



The Clinical Research Center

Spotlight on Science ~ Division of GI/Nutrition

The Division of Gastroenterology, Hepatology, and Nutrition has a rich and productive history of basic science and clinical research. The division currently supports two CRC biostatisticians: **Paul Mitchell, MPH**, who has collaborated with GI/Nutrition investigators since joining BCH in 2007, and **Dr. Heather Litman**, who came to BCH in September of this year. Each work with investigators from several centers for excellence, including among others: **nutrition, hepatology, inflammatory bowel disease, gastrointestinal motility disorders, and celiac disease**. Combined, Dr. Litman and Mr. Mitchell are assisting with more than **40 projects in various stages of development**, six of which are currently under peer review.



Drs. Margot Tang, Heather Litman, Maureen Jonas, Christopher Duggan and Paul Mitchell

Currently, Dr. Litman is collaborating with **Dr. Margot Tang** and **Dr. Christopher Duggan** of GI/Nutrition on a study of nutritional status of peri-urban Peruvian children. Obesity in children and adolescents is an emerging trend in the developing world, but the relationship between early life nutritional status and adolescent obesity is unclear. An **observational study** was conducted **among 380 adolescents** who as **infants had participated in a randomized trial of vitamin A supplementation**. The study finds that among Peruvian children, **risk factors for adolescent overweight include higher infant weight, although higher infant weight was also associated with a lower incidence of stunting. Infant nutritional status is associated with adolescent overweight and height achievement**. Results are being drafted for an abstract to submit to an upcoming pediatric conference.

Mr. Mitchell is collaborating with **Dr. Maureen Jonas** and **Dr. Rima Fawaz** from the **Center for Childhood Liver Disease**, and **Dr. Gregory Sawicki** of the **Cystic Fibrosis Center**, on a **longitudinal cohort study of liver disease in children and young adults with cystic fibrosis (CF)**. Liver disease is the third leading cause of death in CF patients. Liver biopsy, the current standard of measurement, is invasive and abstracts a sample of only 1/50,000th of the total liver, leading to undetected cirrhosis in 10-30% of adults according to recent studies. This study is investigating a **non-invasive, ultrasound-based technology, known as transient elastography (TE), to measure liver stiffness** in this at-risk population. FibroScan®, the technology used to measure TE, was approved by the FDA on April 5, 2013 for use in adults only, but is still not approved for children. This study will investigate **FibroScan® as a non-invasive means of assessing and monitoring liver stiffness in CF patients at risk for cirrhosis**.

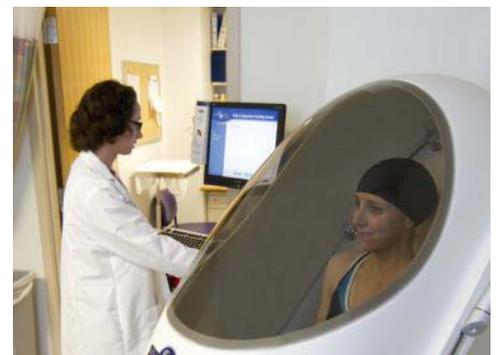
In addition to supporting research at large within GI/Nutrition, Mr. Mitchell and Dr. Litman are each supported by **Gates Foundation** and **NIH grants awarded to Dr. Duggan**. Mr. Mitchell is working with existing data from the **Pediatric Intestinal Failure Consortium** and Dr. Litman with **markers of gut function** to identify children at risk of stunting and neurodevelopmental delay from a well-characterized population of young Tanzanian children. In keeping with the **educational mission of the CRC**, Mr. Mitchell and Dr. Litman will present in the coming months at the bi-monthly Clinical Research Conference. Past topics have included **“Help Us Help You: Common barriers to a speedy statistical analysis”** and a two-part presentation on **survival (time-to-event) analysis**. Each also serves as a biostatistical representative on several Division Scholarship Oversight Committees for senior fellows.

BOD POD...

...is now available! It uses air displacement plethysmography (ADP) to measure body mass and body volume, with a calculation of body density, percent fat, and percent fat free mass using age and sex-specific equations. ADP is an easy, safe and quick (approximately 5 minutes total test time) procedure. The machine is located on Pavilion 5 in the GPU clinic and is available on Mondays, Tuesdays, Thursdays and Fridays. To schedule a research BODPOD appointment, please contact Nicolle Quinn, CTSU Nutrition Manager.

Questions?

Please email: [Chris Duggan](#), [Lori Bechard](#) or [Nicolle Quinn](#)



CRC Items of Interest

Harvard Catalyst recently sponsored an afternoon symposium, **“Transforming Child Health through Genome Biology,”** held at Harvard Medical School’s Joseph B.

Martin Conference Center. **Ellis Neufeld, MD, PhD**, Co-Chief of the CRC opened the symposium; more can be found [here](#).

Available Here: [Strategies for Developing Biostatistics Resources in an Academic Health Center](#)

Appearing in *Academic Medicine*, April 2013, an article identifying strategies to develop biostatistics resources: recruit and retain, efficiently use the resources, improve contributions to science

New Course ~ Build a REDCap Database Workshop!! This Hands-on Training will:

1. Assist research staff with initial REDCap Database programming for a new research study
2. Describe and show how to navigate within REDCap, from initial steps to releasing database to production
3. Share Tips for database development, ensuring that good research practices are applied and study objectives will be met
4. Provide REDCap study tools and checklists
5. Build participants’ knowledge base so future REDCap databases can be built independently

****Starts January 14th and then held monthly (2/11/, 3/11, 4/8); Click [HERE](#) to Register!**

The CTSU (Clinical & Translational Study Unit) of the CRC had over **3,200 outpatient pediatric** visits this past fiscal year with **110+ active studies** scheduling visits. Studies ranged from **gene therapy to interventional trials of novel therapeutic agents** for multiple pediatric diseases to **dietary interventions for obesity**.

Inpatient studies also included a **Phase I trial** of a novel long acting **local anesthetic**.



CTSU Staff dressed up as Minions from the Despicable Me movie this past Halloween.

Back Row: Ivy Dang, Tina Kim, Nicolle Quinn, Kyla Almeida, Alicia McAllister, Laura Feloney, Courtney Silver; Front Row: Chelsea Tyler, Kayla Arouchon, Joanna Sullivan

The [CRC](#), [Research Pharmacy](#) and [Behavioral Science Core](#) offer “free” one-hour consults, click on the name!

Upcoming Courses...

Nov 19, Dec 17, Jan 21, Feb 18, Mar 18
CRC Grand Rounds

Dec 6, Feb 7, Apr 4
Orientation for New Study Coordinators

Dec 19, Jan 15, Feb 20
Coordinator Rounds

December 10 & 12
Art & Anatomy of Grant Writing

Jan 14, Feb 11, Mar 11, Apr 8
Advanced REDCap: Build a REDCap Database

*Save the Date!
Registration Open Soon!*

Starts January 23rd
Introduction to Longitudinal Analysis

Starts February 25th
Introduction to Regression Analysis

Starts February 5th
Economic Evaluation

*Thank you to Dr. Jenifer Lightdale who has been our
Education Core Director for the last seven years.*

*She'll be leaving Children's at the end of the year; we
wish her the best in her new adventure!*

Project Management/Study Coordinator Services

CATALYST-SUBSIDIZED SERVICES—Click [HERE](#) to Apply

Subsidized hours for Junior Investigators (Assist. Prof. and below) are now available; guidelines below:

Project Management Services

(a mix of RN project manager, non-RN project manager, data manager and study coordinator)

1. Junior Investigators eligible, used only once; 150 hrs, up to 1 year
2. Senior investigators (Assoc and Prof) can petition for the subsidized hours one time only.
3. If Project Management hours are allocated, then the number of subsidized coordinator hours decrease to 100 hours

Study Coordinator Hours Only

1. Junior Investigators eligible, used only once; 200 hours up to 1 year

Note: Data Management Only requests will always be funded by investigator. If paired with a study coordinator or project manager, then the investigator is eligible; we do not support data entry only requests with study coordinator support.



New Staff

Kathryn Williams, *Biostatistician, DAC*

Kayla Arouchon, *Diet Technician, CTSU*

Chelsea Tyler, *ASR II, CTSU*

Joanna Sullivan, *Ambulatory RN, CTSU*

Cristina Camayd, *CR Coordinator, DOC*

Stephanie Patriarca, *Lab Technician, CTSU*

Chiefs' Corner



Dear Colleagues,

As we head into another busy holiday season, it tends to be the best time to reflect on our accomplishments and lessons learned from this past year. The CRC has had another productive year, even with transitions in staff. While we owe a big "thanks" to our staff, we also owe one to you, our users. As we look ahead, we plan to continue to strengthen the resources we have available and to creatively build ways to help investigators do clinical research. Henry Ford once said, "Coming together is a beginning; keeping together is progress; working together is success."

Happy Thanksgiving,
Ellis and Voula

The Clinical Research Center, Questions or Feedback?

Contact CRC@childrens.harvard.edu

Past CRC Newsletters can be found [HERE](#)