



# The Clinical Research Center

## Spotlight on Science

### PRROTECT Peanut Study Works Across Boston Children's Hospital Research Programs in order to Work Across U.S. Sites

It takes a village... to make this multi-center Phase II drug trial possible. The PRROTECT (Peanut Reactivity Reduced by Oral Tolerance in an anti-IgE Clinical Trial) study being conducted by Dr. Dale Umetsu, Professor of Pediatrics, brings together several research programs and offices from Boston Children's Hospital to plan and implement this Phase II drug trial. Putting together an investigational drug trial that will be sponsored by a Children's Hospital Investigator, regulated by the Food and Drug Administration and conducted at four Children's Hospitals (Boston Children's, Children's of Philadelphia, Packard Children's at Stanford, and Lurie Children's of Chicago) requires collaborative support from across the hospital.



The *Clinical Research Center* is providing biostatistical support through Dr. Dionne Graham and Christine Powell, project management support by Dianne DeLucia and data management support by Qiaoli (Lily) Chen. In addition, all patient visits will occur on the CTSU and drug administration and protocol procedures will be performed by CRC nursing and support staff. The *Translational Research Program* is supporting the regulatory requirements of this trial that are required by the FDA by Matt Wladkowski, Regulatory Affairs Coordinator. Trials conducted under an investigational new drug application (IND) require site monitoring that will need to be conducted at all four sites. The *Education and Quality Improvement Program* is supporting the monitoring of the Boston site through Eunice Newbert, and will be identifying qualified monitors who will conduct the monitoring at the three other sites through the data management system being used for this trial.

Rocky Anzaldi in the *Research Pharmacy* will be responsible for the drug accountability requirements the FDA has for use of an investigational protect. Because this trial is using a drug provided by Genetech, Inc., and partially sponsored by the Food Allergy Initiative, all contracts, material transfer agreements and agreements with the participating sites are being finalized through the *Clinical Trials Office* through the *Technology Innovation and Development Office*. Of course before the trial begins, final approval to conduct this trial will be approved by the *Committee of Clinical Investigation* (the official name of Boston Children's IRB). Finally, the study will involve physicians (Lynda Schneider, MD and Rima Rachid, MD) and patients in the Allergy Immunology Program.

Overall, more people from Boston Children's will be involved in this trial than the total number of patients that will be enrolled (36) in the U.S., but if effective, the treatment has the potential to help thousands of children who suffer from peanut allergy!

## New Services

### Behavioral Science Core

Investigators whose studies involve behavioral science outcomes are invited to access the Clinical Behavioral Science core, housed within the **Department of Psychiatry Program for Behavioral Science**. This service, directed by Deborah Waber, Ph.D. and co-directed by Michelle Bosquet Enlow, Ph.D., provides consultation services for the preparation of grants, protocols and clinical trials as well as psychometrician services, including the new NIH Toolbox. To access these services, go to: [www.childrenshospital.org/crc](http://www.childrenshospital.org/crc). For questions, please call Deborah Waber 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.*

### BOD POD!

In Partnership with the GPU (**Gastroenterology Procedure Unit**), the CTSU Core will soon have the capabilities of measuring % body fat via a **BODPOD**. The BODPOD 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 BODPOD provides accurate body composition data for most children and adults, approximately 10 to 250 kg. 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: [christopher.duggan@childrens.harvard.edu](mailto:christopher.duggan@childrens.harvard.edu), [lori.bechard@childrens.harvard.edu](mailto:lori.bechard@childrens.harvard.edu) or [nicolle.quinn@childrens.harvard.edu](mailto:nicolle.quinn@childrens.harvard.edu)

### Project Management Services

The project management services of the Clinical Research Center at Boston Children's Hospital may be provided by a single member or a team of clinical research nurse project managers, non-clinical project managers, data managers and study coordinators depending on the needs of the investigator. Under the direction of the PI, various CRC staff can assist with the planning, coordination and implementation of a research study. The CRC can provide project management services to studies conducted both within and outside the discrete CTSU, including inpatient units, outpatient settings or in the community. Apply via the Harvard Catalyst Clinical Research Center Resource Request: [here](#)

## 1st Annual Career Development Award Night



Last month, the Clinical Research Center held its first Career Development Award Night, honoring academic scientists in the early years of their faculty careers, who have received a Mentored Career Development Award (also known as a "K Award") from the National Institutes of Health (NIH) or from a medical society or foundation. Physician-in-chief **Gary Fleischer, MD**, delivered a keynote address and recognized the honorees.

It was a great night for all!

## Notice to CRC Investigators

To: Investigators using CRC services for interventional clinical trials  
 From: Ellis Neufeld and Voula Osganian  
 Re: Notification to investigators about missing safety data in interventional clinical trials.

Dear CRC investigator:

We're writing to let you know that the Clinical Research Center has implemented a new policy for reporting back to research teams when protocol-specified safety data are missing (or seem to be missing). The purpose of the policy is to help you, the investigator, fulfill your responsibilities to research subjects, to the IRB, and to the institution. If you hold an FDA IND for this trial, you have also stated to the Federal Government that you are personally responsible for the study conduct per protocol.

As you may know, the CRC helps investigators with interventional trials with several services and resources. Some or all of these may apply to you:

Research coordinator effort, for example filling out case report forms or collecting patient-reported outcomes.

Database management; paper or on-line case report form entry.

Statistician effort, as trial statistician, DSMB statistician, or consultant.

Survey design and administration.

Project management.

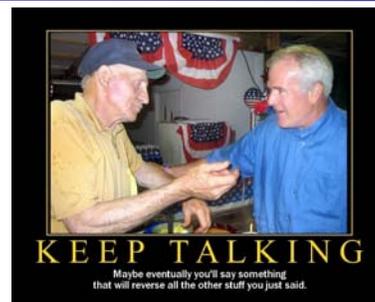
In the course of these regular duties, CRC staff members may become aware of missing protocol-required procedures or data; for example, in monthly or quarterly data report summaries, one or more forms or tests from one or more active study patients may be absent. There are many possible reasons for missing data. Examples include missing a timed visit within the prescribed window because of travel or weather interruptions; a CBC that was clotted and therefore not run; tests done at outside labs or study centers that were completed but not entered in the database.

Strictly speaking, the integrity of the data is always the responsibility of the investigator. Oversight may come from a Data/Safety Monitoring Board, or may not. The IRB always has supervisory authority over trial conduct, whether or not there is a DSMB. The CRC staff cannot and will not become the "trial police" or official monitors. But we can help investigators best by prompt and clear notification about missing data.

Effective immediately, CRC staff are asked to make study team members aware if they encounter missing safety data in the course of their duties. We will ask our CRC team members to let CRC managers know if there is any concern about persistent patterns of missing data, and the managers or co-chiefs will contact you, the investigators, directly in such cases to ascertain the reasons for missing safety information, and to learn whether or not a corrective plan is necessary, whether such a plan is in place, and whether the IRB has been involved. We expect that in most cases, early and open communication about missing safety data will be sufficient for all to be reassured about the safe conduct of the study. In the rare case for which this communication is not sufficient, we expect that this new policy of getting CRC managers involved will assure safer study conduct.

## 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](http://www.childrenshospital.org/crc) and learn more from **Research Pharmacy, Behavioral Science, Clinical Research Information Technology (CRIT)**, or the **Clinical Research Center** (Biostatistics, Survey, Data Management, Project Management, Study Coordinator and CTSU)



## Core Updates

### Clinical & Translational Study Unit (CTSU) Core

Medical Director: Robert Fuhlbrigge

Assistant Medical Director: Andrew Dauber

Nurse Director: Cindy Williams

Nutrition Manager: Nicolle Quinn

- This past August, Dr. Robert Fuhlbrigge, Associate Professor was appointed as the CTSU's new Medical Director. You can email him at [rfuhlbrigge@partners.org](mailto:rfuhlbrigge@partners.org) with any questions.
- The CTSU will continue to be open TWO Saturdays a month. Email [ctsubooking@childrens.harvard.edu](mailto:ctsubooking@childrens.harvard.edu) to book your appointment.  
Future dates: December 8th and 15th      January 12th and 26th      February 9th and 23rd      March 9th and 23rd

### Education Core

Director: Jenifer Lightdale



#### CRC GRAND ROUNDS

Introducing a new monthly educational series open to all members of the BCH community with a focus on topics pertinent to conducting clinical research at BCH..

#### UPCOMING SESSIONS

December 18	Dr. Greg Koski	On Being a PI: Principal Investigator or Practically Invisible?
January 15	Dr. Catherine Gordon	Lessons Learned from Pediatric Models of Malnutrition
February 19	Dr. Deborah Waber	Introduction to The NIH Toolbox: A New Tool for Assessment of Neurological and Behavioral Function in Clinical Trials
March 19	Dr. Ellis Neufeld	Get Ready—the FDA is Coming to Audit our Study! (A fun and interactive guide for investigators and study teams)

#### STUDY DESIGN IN CLINICAL AND TRANSLATIONAL SCIENCE, DR. HENRY FELDMAN

A new 8-part lecture series titled *Study Design in Clinical and Translational Research*, to be presented in weekly sessions between **Feb. 5 and April 1, 2013** by principal statistician, **Henry Feldman, PhD**. Topics will include the classic observational studies, their merits and flaws and keys to success; clinical trials, their special features and claim to being the “gold standard” of clinical research; validity and inter-rater agreement studies; and the ever-nagging question of what is an adequate sample size.

[Click here to Register](#)



## New Staff

Souad Elararri, Lab Technician

Beth Trainor RN Project Manager

Dr. Matthew White, Senior Biostatistician

Jessica LeSage, Clinical Research Coordinator



Dear Colleagues,

The cold weather has started to set in, but work continues to move forward at the Center. One new initiative that we are implementing is a new, integrated Project Management Service. Through partial funding of the Harvard Catalyst (150 hours, up to one year), an expert team of project managers, data managers and study coordinators from the CRC are assembled to help junior investigators get their study off of the ground! We have launched projects with four different departments/divisions and the initial response has been very positive! Assistant Professors and Instructors can apply [here](#)

We wish you a safe holiday season,

~Ellis and Voula

### Chiefs' Corner

