2012 Annual Report for the Clinical Research Center

Stavroula Osganian, MD, ScD, MPH
Co-Chief

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Co-Chief

An interdisciplinary center fostering excellence in clinical research at Boston Children’s Hospital
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We are delighted to share with you the FY2012 and first annual report of The Clinical Research Center (CRC) at Boston Children’s Hospital. Since the merger of our two former programs (CRP and CTSU) just one year ago, we have worked to effectively integrate our teams, work more efficiently and seamlessly with investigators, and successfully meet the goals of our new Center and the mission of our Institution. The Center directly supports a core mission of the hospital, to be the leading source of research and discovery and make significant contributions to the improvement of children’s health through CRC’s four primary areas of focus: 1) clinical research methodology; 2) assistance on research project initiation and implementation; 3) resources for the conduct of clinical research visits and ancillary services; and 4) education on research methods and practice.

This annual report summarizes key accomplishments of the Center and its faculty and staff, who strive to support the mission of the Center and the Hospital. CRC faculty and center staff serve as institutional leaders, mentors, teachers and scientific collaborators. They provide critical expertise and support to junior faculty beginning their research careers, as well as to senior faculty more established in their fields of study. They work to translate innovative research on the diagnosis, prevention and treatment of childhood illnesses into practice with high standards of quality and scientific rigor. They also continue to build partnerships and collaborative relationships with departments throughout the hospital.
Our key accomplishments and activities for FY2012 include:

- Services provided to 334 new requests for assistance from 240 researchers broadly distributed across the various Departments and Divisions of the Hospital.
- Successful collaborations with several BCH investigators on 91 funded projects totaling $956,360 in direct support of CRC activities (representing a 27% increase in dollars of support compared to projects funded in FY2011), with a large proportion (80%) of this funding coming from extramural grants and contracts ($763,699).
- 121 peer reviewed collaborative publications that were co-authored by CRC staff (98 published, 23 Epub).
- Strong support from Departments and Divisions for shared faculty and staff with funding totaling $1,303,689 in FY2012, a 2% increase from FY2011.
- Continued activities to meet demand for clinical research education, with 10 courses or seminar offerings from the CRC’s Clinical Research Education Core drawing 1,219 registrants.
- The launch of the first Boston Children’s Hospital Career Development Award Night with Dr. Gary Fleisher as our keynote speaker. The event recognized and provided a night of education to nearly 100 trainees and junior faculty with active “K Awards” across the Children's enterprise.
- Successful initiation of our triage and pilot navigation system with 4 Departments or Divisions: 45 project requests were handled by this new mechanism to promote collaborative, efficient and strategic use of clinical research resources.
- Growing demand for biostatisticians, study coordinators and research specialists resulting in 20 departmental partnerships with these CRC staff.
- Continued support for robust software tools to effectively and efficiently collect and store research data, including InForm and REDCap.
- Growth in Center faculty and staff with 4 new hires.
- Ongoing integration and collaboration with the Harvard Catalyst Clinical and Translational Sciences Center, which entered its fifth year in 2012.

As the 2012 fiscal year closes, we would like to recognize the support from our collaborators, and we take pride in the work we have accomplished together. During the coming year, we look forward to strengthening our teams and working together to meet the needs of the BCH investigator community in the context of the national fiscal challenges facing research and healthcare.

Ellis and Voula
Co-Chiefs, Clinical Research Center

Our Thanks: We wish to thank Dr. Mandell, CEO, Ms. Fenwick, COO and President, and the hospital leadership for the continued financial support provided to the Center. This support has made it possible for the Center to provide valuable assistance on hundreds of requests from the BCH investigator community and achieve many of its accomplishments.
Center Leadership and Administration

Stavroula Osganian, MD, ScD, MPH  
Co-Chief, Clinical Research Center

Ellis Neufeld, MD, PhD  
Co-Chief, Clinical Research Center

Andrew Dauber MD, MMSc  
Assistant Medical Director, CTSU Core

Robert Fuhlbrigge MD, PhD  
Medical Director, CTSU Core

Colette Hendricks, MSW, MBA  
Operations Director, Clinical Research Center

Jenifer Lightdale MD, MPH  
Director, Education Core
Al Ozonoff, PhD
Director, Design & Analysis Core

Adam C. Simmons, MPH
Manager, Development & Operations Core

Nicolle Quinn, MS, RD, LDN
Nutrition Manager, CTSU Core

Cindy Williams, MSN, RN, PNP, NE-BC
Nurse Director, CTSU Core

Affiliated Staff

Jon Bickel, MD, MS
Director, Clinical Research Information Technology
Center Vision, Mission, and Goals

Vision
To be a state-of-the-art, dynamic, and integrated clinical research program that provides leadership, infrastructure, and resources to support patient-oriented studies.

Mission
The mission of The Clinical Research Center is to promote excellence and quality in clinical research methods, to encourage best practices in clinical study implementation, and to empower investigators to conduct high quality independent research.

Goals

- **Scientific Leadership**: To provide scientific leadership and expertise on the design, conduct, analysis, and reporting of clinical research studies.
- **Education and Training**: To provide education, training and mentoring to the clinical researcher community on clinical research methods and study implementation best practices.
- **Scientific Collaboration and Consultation**: To serve as active scientific collaborators with hospital research initiatives and provide consultation services and/or collaboration in support of the design, conduct, analysis and reporting of clinical research studies.
- **Research**: To conduct independent research that serves to innovate and advance methodology in statistical design and analysis, survey and data collection methods, electronic data capture methods, and clinical research information technology.
- **Integration**: To provide a formal interdisciplinary home that links faculty members from the Program with various Departments and Divisions throughout the Hospital.
- **Growth**: To assist Departments and Divisions throughout the Hospital in recruiting and mentoring faculty members who are engaged in clinical research.
- **Professional Development**: To support the professional development of our faculty and staff so that they may develop their skills and advance their careers.

Values
The Clinical Research Center is committed to ensuring standardized and consistent best practices in clinical research methods, study conduct, data integrity, and the design of ethical protocols for all human subjects.

The Clinical Research Center is committed to providing a positive and motivational work environment that fosters teamwork, mutual respect, integrity, responsiveness and concern for each project, with creative interaction at the interface between areas of science.

The Clinical Research Center is committed to fostering a culture of collaborative, interdisciplinary research of the highest quality, respecting the priorities of each contributing discipline while placing priority on excellence in the joint effort.
Organizational Structure, Staffing and Space

The CRC is an institutional Center, reporting into the CEO and COO, and organized into four functional teams, the Design & Analysis Team, Education Team, Development & Operations Team, and the Clinical & Translational Study Unit. The teams interact closely with the affiliated Clinical Research Information Technology Team located in the Information Systems Department. In FY2012, the CRC included 59 faculty and professional staff and occupied approximately 7,000 square feet of space located at 21 Autumn Street as well as Pavilion 6.
Financial Resources and Expenditures

Institutional, extramural and departmental sources of support for the Center are shown in Table 1. There continues to be a substantial institutional commitment, totaling $2,510,092 million in FY2012, which facilitates its growth and visibility. Equally important has been the funding from departments, totaling $1,418,065, with $1,303,689 supporting jointly hired faculty and professional staff and $114,376 supporting work on specific research projects.

Table 1: CRC Funding Sources and Expenses in FY12

<table>
<thead>
<tr>
<th>Source</th>
<th>Budget</th>
<th>Expenses</th>
<th>Unexpended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional</td>
<td>$2,510,092</td>
<td>$1,782,578</td>
<td>$727,514</td>
</tr>
<tr>
<td>Department (Total)</td>
<td>$1,418,065</td>
<td>$1,418,065</td>
<td>-</td>
</tr>
<tr>
<td>Faculty</td>
<td>$1,303,689</td>
<td>$1,303,689</td>
<td>-</td>
</tr>
<tr>
<td>Projects^</td>
<td>$114,376</td>
<td>$114,376</td>
<td>-</td>
</tr>
<tr>
<td>CGRE</td>
<td>$287,630</td>
<td>$287,630</td>
<td>-</td>
</tr>
<tr>
<td>Harvard Catalyst*</td>
<td>$2,092,416</td>
<td>$1,820,708</td>
<td>$271,708</td>
</tr>
<tr>
<td>Biostats</td>
<td>$204,076</td>
<td>$201,381</td>
<td>$2,695</td>
</tr>
<tr>
<td>CTSU</td>
<td>$1,888,340</td>
<td>$1,619,327</td>
<td>$269,013</td>
</tr>
<tr>
<td>Extramural Projects</td>
<td>$763,699</td>
<td>$763,699</td>
<td>-</td>
</tr>
<tr>
<td>Intramural Projects</td>
<td>$155,754</td>
<td>$155,754</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>$7,227,656</td>
<td>$6,228,434</td>
<td>$999,222</td>
</tr>
</tbody>
</table>

*Grant Year 4 is from May 1, 2011 - April 30, 2012; total amount does not include Education or Bioinformatics funds
^Includes all CTSU project management services (CTSU: $42,511; Other: $71,865)

Ninety-one (91) investigator projects provided financial support to CRC faculty and staff in FY2012 (Table 2 and Figure 1). The majority (n=58) were funded through collaborations with researchers in the Department of Medicine. NIH was also the primary source of funding for these projects (52%), followed by funding from foundations (17%) and Internal Awards (16%). Among the 34 NIH funded projects, 19 were funded through R01’s mechanisms.

Table 2: Funding Sources for 91 Investigator Projects supporting CRC Faculty and Staff

<table>
<thead>
<tr>
<th>Source</th>
<th>Number</th>
<th>Dollars</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>34</td>
<td>$496,648</td>
<td>52%</td>
</tr>
<tr>
<td>Other Federal</td>
<td>4</td>
<td>$55,764</td>
<td>6%</td>
</tr>
<tr>
<td>Foundation/Association</td>
<td>20</td>
<td>$160,967</td>
<td>17%</td>
</tr>
<tr>
<td>Industry</td>
<td>5</td>
<td>$50,320</td>
<td>5%</td>
</tr>
<tr>
<td>Department Projects</td>
<td>7</td>
<td>$36,907</td>
<td>4%</td>
</tr>
<tr>
<td>Internal Awards</td>
<td>21</td>
<td>$155,754</td>
<td>16%</td>
</tr>
<tr>
<td>Total</td>
<td>91</td>
<td>$956,360</td>
<td>100%</td>
</tr>
</tbody>
</table>
Figure 1: Distribution of Departments for the 91 Investigator Projects supporting CRC Faculty and Staff

- DOM: 64%
- Neurology: 10%
- CRC: 5%
- Pathology: 2%
- Surgery: 7%
- Radiology: 3%
- Ophthalmology: 1%
- Anesthesiology: 3%
- Child Advocacy: 1%
- Patient Services: 1%
- Genomics: 2%
- Genetics: 2%
- Immunology: 2%
- Endocrinology: 14%
- Heme/Onc: 10%
- GI/Nutrition: 15%
- Newborn Medicine: 3%
- Emergency: 17%
- Gen Peds: 14%
- Adolescent: 9%
- Dev Medicine: 3%
- ID: 2%
- Nephrology: 2%
- General Med: 5%
Utilization of Services

The Clinical Research Center (CRC) provides a range of services to assist investigators in the design, conduct and analysis of their clinical research studies. Institutional support is provided for limited guidance to investigators who have unfunded studies while greater involvement on projects is provided for collaborative relationships with investigators on funded projects.

During FY2012, the CRC received 334 new requests for assistance from 240 Boston Children’s Hospital faculty or staff as shown in Figure 1, the requests are broadly distributed across several hospital departments and divisions with the majority of requests from investigators with appointments in Medicine (n=157) and within the Divisions of Emergency Medicine (27) and GI/Nutrition (20), followed by the Departments of Neurology (22) and Psychiatry (19).

Of these 334 requests, 33 (10%) were supported by Harvard Catalyst, 197 (59%) supported by Children’s Departments and Divisions and 37 (11%) supported by grants and contracts. The 67 (20%) that were hospital-supported in the first half of the are now supported by other funding.

Figure 1: Distribution of 334 New Requests for Assistance
As in past years, the 240 investigators requesting assistance were more likely to be junior faculty (Figure 2). A substantial number were also non-faculty, hospital staff and trainees (residents and fellows).

Figure 2: Distribution of Rank of 240 Investigators requesting CRC services

These requests for assistance were distributed across the various CRC services as shown in Figure 3. Research design and analysis, project/data management and study coordination remain a significant investigator need.

Figure 3: Distribution of Types of Services Provided for CRC Requests for Assistance
Assistance with grant applications and success in securing funding for research is central to the mission of the CRC (Figures 4 and 5). In 2011, the CRC assisted with 80 applications submitted to a funding agency and of those submitted, 28 were funded (35% overall success rate). Among these, 37 applications were to federal agencies of which 9 were funded (24% success rate). The total direct costs and indirect costs of these awards across all years to BCH were $7,311,098 and $3,081,010 respectively, with $707,260 allocated to support CRC faculty and staff efforts on these projects.

**Figure 4: Follow up of Grant Application Funding Success Rates from 2011**

**Figure 5: Grant Dollars Awarded to BCH and Amount of Dollars Allocated to CRC Staff**
CRC User Feedback Survey

Annually, we survey BCH investigators and staff who have collaborated with the CRC, requested services, or participated in its courses to gather valuable feedback on the impact of our assistance and educational efforts (Table 1). The overall response rate was 25% this year (200 out of 802). Among the 125 respondents who used CRC services (16% of those surveyed), 52 (41%) had worked in the past year with CRC faculty and staff on research projects through the Design and Analysis Core, 29 (23%) worked with the Development and Operations Core, 44 (35%) worked with the CTSU and 51 (41%) had attended an education course. Of the respondents who used services, 3 were professors, 10 were associate professors, 23 were assistant professors, 22 were instructors and 67 were non-faculty.

In general, respondents reported fairly high levels of knowledge of how to design, implement, and report results of their research study after receiving assistance or taking educational courses. They felt the CRC faculty and staff was knowledgeable, professional and responsive, and they were also highly likely to request assistance from the CRC again. These results were consistent across faculty rank and Core and reinforce the valuable contributions of the Center to the education, functional mentoring, and collaborative assistance provided to the BCH clinical research community.

Table 1: Responses to CRC Survey

<table>
<thead>
<tr>
<th>Statement</th>
<th>N</th>
<th>Mean (SD)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>The assistance I received from the CRP was valuable in terms of enhancing the quality of the science and methods of my study.</td>
<td>94</td>
<td>5.20 (0.96)</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more knowledgeable confident in designing a research study.</td>
<td>69</td>
<td>4.77 (0.99)</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more knowledgeable in implementing a research study.</td>
<td>80</td>
<td>5.01 (0.86)</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more knowledgeable in reporting results from a research study.</td>
<td>70</td>
<td>5.04 (0.97)</td>
</tr>
<tr>
<td>The education I received was valuable in terms of enhancing the quality of the science and methods of my research.</td>
<td>51</td>
<td>5.14 (1.02)</td>
</tr>
<tr>
<td>The education I received helped me to feel more confident in designing research studies.</td>
<td>51</td>
<td>5.35 (1.40)</td>
</tr>
<tr>
<td>The education I received helped me to feel more knowledgeable in implementing research studies.</td>
<td>51</td>
<td>5.27 (1.15)</td>
</tr>
<tr>
<td>The education I received helped me to feel more knowledgeable in reporting results of research studies.</td>
<td>51</td>
<td>5.39 (1.18)</td>
</tr>
<tr>
<td>The faculty and staff of the CRP worked with me in a responsive and professional manner.</td>
<td>103</td>
<td>5.35 (0.97)</td>
</tr>
<tr>
<td>The majority of the CRP staff with whom I interacted was knowledgeable about the services that I requested.</td>
<td>105</td>
<td>5.33 (0.87)</td>
</tr>
<tr>
<td>I received assistance in a timely manner.</td>
<td>99</td>
<td>5.02 (1.14)</td>
</tr>
<tr>
<td>I am likely to request assistance from the CRP in the future.</td>
<td>116</td>
<td>5.35 (0.80)</td>
</tr>
</tbody>
</table>

*1 = very strongly disagree to 6 = very strongly agree
Department Triage/Navigation Pilot

In March 2012, a department triage service/navigation pilot was implemented in collaboration with four departments/divisions: Emergency Medicine, Developmental Medicine, Endocrinology and Otolaryngology to provide a point-of-entry process to help investigators more efficiently access clinical research support services. After triage and approval, investigators move on to “navigators,” who will help them determine the type of clinical research services needed and how/where to obtain them. A key aspect of this service is that investigators must consult with their department/division chiefs (or designees) regarding their research project, level of support for their clinical research project, and priority use of available resources for support. They must have approval to obtain institutional resources.

Benefits of this model include:
- Promotes support of high-quality and high-impact clinical research at BCH
- Promotes strategic use of institutional resources
- Reduces investigator time to obtain all necessary support from Cores
- Promotes shorter completion times for clinical research projects
- Enhances investigators’ ability to publish and gain extramural funding
Since March 2012, 45 investigator requests, with 60% located in the ED, have been triaged by a team of staff located in each of the pilot departments. The team consists of a CRC project manager, CRC biostatistician and department/division clinical research designee who sit down with the investigator and discuss his/her research project. The team looks not only at feasibility (funding, space, staff), but also assesses whether the aims and hypotheses are clearly stated, what services are needed and if the research project is aligned with department/division strategic initiatives.

Below is a breakdown of the types of BCH services needed in order for a project to move forward with the 45 requests. Many used the resources of the Center and some needed to access TIDO and Equip monitoring services.
In addition, of the 45 consults that occurred in our pilot departments, 95% (or 43) met the division/department strategic initiatives and were given the “green light” to move forward.

Preliminary data for the pilot supports the feasibility of having a department triage/navigation team by promoting efficient use of institutional resources, reducing investigator time to obtain support from all CRC Cores, and promoting alignment with departmental strategic goals.

In the coming years, the Center will examine whether this system promotes securing of extramural funding, enabling shorter completion times for the clinical research projects, and enhancement of investigators’ ability to publish.
Hospital-Supported Consults

This past year, the CRC implemented hospital-supported one-hour consults for investigators. Since March 2012, our staff has performed 58 consults (43% from Department of Medicine) with requests ranging from the simple to the complex. Examples of scientific questions addressed are: “Can someone advise on available tools for delivering online surveys?”; “I need advice on how to plan data and project management for an upcoming clinical trial”; or “Is there an expert on cost effectiveness studies that can explain some basic concepts as they relate to our study?”

Additionally, out of the 58 consults, 9 (15%) requests have resulted in a scope of work/funded project utilizing CRC services.
Behavioral Science Core

This past year, the CRC partnered with the Department of Psychiatry to create a Behavioral Science Core. Housed within the Department of Psychiatry Program for Behavioral Science, this service is directed by Deborah Waber, Ph.D. and co-directed by Michelle Bosquet Enlow, Ph.D. The Core provides consultation services for the preparation of grants, protocols and clinical trials as well as psychometrician services, including the new NIH Toolbox. Currently, there are three active protocols using these services. In addition, consultation services have been provided to a number of investigators in various departments to assist with protocol development. Partial funding for this service is provided by The Harvard Catalyst Clinical and Translational Science Center.

Project Management Services

With the merger of the CRP and CTSU into the newly created Clinical Research Center (CRC), enhancing and refining the project management services of the Center was a top priority in 2012. Andrew Dauber, Cindy Williams and Adam Simmons comprise the Project Management Triage Team that meets with investigators following their request for project management services. After the initial assessment, The Triage Team assembles a project team tailored to the particular study and investigator’s needs. The triage team aims to: 1) offer an integrated, interdisciplinary approach to project management. 2) best utilize the limited Clinical Research Center resources to ensure study success for multiple investigators 3) provide excellent and timely study execution, full protocol compliance, regulatory compliance, as well as clinical research education for new and experienced investigators.

Junior investigators are awarded 150 grant-funded hours from Harvard Catalyst (that is to say, “free” to the investigator) for any combination of a RN project manager, non-RN project manager or data manager (which is in addition to our 200 grant-funded/“free” study coordinator hours that investigators can also apply for). The interdisciplinary team members include: statisticians, data managers, study coordinators, non-nurse project managers and nurse project managers. Providing up to 350 grant-funded hours of interdisciplinary clinical research expertise/workforce creates a clinical research environment where investigators are guided through best practices in clinical research, will learn in context, and research activities are staged in the proper sequence while integrating the appropriate clinical research resources/services of the institution and the Harvard Catalyst.

The project management service places heavy emphasis on managing study milestones and timelines with an eye toward the investigator’s timeline for future funding submissions. The project management service supports studies that are executed within and outside the discrete CTSU, including inpatient units, outpatient and community settings. Presently, the project management service supports 21 active protocols and studies range from novel biomarker studies to allergy immunotherapy and gene therapy trials.

These project management services offered by CRC at Children’s have been endorsed by Harvard Catalyst leadership as a model to be disseminated across the affiliated medical centers in the second five-year cycle of Harvard Catalyst funding, beginning in 2013.
The Harvard Catalyst CTSC is the largest recipient among almost 60 Clinical and Translational Science Awards (CTSAs) nationwide. The CRC at Boston Children's receives more than $2 million annually from Harvard Catalyst to support patient-oriented research. The merger of CTSU and the CRP to form the Clinical Research Center, discussed elsewhere in this report, represented a major milestone for the hospital’s interactions with Harvard Catalyst by unifying the leadership under Drs. Neufeld and Osganian for the many types of activities supported.

A second major milestone this past year has been the formal launch of the Child Health Committee at Harvard Catalyst. The committee, co-chaired by Dr. Neufeld and by Dr. Elizabeth Goodman at MGH, has a mission to foster and support research in all areas of pediatrics at the university and its affiliated hospitals, and BCH is both the largest and most concentrated focus of these activities.

At Children’s, Harvard Catalyst supports in particular clinical research in the CTSU, as well as biostatistics consultations, research coordinators, and training of young physician-scientists. An emerging area of research support, pioneered at Children’s and now spreading to the other Harvard-Affiliated teaching hospitals, is a system of project management with expert nurses, data specialists and coordinators to help launch clinical studies.

During 2012, the national consortium of CTSAs was reorganized by NIH into an entirely new structure, the National Center for Advancing Translational Sciences. At the same time, Harvard Catalyst entered its fifth year of a five-year support cycle. As the year draws to a close, the many CRC staff members who work closely with Harvard Catalyst are helping to prepare the renewal application to NIH for the period 2013-2018.
Staffing
FY2012 Clinical Research Information Technology staff included the following:

Jonathan Bickel, Director of Clinical Research Informatics
Ramkrishna Chakrabarty
Mohamad Daniar
James Gregoric
Ying-Feng Hsu
Arunkumar Nedunseralathan
Nandan Patibandla
Elizabeth Phillips
Joseph Rezuke

Clinical Research IT Core Mission
The mission of the Clinical Research Information Technology group is to provide leadership and innovative information technology services to enable and support the BCH clinical research enterprise.

Clinical Research IT Core Services
The CRIT provides IT services to the clinical investigator, core program and administrative communities. The CRIT is responsible primarily for sharing technical skills and resources, enhancing collaboration and improving the efficiency of clinical research applications development. The unit serves to champion innovative informatics solutions and expand IT services to the entire clinical research community.

CRIT services include systems for clinical trials data management, subject randomization, Web-based survey research and study coordination and research data warehousing for enhanced analytics. Informatics consultation and custom software applications development are also available.

Clinical Research IT Progress Report
The CRIT continued to provide its core services and has continued to expand its focus to the development of innovative products to support clinical research.

EDC development and use continues to grow using Oracle InForm® and REDCap
FY 2012 continued the trend of the last several years. The use of EDC (electronic data capture) grows as the institution continues to advance its vision of gathering clinical research data into centralized, supported databases.

2012 saw the continued rise of use of REDCap, an academically supported EDC tool grown out of the CTSA grant at Vanderbilt University. The use of this tool has seen tremendous growth. REDCap enables clinical researchers to build and deploy their own clinical research database with little IT intervention. Currently, there are 580 in-production projects. The numbers of users of this tool continues to grow rapidly with current user base of 1697 users.

The Phase Forward InForm EDC (electronic data capture) is in its fifth full year of use. The InForm system has continued to allow the enterprise to support major clinical trials
**Developed new Clinical Research Coordination System**
The CRIT has developed and deployed a new enterprise software application that is used by study teams to coordinate daily research activities. The product, titled the Clinical Research Coordination System, supports the following features.

- Centralized Patient Enrollment
- Study Scheduling
- Task and Patient Contact Management
- Patient Lab and Demographic Data Export from the clinical data warehouse

**Deployed end-user interface for cohort discovery - i2b2**
The CRIT team has continued its service offering of i2b2 as a clinical data warehouse research tool. I2B2’s comprehensive software and methodological framework enables the clinical research community to accelerate the translation of clinical findings into novel diagnostic, prognostic and therapeutic findings. It also provides a collaborative organizational and software infrastructure for basic and clinical researchers.

The CRIT team has greatly expanded the amount of data that is available to use in this data warehouse and is working with the i2b2 development team to expand the functionality of the web client used to access the warehouse.
Design and Analysis (DAC) Staffing
Al Ozonoff, PhD, Director

Henry Feldman, PhD, Principal Biostatistician
Hongyu Jiang, PhD, Principal Biostatistician
Leslie Kalish, ScD, Principal Biostatistician
Dionne Graham, PhD, Senior Biostatistician
Matt Gregas, PhD, Senior Biostatistician
Lin Huang, PhD, Senior Biostatistician
Emily Blood, PhD, Senior Biostatistician
Yolanda Martins, PhD, Senior Survey Methodologist
Michael Monuteaux, ScD, Senior Biostatistician and Epidemiologist
Mihail Samnaliev, PhD, Health Economist
Caterina Stamoulis, PhD, Senior Biostatistician

Kelly Burmeister, MS, Survey Methodologist
Peter Forbes, MA, Senior Biostatistician
Carly Milliren, MPH, Biostatistician
Paul Mitchell, MS, Senior Biostatistician
Christine Powell, MA, Senior Biostatistician
Carter Petty, MS, Senior Biostatistician
Jing Zhou, MS, Biostatistician

DAC expanded its statistical staff during FY12 with the arrival of two Senior Biostatisticians. Ms. Christine Powell and Mr. Carter Petty, who joined us from Pfizer and Massachusetts General Hospital, respectively. Ms. Carly Milliren also joined the DAC staff as a Statistical Programmer/Biostatistician. We saw three of our valued staff depart at the end of FY12. Senior Biostatistician Dr. Gregas, Survey Methodologist Ms. Burmeister and Statistical Programmer, Ms. Courtney Walls will be missed by their friends and colleagues at the CRC.
DAC Mission
In support of the overall mission of the CRC, the mission of the Design and Analysis Core is to furnish biostatistical expertise, methodological resources, and scientific leadership, and to promote excellence in the design and conduct of clinical research.

FY12 Highlights
The DAC provides assistance throughout the lifetime of a research project from design through implementation to analysis and reporting. During design, Core members work with investigators to plan studies, prepare and document statistical analyses, calculate statistical power and sample size, and contribute to the writing of proposals and protocols. During study implementation, Core members supervise and participate in database construction, randomization, data cleaning, quality control, and data and safety monitoring. In the analysis and reporting phase, the Core members perform both routine and innovative statistical analyses, collaborate with investigators to interpret results, and participate as co-authors to prepare scientific abstracts, presentations and journal articles.

FY12 was another successful and productive year for the DAC. The Core demonstrated its commitment to exceptional service by consulting and collaborating on its greatest number of research projects, study protocols and publications to date. In addition, the faculty has independent research activities and prominent collaborative roles in several research projects. Selected highlights from this past year include:

- Dr. Feldman played a key role in two major publications resulting from the long-term collaboration between the CRC and obesity researchers in the Division of Endocrinology. A study reported in the Journal of the American Medical Association (JAMA) showed that after weight loss, adults readjust their energy metabolism to a level that depends critically on the balance of fat and carbohydrate in their new diet, not just on total calorie intake. A community-based trial reported in New England Journal of Medicine showed that eliminating sugar-sweetened beverages from the daily diet of obese teenagers significantly improved their body-mass index after 1 year, particularly among Hispanic subjects. Dr. Feldman was lead statistician for both studies, collaborating with Drs. Cara Ebbeling and David Ludwig of the New Balance Foundation Obesity Prevention Center at BCH, CRC Co-Director Dr. Voula Osganian, and CRC study manager Tracy Antonelli.

- Dr. Jiang was a key contributor, with collaborator and Principal Investigator Dr. Christopher Duggan of the Department of Gastroenterology/Nutrition, towards a research award from the Bill & Melinda Gates Foundation. The 3-year grant will fund a study of plasma citrulline, LPS, and flagellin as biomarkers of gut function and predictors of neurodevelopment among young Tanzanian children.

- Mr. Mitchell contributed to a paper with Dr. Erica Fallon of the Department of Surgery and The Vascular Biology Program, “Effect of sunitinib on functional reproductive outcome in a rabbit model”, which received the 2012 Fertility and Sterility Investigator Achievement Award.

- Dr. Blood, with Dr. Lydia Shrier in the Division of Adolescent Medicine, presented her work at the Society for Adolescent Health and Medicine titled “Analyzing the temporal relationship between affective states and condom use in depressed adolescents using structural equation modeling”. This paper won the Robert H. DuRant Award for Statistical Rigor and Innovation in Adolescent Medicine, awarded by the Society for Adolescent Health and Medicine.
Dr. Stamoulis had two recently published papers in Epilepsy & Behavior and the IEEE Transactions in Neural Systems and Rehabilitation Engineering, respectively. She showed that high-frequency neural activity is measurable in scalp recordings from epilepsy patients and may characterize the dynamics of seizure evolution. This novel finding may have a significant impact on the development of next-generation therapies for medically refractory epilepsy. This work is in collaboration with colleagues in the Epilepsy division at Beth Israel Deaconess Medical Center, and is now extended to pediatric patients. Also, based on a signal processing methodology developed by Dr. Stamoulis for analysis of high-dimensional genomic data, a new R03 grant was funded in collaboration with Dr. Betensky at HSPH, to apply this methodology for genomic data analysis in cancer.

DAC faculty and staff were especially active in educational activities throughout the hospital, including both the continuation of longstanding courses as well as new offerings. They play a prominent role in the educational offerings of the CRC. Dr. Graham assumed co-directorship of the yearly Introduction to Clinical Research, a two-day overview for fellows and junior faculty, which featured five hours of statistical material taught by Core faculty (Drs. Feldman, Graham, Monuteaux, and Samnaliev). The introductory course generates demand for more advanced short courses, some of which are well-established while others are in development. Dr. Monuteaux and Ms. Milliren taught Introduction to Biostatistics with SPSS, which combines eight lectures on elementary descriptive and inferential statistics with companion computer laboratory sessions and is available via webcast to address high demand. For the third consecutive year, Dr. Gregas taught an advanced course titled Introduction to Regression with support from Mr. Forbes. In addition to the CRC short-course program, members of the Biostatistics Core regularly deliver hospital seminars and conduct training at national meetings. Below is a selection of other educational activities from FY12:

- Dr. Feldman delivered 8 lectures to the Harvard Catalyst Program in Applied Biostatistics; videotaped 4 lectures for the Harvard-Portugal Clinical Scholars Research Training Program; and acted for the fifteenth consecutive year as faculty in the American Heart Association Ten-Day Seminar on Epidemiology and Prevention of Cardiovascular Disease.
- Under the continued leadership of Dr. Graham, the faculty of the Design and Analysis Core provided its sixth year of statistical mentorship to the Harvard Pediatric Health Services Fellowship at their bimonthly Works in Progress sessions. Dr. Graham also provided statistical oversight to several fellows’ projects.
- Dr. Jiang and Mr. Mitchell continued their annual educational outreach in the Department of Gastroenterology/Nutrition with three mini-workshops: “Tutorial on Survival Analysis”, “Common Barriers to a Speedy Statistical Analysis”, and “Design and Report of Observational Studies”.

An important organizing principle of CRC is the integration of its faculty with BCH Departments and Divisions, which provide academic appointments and/or funding, so as to foster creative research collaborations between department-based investigators and CRC-based biostatisticians. All of the Core masters-level statisticians are also funded by BCH Departments or Divisions. Typically, the department supports a substantial fraction of a biostatistician’s effort, drawing on departmental funds and/or research grants. The purpose is to provide the methodologist with scientific focus and continuity of collegial contact, leading to a facilitative environment for informal consulting, generating new ideas and attracting new grant support. The following departmental academic affiliations and/or funding sources are in place.
• Dr. Blood, Instructor, Division of Adolescent and Young Adult Medicine and Department of Psychiatry
• Dr. Feldman, Associate Professor in the Division of Endocrinology
• Dr. Graham, Instructor, Department of Cardiology and Program for Patient Safety and Quality
• Dr. Huang, Instructor, Departments of Urology and Otolaryngology
• Dr. Jiang, Assistant Professor, Division of Gastroenterology and Nutrition
• Dr. Kalish, Associate Professor, Division of Infectious Diseases and Department of Orthopedics
• Dr. Monuteaux, Assistant Professor, Division of Emergency Medicine
• Dr. Stamoulis, Assistant Professor, Department of Radiology and Department of Orthopedics
• Mr. Forbes, Department of Psychiatry
• Mr. Mitchell, Division of Gastroenterology and Nutrition
• Ms. Milliren, Department of Adolescent Medicine
• Ms. Powell, Departments of Neurology and Developmental Medicine
• Ms. Zhou, Department of Cardiology and Program for Patient Safety and Quality
Development and Operations Core

Development and Operations (DOC) Staffing
Adam C Simmons, MPH, CCRC, Manager

Lucy Abernethy, BA, Senior Clinical Research Coordinator
Ed Anderson, BA, CCRP, Senior Clinical Research Coordinator
John A Andrea, BS, Clinical Research Coordinator
Mark Berry, MA, CCRC, Senior Clinical Research Specialist
Qiaoli (Lily) Chen, MS, CCDM, Senior Research Data Manager
Kimberly Chin, BA, Clinical Data Manager
Audrey Gill, BA, Clinical Research Coordinator
Rajna Filip-Dhima, MS, Senior Clinical Research Specialist
Jisun Jang, MA, Statistical Programmer
Jessica LeSage, BS Clinical Research Coordinator
Prajakta Mangeshkar, MSc, MS, Senior Clinical Research Specialist
Kaitlin Morris, BA, Clinical Research Coordinator
Wendy Mayer, BA, Clinical Research Coordinator
Jessica Oribabor, MS, Clinical Research Coordinator
Sarah Steltz, MPH, Senior Clinical Research Specialist

The Core welcomed the hires of Kimberly Chin, BA; Jessica LeSage, BS and Kaitlin Morris, BA with the Division of Emergency Medicine; and Wendy Mayer, BA with the support of Harvard Catalyst. In addition, Ed Anderson and Lucy Abernethy were promoted to Senior Clinical Research Coordinator.
DOC Mission
In support of the overall mission of the CRC, the mission of the Development and Operations Core is to provide leadership and guidance in clinical research practice, data management and data integrity for BCH clinical investigators.

FY12 Highlights
With the merger of the former CRP with the CTSU, the former Project and Data Management Core took on the name Development and Operations Core (DOC) to reflect the work done by the growing pool of study coordinators (now at 5) available to investigators working with the CRC. In addition, there are three coordinators exclusively dedicated to the Division of Emergency Medicine. The DOC now offers a full range of staff, tools and services to compliment the Design and Analysis Core and CTSU for full clinical research support.

The DOC was also very involved with staffing of the Pilot Department Triage systems. Rajna Filip-Dhima worked with the Department of Otolaryngology and Division of Endocrinology in the development and operations of their intake and triage process; Mark Berry with the Division of Emergency Medicine and Prajakta Mangeshkar with the Division of Developmental Medicine.

FY12 marked a change where DOC had once supported more hospital supported consultative services to exclusively support Investigator and Catalyst-funded project management and study support. DOC supported project management for a number of NIH, foundation and industry sponsored trials. Some of these include several industry-funded trials with Novartis and Seaside Pharmaceuticals of Autism spectrum disorders conducted with the Division of Developmental Medicine, managed by Prajakta Mangeshkar and coordinated by Lucy Abernethy. The DOC (Sarah Steltz, Kimberly Chin and Adam Simmons) also supported project management of research projects coordinated by the New Balance Foundation Obesity Prevention Center: such as the POOL registry with Stavroula Osganian from the Division of General Pediatrics. Jisun Jang has worked with members of the Design & Analysis Team providing data support for Pediatric Healthcare Quality Measures Program Centers Of Excellence Projects with Drs. Mark Schuster and Jay Berry from the Division of General Pediatrics.

As in years past, the DOC offered coordinator staffing to support the Harvard Catalyst Clinical Research Center (HCCRC). In 2012, the DOC supported 13 different investigators across clinical departments and divisions including Cardiology, Surgery, Immunology, Cardiac Surgery, Developmental Medicine, Gastroenterology, Hematology/Oncology and Patient Services.

DOC staff also played significant leadership roles and participated in CRC educational offerings including the Orientation for Study Coordinators. Prajakta Mangeshkar served as course director and this monthly orientation is available to all new Boston Children’s clinical research staff. DOC staff led sessions during the orientation, including: Obtaining Informed Consent/Assent: A Practical Approach, presented by Mark Berry and Study Implementation & Timeline Development, Principles of Data Management, and Case Report Forms & Manual of Operations, presented by Adam Simmons. Mr. Simmons also presented in the education core’s annual Introduction to Clinical Research giving his talk on Data Management Best Practices for Clinical Researchers: minimizing bias and the perception of bias from your research data. Mr. Simmons also presented at the Association of Clinical Research Professionals Global Conference in 2012 on Data Management for Investigator-Initiated Studies.

DOC staff served on a number of committees in the Harvard community. Sarah Steltz and Rajna Fillip-Dhima served on the Harvard Catalyst Data Protection Sub-Committee, a committee that looks at how electronic research data is protected across Catalyst institutions. In addition, Adam Simmons, Prajakta Mangeshkar, Mark Berry and Ed Anderson have served as voting members on the Beth Israel Committee on Clinical Investigation.
The Core welcomed the hires of Kyla Almeida, Laura Feloney, Molly McDonald and Bethany Trainor during this past fiscal year. We would also like to thank Dr. Catherine Gordon for her service to the CTSU during the past fiscal year as Medical Director and welcome Dr. Robert Fuhlbrigge in this role for the upcoming year.
CTSU Mission
The CTSU provides state-of-the-art 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. Funding for the CTSU services is from the Harvard Catalyst, which is an affiliate-wide effort to facilitate laboratory-to-bedside translational research and to encourage researcher collaboration.

FY12 Highlights
The CTSU provides resources to help facilitate clinical research. A varied portfolio of studies has been supported this past year. Several examples of studies are:

Role of Modified Ultra Filtration in Blood Utilization and Postoperative Resource Utilization in Neonates Undergoing Cardiac Surgery: A Pilot Study; PI: Meena Nathan, MD
It is known that ultrafiltration ameliorates the deleterious effects of Hemodilution which typically occurs in children undergoing cardiac repair on cardiopulmonary bypass (CPB). Conventional practice is the use of ultrafiltration during the rewarming phase of CPB, but this may be limited by circuit volume. Modified ultrafiltration (MUF) is typically performed after discontinuation of cardiopulmonary bypass and thus is not limited by circuit volume and can thus allow a greater degree of hemo-concentration. This study's main hypothesis is that utilization of Modified Ultra Filtration (MUF) in neonatal cardiac surgery will decrease blood and blood product utilization and thus decrease resource utilization. This is a prospective stratified randomized study of 150 neonates (under 30 days old) undergoing cardiac surgery on cardiopulmonary bypass. The two groups are followed prospectively for amount of blood (red blood cells only) and other blood products utilized in the first 48 hours and first 7 days post operatively.

A randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of AFQ056 in adolescent patients with Fragile X Syndrome; PI: Ramzi Nasir, MD
This is a multi-center, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of three doses of AFQ056 compared to placebo in patients with Fragile X Syndrome. Data from this study will be used to support the registration of AFQ056 in this population and to guide future development of the drug in younger patients with FXS.

Randomized, Double- Blind Phase 2 Trial of RAD001 for Neurocognition in Individuals with Tuberous Sclerosis Complex; PI: Mustafa Sahin, MD, PhD
The purpose of this study is to assess the efficacy and safety of RAD001 in treating neurocognitive deficits associated with tuberous sclerosis complex (TSC). This is a prospective, double-blind, randomized, parallel group, placebo- controlled, two- center phase 2 study evaluating treatment with RAD001 versus placebo in 50 patients with TSC. There are three phases in this study in this study: pre-treatment (screening/baseline), blinded treatment, and follow-up.

The nutrition team successfully launched a snack program to provide healthy and delicious snacks to participants involved in protocols that require extended visits in the CTSU. Throughout the year, the team has been involved in many protocols, including preparing double blind placebo controlled food challenges for Dr. Umetsu's peanut allergy study, measuring resting energy expenditure via indirect calorimetry for Drs. Mark Kieran's and Monica Kleinman's ongoing Progeria trial and the team has analyzed more than 300 food recalls for several other protocols. The team is now trained to complete body composition analysis using the BodPod, in collaboration with the Division of GI/Nutrition.
FY12 was another successful and productive year for the CTSU and one of the busiest since the Harvard Catalyst started in 2008

- There was an increase of 194 visits or a 5.7% increase from FY11 (Figure 1).
- More than half of the investigators receiving services in FY12 were Junior Investigators (Figure 2).
- The CTSU had over 114 active protocols and worked with over 20 different departments and divisions (Figure 3).

![Figure 1. CTSU Visits Fiscal Year 2010 – 2012](image)

![Figure 2. Distribution of Rank of FY12 Users](image)
Figure 3. FY12 CTSU Users by Department/Division

- Medicine: 70%
- Cardiology: 12%
- Neurology: 8%
- Surgery: 3%
- Psychiatry: 3%
- GI/Nutrition: 9%
- Genetics: 13%
- Endocrinology: 11%
- Immunology: 15%
- ID: 2%
- Gen Med: 1%
- Nephrology: 6%
- Pulmonary: 4%
- Adolescent: 4%
- Critical Care: 7%
- Dev Med: 5%
- Emergency: 4%
- Heme/Onc: 19%
- Adolescent, 4%
- Critical Care, 7%
- Dev Med, 5%
- Emergency, 4%
- Endocrinology, 11%
- GI/Nutrition, 9%
- Genetics, 13%
- Heme/Onc, 19%
- Immunology, 15%
- ID, 2%
- Gen Med, 1%
- Nephrology, 6%
- Pulmonary, 4%
Education Core

Education Staffing
Jenifer Lightdale, MD, MPH, Director
Chau Tran, Education Program Coordinator

Education Mission
In support of the overall mission of the CRC, the Clinical Research Education Core aims to provide an integrated, useful, scientifically accurate, and comprehensive educational curriculum with course offerings that primarily aim to enhance quality of clinical research at Boston Children’s Hospital.

FY12 Highlights
The Education Core continues to deliver a range of services to the Boston Children’s Hospital clinical research community, including:

- Developing, coordinating, and implementing courses and seminar series on research methods and topics for faculty, fellows, residents, and clinical research staff
- Offering didactic series on other advanced topics of interest to the broad research community at Boston Children’s Hospital
- Serving on hospital and university research education-related committees
- Developing Web-accessible best practices and educational tools for researchers
Under the direction of Dr. Jenifer R. Lightdale, the Education Core has consistently provided considerable educational opportunities for BCH staff and faculty involved in clinical research. Core achievements over the past year include the support of regular instruction in NIH-funded comprehensive software packages (i.e. REDCap and i2B2) that are becoming essential tools for academic clinical investigation in the new era of healthcare informatics and electronic data capture.

Total CRC course enrollment from 2006 to 2012 continues to reflect strong demand for CRC educational offerings from clinical research faculty and staff across the entire hospital (Figure 1 and Table 1). The Education Core continues to build upon its curriculum by adding 1-2 new courses a year (Table 2). Our annual introductory clinical research and biostatistics courses are designed to teach junior investigators and fellows the fundamentals of study organization, analysis and data management. In 2012, we collaborated with the Clinical Research Information Technology (CRIT) core to offer an introduction to i2B2, a scalable computational framework designed to help accelerate case finding and hypothesis testing across and beyond all of the Harvard hospitals. We were also successful in working with the Harvard Catalyst to promote instruction in REDCap, an NIH sponsored, freely available, GCP-compliant database package. The Education Core also supported the continued availability of many advanced biostatistics courses introduced in recent years, including Introduction to Regression, and Introduction to Longitudinal Analysis and were happy to continue our support of the Program for Research Assistant Development and Achievement (PRADA), a biweekly program for research assistant and study coordinator career development.

As a final accomplishment in FY 2012, the Education Core was proud to design and sponsor the first Boston Children’s Hospital Career Development Award Night – which recognized and provided a night of education to nearly 100 trainees and junior faculty with active “K Awards” across the Children’s enterprise. Physician-in-chief Gary Fleischer, MD, delivered a keynote address and recognized the honorees. Breakout sessions during the Award Night addressed a number of issues directly and uniquely encountered by junior investigators working to transition from training to being an independently funded faculty investigator. All awardees who attended had received “K Awards,” or other similar career development awards from societies such as the American Heart Association, Howards Hughes Medical Institute, the Bill and Melinda Gates Foundation and the Robert Wood Johnson Foundation. Mentors were also invited, and spent time in a breakout session dedicated to helping ensure the success and support of that role.

Among the mentee/mentor teams honored during the Career Development Award Night were:

- **Alyna Chien, MD, MS**, assistant in Medicine, who has been mentored by **Mark Schuster, MD, PhD**, chief of General Pediatrics, in her work studying the effect of performance incentives on healthcare quality for vulnerable populations.
- **Andrew Dauber, MD, MMSc**, assistant program director, Clinical Translational Study Unit, has been mentored by **Joel Hirschhorn, MD, PhD**, director of the Center for Basic and Translational Obesity Research, in his work studying the influences of genetic components on height.
- **Maitreyi Mazumdar, MD, MPH, MSc**, assistant in Neurology, has been mentored by both David Christiani, MD, MPH, MS, of Massachusetts General Hospital, and **Alan Leviton, MD**, director of Boston Children’s Neuroepidemiology Unit, in her work studying the role of environmental contaminants in the development of neurological injury and disease in children.
Laura Simons, PhD, staff psychologist, was mentored by David Borsook, MD, principal investigator in Anesthesiology Research, in her research into utilizing neuroimaging (fMRI) and psychophysiological techniques to enhance our understanding of the physical and psychological consequences associated with chronic pain.

In fiscal year 2013, the Education Core will be launching a Grand Rounds seminar series that highlights the collaborators, faculty and accomplishments of the entire Clinical Research Center, while continuing to monitor and improve existing course curriculum. In addition, as part of a multi-disciplinary effort, the Education Core will be co-sponsoring an encore production of a seminar series with Brigham and Women’s Hospital, entitled The Art and Anatomy of Writing a Career Development Grant. Agendas for our longstanding and regularly featured Introduction to Clinical Research and Orientation for Study Coordinators sessions are shown in the Appendix.

Table 1. CRC Course Registration, 2004-2012; Total: 1,219

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<th>CRC Course</th>
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**Statistical Mini Courses:**

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Figure 1. CRC Course Attendees by Department 2012; Total: 1,163*

*Some registrants did not provide department/division/program information.

Table 2. CRC Course Listings 2004-2012

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<td>Program for Research Assistant Development and Achievement</td>
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Statistical Mini Courses:

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<td>Beyond Chi-Squares: Drawing Inferences from Tables</td>
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<td>Statistics for Small Sample Size Studies</td>
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<td>Introduction to Statistical Genetics</td>
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course offered ***
Staff Publications

2012 Published


2012 Epub


Acknowledgements


This study was supported by a grant from the National Institutes of Health (U56 CA118641); Dr. Pischke was supported by R25 CA057713-05. We gratefully acknowledge the leadership and support of Drs. Karen Emmons and Ada´n Colo´n-Carmona. We also thank the following for their participation and support: Milagros Abreu, Erick Alcantata, Esteban Barreto, Lois Biener, Karen Burns White, Katia Canenguez, Magnolia Contreras, Ana Ga´leas, Maria De Jesus, Ericka Gonzalez, David Hurtado, Thelma Juarez, Bryan Leyva Vengoechea, Yolanda Martins, Yudy Muneton, Leyla Pe´rez-Gualdro´n, Maria Nieves Sesma, Max Stewart, and Jamielle Walker.


We thank the following members of the Clinical Research Program for assistance with administering the random treatment assignments since they had no vested interest in results of the trial: Clarissa Valim, MD, ScD, Susan McDermott, MPH, RN, Lin Huang, PhD, and Adam Simmons.
# INTRODUCTION TO CLINICAL RESEARCH
## FALL 2012 COURSE AGENDA

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<thead>
<tr>
<th>AM</th>
<th>Day One: Tuesday, September 11, 2012</th>
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<tbody>
<tr>
<td>7:45-8:00</td>
<td>Registration &amp; Check-in</td>
</tr>
<tr>
<td>8:00-8:15</td>
<td>Introduction and Overview</td>
</tr>
<tr>
<td>8:15-9:00</td>
<td>Overview of Clinical Research at Children’s Hospital</td>
</tr>
<tr>
<td>9:00-9:05</td>
<td>Break</td>
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<tr>
<td>9:05-10:05</td>
<td>Statistics in Clinical Research: An Overview</td>
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<tr>
<td>10:05-10:10</td>
<td>Break</td>
</tr>
<tr>
<td>10:10-10:55</td>
<td>Ethics and Integrity in Clinical Research</td>
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<tr>
<td>10:55-11:00</td>
<td>Break</td>
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<tr>
<td>11:00-11:45</td>
<td>Human Subjects and the Institutional Review Board</td>
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<tr>
<td>11:45-12:15</td>
<td>The IRB Review Process: An Insider’s View</td>
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<td>12:15-12:55</td>
<td>Lunch</td>
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<tr>
<th>PM</th>
<th>Day One: Tuesday, September 11, 2012</th>
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<tbody>
<tr>
<td>12:55-1:55</td>
<td>Observational Study Designs</td>
</tr>
<tr>
<td>1:55-2:00</td>
<td>Break</td>
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<tr>
<td>2:00-2:45</td>
<td>Clinical Trials: Design and Monitoring</td>
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<td>2:45-2:50</td>
<td>Break</td>
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<tr>
<td>2:50-3:35</td>
<td>Grant Writing 101</td>
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<td>3:35-3:45</td>
<td>Break</td>
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<tr>
<td>3:45-4:15</td>
<td>10 Questions Every Investigator Should Ask Before doing a Study with Drugs, Devices or Biologics</td>
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<td>4:15-4:20</td>
<td>Break</td>
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<tr>
<td>4:20-5:20</td>
<td>Writing for Scientific Publication</td>
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Boston Children’s Hospital

Clinical Research Center
Education Core
<table>
<thead>
<tr>
<th>AM</th>
<th>Day Two: Friday, September 14, 2012</th>
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<tbody>
<tr>
<td>7:45-8:00</td>
<td>Arrival/ Check In</td>
</tr>
<tr>
<td>8:00-9:15</td>
<td>Descriptive and Univariate Statistics D. Graham</td>
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<td>9:15-9:20</td>
<td>Break</td>
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<tr>
<td>9:20-9:50</td>
<td>I2b2 and Current Technologies J. Bickel</td>
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<td>Break</td>
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<tr>
<td>9:55-10:55</td>
<td>Collecting and Managing Clinical Research Data A. Simmons</td>
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<td>10:55-11:00</td>
<td>Break</td>
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<tr>
<td>11:00-11:30</td>
<td>Common Study Documentation Errors &amp; Best Practices E. Newbert</td>
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<td>11:30-12:10</td>
<td>Lunch</td>
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<td>12:10-1:05</td>
<td>Introduction to Regression Analysis H. Feldman</td>
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<td>1:10-1:55</td>
<td>Industry and Philanthropy S. Nurko</td>
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<td>1:55-2:00</td>
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<td>2:00-2:30</td>
<td>Introduction to Cost-Effectiveness Analysis M. Samnaliev</td>
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<td>2:30-2:35</td>
<td>Break</td>
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<tr>
<td>2:35-3:20</td>
<td>Designing Surveys and Questionnaires S. Ziniel</td>
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<td>3:20-4:05</td>
<td>Evaluating Measures in Clinical Research S. Ziniel</td>
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<td>4:10-4:55</td>
<td>Scientific Presentations J. Finkelstein</td>
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<td>4:55-5:10</td>
<td>Final Wrap-Up D. Graham</td>
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<tr>
<td>9:00 - 9:25</td>
<td>Welcome and Overview</td>
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<td>9:25 - 9:40</td>
<td>The Study Coordinator’s Central Role in Clinical Research</td>
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<td>9:40 - 9:45</td>
<td>Break</td>
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<tr>
<td>9:45 - 10:05</td>
<td>Human Subject Protections IRB Issues: Before the Research Begins</td>
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<td>IRB Issues: During the Research</td>
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<td>10:30 - 10:40</td>
<td>Protecting Patient/Subject Information</td>
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<td>10:40 - 11:10</td>
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<td>11:10 - 11:25</td>
<td>Considering the Research Volunteer Perspective</td>
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<td>11:35 - 12:00</td>
<td>Informed Consent/Assent/Subject Recruitment</td>
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<td>12:00 - 12:30</td>
<td>Catered Lunch</td>
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<tr>
<td>12:30 - 1:30</td>
<td>Obtaining Informed Consent/Assent: A Practical Approach</td>
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<td>1:30 - 1:40</td>
<td>Break</td>
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<td>1:40 - 2:35</td>
<td>Introduction to the Education &amp; Quality Improvement Program (EQuIP)</td>
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<td>Study Documentation: Common Errors</td>
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<td>2:45 - 3:30</td>
<td>Introduction to the Clinical Research Center (CRC)</td>
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<td>Study Implementation &amp; Timeline Development</td>
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<td>Principles of Data Management</td>
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<td>Case Report Forms &amp; Manual of Operations</td>
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<td>3:30 - 3:50</td>
<td>Wrap-Up &amp; Review</td>
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