



# DIGEST



UNC  
SCHOOL OF MEDICINE

*Our mission is to advance the biopsychosocial understanding and care of patients with functional GI & motility disorders through research, training and education.*



## TRIBUTE TO NANCY NORTON AND THE IFFGD

President and Founder of the International Foundation for Functional Gastrointestinal Disorders (IFFGD)

Nancy Norton is one of the two most influential people to the development of the field of functional gastrointestinal and motility disorders. She is the President and founder of the International Foundation for Functional Gastrointestinal Disorders (IFFGD) and is acknowledged to be the spokesperson and the principal advocate for patients with these disorders. In this role she is frequently asked to sit on advisory panels for the National Institutes of Health and for professional societies such as the Rome Foundation and the American Neurogastroenterology and Motility Society. She also contributes importantly to physician awareness of the functional GI disorders by hosting a major international conference every two years.

We are proud of the long-standing close ties between the UNC Center for Functional GI and Motility Disorders and the IFFGD. Nancy has participated in the Center's Patient Day symposium on multiple occasions, and Center director, William Whitehead, partnered with her in organizing the first national consensus conference on the "Impact of Fecal Incontinence on Quality of Life" in 1999 and a second conference in 2002 titled "Advancing the Treatment of Fecal and Urinary Incontinence through Research". These

conferences were instrumental in persuading the NIH to sponsor the "NIH State-of-the-Science on Prevention of Fecal and Urinary Incontinence in Adults" conference in 2007, and the workshop which is scheduled for August 19-20 titled "Developing a Clinical Research Agenda for Fecal Incontinence".



*Nancy Norton with the IFFGD Research Award Winners and Selection Committee Members*

Nancy also collaborated with former Center Co-Director, Doug Drossman, on studies of the severity and quality-of-life impact of irritable bowel syndrome (IBS) by surveying the patient membership of IFFGD. This research resulted in several influential



*The UNC Center for Functional GI and Motility Disorders Clinical Team includes Drs. Ringel, Dorn, Scarlett, and Danielle Maier, MPAS, PA-C. Robin Dever, RN is nurse coordinator and Jennifer Layton is administrative support for clinical services.*

*For information on how to schedule an appointment, please visit our website, <http://www.med.unc.edu/ibs/>*

Over the past decade, the UNC Center for Functional GI and Motility Disorders has enjoyed significant grant support from a number of private foundations and corporations. These grants have ranged from sponsorships of specific events (symposia or CME courses) to unrestricted grants in support of fellowships and the Center's education and training effort. Support for the Digest Newsletter is provided by Takeda Pharmaceuticals North America, Inc.



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The Center's director is **William E. Whitehead, PhD**, Professor of Medicine and Gynecology.

For more information about the Center, please visit our website at [WWW.MED.UNC.EDU/IBS](http://WWW.MED.UNC.EDU/IBS)

# DIGEST

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## DIGESTIVE DISEASE WEEK: WHERE THE FUTURE OF GASTROENTEROLOGY UNFOLDS

-OLAFUR S. PALSSON, PSY.D

Digestive Disease Week, popularly called DDW, is an extraordinary annual event. Held in May each year, it is the world's largest meeting of GI professionals. It is a gathering of close to twenty thousand people altogether: Approximately fifteen thousand of them are clinicians, researchers and academicians whose work focuses on the gastrointestinal tract. The rest are support staff as well as a couple of thousand people from industry – companies that are there to exhibit GI products and services and connect with the GI professionals attending the meeting.

For researchers like myself who study gastrointestinal disorders, DDW is the most comprehensive and prestigious scientific meeting in the topic area, so it is almost a must to attend – both to present the progress we are making in our own research and to learn what is new in the work of other investigators. The meeting is kind of like an enormous empirical harvest festival. GI researchers across the U.S. and all over the world spend weeks or months each autumn processing and interpreting their latest crop of data in order to summarize their findings in succinct research abstracts that are submitted in December for next year's DDW. All of the thousands of submitted abstracts are then reviewed by topic experts, and the abstracts that are of good quality and have sufficient information value are selected for presentation at the meeting. The great majority of the accepted research abstracts are presented as posters, which means that

the researchers stand during certain pre-designated two-hour periods in front of large boards with text, graphs and tables that detail their studies, and interested colleagues come by to ask questions about the research and share ideas. Certain research studies that are of importance or likely to be of high interest to a lot of attendees are selected for oral presentations with slides in large meeting rooms.

One of the most exciting things about DDW is that because the studies presented at the meeting are generally the very latest work of each research team, and often that work is still in progress, attending the meeting gives a veritable glimpse into the future. You get an advance look at what is coming in the field — such as new emerging treatments, new scientific discoveries and highly innovative projects – months or years before it is published in professional journals or covered in the media.

In addition to all of these presentations of research studies, there are also invited talks by top experts in the field on important issues, as well as symposia providing educational updates in particular areas. So whatever your focus is within the field, you can count on learning from the leading authorities in that domain, and if there is something important that you need expert perspective on, you can generally even find opportunities to ask them in person.





With about five thousand research summaries presented during the meeting and numerous expert updates and educational sessions on top of that, DDW can easily feel overwhelming. Of course, no one person is interested in nearly all of this information content, for it covers such a wide range of topics on anything and everything related to digestive diseases. But even keeping up with one's own particular sub-interest area within GI at the meeting is more than enough to handle. It is fortunate, therefore, that Digestive Disease Week is not really a week in spite of the name (although for some attendees, add-on meetings and training courses can stretch it out to a full week). DDW is formally four days of non-stop meetings and presentations. On the last day it is not uncommon to see people sitting on the floor in the hallways staring into space, or standing around with a dazed look on their faces that spells "please speak slowly – brain full".

Beyond all the formal scientific and clinical presentations, DDW also serves tremendously important social and networking functions. Under the umbrella of this mega-meeting various smaller groups hold their meetings, scientific teams from different parts of the world meet with each other, and like-minded professionals get and give feedback and advise, network, share ideas, and build and reinforce important collaborations. It always amazes me to observe the amount of dynamic and formative exchanges of ideas that happens at the meeting. People really listen to each other in the countless face-to-face interactions that occur at the meeting, and the course of work that is still in progress is significantly shaped as a result. I have repeatedly read journal articles where the analyses and presentation of research findings have clearly been influenced by

comments and discussions that I witnessed or even personally participated in at DDW. In some cases whole extra studies have even been conducted after constructive feedback from colleagues at the meeting.

Our research team always comes back from DDW energized — full of new ideas from work presented there and interactions with other investigators, more knowledgeable than before about what is emerging, and better prepared to make progress in the work of the coming year. That is how important DDW is. It is the place where the future of gastroenterology unfolds, and to no small extent it is the meeting that drives that progress. And you plain and simple do not want to miss out on all of that.

This article was written by Dr. Olafur Palsson and was originally published on his blog, <http://fgidupdate.wordpress.com>, on May 12, 2012.



## CARA O'CONNELL-EDWARDS, PhD APPLICATIONS OF COGNITIVE BEHAVIORAL THERAPY FOR FGID'S

*Dr. Cara O'Connell-Edwards is an assistant professor at UNC Chapel Hill and licensed clinical psychologist in the Division of Gastroenterology and Hepatology. She completed her postdoctoral fellowship at Duke University Medical Center in the Department of Psychiatry and Behavioral Sciences and received her PhD and Master's degrees in Clinical Psychology at West Virginia University. She has expertise in both cognitive and dialectical behavior therapy as well as guided imagery and hypnosis.*

Each of us must contend with the physical and psychological impact of living with stress. Unfortunately, its influence on our ability to manage our health and daily commitments is not always immediately recognizable. When we become aware of the effects of chronic stress—which may happen in various and sometimes unpleasant ways—a far smaller ‘leap of faith’ is required to accept the beneficial impact of learning simple yet effective strategies for stress management. Patients with functional gastrointestinal disorders (FGIDs) often derive significant benefits from applying cognitive and behavioral coping strategies for regulating stress responses. For patients with FGIDs, understanding the ‘brain-gut axis,’ alterations in central processing, and repeated activation of the enteric nervous system are critical for understanding why GI symptoms may persist in the absence of organic findings. Individuals with FGIDs have an opportunity to learn strategies to

reduce stress, manage both physical and psychological symptoms more effectively, and use the mind-body connection to their advantage. In the GI Psychology Clinic, cognitive behavioral therapy (CBT) is the primary modality used to provide treatment tools to more effectively manage FGIDs. Both general stress management interventions and CBT are applied to assist patients presenting with FGIDs and the often-present comorbid psychological disorders (e.g., poorly managed depression, anxiety disorders) commonly associated with these conditions.

Cognitive behavioral therapy is a problem-focused, collaborative, and evidence-based approach to treatment. From a cognitive behavioral perspective, thoughts and interpretations are generated in response to events. These thoughts are often automatic, overlearned patterns of responding that have a powerful influence on emotions and behavior<sup>1</sup>. In medical populations, CBT involves identifying patterns of thinking that reduce an individual's ability to cope with illness, while assisting the patient to develop more adaptive approaches to managing physical symptoms or other important aspects of their health condition<sup>2</sup>. The application of CBT for FGIDs offers a safe, time-limited, and effective approach to treatment<sup>3-4</sup>.

When patients are evaluated in the psychology clinic, the impact of environmental stressors, thoughts, and emotions on gastrointestinal symptoms

is evaluated in a manner that reinforces the connection between the brain and digestive system and the responsiveness of the enteric nervous system to such factors. This approach helps to alleviate fears that the referral to a psychologist signifies that their problem is 'not real' or is strictly psychological in nature. Rather, the interdisciplinary approach to treatment is emphasized, and the evidence for incorporating CBT into treatment is reinforced to provide the patient with tools and information to better understand and actively participate in their own treatment plan. Many individuals with FGIDs are ultimately quite receptive to the 'brain in the gut' phenomenon. This is particularly true when we draw parallels between their current experiences and widely relatable examples of experiencing 'butterflies in the stomach' prior to a stressful event, or commonly referenced expressions such as 'I was so worried, my stomach was in knots.

The cognitive interpretation of gastrointestinal symptoms often has a significant impact on functioning<sup>5</sup>. As noted, the work involved in CBT begins with assisting the patient to identify core thoughts or beliefs that may not be automatically recognizable but have a profound impact on how they interpret and respond to external events and internal stimuli. This is particularly significant when GI symptoms trigger anxiety provoking thoughts such as "this cramping is so awful I can't stand it and no one is helping me," or "if I have to suddenly use the bathroom during a meeting I will be humiliated in front of all of my coworkers." It is not difficult to understand why automatic thoughts in response to

symptoms result in distress, including anxiety and discomfort in social situations or mood changes regarding a perceived loss of independence or functioning.

CBT offers individuals tools to consistently identify these patterns of thinking, challenge them, and generate alternative, adaptive (and often more accurate) cognitive responses. For example, the patient who experiences distress regarding their abdominal cramping and discomfort may require assistance identifying the automatic thoughts generated by their symptoms. In the context of therapy, he or she will learn to generate alternative interpretations of these triggers for negative thinking (See Table 1). This approach to recognizing cognitive errors and developing alternative interpretations requires practice. Patients unfamiliar with CBT might be surprised to receive 'therapy homework' between sessions, but taking an active role in treatment is a critical component of CBT.

What should a patient expect when referred to the GI Psychology Clinic?

First, a comprehensive evaluation, starting with their medical and social history, health behaviors, and perspectives regarding their symptoms is gathered. A full psychological history is also obtained, but the approach to intake is structured such that general aspects of health and GI symptoms, followed by their social situation, and finally mental health concerns, are discussed (funneling from what is generally most comfortable to disclose to the most private aspects of their history). Feedback regarding the role of psychology is provided during this evaluation, as well

as treatment recommendations and a plan for follow-up. Generally, CBT is comprised of 8-10 sessions, which may be conducted in clinic or referred to an outside provider when available. It is not unusual for patients to return for this follow-up in the GI Psychology Clinic, even in situations that require significant travel or allow for only semi-regular attendance. This model is appropriate for many of our patients who have barriers to accessible care (such as residing in a rural or underserved area) or who appreciate the interdisciplinary approach offered at UNC.

As a clinical psychologist, working with the GI providers and their patients is extremely gratifying. I believe CBT-based interventions provide an opportunity to empower individuals to take more effective control of their physical symptoms, their health, and the overall quality of their lives.

If you would like to make a referral to the GI Psychology Service, you may contact scheduling at **(919)966-6000** or reach me directly at **coconnel@email.unc.edu**.

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"YOUR GUT HAS A MIND OF ITS OWN."

- MICHAEL GERSHON, MD



Table 1					
Trigger	Automatic Thought	Emotion	Cognitive Distortion	Alternative Thought	Emotion
Sharp pain in my abdomen	“This pain is horrible & it is never going to get better.”	Despair  Fear	Catastrophizing	I am uncomfortable right now, but I can use deep breathing and relaxing imagery to reduce the intensity of these sensations.	Hopeful  Calm
			Overgeneralization	I know this will get better because it always does.	
			Fortune Telling Error	I don’t know what the future holds, but I am attending therapy and learning skills to better manage these symptoms.	
Adapted from <i>Feeling Good: The New Mood Therapy (Revised and Updated)</i> , 2008 <sup>6</sup>					



## DR. OLAFUR PALSSON, PSYD HAS BEEN PROMOTED TO PROFESSOR OF MEDICINE

On May 1, Olafur Palsson, PsyD, was promoted to Professor of Medicine in the School of Medicine at UNC-Chapel Hill. Dr. Palsson has made many contributions to the Center's research program on irritable bowel syndrome (IBS), fecal incontinence, and constipation. He is known internationally for the development of a fully-scripted hypnosis treatment for IBS. This so-called "North Carolina model" is used by hundreds of clinicians and researchers across the U.S. and in several other countries, and it has generated many research studies and publications. In a related area, he was a key member of the research team which conducted a randomized controlled trial showing that the meditation procedure called mindfulness-based stress reduction is an effective treatment for IBS. The comorbidity of IBS with other medical disorders is another area in which Dr. Palsson has made major contributions; he authored an influential systematic review of comorbidity, developed and validated new questionnaires for its measurement, and has published some of the most frequently cited studies on the mechanisms responsible for the excess reporting of medical comorbidities in IBS. He is also an expert in biostatistics and data management. He headed the Center's Data Core and developed a number of innovative technologies for more efficient and reliable collection of questionnaire data, including the development of a method for collecting daily symptom

reports for IBS patients over extended periods of time. The latter has led to new insights into the natural history of IBS, specifically the alternation between constipation and diarrhea episodes, which has implications for the safest and most effective ways to dose IBS medications. He has authored over 200 articles, abstracts, and book chapters and is frequently asked to teach continuing education programs for other health professionals. He has also been featured for his hypnosis research in Oprah magazine, Newsweek, Prevention magazine, and American Health magazine.

Dr. Palsson completed his doctoral degree in clinical psychology in 1993 from Virginia Consortium Program in Clinical Psychology and a two-year research fellowship in behavioral medicine from the Department of Medicine at UNC Chapel Hill. He was then recruited to East Virginia Medical School to head their Behavioral Medicine Clinic for 4 years, and while at EVMS he collaborated with scientists at NASA's Langley Research Center. Working with NASA scientists, he co-invented biofeedback applications designed to optimize mental and physical performance in pilots and astronauts, as well as innovative biofeedback instruments for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) and other health conditions. He was recruited back to UNC's Division of Gastroenterology and Hepatology 10 years ago as Associate Professor of Medicine.



## PSYCHOLOGICAL HEALTH AND IBS: WHAT CAN WE DO TO REDUCE IBS SEVERITY?

- MIRANDA VAN TILBURG, PHD

Anyone who has ever felt butterflies in the stomach before giving a speech, has experienced how close our brain and gut are connected. Long nerves run between our gut and brain that communicate all kinds of information ranging from when our stomach is empty or our bowel full, to feelings of happiness or anger. Feelings in the gut can influence feelings in our brain and vice versa. Most Irritable Bowel Syndrome (IBS) patients are very familiar with the brain-gut connection. They have noticed that an upset stomach can make one worry, and conversely, that being under a lot of stress can make IBS worse. Scientists have also studied this phenomenon in depth and collected a tremendous amount of evidence that psychological health is closely related to IBS severity. Patients who are less anxious or stressed and who are better at coping with symptoms will fare better.

Psychological health includes various psychological factors; some have common names such as anxiety and stress; other more exotic ones such as somatization and catastrophizing (see Table 1 for an explanation). Surprisingly few studies have studied which psychological factors are most relevant to IBS. This is important to know, as it may give us tools to help IBS patients. For example, is it better to focus on reducing stress or would it be more helpful to work on being less anxious? At UNC, Drs van Tilburg, Palsson and Whitehead conducted a study to answer this question. This study appeared in the

June issue of the Journal of Psychosomatic Research.

In this study, we asked 286 IBS patients to answer questions about their psychological health. A list of psychological factors included in our study is given in Table 1. We proposed that all of these factors influence IBS symptom severity, but some of them have a direct effect on symptom severity (e.g., being anxious may increase IBS symptoms), while others indirectly affect severity by increasing (e.g, stressful life events make one more anxious and the anxiety in turn may make bowel symptoms worse).

*Table 1: Psychological factors included in the study*

Psychological Factor Name	Description
Neuroticism	Neuroticism is a personality trait that describes people who easily experience negative emotions (e.g., anger, sadness, irritability, hopelessness etc.). People high in neuroticism react more strongly to stress. Neuroticism is one of the few personality traits consistently found to be important in IBS.
Stressful Life Events	Certain events are stressful to anyone. Think about a death of a loved one, moving to a new house or losing one's job. These are called Stressful Life Events. IBS patients report more lifetime stressful events than healthy controls.

Sexual Abuse	Abuse is a stressful life event that is very common in IBS. Studies have shown that 30-60% of IBS patients report a history of abuse. Sexual abuse in particular influences the severity of IBS symptoms.
Anxiety	Anxiety is a feeling of worry, nervousness or unease. Anxiety is common among IBS patients, and associated with more gastrointestinal symptoms
Catastrophizing	The way patients cope with stress and pain is very important in health outcomes. One of the most robust predictors of pain intensity is a coping strategy named Pain Catastrophizing. When catastrophizing patients magnify the threat or seriousness of pain and feel helpless to do anything about it. Catastrophizing is associated with more intense pain and greater disability in IBS.
Somatization	Somatization refers to the tendency to report multiple physical symptoms. Common non-IBS symptoms that are reported by patients are other types of pain (e.g., headache), fatigue, frequent urination, bad breath and heart palpitations. These symptoms are not due to a disease or abnormality. Rather, somatization is caused by more easily noticing bodily symptoms and worrying that these symptoms may be a sign of a disease.

We used a statistical technique called path analysis to determine which psychological factors have direct effects on bowel symptoms and which have indirect effects. Path analysis examines how strongly psychological factors relate to each other and to bowel symptoms. Based on this information, path analyses draws inferences about the relationship between variables. These inferences are

represented in a diagram such as Figure 1. In this figure, an arrow shows that one variable has a direct influence on another variable, and an arrow with arrow-heads on both ends means that there is a reciprocal relationship between the variables; for example, Figure 1 shows that anxiety affects catastrophizing and that the reverse is also true – catastrophizing affects the amount of anxiety experienced.

The path analysis showed that 36% of IBS symptom severity is driven by psychological factors. This means that a patient can reduce more than 1/3 of symptoms by striving for good psychological health. What does ‘good psychological health’ stand for?

Figure 1 shows that for IBS patients the two most important psychological factors affecting the severity of bowel symptoms are somatization and catastrophizing. These were the only two psychological variables with a direct arrow connecting them to IBS severity in Figure 1. Thus, reducing somatization and replacing catastrophizing with better coping skills should lead to less pain and altered bowel habits. This may be easier said than done. You feel what you feel, so reducing the number of physical symptoms (somatization) may not be so easy. Similarly, it is complicated to change feeling threatened and helpless by IBS (catastrophizing)– these thoughts are automatic. Psychological therapies designed for IBS, can be very helpful. These include Cognitive Behavioral Therapy (to reduce catastrophizing) and Medical Hypnosis (to reduce somatization).

What can you do if you do not have access to or do not wish to go to these therapies? Our model suggests that by lowering anxiety, you can also reduce somatization and catastrophizing. Figure 1 shows



that anxiety has an indirect effect on IBS symptoms, by lowering somatization and catastrophizing. There are many ways to reduce anxiety. Some simple and effective techniques are deep breathing exercises, progressive muscle relaxation, meditation and guided imagery. Help can be sought from a therapist/counselor or through self-help tapes, books and internet resources. If anxiety is not too overwhelming, simple things such as laughing with friends, listening to music, indulging in a massage, exercising or taking a bubble bath can be great anxiety-relievers as well.

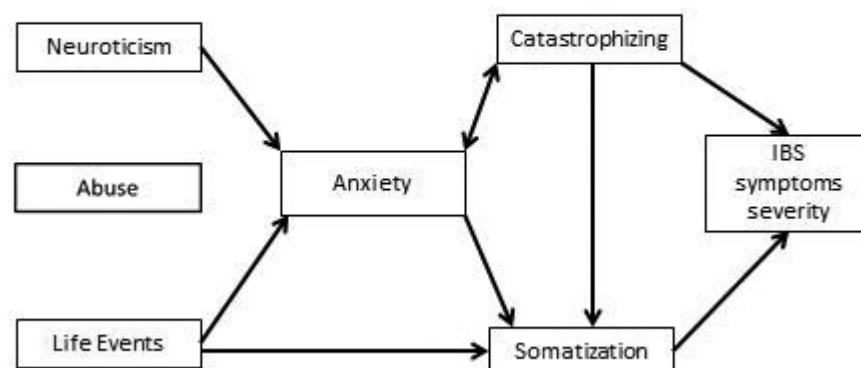
The good news is that neuroticism, abuse, and stressful life events have no direct influence on (there are no arrows connecting them to) IBS severity. These factors are hardest to change. Abuse or other stressful life events have happened to you in the past – it is not something you can change after the fact. Likewise, personality is something you are born with and it is very hard to alter. Our model suggests that although these factors increase your risk for IBS, they do not determine it. It is much more important how you cope with stressors and your symptoms. Thus, personality and major stress will make it more difficult, but

they do not need to be limiting factors to your overall psychological health and IBS symptoms.

Although it appears from our model that there is a cause and effect – psychological factors seem to cause IBS symptoms – we cannot say so with certainty. Did IBS symptoms increase because of ineffective coping or did patients feel they could not cope because their symptoms were too severe? Although we cannot answer this question from the current study, previous studies have shown that decreasing catastrophizing through therapy decreases IBS symptoms. This suggests that psychological health can cause IBS symptoms to wax and wane. We need more studies to test cause and effects in our model. Despite these caveats, our current findings implicate that the most fruitful approach to curb negative effects of psychological factors on IBS is to reduce catastrophizing and somatization.

Van Tilburg MAL, Palsson OS, Whitehead WE. Which psychological factors exacerbate Irritable Bowel Syndrome? Development of a comprehensive model. *J Psychosom Res.* 2013; 74: 486-492. DOI: 10.1016/j.jpsychores.2013.03.004.

**Figure 1: Model of Psychological factors in IBS**



## RESEARCH SUBJECTS NEEDED

## CAUSES OF SYMPTOMS STUDIES

**Energy Metabolism in Pediatric Chronic Abdominal Pain**

This study is looking at the way cells handle energy and how they play a role in children who have chronic stomachaches. We are studying both patients and healthy controls.

Parents of children between the ages of 4 - 18 with and without chronic stomachaches will be asked to complete a phone interview about their family's health history. Participation involves one phone interview and no visits to UNC.

We are looking for mothers of children who either:

- Have been diagnosed, by a physician, with chronic abdominal pain (This includes functional abdominal pain, recurrent abdominal pain, or irritable bowel syndrome) OR
- Control subjects who have never been diagnosed with chronic abdominal pain.

**Principal Investigator:**  
Dr. Miranda van Tilburg

Dr. Miranda van Tilburg  
919-843-0688  
abdominalpainstudy@unc.edu

More information:  
abdominalpainstudy.  
doodlekit.com

**Parents of Children who suffer from frequent stomachaches needed for a Research Study**

Would you like to learn new ways to manage your child's stomachaches?

Researchers at UNC are conducting a research study evaluating different methods for parents to manage their child's stomachaches.

You may be eligible if:

- Your child is between the ages of 7 - 12.
- Your child has frequent stomachaches.

Participation

- 3 - 30 minute training sessions
- Parents and children complete 5 surveys over the course of 1 year
- Parents receive \$150 and children receive \$25.

**Principal Investigator**  
**Dr. Miranda van Tilburg**

**Contact Information**

Dr. Miranda van Tilburg  
919-843-0688  
tilburg@med.unc.edu



## TREATMENT STUDIES

## RESEARCH SUBJECTS NEEDED

**Recruiting adult women with diarrhea predominant irritable bowel syndrome for a research study**

We are looking for adult women with a specific type of irritable bowel syndrome (IBS) to join a research study assessing a potential new medication for IBS.

The RESTORE 5 Study will last for up to 8 weeks and involve about 5 clinic visits.

You may be able to take part in the RESTORE 5 Study if you:

- Are a woman 18 - 65 years of age
- Have had symptoms of IBS (including abdominal pain/discomfort and diarrhea) for at least 6 months
- Have loose or watery stools > 25% of the time and hard or lumpy stools < 25% of the time.

To participate in this trial, you must NOT;

- Have been diagnosed with;
  - Crohn's Disease
  - Ulcerative Colitis
  - Diabetes mellitus
  - Lactose Malabsorption
  - Malabsorption syndromes
  - Celiac Sprue
- Be pregnant or planning to become pregnant.

Qualified participants will receive study-related care including comprehensive physical exam and investigational study drug at no cost. Monetary compensation for study visits will be provided.

**Principal Investigator**

Lisa Gangarosa, MD

**Research Coordinator**

Angela Kibiy, RN, MPH

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**Men and Women Needed for Anal Fissure Research Study**

Has your physician diagnosed you with an anal fissure? The UNC Center for Functional GI and Motility Disorders is conducting a research study to evaluate an investigational drug (diltiazem).

Eligibility: To be eligible, you must be over the age of 18 and less than or equal to 75 years old, and diagnosed with an anal fissure. You must be able to complete a daily phone diary for the entire study about overall anal fissure related pain.

Participation includes:

- Documenting anal fissure pain daily
- Documenting bowel movements and symptoms
- Giving blood samples
- Completing a no-cost physical exam
- Completing 5 visits during the 5-week study
- Self - administering study medication three times a day

**Primary Investigator:**

Spencer Dorn, MD

**Contact Information**

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## TREATMENT STUDIES

## RESEARCH SUBJECTS NEEDED

**Rifaximin Phase III Trial for the treatment of IBS-D**

The UNC Center for Functional GI and Motility Disorders is currently conducting a Phase III drug trial to investigate the long-term efficacy of Rifaximin for the treatment of IBS-D symptoms.

Rifaximin is a non-absorbed antibiotic currently approved by the FDA for the treatment of Traveler's Diarrhea and Hepatic Encephalopathy. Previous studies have shown significant improvement of symptoms with Rifaximin treatment in subjects with IBS-D.

Eligibility requirements:

- At least 18 years of age
- Diagnosed with IBS-D or have experienced the symptoms (abdominal pain, bloating, and diarrhea) at least 3 days per month over the last 3 months.
- No history of inflammatory bowel disorders
- Colonoscopy with biopsy within the last 10 years or willing to have one for the study

Eligible participants will be asked to complete up to 9 visits during which vital measurements will be taken along with blood, urine, and stool samples. In addition, participants will be asked to keep a daily log of their symptoms over the course of the study.

**Primary Investigator:**  
Yehuda Ringel, MD

**Contact Information**  
Daniel Temas  
919-843-1003  
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**Participants with IBS-D needed for an investigational drug research study.**

Need Men and Women 18-80 years old with IBS-D

The purpose of this research study is to try to evaluate an investigational drug for improving diarrhea predominant Irritable Bowel Syndrome (IBS-D).

To be eligible, you must be between 18-80 years old, diagnosed with IBS-D and had a colonoscopy within 5 years.

- Complete the electronic diary throughout entire study
- Complete a no-cost physical exam and lab work
- Self-administering study medication twice daily
- Complete up to ten study visits at UNC Hospital over a 34-week period

**Primary Investigator:**  
Spencer Dorn, MD

**Contact Information**  
Meley Woldeghebriel  
919-966-8328  
meley\_woldeghebriel@med.unc.edu

EXPERT UPDATE ON TREATMENTS FOR FUNCTIONAL GI DISORDERS (FGID'S): A SYMPOSIUM FOR PATIENTS.

LISTEN AND WATCH VIDEOS FROM PROMINENT EXPERTS IN THE FIELD OF FUNCTIONAL GI DISORDERS WITH THE LATEST INFORMATION ON AVAILABLE TREATMENTS

[HTTP://FGIDPATIENTUPDATE.COM/](http://fgidpatientupdate.com/)





## Upcoming Events Hosted by the UNC Center for Functional GI and Motility Disorders

### NEW RESEARCH FINDINGS FROM THE UNC CENTER FOR FUNCTIONAL GI AND MOTILITY DISORDERS

FRIDAY, NOVEMBER 1 2013

1. Accidental Bowel Leakage
2. Internet-Facilitated Medical Research and Patient Care
3. Diagnosis and Management for FGID's

### CME EVENT: HOW TO TREAT IBS EFFECTIVELY: EXPERT UPDATE FOR HEALTH CARE PROFESSIONALS

SATURDAY, NOVEMBER 2013

1. Pharmacologic Treatment Options
2. Probiotics, Antibiotics, and Diet
3. Effective Psychological Interventions
4. The Rome Criteria in Clinical Practice

### *Speakers*

- William E. Whitehead, PhD
- Steve Heymen, PhD
- Lalitha Kunduru, Medical Student
- Catherine Matthews, MD
- Olafur Palsson, PsyD
- Miranda van Tilburg, PhD
- Spencer Dorn, MD, MPH
- Ryan Madanic, MD
- Nancy Zucker, PhD

### *Speakers*

- William Whitehead, PhD
- Doug Drossman, MD
- William Chey, MD
- Lin Chang, MD
- Magnus Simren, MD
- Sheila Crowe, MD
- Jeffrey Lackner, PhD
- Olafur Palsson, PsyD
- Laurie Keefer, PhD

*Save the Date!*

November 1-2, 2013

For Information on registration, please contact Stefanie Twist at  
Stefanie\_Jeremiah@med.unc.edu

For Information on opportunities to sponsor this program, please contact  
Ceciel Rooker at cecielrooker@yahoo.com

<http://www.med.unc.edu/ibs>





## WHAT KEEPS PATIENTS AND DOCTORS FROM ADDRESSING FECAL INCONTINENCE?

- OLAFUR PALSSON, PSYD

*Dr. Olafur Palsson, PsyD publishes a blog on FGIDs to provide information to patients about novel treatments, epidemiology and prevalence, and new discoveries about FGIDs. To find out more information on Dr. Palsson's blog, please visit the website, <http://fgidupdate.wordpress.com/>*

Fecal incontinence (accidental loss of liquid or solid stool), which will be abbreviated FI here, is a sensitive and difficult health problem that is present in about 9% of the overall adult population<sup>1</sup>. It becomes more common with age, rising in prevalence from about 3% of people aged 20-30 to more than 15% in those 70 years and older<sup>1</sup>. When FI happens frequently (2.7% of U.S. adults have FI episodes once a week or more) it can have a major adverse impact on people's lives if untreated, leading to substantial problems in areas such as mobility, work, social life, and self-esteem.

FI is a highly treatable problem. Anorectal biofeedback<sup>2</sup> and sacral nerve stimulation<sup>3,4</sup> are both treatments that seem to help get rid of the problem entirely in half of cases and also significantly improve about half of the remaining cases where complete continence is not achieved. Furthermore, a much simpler treatment that consists of systematic use of pelvic floor exercises results in improvement in FI in roughly half of cases as well<sup>5</sup>. But even though these methods are highly effective, they actually benefit far fewer individuals than one might hope, because most cases of fecal incontinence never even come to the attention of healthcare providers and no

treatment can therefore be offered. Surveys indicate that 70 to 90 percent of individuals who have FI have not talked to their doctor about it<sup>6</sup>. Although it is understandable that fecal incontinence can be hard to talk about, there are important and often severe adverse personal consequences that can be prevented only by addressing the problem in healthcare encounters. Finding ways to systematically overcome the barriers that keep fecal incontinence a largely hidden and unaddressed health problem could improve the lives of millions of adults who now suffer the consequences without any help. The first step is to understand what keeps patients and doctors from addressing the problem.

In a poster presentation at this year's Digestive Disease Week in Orlando, Florida, in May, investigators in our UNC Center for Functional GI & Motility Disorders reported the findings of a study led by Center Director Dr. Whitehead, that aimed at providing insights into the barriers that keep the majority of FI problems from being addressed. The study included 124 adults who were identified as having FI by asking them about it when they came to clinic visits in a variety of clinics in the UNC Healthcare System (primary care, urogynecology, gastroenterology and geriatrics). Eighty-eight of these individuals had consulted with doctors about their FI problem (those can be called FI consulters) but 36 had not done so (i.e., they were FI non-consulters). The patients were surveyed through written questionnaires to evaluate the severity and frequency of their FI and

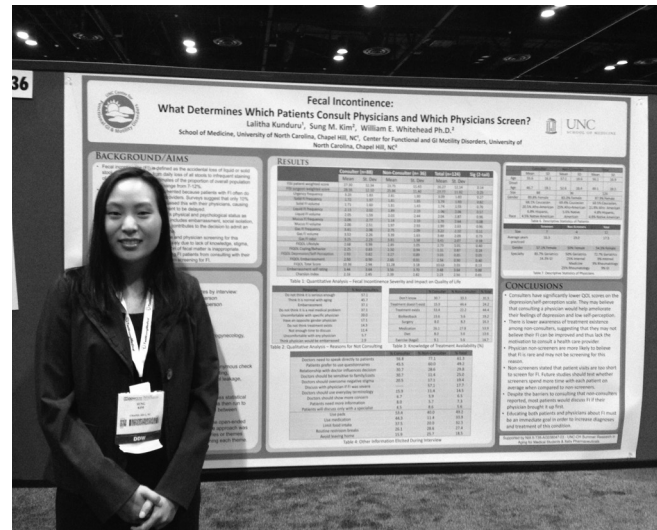


its impact on their lives, and they were also interviewed over the phone about their experiences and views on interacting with healthcare providers about it and outlook on treatment for the problem.

Some of the key findings were:

- The severity and frequency of fecal incontinence episodes was not different between FI consultants and non-consulters (as measured on the validated Fecal Incontinence Severity Index)
- Most (77.1%) FI non-consulters stated that doctors need to ask directly about incontinence. However, half of them also indicated a preference for being asked about it through a questionnaire.
- The only aspects of quality of life impact of fecal incontinence (measured on a validated FI-QOL scale) that was different between consultants and non-consulters was depression/self-esteem impact, which was greater in consultants
- Among FI non-consulters, 44.4% reported that they believed that there was no effective treatment available for fecal incontinence, versus only 15.6% of FI consultants.
- The three most common reasons FI non-consulters gave for not discussing their FI problem with their doctor were not thinking it was serious enough (57.1%), thinking it was just a normal part of aging rather than a medical problem (45.7%), and embarrassment (37.1%).

The investigators also interviewed 11 physicians in the clinics where the patients were recruited, to get a sense of the reasons



Sung Min Kim, BS presented results from the FIB (Fecal Incontinence Barriers) research study at DDW 2013.

why doctors fail to screen routinely for fecal incontinence by asking their patients about it. Only 4 of the 11 doctors reported that they did not screen for fecal incontinence, and they mostly stated lack of time in patient visits as a reason not to do so. They were also more likely than doctors who screened to believe that fecal incontinence is a rare condition.

This study gives a fairly clear idea of what keeps so many patients and doctors from addressing FI in clinical encounters, and also provides some insights about what is needed to overcome those barriers. The results indicate that more than half of the patients who do not report FI to their doctors simply do not regard their FI as a significant problem. However, many other patients are held back from reporting FI to doctors by embarrassment or because they wrongly do not believe it is treatable. It would seem that the patients in the latter category need to be helped to overcome the hindrances to getting help for FI by making education about effective treatments for FI



widely available and by screening for FI in a way that minimizes embarrassment and doctor time burden. It is noteworthy that individuals with FI who have not consulted doctors mostly do feel that doctors and clinics should ask them about it directly and many of them would prefer that this be done via a questionnaire. Routine use of a few simple questions (or even a single one) on paper to screen for this problem in all visits to major healthcare service settings like primary care and geriatric clinics would enable healthcare providers to reliably identify and offer care for fecal incontinence in most adults who make any use of healthcare.

#### The Digestive Disease Week Presentation:

Sa2036. "Fecal Incontinence: What Determines Which Patients Consult Physicians and Which Physicians Screen?" Lalitha Kunduru, Sung M. Kim, Steve Heymen, William E. Whitehead. Center for Functional GI and Motility Disorders, University of North Carolina, Chapel Hill, NC.

This article was written by Dr. Olafur Palsson during Digestive Disease Week and originally published on his blog, <http://fgidupdate.wordpress.com>, on May 19, 2013.

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2. Heymen S, Scarlett Y, Jones K, Ringel Y, Drossman D, Whitehead WE. Randomized controlled trial shows biofeedback to be superior to pelvic floor exercises for fecal incontinence. *Dis Colon Rectum* 2009;52:1730-1737.
3. Tjandra JJ, Chan MK, Yeh CH, Murray-Green C. Sacral Nerve Stimulation is more Effective than Optimal Medical Therapy for Severe Fecal Incontinence: A Randomized, Controlled Study. *Dis Colon Rectum* 2008;51:494-502.
4. Wexner SD, Collier JA, Devroede G, Hull T, McCallum R, Chan M, Ayscue JM, Shobeiri AS, Margolin D, England M, Kaufman H, Snape WJ, Mutlu E, Chua H, Pettit P, Nagle D, Madoff RD, Lerew DR, Mellgren A. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. *Ann Surg* 2010;251:441-449.
5. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology*. 2003 Nov;125(5):1320-9.
6. Dunivan GC, Heymen S, Palsson OS, von Korff M, Turner MJ, Melville JL, Whitehead WE. Fecal incontinence in primary care: prevalence, diagnosis, and health care utilization. *Am J Obstet Gynecol*. 2010 May;202(5):493.e1-6. doi: 10.1016/j.ajog.2010.01.018. PubMed PMID: 20223447.



## NIDDK Conference on Fecal Incontinence

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has announced that on August 19 - 20, 2013 they will be holding a conference on the development of a clinical research agenda for fecal incontinence (FI).

### Agenda Topics

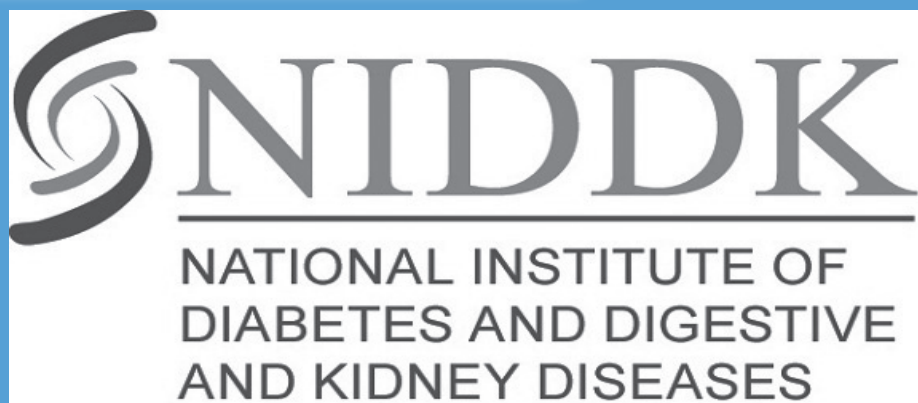
1. Epidemiology of Fecal Incontinence (FI)
2. Etiology, Quantification, and Classification of FI
3. Review of past FI treatment studies (successes and deficiencies in research)
4. Strategies for future treatment studies about FI
5. Where we go from here

### Workshop Contact

Dr. Frank Hamilton  
HamiltonF@extra.niddk.nih.gov

### Logistical Contact

Angela Meadows  
ameadows@scgcorp.com



For more information, please visit  
<http://www.scgcorp.com/incontinence2013>

## TRIBUTE TO NANCY NORTON AND THE IFFGD (CONTINUED FROM COVER)

papers on IBS patient burden and led to the development of a new clinical tool for assessing the severity of IBS. Doug Drossman has also chaired the program committee for the IFFGD's biannual symposia since 1995.

Nancy began life as a young artist who worked as a conservator for the Milwaukee Public Museum. However, she sustained a severe obstetrical injury during the birth of her son in 1985, which resulted in chronic fecal incontinence and changed the course of her life. This also had repercussions for the rest of us. After a frustrating and ultimately futile effort to find a medical or surgical cure for accidental bowel leakage, Nancy founded the IFFGD in 1991. Early on she decided to broaden IFFGD's focus beyond fecal incontinence by including the full spectrum of functional gastrointestinal disorders because she recognized that fecal incontinence often co-exists with IBS and because patients with other functional gastrointestinal disorders share a similar burden of having embarrassing symptoms for which there is inadequate medical treatment.

The mission of IFFGD is "to inform, assist and support people affected by gastrointestinal disorders." Some of the services the IFFGD provides to patients include a telephone hotline, educational brochures, ten separate websites with information about specific functional GI disorders, patient brochures, and resources

to help patients find a knowledgeable health provider. For details on these resources see the website, [www.iffgd.org](http://www.iffgd.org).

Congressional advocacy has also been a major part of Nancy's service to the field. IFFGD organizes a trip to Washington by a group of academic investigators and patients each year to meet with congressmen and senators and encourage them to support the budget of the NIDDK and funding for research on Gulf War Syndrome.



*Nancy Norton with Ohio Senator Brown*

This has been effective in increasing budget allocations to NIDDK and sustaining the interest of the NIDDK in functional GI and motility disorders. Nancy was instrumental in drafting a resolution called “the Functional Gastrointestinal and Motility Disorders Research Enhancement Act” which was first sponsored as a house bill in 2011 and is now before congress as H.R. 842. This bill would grant NIH new authority to initiate innovative research in our area and would establish regional Centers of Excellence on functional GI and motility disorders among other things. While not yet enacted into law, momentum is building for this legislation.



There is no NIH research program on pelvic floor disorders or functional bowel disorders that does not have Nancy’s fingerprints all over it. She served on the Advisory Council for NIDDK from 2001 to 2005 and on the Advisory Board of the

Pelvic Floor Disorders Network from 2003 to the present. She was on the planning committees of the NIH State-of-the-Science conference in 2007 and the upcoming NIDDK workshop. This workshop will focus the attention of clinicians and the research community on the hidden epidemic of fecal incontinence, and it is a major step in fulfilling Nancy’s goal of providing new, more effective treatment options for patients who are afflicted with fecal incontinence. All of us share Nancy’s hope that this conference will result in an NIH Request for Proposals and a commitment to fund more research on the treatment of fecal incontinence.

We at the Center would like to pay tribute to Nancy Norton; she turned a personal tragedy into a lifetime commitment to help others affected by symptoms of abdominal pain, altered bowel habits, and fecal incontinence. Her achievements have given hope to these patients and help to the research community.

# HILLSBOROUGH MEDICAL OFFICES

## WHO IS MOVING AND WHEN?

As of July 1, 2013, the UNC GI Medicine, GI Procedures, and Pelvic Floor Biofeedback Program will be moved from UNC Chapel Hill Hospital campus to the UNC Health Care Hillsborough Campus. Directions to the new location are listed in this article.

The address for the Hillsborough campus is;

460 Waterstone Drive  
Hillsborough, NC 27278

### Clinics affected include;

- Imaging (Bone Density, Mammography, Ultrasound)
- Laboratory
- Medical Oncology & Infusion
- Pharmacy
- Surgical Oncology

### UNC Physician Services include;

- Dermatology & Skin Cancer Center
- GI Medicine
- GI Procedures
- Pelvic Floor Biofeedback Therapy
- OB-GYN Women's Primary Health
- Surgical Procedure Suite
- Urogynecology
- Urology Services

If you have any questions about your appointment with a provider in gastroenterology, please call **919-966-6000**.

If your appointment is with another department, please call the UNC Hospital Operator at **919-966-4131** and ask to be connected to the clinic in which your appointment is with.

### Directions from the West (Greensboro)

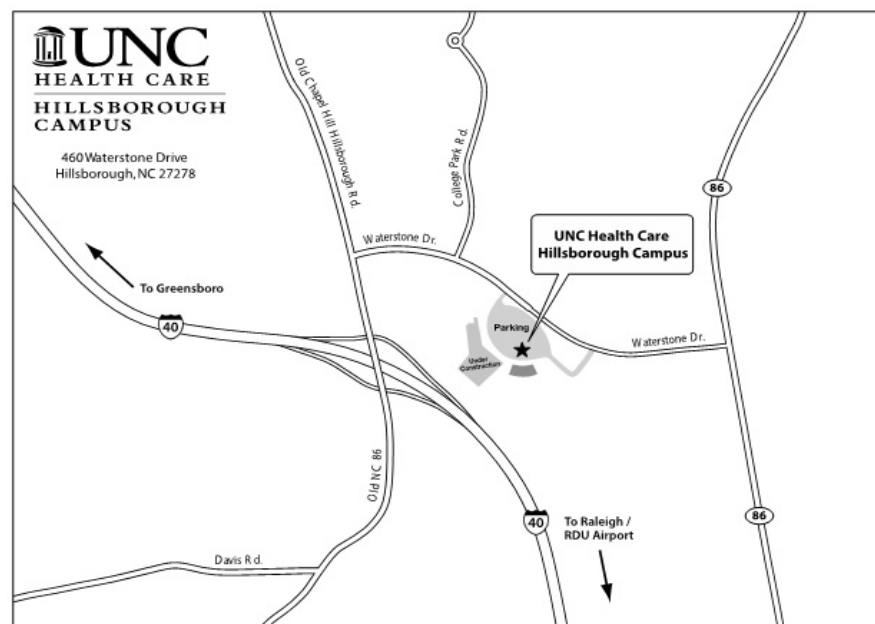
- Take 1-40 East / 1-85 North towards Burlington / Durham
- Merge onto 1-85 North
- Take the Exit NC-86 South and keep right at the fork and continue following signs for NC 86 South
- Turn Right onto Waterstone Drive and the parking lot and clinic will be on the left.

### Directions from the South (Pittsboro)

- Take 15-501 North towards Chapel Hill and continue to Columbia Street as if you were heading to the hospital.
- Continue on Columbia St. until you cross over Rosemary St. where you will bear right slightly to continue onto NC 86 North / Martin Luther King Jr Blvd.
- Turn left onto Waterstone Dr and the parking lot and the clinic will be on the left.

### Directions from the East (Raleigh)

- Take I-40 West towards Greensboro
- Take Exit for NC 86 North
- Turn left onto Waterstone Dr and the parking lot and the clinic will be on the left.





## WHAT'S HAPPENING AT THE CENTER?

Mickey and Minnie Mouse paid a visit to Digestive Disease Week (DDW) and wanted their picture taken with UNC's own Dr. Lisa Gangarosa!



## OPPORTUNITY TO SUPPORT

### CONTACT INFORMATION

_____		Name	
_____		_____	Primary Phone
_____		_____	Secondary Phone
_____		_____	State / Province
_____		_____	Postal / Zip Code
_____		Email	

I would like to make a donation to the Center. Enclosed is my donation in the amount of:

- ☐ \$1,000 and above  
☐ \$500  
☐ \$100  
☐ \$50  
☐ \$ \_\_\_\_\_

Please send me more information on the following:

- ☐ Functional GI and Motility Disorders  
☐ Irritable Bowel Syndrome (IBS)  
☐ Psychological Services  
☐ Research Studies  
☐ Constipation  
☐ Fecal Incontinence  
☐ Other \_\_\_\_\_

☐ Check here if your contribution is designated for the Alan Wayne Ducoff Memorial Fund

☐ Check here if you do NOT want to be publicly acknowledged for your contribution to the Center

**Send your contribution to:**  
 UNC Center for  
 Functional GI & Motility  
 Disorders  
 CB 7080, Bioinformatics Bldg  
 Chapel Hill, NC 27599-7080

**Phone:** (919) 966-4847  
**Fax:** (919) 966-8929  
**www.med.unc.edu/ibs**

Make your check payable to:  
*UNC Center for Functional GI &  
 Motility Disorders*

**OR:** Include the following credit card information

☐ Mastercard | ☐ Visa

\_\_\_\_\_ Credit card #

\_\_\_\_\_ Expiration date

\_\_\_\_\_ Signature

Contributions from individual donors and grants from foundations and corporations are essential to enhancing and expanding the Center's comprehensive and multi-disciplinary approach to clinical care, research, training and education in functional GI and motility disorders.

#### Memorial Research Fund

The Alan Wayne Ducoff Memorial Fund provides an opportunity for families and friends to remember and honor their loved ones by making a designated contribution to the Center's research program. To make a donation to the Alan Wayne Ducoff Memorial Fund, please check off the appropriate box on the donation form.

# FACULTY AND STAFF AT THE CENTER

## LEADERSHIP

**William E. Whitehead, PhD**

Director

**Yehuda Ringel, MD**

Associate Director

## CLINICAL TEAM

**Spencer Dorn, MD, MPH**

Director, GI Medicine  
Clinic

**Ryan Madanick, MD**

Director, GI and  
Hepatology Fellowship  
Program

**Yolanda Scarlett, MD**

Director, GI Motility Lab

**Lisa Gangarosa, MD**

Functional GI Services

**Cara O'Connell-Edwards, PhD**

Psychological Services

**Danielle Maier, MPAS,  
PA-C**

GI Motility Services

**Mary Scholz, RN, PhD**

Pelvic Floor Biofeedback  
Therapist

**Robin Dever, RN**

Nurse Coordinator

**Jennifer Layton**

Administrative Services

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Project Manager

**Renuka Kelapure**

Project Manager

**Sung Min Kim**

Research Coordinator

**Meley Woldeghebriel**

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**Daniel Temas**

Research Coordinator

**Stefanie Twist**

Center Coordinator

**Laverne Milliken**

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