What’s New and Improved

One Hour Consults!

For any clinical research projects, you can now request one-hour consults from various areas. Follow the link to submit a request: www.childrenshospital.org/crc and learn more from Research Pharmacy, Behavioral Science, Clinical Research Information Technology (CRIT), or the Clinical Research Center (Biostats, Survey, Data Management, Project Management, Study Coordinator and CTSU).

New Service!

The Clinical Research Center is pleased to announce availability of a new Clinical Behavioral Science core, to be housed within the Department of Psychiatry Program in Behavioral Science. This service, to be co-directed by Deborah Weber, Ph.D. and co-directed by Michelle Bosquet Enlow, Ph.D., started June 1, 2012 and will provide consultation services and psychometrician services. To access these services, go to: www.childrenshospital.org/crc. For questions, please call Deborah Weber at 617-355-6523 or Michelle Bosquet Enlow at 617-919-4680.

Partial funding for this service is provided by Harvard Catalyst | The Harvard Clinical and Translational Science Center.

Orientation for New Study Coordinators!

Prajakta Mangeshkar, MSc, MS, has assumed leadership of the course and is actively working to update the curriculum and modernize it, in part by increasing the participant interaction. According to Prajakta, “Research coordinators play key roles in the clinical research activities at our hospital. My goal is engage new study coordinators and provide them with a solid foundation to contribute to and grow within the clinical research community at Children’s.” The updated orientation will be implemented for the July 20 and August 24 sessions.

Coming Soon ~ BOD POD!

In Partnership with the GPU (Gastroenterology Procedure Unit), the CTSU Core will soon have the capabilities of measuring % body fat via a BOD POD. The BOD POD 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 BOD POD provides accurate body composition data for most children and adults, approximately 10 to 250 kg.

Any questions, please email: christopher.duggan@childrens.harvard.edu, lori.bechar@childrens.harvard.edu or nicolle.quinn@childrens.harvard.edu.

Spotlight on Science

The CRC’s Henry Feldman, PhD, was a co-investigator, contributing statistical design and analysis, to a study called “Popular Diets,” conducted by Drs. Cara Ebbeling and David Ludwig, that sought to compare diets with a tightly controlled experiment in which 21 adults, after losing weight, spent three full months adhering to three extremely different diets, all as advocated in popular books. A low-fat diet was formulated along the lines of the Ornish’s “Eat More, Weight Less;” a very low-carbohydrate diet similar to Atkins’ “The New Diet Revolution;” and a low glycemic load diet followed Sears’ “The Zone.”

Study staff oversaw preparation and distribution of the meals and measurements of energy expenditure and related metabolites were recorded during each diet period. The rigorous crossover design helped this study overcome the limitation of small sample size, providing the precision needed to pinpoint spontaneous adjustments in energy metabolism that may be key in keeping weight off. Results were published in the June edition issue of the Journal of the American Medical Association.

Dr. Mustafa Sahin from Boston Children’s Hospital, in collaboration with Cincinnati Children’s Hospital Medical Center, is conducting an investigator-initiated, Phase II clinical trial to see if Everolimus (RAD001) might have positive benefits on neurocognition (how the brain learns, remembers, and thinks) in children with Tuberous Sclerosis Complex (TSC). The trial is sponsored by TS Alliance, Autism Speaks and Novartis Pharmaceuticals and is looking at the impact of Everolimus on seizure frequency, sleep and autistic behaviors. Study participants are treated with either Everolimus or placebo for a 6 month period. Participants have to be between the ages of 6 and 21 years, diagnosed with TSC, and have an IQ of 60 or above. Enrollment is currently ongoing at BCH and CCHMC. With the help of the Clinical Research Center, 10 patients have been enrolled at BCH and recruitment will continue for the next two years. The CRC team includes: Rajna Filip-Dhima, Lily Chen, Mohammad Daniar, Nandan Patibandla, Christine Powell, Ivy Dang and Courtney Silver. CRC staff members are excited to contribute and be part of such an important study.
Design & Analysis (DAC) Core
Director: Al Ozonoff
Check out the new survey resources for investigators; click here.

Development & Operations (DOC) Core
Manager: Adam Simmons
The CRC COPS (Committee of Programming Standards) has been busy this past year. . .
- A CRC InForm library with CDASH/CDISC standards and a GI REDCap library database was built;
- Case Report Form and REDCap Database Checklists were created to help investigators
- A database validation SOP standard created as well.

Clinical & Translational Study Unit (CTSU) Core
Medical Director: TBD
Assist. Medical Director: Andrew Dauber
Nurse Director: Cindy Williams
Nutrition Manager: Nicole Quinn
- Biorepository: The CTSU is moving their long-term storage to the Boston Children’s Biorepository this fall/winter 2013.
- Catherine Gordon, MD, MSc, CTSU Medical Director left Bch and joined Hasbro this past month; we’re grateful for all of the work she did with the CTSU over the past years. A search is in place for her replacement.

Clinical Research Center Staff Projects...

Christine Powell, MA, is collaborating with Dr. Wen-Han Tan on his Angelman syndrome disorder project in which it explores the natural progression of neurodevelopment in children and adults with this rare disease.
-Al Ozonoff, PhD, has a nationwide study involving thousands of patients, with partner Kaiser Permanente and Dr. Adam Rose at the Veterans Health Administration. It will be one of the largest to date examining measures of dose control during warfarin therapy and their associations with adverse outcomes such as stroke among U.S. patients with atrial fibrillation.
-Mihail Samnaliev, PhD, Chau Tran, MA, MPH, Steven Sloan, Jenifer Lightdale, MD, MPH, Izabela Gasior, Robert Brustowicz recently completed an economic evaluation of intraoperative red cell salvage which translated into net savings and cost-effectiveness.
-Carly Milliren, MPH, and Dionne Graham’s, PhD, paper Racial and Ethnic Differences in Wait-List Outcomes in Patients Listed for Heart Transplants in the United States was published in Circulation and picked up by the popular media, including Reuters and Fox News. The study demonstrated that there are clear (and concerning) differences across race and ethnicity in heart transplant wait-list and post-surgery outcomes.
-Dr.Anne Stack, MD, Ayobami Akenroye, M.B.Ch.B. and Mihail Samnaliev, PhD are conducting an economic evaluation of an evidence based guideline (EBG) for the management of broncholitis in the ED.
-Andrew Dauber, MD, MMSc, just finished the first trial of closed-loop insulin therapy in children less than 7 years old with type 1 diabetes. Ten subjects were admitted to the inpatient CTSU for a 48-hour admission; results will be presented at the upcoming American Diabetes Association meeting.
-Al Ozonoff, PhD, open testimony at the FDA as reported on the Time Magazine health blog. He and Dr. Walley, Assistant Professor at BU, designed an evaluation study of an innovative program to distribute overdose prevention kits to civilian bystanders; scientific paper currently under review at the Lancet.
-Kelly Burmeister, MS, had two papers in BMC Medical Research Methodology: “Telephone follow-up to a mail survey: when to offer an interview compared to a reminder call” and “Getting physicians to open the survey: little evidence that an envelope teaser increases response rates.”
-Caterina Stamoulis, PhD, was recently nominated for the HGWISE (Harvard Graduate Women in Science and Engineering) Mentor of the Year Award. This award honors the dedication, openness and leadership of mentors.
-Hongye Liu, PhD, just published a book chapter on “Information processing in bioinformatics.”
**... Presentations...**

*Caterina Stamoulis, PhD* was invited to the NSF Frontiers in Mathematical Biology, Young Investigator Conference to present her work on mathematical models in epilepsy.

*Michael Monuteaux’s, PhD,* platform presentation presented at the Pediatric Academic Society on Abused Children Treated in the ED at Risk of Return is featured in the [news](#).

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**... and Publications**


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**New Staff in 2012**

-Kimberley Chin, Data Manager

-Dianne DeLucia, Clinical Trial Manager

-Gina Healey, Administrative Associate III

-Wendy Mayer, Research Coordinator I

-Molly McDonald, Ambulatory Representative II

-Carter Petty, Senior Biostatistician

-Christine Powell, Senior Biostatistician

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**Staff Spotlight**

-Nancy Shaffer, MSN

**What has surprised you about working in clinical research?**

The fact that it is so interesting! Research is sometimes viewed by “outsiders” as dry and boring, when in fact it is quite multi-faceted and exciting!

**What is the best career advice given to you?**

Remain flexible. You never really know where your path is going to lead. I went into nursing as a second career when I was in my late twenties, and it was the best decision I ever made.

-Henry Feldman PhD:

**Can you describe a project that is particularly meaningful?**

In my experience with molecular and community studies I had never thought much about bones. In children, what could be more important than healthy bone growth? Contributing design and analysis for a series of Dr. Catherine Gordon’s studies of bone formation in healthy and ill children has been a constant source of scientific interest and professional satisfaction for me.

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**CRC Staff Service Awards**

-5 year service awards:

-Nancy Shaffer, Clinical Research Nurse Coordinator

-Courtney Silver, Staff Nurse II

-Jing Zhou, Biostatistician

-10 year service awards:

-Henry Feldman, Principal Biostatistician

-Voula Osganaian, Co-Chief

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Dear Colleagues,

Summer time is here...and we are as busy as ever! As you can tell, it’s been a productive year so far: our Triage/Navigation Pilot where we are partnering with Endocrine, ORL, ED and Developmental Medicine continues to help investigators start their research projects off on the right foot; we’re in the process of recruiting a new Medical Director for the CTSU Core; the number of appointment requests for the unit has a reached an all-time high; our staff are involved with over 20 different departments/divisions at BCH intensively working and collaborating on all types of clinical research; we are putting on a first-ever Career Grant Award Program this fall and the new CTSA (Harvard Catalyst) RFA was just announced. We couldn’t be more pleased with our staff and the continued support from all of you and the hospital. Have a safe and productive summer,

-Ellis and Voula

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The Clinical Research Center, Questions or Feedback? Contact CRC@childrens.harvard.edu