

## **The Clinical Research Center, Children's Hospital Boston Resources and Environment**

*Last Updated January 2014*

The Clinical Research Center (CRC) at Children's Hospital Boston promotes collaboration with clinical research methodologists and provides infrastructure for the conduct of clinical research at the hospital. The CRC provides methods and analyses expertise to the hospital's diverse clinical research community to achieve continued excellence in the highest quality clinical research. Support is provided to investigators at all stages of protocol development and study conduct in order to ensure that research is designed in such a way as to maximize benefits and minimize risks to human subjects who enroll in the clinical trials. Partial funding for these services is from the Harvard Catalyst, an NIH-funded pan-Harvard CTSA that encourages researcher collaboration and provides increased opportunities for collaborations across the Harvard teaching hospitals in order to optimize the infrastructure for the conduct of effective clinical research at Children's Hospital Boston.

The CRC is housed in an office area of approximately 4,000 square feet located just west of and in the main hospital. CRC staff work closely with the Office of the Committee on Clinical Investigation, which has responsibility for the ethical conduct of research at Children's Hospital. The Center presently provides study management and coordination, data management, designated clinical space and biostatistical support for over 95+CTSU sponsored grants or awards funded by federal agencies, foundations, and private sponsors.

Led by Voula Osganian, MD, ScD and Ellis Neufeld, MD, PhD, Co-Chiefs, The Center includes senior clinical researchers with extensive experience in conducting clinical research studies, biostatisticians, survey epidemiologists, clinical research specialists, applications specialists, project directors, data managers, study coordinators, research nurses, nutritionists, and budget specialists, all of whom are available to the CHB researchers for consulting services. All staff are provided with office space, personal computers, and network accounts.

The faculty and staff of the Design and Analysis Core guide clinical investigators in protocol and grant development, formulation of research questions and study design, implementation of trials and observational studies, data analysis, survey design, development, implementation, and analysis.

Core survey methodologists provide guidance and expertise for formulation of survey questions, validation, pilot testing, deployment in all the available modes including Web administration, and interpretation of results.

Core biostatisticians collaborate to produce sample-size calculations, statistical analysis plans, randomization schemes, interim monitoring reports, final data analyses, and scientific manuscripts for publication. CRC maintains a library of statistical software including SAS, SPSS, S-plus and Stata for analyses; PASS and nQuery for sample size calculations; and further software resources for project-specific needs or specialized applications.

The staff of the Development and Operations Core assist clinical investigators with study planning, management and coordination, regulatory document preparation and filing, data form design and development, database construction, randomization methods and materials, data management, data entry, staff training and certification, and development of quality-control procedures. The Core staff is trained in the use of both small-scale and large-scale software for clinical data entry and management.

The Clinical Research Informatics Team has designed and developed a variety of informatics tools to address the growing needs of the Children's Hospital clinical research enterprise, including application software for creating randomization schemes, Web-based clinical data management systems, and online collaborative workspaces. The Informatics Team provides expertise in the use of InForm™, a Web-based electronic data capture and clinical data management system supported by Children's Hospital. InForm™ is the recommended technology for all investigator-initiated and sponsored FDA-regulated trials conducted at Children's Hospital, featuring enhanced reporting and integration capabilities compliant with pharmaceutical industry standards for FDA-regulated research. InForm™ is designed to facilitate the integration of disparate clinical or bioinformatics data sources as well as furnishing secure Web services and data storage. In addition to data-management applications, the Informatics Team creates online collaborative workspaces for clinical

investigations, offering research groups a secure environment in which to host discussion threads, share documents, manage content revisions, and track project tasks.

The network and computing infrastructure for clinical research at Children's Hospital is supported by the Information Systems Department (ISD) and Research Computing facilities. ISD provides the physical security, hardware recovery, contingency planning, and data recovery and backup routines for all informatics services. Research data are secured through a combination of network and application-level user authentication and authorization mechanisms. Data auditing schemes are employed by all clinical data management systems and online workspace implementations.

The Education Core directs the development, conduct, and evaluation of seminars and lecture series, currently numbering approximately a dozen and targeting both active and prospective clinical researchers. Topics include both the principles and the logistics of conducting clinical research. The central offering is a 16-hour series titled "Introduction to Clinical Research," which exposes Fellows and junior faculty not only to the key tenets, issues, and techniques of clinical research but also to the multiple support services available from CRC and other units throughout the hospital. Other educational offerings include introductory courses in grant-writing, biostatistics, data management, clinical trials, survey methods, and use of statistical software. CRC sponsors a bimonthly orientation for new study coordinators and a regular seminar series for active coordinators on such topics as patient recruitment and retention, case report form and survey design, and human subjects requirements for research in children.

The CTSU (Clinical & Translational Study Unit) Core provides clinical research infrastructure for investigators in the design, initiation, conduct and reporting of clinical research with the goal of translating scientific knowledge into new therapies for pediatric conditions. See attached sheet for more specific information.

**Resources - Children's Hospital, Boston Clinical and Translational Study Unit**

**Laboratory:** The Children's Hospital, Boston Clinical Translational Study Unit (CTSU) has a processing laboratory (200sq. ft) located next to and above the Children’s Hospital Clinical Laboratories The CTSU laboratory is experienced in basic sample processing.

**Clinical:** The inpatient CTSU is an 8 bed unit centrally located within the main building of Children’s Hospital with over 5,000 sq. ft., and is organized to support the management of children participating in clinical research. The ambulatory CTSU (5,024 sq. ft.) is adjacent to the inpatient CTSU, as well as part of the CAT/CR program located in an adjoining building. The outpatient unit has 4 private exam rooms, 2 consult/behavioral testing rooms, and 1 phlebotomy room. The CTSU includes a metabolic kitchen and dining room. CTSU nurses are experienced research RN’s, CPR certified, proficient with IV insertion and maintenance, and experienced with timely collection and bedside processing of blood, urine, and other body samples.

The main CTSU is supplemented by a similar unit in the Children’s Hospital Boston community satellite located in Waltham, Massachusetts about 30 minutes drive from the main campus where some studies occur The Infusion Center there contains 8 beds and 3 rooms for both patient care and clinical research, a phlebotomy room, processing laboratory, offices for clinicians and nurses, and multiple computer work stations. All services and information technology are supported by and linked to the main campus.

**Computer:** The CTSU has its own server located in the Children’s Hospital Data Center for 24x7x365 monitoring and nightly back-ups, along with an Informatics staff for the development of databases and report creation to assist clinical investigators. Data management and storage services are available

**Office:** All CTSU staff have offices or working areas with computers.

**Other:** There are Nutrition research services available within the CTSU. There is a CTSU Dietitian on staff experienced with developing/planning meals for research studies. The CTSU has its own metabolic kitchen for food storage and preparation. The Dietitian is able to perform anthropometric measurements, dietary analysis, nutrition education, measurement of resting energy expenditure using indirect calorimetry and body composition using the BodPod. The nutrition staff is available to travel within the institution as well as into the local community if requested.

A Hologic Model A Discovery Dual Energy X-ray Absorptiometry machine for measurement of bone density and/or body composition is located in the outpatient CTSU on Pavilion 6. The CTSU also houses a BIA for body composition, and a portable ultrasound for measurement of bone density. The CTSU has recently acquired a Orthometrix, model XCT 3000 peripheral quantitative computed tomography (pQCT) scanner to assess bone density. The pQCT scanner is housed in the outpatient CTSU on Pavilion 6. A staff of “off-unit” study coordinators and nurses is also available to serve research protocols which take place outside of the dedicated PCIR space.

**Laboratory**

**Patient Care:** Units fully equipped.

- 1 Forma Scientific –80 Degree Freezer
- Refrigerated centrifuges / centrifuges
- 1 -20 Degree and 1 4 Degree Freezers

- Below lists specialty items (\*access via CRC personnel):
- Hologic Model A Discovery Xray Bone Densitometer\*
  - V-max Metabolic Monitor
  - Hemocue Glucose Analyzer
  - Med System III Continuous Infusion Pump
  - “Hot Box” (Hand warmer for arterialized blood sampling)
  - Orthometrix model XCT 3000 pQCT scanner\*
  - BodPod\*