering and presenting information about the Center is challenging, because it is always a busy year with activities going on in many different arenas. But, the annual review is also 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, and corporate sponsors. This report is about all of us and we hope it provides thanks and celebration.

In 2004, the Center was awarded 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, focused on the causes and treatment of functional GI 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 one of the first to advocate this biopsychosocial approach to the study and treatment of functional GI and motility disorders.

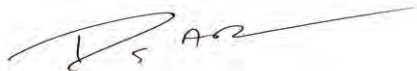
In addition to this “mind-body infrastructure grant,” our annual report chronicles other significant activities and accomplishments, including these highlights:

- Recruitment of several new faculty and investigators to the Center
- Recruitment of internal and external advisory boards for the NIH infrastructure grant
- Planning and hosting the first annual *Research Day 2005: Gastrointestinal Biopsychosocial Research at UNC*
- Completion of the first year of Seed Grant awards funded through the infrastructure grant
- Continued generous support from individual donors and corporate sponsors
- 69 journal article / editorials/commentaries, 32 published abstracts, 17 books or book chapters
- Foundation support for a physician assistant and psychologist.

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

The Year 2006 is off to a promising start and we look forward to getting back to our readers next year with further reports of our growth in research, training and patient care.

With gratitude,



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



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

Highlights of 2005

Faculty Changes

- Denesh Chitkara, MD, joined the Center as an Assistant Professor in Pediatrics
- Motoyori Kanazawa, MD, PhD, was appointed Adjunct Assistant Professor of Medicine
- Spencer Dorn, MD, joined the Center as a post-doctoral Epidemiology Fellow in Digestive Disease
- Young-Hyo Chang, PhD, joined the Center as post-doctoral fellow working with Drs. Yehuda Ringel and Balfour Sartor

Mind-Body Infrastructure Grant

- Infrastructure Grant Advisory Board of UNC leaders was recruited and held its annual meeting (March 21, 2005)
- Seed Grant awards were granted to Miranda Van Tilburg, PhD; Yehuda Ringel, MD; and Denesh Chitkara, MD.
- Scientific Advisory Board of leading experts in functional GI and motility was recruited and held annual meeting (June 10, 2005)
- Research Day 2005: Gastrointestinal Biopsychosocial Research at UNC was hosted on the campus of the UNC School of Medicine (June 11, 2005)

Educational Grants

- The S&R Foundation and Sucampo Pharmaceuticals are two new sponsors of the Center who 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 from the The Procter & Gamble Company (P&G), Novartis Pharmaceuticals, AstraZeneca Pharmaceuticals, Solvay Pharmaceuticals, and Vela Pharmaceuticals.

Awards, Appointments, Special Honors

- Olafur Palsson, PsyD, received an Award of Merit from the American Society of Clinical Hypnosis.
- Shrikant Bangdiwala, PhD, received a Fulbright Senior Specialist award in the field of Global/Public Health.
- Dr. Drossman was selected by the ACG as Master of the American College of Gastroenterology.
- Posters presented by Miranda Van Tilburg, PhD, and Steve Heymen, MA, were selected by the AGA Council for "Poster of Distinction" recognition.
- Doug Morgan, MD, has been appointed to the International Committee, American Gastroenterology Association (AGA).
- Douglas Drossman, MD, received the AGA Miles and Shirley Fiterman Joseph B. Kirsner Award in Clinical Research.
- Dr. Palsson was editor of a special issue on hypnosis for GI disorders for the International Journal of Clinical and Experimental Hypnosis.
- Syed Thiwan, MD, received a 2005 Young Investigator Award from the Functional Brain-Gut Research Group (FBG).
- Dr. Drossman was appointed to the Institute of Medicine (IOM) Committee on Stress and the Gulf War Veteran.
- Nicholas Shaheen, MD, received the AGA Young Clinical Investigator Award for "originality and innovative insight into a major problem in gastroenterology."
- Dr. Drossman and Mary Ann Bella received the 2005 Communicator Award-Medical/Government Category for the "Irritable Bowel Syndrome" video (Bella International Productions, Inc.).
- Dr. Palsson provided testimony at a seminar of NIH representatives and congressional staff, sponsored by the Association for Applied Psychophysiology and Biofeedback.
- Dr. Drossman was appointed as an ad hoc member of the NIH (NCCAM) Grants Advisory Board for final review and decisions on NIH research grants for complementary and alternative medicine.
- Dr. Drossman continued to be recognized among "Best Doctors in America", "Best Doctors Southeast Region", Who's Who in Medicine and Health Care", and "Who's Who in America".
- Nicholas Shaheen, MD, received the Sophomore Basic Science Teaching Award from the second-year class to the most outstanding teacher in the second-year curriculum (UNC School of Medicine). Dr. Shaheen also received the Department of Medicine Teaching Recognition Award.
- Dr. Shaheen was also recognized among "Best Doctors in America."
- William Whitehead, PhD, was appointed to the Nominating Committee of the AGA.

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 & 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:

- I. **Patient Care** – To offer state-of-the-art evaluation and treatment for the full range of functional GI and motility disorders.
- II. **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.
- III. **Training** – To provide multidisciplinary training and education in clinical and research skills, with an emphasis on patient-centered care and advanced research methods.
- IV. **Public Education** – To provide helpful 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 longstanding 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 350 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 and Rome II editions, with Rome III in progress). In addition, he serves on six editorial boards in medicine, gastroenterology and psychosomatic medicine, is associate editor of Gastroenterology, and is GI section editor of the Merck manual.

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 and in gastroenterology at the University of North Carolina in 1976-1978.

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 Co-founder/Past President of the Functional Brain-Gut Research Group of AGA. He is currently a member of the AGA Media Committee. Dr. Drossman is a Fellow of the American College of Physicians and a Master of the American College of Gastroenterology. Most recently, he has been appointed a member of an Institute of Medicine

William E. Whitehead, PhD

Professor of Medicine



Dr. Whitehead is Professor of Medicine at the UNC School of Medicine and 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 (Division of Gastroenterology and Hepatology). He has been involved in research on functional gastrointestinal disorders for 32 years and is recognized internationally for his research and teaching on constipation, fecal incontinence, and irritable bowel syndrome (IBS).

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 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, continued to evolve his

D. Drossman, cont.

committee to assess the effects of stress on veterans, and as an Ad Hoc Advisory Board member of the NIH National Center for Complementary and Alternative Medicine (NCCAM).

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.

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, including a recent 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 has begun looking at brain imaging (fMRI) in functional bowel disorders to determine if reported changes in the brain 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.

W. Whitehead, cont.

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.

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 the 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 200 journal articles, books, and book chapters and more than 200 abstracts on these topics.

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 was invited to join the steering committee of the Multinational Working Team Project to Develop Diagnostic Criteria for Functional Gastrointestinal Disorders – known as the “Rome Committees.” He was also invited to chair the working committee on Anorectal Disorders. The steering committee later asked him to organize and chair the International Resource Committee, comprised of representatives from the Food and Drug Administration (FDA), National Institute of Diabetes and Digestive & Kidney Diseases (NIDDK), and International Foundation for Functional Gastrointestinal Disorders (IFFGD).

Dr. Whitehead is currently a member of the Executive Committee for the Rome Foundation. He was a co-editor of *The Functional Gastrointestinal Disorders – Diagnosis, Pathology and Treatment*, a Multinational Consensus (Rome I and Rome II). He is Co-Chair of the Design of Treatment Trials working team for the Rome III Committees, with Rome III to be published in 2006. Dr. Whitehead also organized and chaired an international symposium in Vienna which was organized to develop a consensus on the definition of a “responder” in clinical trials for functional GI disorders. Dr. Whitehead has received awards and

D. Drossman, cont.

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 I: The Functional Gastrointestinal Disorders in 1994; Rome II: The Functional Gastrointestinal Disorders, 2nd edition, in 2000; and senior editor of Rome III to be published in 2006
- 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
- From 2003-2005, chair of the Nerve-Gut Section of the AGA Council
- Co-founder and past chair of the Functional Brain-Gut Research Group special interest section within the American Gastroenterological Association
- 1999 Chair of the Digestive Health Initiative on Functional GI Disorders sponsored by the American Digestive Health Foundation
- Past-president of the American Psychosomatic Society
- Fellow of the American College of Physicians
- Master of the American College of Gastroenterology
- Charter fellow of the American Academy of Physician and Patient
- Since 2001, Associate Editor of Gastroenterology, the official journal of the AGA
- Author of the AGA Clinical Teaching Project on IBS – Unit 13 (1997)
- Author of the AGA Clinical Teaching Project on IBS II (2003)
- Editor of the Manual on GI Procedures (now in its fourth edition)
- On the board of the medical website Medscape Gastroenterology
- Gastroenterology Section editor of the Merck Manual

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.

had significant involvements with a variety of leading national and international organizations:

- Co-founder and past chair of Functional Brain-Gut Research Group's special interest section within the American Gastroenterological Association
- Head of the steering committee and chair of two multidisciplinary conferences on fecal incontinence sponsored by the International Foundation for Functional Gastrointestinal Disorders -- a third is being planned for next year (2006)
- Since 2000, Associate Editor of Gastroenterology, the official journal of the American Gastroenterology Association
- 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
- Advisory Board for the General Clinical Research Center at the UNC School of Medicine
- Functional Brain-Gut Research Group Research Scientist Award for Clinical Research in 1999
- IFFGD Award for Research Excellence in 2003
- Janssen Award for Outstanding Research in Gastroenterology in 2004.

Faculty, Clinicians and Investigators



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- Eric Westman, MD — *Duke University Medical Center, Durham, NC*
- Peter Whorwell, MD — *University of South Manchester, Manchester, UK*
- Steven Young, MD — *Div. of Reproductive Endocrinology, OBGYN, UNC School of Medicine, Chapel Hill, NC*
- Li Zhiming, MD, MPH — *Global Health Economics Pharmacia and Upjohn Laboratories*

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 Duane D. Webb, MD, FACG; Christine B. Dalton, PA-C; Danielle Maier, PA-C, MA PAS; and Charles K. Burnett, PhD, DrPH.

On some afternoons, the clinic is also staffed with a Fellow (gastroenterologist in training), who is supervised by Drs. Drossman and 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).



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, facilitated by Dr. Ringel and 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. Visiting gastroenterologists and trainees from other states and countries also attend the Clinical Case Conference.

GI Motility Program

The GI Motility Program at UNC Hospitals was established by Dr. Whitehead. However, diagnostic evaluations and clinical care are now managed by other faculty -- Dr. Yolanda Scarlett (Medical Director) for lower GI motility disorders, and Dr. Nicholas Shaheen (Medical Director) and Dr. Doug Morgan for swallowing disorders and ambulatory pH testing. Sheila Crawford, RN, is the head nurse for the GI Motility Program.

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 Program 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 Program is recommended. The following services are provided by the GI Motility Program:

- Diagnostic anorectal motility tests for fecal incontinence, constipation or rectal pain
- Biofeedback treatment for fecal incontinence or constipation
- Ambulatory pH studies
- Esophageal motility testing
- Hydrogen breath tests for small bowel bacterial overgrowth and carbohydrate malabsorption
- Breath tests for h. pylori infection

Pelvic Floor Disorders Case 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 Program. 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, or to the surgical treatment trials and epidemiological studies sponsored by the Pelvic Floor Disorders Network, for which UNC serves as one of seven sites. The conference also provides an opportunity for updates on new publications, research conferences, and new research initiatives.

Psychological Services

Charles K. Burnett, PhD, DrPH, is a Clinical Associate Professor of Medicine and the Center's Director of Psychological Services. Patients are referred to him 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, then Dr. Burnett or a psychology intern working with him is brought into the patient's overall care

as part of our multi-disciplinary team approach. Dr. Burnett specializes in the treatment of patients with chronic illnesses, using one or more of the following techniques or therapies, in collaboration with the patient's other health care providers and medications:

→ **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. By understanding and focusing on all three components, 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.

→ **Biofeedback:** Biofeedback is a technique in which the person is trained to change a specific physical response. Biofeedback requires equipment that can be used in a therapist's office, or can be purchased or rented for personal home use. Biofeedback has been used to successfully treat many diseases and disorders, including IBS. Through biofeedback, a patient can gain control over his/her physical responses and manage the unpleasant symptoms to a point where the equipment becomes unnecessary.

Research

An important goal of the Center is conducting 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. In 2005, grants from NIH and contracts with pharmaceutical companies provided over \$2.6 million in support for Center research activities.

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.

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 establishes a Gastrointestinal Biopsychosocial Research Program within the Center. The Center's Co-Directors — Drs. Whitehead and Drossman — are Co-PIs for this grant. In 2005, 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 were recruited to provide advice 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, and biofeedback for fecal incontinence and constipation.

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. The Research Administration Core also assembles and maintains records and forms that are made available to investigators who are dealing with regulatory issues that affect the conduct of research (i.e., IRB and GCRC forms, website where grant applications can be obtained, etc.).

→ 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 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 generation 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 the data and developing research reports for publication. Fifty percent of the Biometry Group's time and expertise are reserved as a core resource available through the Infrastructure Grant.

→ Data Acquisition & Technology Applications Core (DATA)

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), with application deadlines in December, April and August. 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 young investigators for studies related to functional GI and motility disorders under the following eligibility criteria:

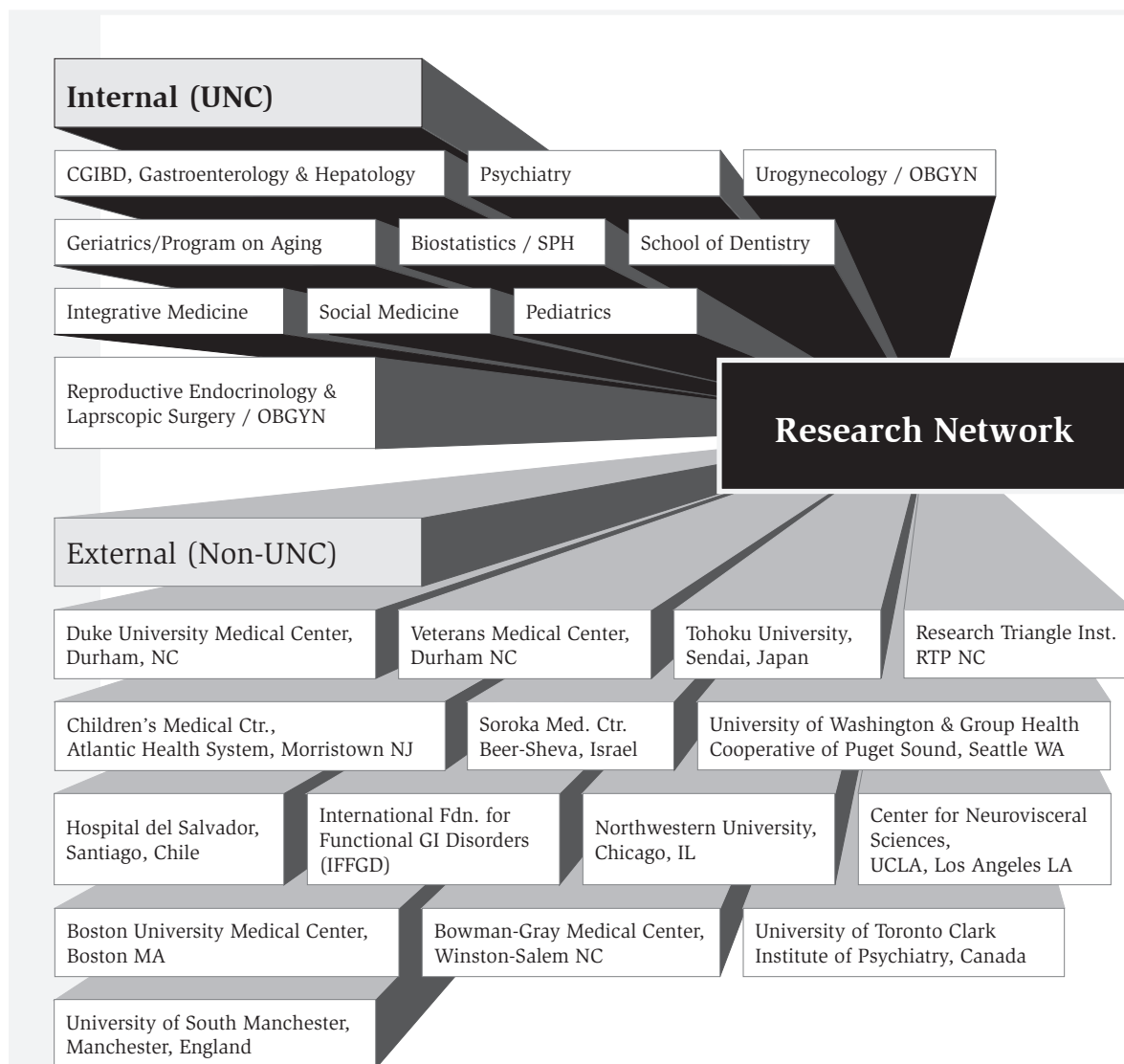
- The Seed Grant Program is open to any investigator at UNC (whether a member of the Center or not) and to any investigator within the Research Network associated with the Center.
- Investigators who have already received NIH support as a principal investigator are not eligible for Seed Grant funds. 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 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 PHS 398 form with a Center cover page and page restrictions. Nicholas Talley, MD, of the Mayo Clinic in Rochester, MN, 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; (f) relevance to functional gastrointestinal or motility disorders; and (g) no support for pharmaceutical or device trials (ineligible).

In Fiscal Year 2005, the following seed grants were 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



Research Day 2005:

Gastrointestinal Biopsychosocial Research at UNC

Saturday, June 11, 2005

“Research Day 2005” was hosted by the UNC Center for Functional GI & Motility Disorders on the campus of the UNC School of Medicine. This non-CME convocation was held in conjunction with the Center for Gastrointestinal Biology & Disease (CGIBD), UNC Division of Gastroenterology & Hepatology.

The aims of the conference were: (1) to provide an outstanding educational experience by having the internationally recognized members of our Scientific Advisory Board give state of the art presentations on their research areas, (2) to introduce local researchers from UNC and nearby institutions to the Center’s research programs, and (3) to obtain a critical review of the Center’s research from the Scientific Advisory Board and the audience. The symposium had over 60 registrants from Duke University, Wake Forest University, and North Carolina State University as well as UNC. We also had participants from other states, Norway and Japan. A summary of the presentations is posted on the Center website www.med.unc.edu/ibs Seven research areas were profiled, each with a state-of-the-art presentation from an outside speaker and one or more “on-going research and future research directions” presentations from UNC investigators:

Newer Pharmacological Treatments

- **Ray E. Clouse, MD** – Prof. of Medicine & Psychiatry, Washington Univ. School of Medicine, St. Louis, MO
Antidepressants & Medical Disorders
- **Douglas A. Drossman, MD** – Prof. of Medicine & Psychiatry, UNC School of Medicine, Chapel Hill, NC
NIH research on desipramine

Genetics and Phenotyping of FGIDs

- **Robin C. Spiller, MD** – Prof. of Gastroenterology, University Hospital, Queens Medical Centre, Nottingham, England
Abnormalities of serotonin metabolism in IBS
- **William E. Whitehead, PhD** – Prof. of Medicine, UNC School of Medicine, Chapel Hill, NC
Is IBS one disease or many? Test of the heterogeneity hypothesis & implications for heritability studies

Pediatric FGIDs

- **Rona L. Levy, PhD** – Professor, University of Washington, Seattle, WA
Intergenerational transmission of the FGIDs: Nature or nurture?
- **Denesh Chitkara, MD** – Assistant Prof. of Pediatrics, UNC School of Medicine, Chapel Hill, NC
Functional dyspepsia in children: Is this one disorder or many?

Brain Imaging

- **Emeran A. Mayer, MD** – Prof. of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, LA
Brain imaging in IBS and FGIDs
- **Yehuda Ringel, MD** – Assistant Prof. of Medicine, UNC School of Medicine, Chapel Hill, NC
Past and proposed brain imaging work

Pelvic Floor Disorders

- **Anne W. Weber, MD** – Associate Prof. of OBGYN & Reproductive Sciences, Magee Women’s Hospital, University of Pittsburgh, Pittsburgh, PA
Pelvic floor disorders: Unmet needs and next steps
- **Steve Heymen, MS** – Instructor in Medicine, UNC School of Medicine, Chapel Hill, NC
Randomized controlled trials of biofeedback for the treatment of fecal incontinence and outlet-dysfunction constipation
- **Anthony Visco, MD** – Assistant Prof., Div. of Urogynecology & Reconstructive Pelvic Surgery, Dept. of OB/GYN, UNC School of Medicine, Chapel Hill, NC
Pelvic floor disorders

Hypnosis

- **Peter J. Whorwell, MD** – Senior Lecturer/Prof. in Gastroenterology, University Hospital of South Manchester, Manchester, UK
Hypnosis treatment for IBS – the Manchester model
- **Olafur S. Palsson, PsyD** – Associate Prof. of Medicine, UNC School of Medicine, Chapel Hill, NC
Hypnosis treatment for IBS – the North Carolina model
- **Miranda Van Tilburg, PhD** – Assistant Prof. of Medicine, UNC School of Medicine, Chapel Hill, NC
Treating pediatric IBS with self-hypnosis

Patient Education

- **Albena Halpert, MD** – Clinical Instructor, Boston University medical Center, Boston, MA
Ongoing research in patient education

This event was supported through grants from NIH (R24 DK67674), Novartis Pharmaceuticals, AstraZeneca Pharmaceuticals, and Solvay Pharmaceuticals.

2004 Research Grants, Contracts and Awards

NIH and other Federally-Supported Studies

R24 DK067674 – Whitehead and Drossman, Co-PIs	7/1/04-6/30/09
NIDDKD	\$4,450,000
<i>Infrastructure grant titled “Gastrointestinal Biopsychosocial Research Center,” submitted in response to RFA OB-03-004, Mind-Body Interactions and Health: Research in Infrastructure Program</i>	
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 such investigations through core resources (biostatistics, data acquisition technology, subject recruitment, project management), and (3) to recruit and train new investigators in this field.	
RO1 DK31369 – Whitehead, PI; Drossman, Co-Investigator	12/1/02-11/31/07
NIDDKD	\$1,714,897
<i>Psychophysiology of IBS</i>	
Aim of three proposed studies is to determine whether IBS is uniquely associated with specific co-morbid conditions, which would suggest shared pathophysiology, or whether co-morbidity is an expression of psychological contributions to the etiology of IBS. Study III, which is currently ongoing, tests 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. To test this hypothesis, we plan to recruit 150 IBS patients and 50 healthy controls, to assess all the proposed mechanisms for the etiology of IBS, and to use the statistical method of cluster analysis to determine whether there are distinct subgroups. If the heterogeneity hypothesis is supported by this analysis, the plan is to test a new sample of 150 IBS patients to determine whether the same subgroups can be confirmed by replication.	
RO1 HD36069 – Whitehead, PI	04/01/99-03/31/07
NICHHD & NIDDKD	\$203, 510 (Subcontract)
<i>Intergenerational Transmission of Illness Behavior</i>	

Aims of first grant: (1) assess the ways parents respond to their children’s somatic complaints, and whether this contributes to the clustering of functional GI disorders within families, and (2) determine whether these social learning effects are independent of family stress, academic competence, and parent and child psychological symptoms. Aims of competitive renewal funded 4/03-3/07: To carry out a prospective clinical trial to treat recurrent abdominal pain in children. The treatment model is based on findings from the initial grant.

RO1 DK57048 – Whitehead, PI	09/30/99-11/31/05
NIDDKD	\$816,485
<i>Biofeedback for Fecal Incontinence and Constipation</i>	
Aims: (1) to compare biofeedback to alternative therapies for which patients have a similar expectation of benefit; (2) to identify which patients are most likely to benefit; and (3) to assess the impact of treatment on quality of life. Two parallel randomized controlled trials are being conducted. One compares biofeedback to Kegel exercises for the treatment of fecal incontinence, and the second RCT compares biofeedback for pelvic floor relaxation to a muscle relaxing drug (diazepam) or to placebo tablets.	

FRN 63138 – Toner, PI; Drossman, PI UNC Site	09/01/05-08/31/10
Canadian Institute for Health Research (CIHR)	\$500,000
<i>Multicenter trial of combined cognitive behavioral antidepressant treatment of functional bowel disorders</i>	
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.	

U10 HD41267 – Visco, PI; Whitehead, Co-Investigator	09/01/02-06/30/06
NICHHD	\$1,452,170
<i>UNC Pelvic Floor Disorders Research Collaborative</i>	

This grant funds UNC as a component of a pelvic floor research network that will conduct one or more multi-center studies of the treatment of pelvic floor disorders, including fecal and urinary incontinence. Current studies: (1) compare different surgical techniques for repair of pelvic organ prolapse, (2) assess the incidence of fecal and urinary incontinence following external anal sphincter disruption during childbirth, (3) assess the prevalence of fecal and urinary incontinence in the NHANES study, and (4) validate a physical examination rating scale for pelvic floor. Projects for which our Center is taking the lead include: (5) validation of a telephone survey for assessing fecal incontinence severity and quality of life impact, (6) assessing the impact of usual bowel habits (stool consistency) on the risk of fecal incontinence following obstetric injury, and (7) assessing the GI complications of abdominosacrocolpopexy surgical repair for pelvic organ prolapse.

K23 DK59311-01 – Shaheen, PI	8/1/01-8/30/06
NIH	\$100,000 (one year)
<i>Epidemiologic Case-Control of Barrett's Esophagus</i>	
The goal of this project is to assess the risk factors for the development and progression of Barrett's esophagus, using case-control study methodology.	

K01 CA93654-01 – Keku, PI	8/1/02-7/31/06
NIH	\$668,227
<i>Insulin Resistance and Colon Cancer in Blacks and Whites</i>	
The major goal of this project is to examine genes related to insulin resistance and environmental and lifestyle factors that might be associated with colon cancer in African Americans and whites in North Carolina. Polymorphisms in IGF-I, IGF-II and IRS-1 will be correlated with serum levels in IGF-I, IGF-II, insulin and IGFBP-3 and environmental risk factors.	

P30 DK56350 – Zeisel, PI; Keku is PI of a subproject	9/30/04-9/29/05
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Other Research Support and Awards

NIH Clinical Nutrition Research Center	\$25,000
<i>Clinical Nutrition Research Center Pilot Feasibility (Keku, PI)</i>	
Midkine expression in the progression of normal colonic mucosa to adenoma.	

NIH 1P50CA106991-01 – Tepper, PI; Keku, Co-Investigator	08/09/04-01/31/09
Project I of GI SPORE	
<i>Predictive and Prognostic Factors in Colorectal Cancer</i>	

K12 – Ringel, PI	01/01/06-12/31/07
NIH Clinical Nutrition Research Center	\$156,648
<i>The Role of Intestinal Inflammation in the Pathophysiology of Functional GI Disorders</i>	

Whitehead, PI; Drossman, Co-PI	06/15/05-06/14/06
Rome Foundation	
<i>Validation of the Rome III Questionnaire and Evaluation of Response Frequencies.</i>	
This subcontract has as its aims: (1) assess the understandability of individual questions in the Rome III Modular Questionnaire, (2) assess test-retest reliability of individual questions and diagnoses based on the Rome III diagnostic criteria, (3) describe the frequency of occurrence of individual symptoms in a large group of healthy controls to provide guidance to the Rome committees in setting thresholds for diagnosis, and (4) assess the sensitivity and specificity of the Rome III diagnoses by comparison to medically diagnosed groups of patients with the commoner functional GI disorders – IBS, dyspepsia, and chronic constipation. The coordinating center for the validation study is UNC. Three other centers will contribute patients.	

Drossman, PI	07/01/05-06/30/06
Miles and Shirley Fiterman Joseph B. Kirsner Award in Clinical Research	
American Gastroenterological Association (AGA)	
Awarded for distinguished lifetime research in the area of clinical gastroenterology.	

Drossman and Austin, Co-PI	08/01/05-07/30/06
Atkins Foundation	
<i>Study of the Effects of a Very Low Carbohydrate Diet on Symptoms of IBS</i>	
This study will evaluate the effects of a very low carbohydrate diet on IBS symptoms. Secondary analysis will include a determination of the mediating effects of postprandial serotonin release on GI symptoms.	

Drossman, PI; Dorn, Co-PI	12/01/05-11/31/06
Columbia University Center for the Study of Celiac Disease	
<i>Prediction of Psychosocial Factors and Disease Markers on Health Status in Celiac Disease</i>	
This study will evaluate the predictive effects of severity of celiac disease relative to psychosocial factors on clinical outcome and quality of life.	

Morgan, Co-PI	07/01/05-06/30/06
UNC Center for Gastrointestinal Biology and Disease. Pilot Grant	
<i>Biochromoendoscopy -- Novel imaging for early gastric cancer and gastrointestinal tract neoplasms.</i>	

Ringel, PI	07/01/03-06/31/05
ACG Junior Faculty Development Award	
The American College of Gastroenterology	
<i>Intestinal Sensory Function in Health and Disease</i>	
BSF 2001043 – Sperber/Drossman, Co-PIs	10/01/02-09/31/05
US-Israel Binational Science Foundation	
<i>Is Gynecological Surgery Associated with Subsequent Development of IBS and other Painful Disorders</i>	
To determine the frequency and determinants of IBS and visceral hypersensitivity in patients who have undergone gynecological surgery.	
Morgan, PI	01/01/04-12/31/05
UNC Mentored Clinical Research Scholar Award (K12)	
<i>Gastric Cancer Epidemiology in Central America. Focus: Host Genetics.</i>	
Morgan, PI	10/01/03-09/30/05
UNC School of Public Health, CNRC	
<i>Selenium and Gastric Cancer in a High Incidence Region in Central America</i>	
Systematic evaluation of selenium deficiency in gastric cancer patients in Honduras, examining dietary intake, soil levels, and serum levels; pilot grant.	
Morgan, PI	7/1/03-6/30/05
Rome Committees	
<i>The Epidemiology of Functional Gastrointestinal Disorders in Latin America: A Population-Based Study</i>	
The goal of this study is to examine the prevalence and risk factor associations in nested case-control design utilizing a novel developing nation epidemiology surveillance system with the University of Nicaragua.	

Research Contracts and Clinical Trials with Pharmaceutical Companies

In 2005, 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.

CHTF919A US21 – Whitehead, PI	12/1/02-06/30/05
Novartis Pharmaceuticals	
<i>Evaluate SERT Gene Polymorphisms and Serotonin Levels in IBS Subgroups</i>	

This subcontract is linked to RO1 DK31369 in which we are attempting to identify subgroups of IBS patients based on a screen of all likely physiological and psychological mechanisms for symptoms development. Aims: (1) Evaluate the distribution of SERT gene polymorphisms in 200 clinically well-characterized patients and relate SERT polymorphisms to IBS subgroups. (2) Evaluate serotonin levels during fasting and in response to meal ingestion in 200 well-characterized patients and relate serotonin levels to IBS subgroups. Further investigations of genetic markers for IBS are planned in collaboration with Dr. Tope Keku.

CHTF919AUS04 – Whitehead, PI	1/1/04-6/30/05
Novartis Pharmaceuticals	
<i>Validation of a Bloating Questionnaire</i>	
Aims: (1) to validate a bloating severity questionnaire by assessing correlation with impaired quality of life, (2) to validate the responsiveness of the bloating severity questionnaire by experimental manipulation of bloating in lactose malabsorbers, and (3) to validate a bloating differential diagnosis questionnaire by testing clinically defined subgroups of bloaters.	

CHTF919-US-32 – Drossman, PI	09/30/03-12/31/06
Novartis Pharmaceuticals	
<i>Clinical and Physiological Features of Subgroups of IBS: A Comparison of IBS with Constipation, IBS with Diarrhea, and Mixed/Alternators</i>	
This study uses Dr. Drossman's NIH treatment trial dataset to evaluate the differences in clinical and psychosocial features among patients with IBS-D, IBS-C and IBS-mixed alternators. Additional work includes determining what factors predict each IBS subgroup.	

HTF919A2417 – Drossman and Dalton, Co-PI	11/30/04-11/30/05
Novartis Pharmaceuticals	
A 4-Week Multicenter, Double-Blind, Parallel-Group, Placebo-Controlled, Randomized Clinical Study to Evaluate the Efficacy of (Drug) in Relieving the Symptoms of Female Patients with IBS, Excluding Those with Predominant Diarrhea IBS	

DNK3332201 – Drossman and Dalton, Co-PI	11/30/04-11/30/05
Novartis Pharmaceuticals	
A 2-Week Multicenter, Double-Blind, Placebo-Controlled, Randomized Pilot Study to Evaluate the Efficacy, Safety and Tolerability of (Drug) (25mg and 100mg BID) Given Orally in Female Patients with IBS with Diarrhea (IBS-D)	

CHTF919D2302 – Ringel, PI	04/01/04-12/31/06
Novartis Pharmaceuticals	

A 6-Week Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess to Efficacy and Safety of Oral (Drug) and Placebo in Female Patients with Dyspepsia (extension is **HTF919D2302E1**)

CHTF919B2203 – Ligozio, PI; Shaheen Co-Investigator 01/01/01-05/01/05

Novartis Pharmaceuticals

A Randomized, Double-Blind, Placebo-Controlled Trial of (Drug) Alone or in Combination with (Drug) in Patients with Non-Erosive GERD

Ringel, PI 07/01/05-06/30/07

GlaxoSmithKline/GSK

Genetic Surrogate Markers for Irritable Bowel Syndrome Susceptibility, Co-Morbidity and Disease Characterization

WA 36755 – Shaheen, PI 07/01/04-07/01/05

Eisai-Janssen Pharmaceuticals

GERD as an Etiology of Sleep Disturbances

TRN-002-20 – Drossman and Dalton, Co-PI 02/24/05-02/23/07

Trine Pharmaceuticals

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

05IBD05 – Drossman and Dalton, Co-PI 07/01/05-06/30/06

Prometheus Pharmaceuticals

Procurement of serum samples from irritable bowel syndrome (IBS) subjects for use in development of a diagnostic test for inflammatory bowel disease (IBD)

SPI/0211SIB-0432 – Drossman and Dalton, Co-PI 08/01/05 - 09/29/06

Sucampo Pharmaceuticals

A 12-Week, Multicenter, Double-Blind, Randomized Efficacy and Safety Study of (Drug) in Subjects with Constipation-Predominant Irritable Bowel Syndrome (Phase III)

Morgan, PI 01/03/05-01/03/07

Roche Laboratories, Inc.

Prospective efficacy study of (drugs) in treatment-naïve Latino patients versus Caucasian patients with chronic hepatitis C infection. The first treatment trial for Latino patients with hepatitis C.

PTI901NB – Drossman and Dalton, Co-PI 1/15/04-7/1/05



Pain Therapeutics

A Multicenter, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Low-Dose (Drug) in Female Patients with IBS

PTI901NC – Drossman and Dalton, Co-PI 1/15/04-7/1/05

Pain Therapeutics

A Multicenter, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Low-Dose (Drug) in Male Patients with IBS

Ringel, PI 12/01/03-06/30/05

AstraZeneca LLP

Clinical Efficacy of (Drug) in Patients with Diarrhea Predominant IBS or Functional Diarrhea

D1803C0001 – Drossman and Dalton, Co-PI 7/1/04-6/30/05

AstraZeneca LLP

A Multicenter, Double-Blind, Randomized Clinical Study Comparing (Drug) to Placebo in the Treatment of IBS

IRUSE SOM0313 – Shaheen, PI 01/01/05-01/01/07

AstraZeneca LLP

Training

The 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.

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 the University of Illinois. She plans to continue her research interest in psychological factors that influence the development of functional bowel disorders.

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 2005 included:

Denesh Chitkara, MD

Children's Hospital,
Boston
January 4 - 8

Nader Youssef, MD

Children's medical
Center, Morristown, NJ
January 20 - 21

Lucy Harris, MD

Mayo Clinic, Scottsdale
March 21 - April 1

Fernando Azpiroz, MD

Barcelona, Spain
May 19 - 20

Ami Sperber, MD, MPH

Beer-Sheva, Israel
May 23 - 27

Frank Tu, MD

Northwestern University
Hospital, Evanston
October 17

Ronnie Fass, MD

University of AZ, Tucson
October 20

Bette Bischoff

University of Kansas
Medical Center
October 3 - 28

Susan Lucak, MD

Columbia Medical
Center, New York City
November 6-11

Freddy Squella, MD

Santiago, Chile
*November 1, 2005 -
January 31, 2006*

Kok-Ann Gwee, MD

Singapore
December 5 - 7

Visiting Scientist 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 write academic publications 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. Visiting Scientists in 2005:

→ Young-Hyo Chang, MD

Dr. Chang received his doctorate from Korea University. Before coming to UNC, he worked as a Research Scientist at the Korea Research Institute of Bioscience and Biotechnology.

Dr. Chang's current research interests are the function and role of probiotics and intestinal anaerobic bacteria in the GI tract. During his stay at UNC, he will work on several research projects related to the role of intestinal bacteria in the pathophysiology of IBS and other functional GI disorders. He will investigate whether specific strains of colonic bacteria contribute to IBS symptoms and whether altering the bacterial milieu will lead to improvement of IBS. He will apply advanced molecular techniques -- such as quantitative PCR, SSCP and in situ hybridization -- to analyze microbial compositions of intestinal ecology.

Postdoctoral Training Program

The Center hosts postdoctoral fellows on an ongoing basis. Postdoctoral fellows typically stay for two or more 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.

Currently, Syed Thiwan, MD, is a Fellow in the Postdoctoral Training Program. He is in a three-year postdoctoral fellowship, for which Dr. William Whitehead serves as his research mentor and Dr. Douglas Drossman teaches him skills in interviewing and treating patients with functional GI disorders. Dr. Thiwan is also collaborating with Dr. Ringel on research. He will train in clinical gastroenterology beginning in 2006.

In addition, Spencer Dorn, MD, is a Post-Doctoral Fellow in Digestive Disease Epidemiology, mentored by Robert Sandler, MD, William Whitehead, PhD, and Douglas Drossman, MD. After his epidemiology fellowship, he will train in clinical gastroenterology.

Seminars

In the Patient Care section of this annual report, we have already described the Clinical Case Conference and the Pelvic Floor Disorders 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 (with the patient's permission). Over 25 years ago, Dr. Drossman began this monthly evening seminar for health care professionals that includes 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.

Public Education & Information

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, chat rooms, printed materials and publications, videos, and the website <http://www.med.unc.edu/ibs>. These activities are supported through donations from individuals and educational grants from corporate sponsors.

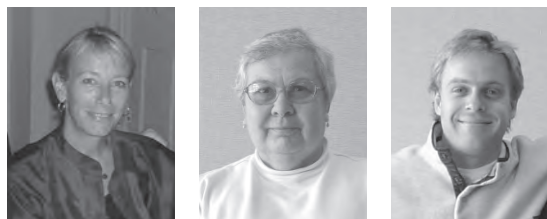
The Center's website at www.med.unc.edu/ibs has evolved as a leading on-line resource for information on IBS and other functional GI and motility disorders for patients, health care providers and scientists, and the public at large. Our website averages 20,000 to 40,000 visitors per month. Content is added every week, 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 and computerized questionnaires.

Once a quarter, our website hosts an on-line chat room -- "An Evening with the Experts" -- where the audience can engage in questions and answers on the topic selected for that evening. Topics in 2005 included:

- ➔ **Functional Dyspepsia – Is it the IBS of the upper gastrointestinal tract?** — Yehuda Ringel, MD
- ➔ **Pelvic Pain** — Denniz Zolnoun, MD and Jane Leserman, PhD
- ➔ **Antidepressant treatment for IBS** — Doug Drossman, MD and Syed Thiwan, MD
- ➔ **What is a functional GI disorder?** — Doug Drossman, MD

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, and Psychological Services.

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 (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 <http://www.med.unc.edu/ibs> and hard copies are distributed through the Center's extensive mailing list, at various events, and upon request.

An all-day “Patient Symposium” is being planned for July 15, 2006, and will be held in Chapel Hill, NC. This event will include plenary sessions and breakout sessions on a variety of topics, such as:

- ➔ What is a functional GI disorder
- ➔ Types of IBS and risk factors
- ➔ Diagnosis and tests for IBS
- ➔ IBS medications – effective treatments and new options
- ➔ Behavioral and alternative treatments – CBT & other relaxation therapies, hypnosis, biofeedback
- ➔ New leads in the biology of IBS
- ➔ IBS diet and nutrition
- ➔ Pediatric functional GI disorders
- ➔ Incontinence, constipation, bloating
- ➔ Functional dyspepsia and other upper GI symptoms.

Publications in 2005

In 2005, there were 69 journal articles/commentaries/editorials, 17 books/chapters, and 32 abstracts published by Center faculty and investigators.

Journal articles, commentaries, editorials

1. Bushnell DM, Patrick DL, Martin ML, Ricci JF, Drossman DA. Cross-cultural evaluation of the irritable bowel syndrome – quality of life scale (IBS-QOL). *Digestive Diseases and Sciences* 2005 (in press).
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3. Chiarioni G, Whitehead WE, Pezza V, Morelli A, Bassotti G. Biofeedback is superior to laxatives for normal transit constipation due to pelvic floor dyssynergia. *Gastroenterology* 2006;130:657-664.
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17. Drossman DA: Functional GI disorders: what's in a name? *Gastroenterology* 2005;128(7):1771-1772.
18. Drossman DA. Functional versus organic: an inappropriate dichotomy for clinical care. *American Journal of Gastroenterology* 2006 (in press).
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Books, chapters

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Visiting Scholars Program

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Bette Bischoff



Ami Sperber



Lucy Harris



Frank Tu



Susan Lucak



Fernando Azpiroz



Ronnie Fass



Freddy Squella Boer



Nader Youssef

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. His research team includes: Shrikant Bangdiwala, PhD; Jane Leserman, PhD; Christine Dalton, PA-C; Danielle Maier, PA-C, MA PAS; J.B. Hu, PhD; Carolyn Morris, MPH; Kim Meyer, CRC; Ann Selph, Susan Scheck, MS; Ann Selph; Jane Hankins, MAT; Gary Koch, PhD; Syed Thiwan, MD, and Spencer Dorn, MD.

William E. Whitehead, Co-Director

Professor of Medicine

Dr. Whitehead's research team includes: Yolanda Scarlett, MD; Olafur Palsson, PsyD; Miranda Van Tilburg, PhD; Steve Heymen, MS; 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 and Temitope Keku, PhD.

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. Dr. Bangdiwala chairs the Resource Allocation Committee of the Biopsychosocial Research Program.

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.

Young-Hyo Chang, MD

Visiting Scientist with Drs. Yehuda Ringel and Balfour Sartor

Dr. Chang received his doctorate from Korea University, where he studied growth-enhancing supplements of bifidobacteria as well as the selection and characterization of intestinal anaerobes. Before coming to UNC, he worked as a Research Scientist at the Korea Research Institute of Bioscience and Biotechnology. Dr. Chang's work has focused on biochemical and molecular characterizations and descriptions of novel bacteria isolated from fecal, soil, water and environmental samples. He has published several articles on the treatment of genomic DNA with restriction enzymes as well as the binding of extracellular matrix molecules by probiotic bacteria. Dr. Chang's current research interests are the function and role of probiotics and intestinal anaerobic bacteria in the GI tract. During his stay at UNC, he will work on several research projects related to the role of intestinal bacteria in the pathophysiology of IBS and other functional GI disorders. He will investigate whether specific strains of colonic bacteria contribute to IBS symptoms and whether altering the bacterial milieu will lead to improvement of IBS. He will apply advanced molecular techniques -- such as quantitative PCR, SSCP and in situ hybridization -- to analyze microbial compositions of intestinal ecology.

Denesh Chitkara, MD

Assistant Professor of Pediatrics

Dr. Chitkara is a pediatric gastroenterologist and Assistant Professor of Pediatrics at the University of North Carolina at Chapel Hill. He received his MD from Ohio State University College of Medicine and did his fellowship training in pediatric gastroenterology at The Floating Hospital for Children/Tufts School of Medicine and at Children's Hospital Boston/Harvard Medical School. He then completed a clinical and research fellowship in Clinical Enteric Neuroscience under the mentorship of Michael Camilleri, MD and Nicholas J. Talley, MD, PhD at Mayo Clinic Rochester. Dr. Chitkara was then recruited to join staff at Children's Hospital Boston and was an Instructor in Pediatrics at Harvard Medical School. During this time period, he completed physiologic studies in children with disorders of oxidative phosphorylation, functional dyspepsia, constipation, gastro-esophageal reflux disease, and aerophagia. Dr. Chitkara has also initiated epidemiologic studies on gastro-esophageal reflux disease, recurrent abdominal pain, and constipation in children. Dr. Chitkara joined the UNC faculty in October 2005. Through mentorship and collaboration with Dr. William Whitehead and Dr. Miranda van Tilburg at the UNC Center for Functional GI & Motility Disorders, he has begun investigations on psychological, familial and physiologic effects on symptoms in children with functional gastrointestinal disorders. Dr. Chitkara has also continued his involvement with epidemiologic studies in collaboration with Mayo Clinic Rochester, designed to evaluate childhood factors involved in the persistence of adult functional GI disorders.

Christine B. Dalton, PA-C

Physician Assistant

Ms. Dalton has been a Physician Assistant (PA) in the Functional GI & Motility Disorders Clinic for ten years. She participates in both patient care and 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

Post-Doctoral Fellow in Digestive Disease Epidemiology

Dr. Dorn is a graduate of the University of Michigan and SUNY at Brooklyn College of Medicine. He trained in internal medicine at Brigham and Women's Hospital/Harvard Medical School. Dr. Dorn joined the center in July, 2005 as a post-doctoral research fellow in digestive disease epidemiology. His fellowship is sponsored by the NIH and is under the direction of Dr. Robert Sandler. Dr. Dorn is concurrently pursuing a Masters in Public Health, rotating as a fellow in the functional GI clinic, and performing research with Dr. Drossman and Dr. Whitehead. Projects have included a study of the predictors of health status in celiac disease as well as a study of the determinants of visceral sensitivity in IBS.

Steve Heymen, MS

Instructor in Medicine, Director of Biofeedback Services

Mr. 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 is currently working on his dissertation for a PhD in Biological Psychology through the UNC Department of Psychology.

Temitope O. Keku, PhD

Research Associate Professor of Medicine

Dr. Keku carries out translational research that combines basic science with epidemiology to gain a better understanding of the etiology and pathogenesis of cancer, especially colorectal cancer. Her primary research interests include gene environment interactions, gene-gene interactions, and molecular epidemiology. She is currently conducting a study to evaluate the relationship between insulin resistance and colorectal cancer in African Americans and Whites, with a specific focus on gene-environment interactions involving genetic polymorphisms in genes associated with insulin resistance and obesity as well as lifestyle/dietary risk factors. Dr. Keku collaborates with Drs. Whitehead and Morgan on genetic polymorphisms that contribute to irritable bowel syndrome (IBS), and she also collaborates with Dr. Ringel. She is a co-investigator on the GI SPORE 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 Medical Parasitology



(Epidemiology) from the UNC School of Public Health. Dr. Keku's research team includes: Jeff Barnes, MS (Research Technician III), Janie Peacock, BS (Research Technician II), Katharine Thompson, BS (Research Technician III), Maya McDoom (Laboratory Research Assistant), Seun Omofoye (Laboratory Research Assistant), Helen Onabanjo (Laboratory Research Assistant).

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. Dr. Leserman's 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. Dr. Leserman also serves as a research mentor for younger faculty and trainees. Dr. Leserman's research team includes: Samantha Meltzer-Brody, MD (Collaborator), Denniz Zolnoun, MD (Collaborator), and Katherine Rinaldi (Research Coordinator).

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. Drossman, Ringel and Webb. She has completed intensive training in the biopsychosocial care of patients and has completed her Masters degree in physician assistant studies with a focus on functional bowel disorders. She is a PA graduate of the Wake Forest School of Medicine, where she graduated with high honors.

Douglas R. Morgan, MD

Assistant Professor of Medicine

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 nascent 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 Foundation. 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

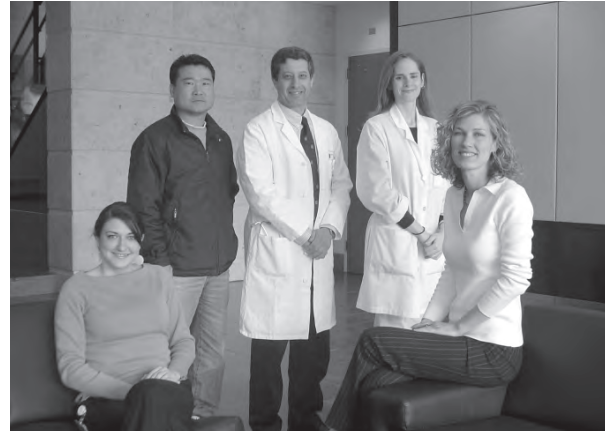
Associate Professor of Medicine

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. He also initiated and moderates the Center's on-line "Chat with the Experts."

Yehuda Ringel, MD

Assistant Professor of Medicine; Coordinator, Brain Imaging Research Project

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 and Motility awarded by the Foundation for Digestive Health and Nutrition; ACG Junior Faculty Development Award; and the Annual 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”.

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 pelvic floor 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

Dr. Shaheen 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: Melissa Brennan, RN (Study Coordinator); Paris Heidt (Study Coordinator); Kate Lawrence (Doris Duke Fellow); and Lindsay West (Study Coordinator).

Syed Thiwan, MD

Gastroenterology Fellow

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, and he plans to present additional data from these projects during DDW 2006. 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 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 came to the UNC Center for Functional GI & Motility Disorders as a post-doctoral fellow and then joined the faculty of the School of Medicine in 2004. She has a special interest in pediatric functional GI disorders, especially Recurrent Abdominal Pain (RAP). Compared to adults, children’s functional GI disorders have received little attention and Dr. van Tilburg hopes to expand the Center’s research activities in this area. Dr. van Tilburg is involved in many studies. Her main focus is on how to effectively involve parents and children in their own care. In collaboration with Dr. Palsson, she is currently testing a home-based Guided Imagery treatment for RAP/IBS that children can use with only minimum guidance from their physician. In addition, her work aims to understand why some parents are better than others at helping their child cope effectively with pain or other GI symptoms. She has developed a questionnaire to assess parental thoughts and worries about abdominal pain which are associated with disability. In collaboration with Dr. Chitkara, she will expand this project to include parental care and worries about fecal soiling.

Duane D. Webb, MD, FACC

Adjunct Professor of Medicine

Dr. Webb is the former Chair of Gastroenterology at East Carolina University and was Global Director of GI Research at Glaxo-Wellcome. He has a private practice at Chapel Hill Internal Medicine. His major area of clinical research interest is the relationship between upper GI disorders such as non-ulcer dyspepsia and lower GI motility disorders including irritable bowel syndrome. He sees patients in the Functional GI & Motility Disorders Clinic and participates in the clinical conference and other Division activities.

Other Center Staff

Toni Allen – Ms. Allen is the Data Technician (Social Research Assistant) for the DATA Core. Her prior experience includes contract work for IBM, EDS, GSK, and Anixter, among others. She has a BS degree from N.C. Central University in Criminal Justice, with a minor in Computer Information Systems (CIS). She is now working on a Master’s of Science in Information Assurance.

Sherwood Baskerville – Mr. Baskerville is Accounting Manager for the Center and for Dr. Drossman’s Functional Bowel Disorders research group.

Gae Caudill – Ms. Caudill is a part-time administrative assistant. Her primary responsibilities include maintaining the Center’s computerized database, responding to requests for information, mailing the Center’s newsletter and annual report, and assisting with a variety of duties associated with Center meetings and events.

Sheila Crawford, RN - Ms. Crawford is the charge nurse for the 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.

Sarah Van Heusen-Causey, MS – Ms. Causey is Dr. Ringel's research project coordinator focused on studies in IBS, probiotic bacteria and intestinal microflora. She comes from the Carolina Population Center, where she was a project coordinator on the Pregnancy, Infection and Nutrition Study for over four years. Sarah 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.

Jane Hankins, MAT – Jane Hankins is the study coordinator for the Atkins study and the Electrogastrogram (EGG) study. She also assists Kim Meyer with clinical trials.

John Herr – Mr. Herr is Web Applications Developer and Multimedia Producer (Media Coordinator), which entails the creation of web applications and multimedia products for the Center. His responsibilities include programming (Perl, MySQL and PHP), systems administration (RHEL), print design (annual report, DIGEST newsletter), and other computing, graphic design, and audio/visual services.

Yuming J.B. Hu, MA, PhD – Dr. Hu is Assistant Director of the Biometry Core and is involved with data management and analysis of the 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.

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 functional 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. She will be attending NC Central University in fall 2006 to complete the Health Education Program.

Carolyn Morris, MPH – Ms. Morris is the Biostatistician for 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 marketing/press relations, editor/writer for the Center's website and publications, fundraising, and organizational development. She is also Administrator of the NIH Mind-Body Infrastructure Grant. Ms. Nyrop is enrolled part-time in the PhD program at the UNC School of Social Work.



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.

Susan Schneck, MS – Ms. Schneck is both Research Administrator and Administrative Assistant to Dr. Drossman. She is also an assistant to Dr. Burnett and is among the first contacts for patients referred to the Center's clinic.

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 study participants. Her responsibilities include recruiting study participants, preparing and scanning scannable questionnaires, sending out and tracking participant responses, and data management.

Marsha Turner, M.S. – 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 Yeskel – Ms. Yeskel is Dr. Ringel's research assistant. The research she will be working on includes functional dyspepsia, IBS, probiotic bacteria, and intestinal microflora. She is a recent graduate of Dickinson College in Carlisle, PA, where she received her bachelor's degree in Biology. Ms. Yeskel has research experience in ecological and biomedical research; specifically oncology, small mammal ecology, and forest ecology.

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