

## Clinical Research Program

# 2011 Annual Report of the Clinical Research Program

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An interdisciplinary program fostering excellence in clinical research at Children's Hospital Boston



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#### PROGRAM DIRECTOR'S REPORT

#### **From the Program Director**

The Clinical Research Program (CRP) at Children's Hospital Boston is pleased to share its Annual Report for fiscal year 2011. As an institutional, academic and service research program, we provide assistance and education to the clinical research community at Children's Hospital. The program directly supports a core mission of the hospital, to be the leading source of research and discovery through its three primary areas of focus: clinical research methodology; assistance on research project initiation and implementation; and education on research methods and practice.

This annual report summarizes key accomplishments of the Program and the many faculty and staff who strive to support the mission of the Program and the Hospital. Our faculty and staff serve as institutional leaders, mentors, teachers and scientific collaborators. They provide critical expertise and support to junior faculty as they launch their research careers, as well as to senior faculty who are 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 FY2011 include:

- Support or consultation on 495 new investigator requests for assistance from 331 researchers in the institution, representing a 10% increase in new requests from FY2010.
- Successful collaborations with several CHB investigators and other institutional programs on 95 funded projects totaling \$755,634, representing a 27% increase in the number of funded projects and a 20% increase in dollars of support from FY2010, with a large proportion of this funding coming from extramural and intramural grants (\$647, 610).
- 84 peer reviewed collaborative publications that were co-authored by CRP staff. (64 published, 20 Epub ahead of print).
- Increases in joint faculty and staff recruits with Departments and Divisions with a corresponding 45% increase in department funding of CRP faculty and staff.
- Continued demand for clinical research education, with 9 course offerings from the Clinical Research Education Core drawing 660 attendees.
- Growing demand for study coordinators and research specialists resulting in 4 departmental partnerships with these CRP staff.
- Continued support for robust software tools to more effectively and efficiently collect and store research data, including InForm, REDCap and SPSS Data Collection Author.
- Growth in Program faculty and staff with 6 new hires

As the 2011 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 joining our colleagues from the Clinical and Translational Study Unit, becoming the newly established Clinical Research Center and working together to meet the challenges and needs of the CHB investigator community.

Stavroula Osganian, MD, ScD, MPH Director, Clinical Research Program

**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 Program. This support has made it possible for the Program to provide valuable assistance on hundreds of requests from the CHB investigator community and achieve many of its accomplishments.

#### **Program Leadership and Administration**



Stavroula Osganian, MD, ScD, MPH Director, Clinical Research Program



**Jenifer Lightdale, MD, MPH** Director, Education Core



Al Ozonoff, PhD
Director, Biostatistics Core



Adam C. Simmons, MPH
Manager, Project & Data Management Core



**Laura Haley**Program Administrative Coordinator

#### **Program Vision, Mission, and Goals**

#### Vision

To be a state-of-the-art, robust, and integrated clinical research program that provides leadership and infrastructure to support patient-oriented, community, and population-based studies.

#### **Mission**

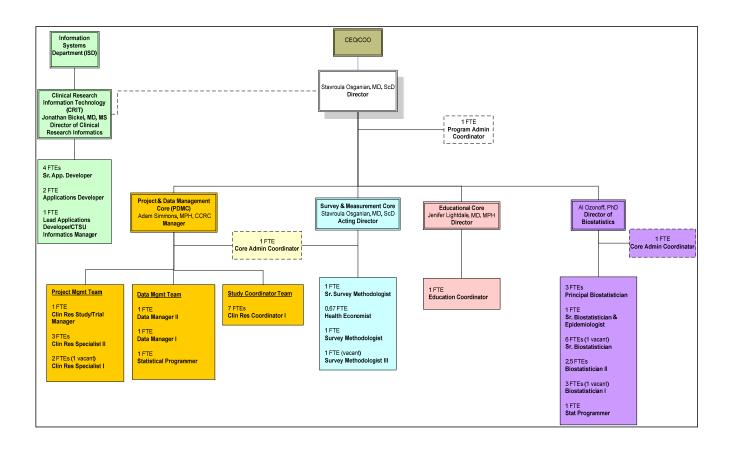
The mission of the Clinical Research Program is to promote excellence and quality in clinical research methods and best practices, and to empower our investigators to conduct high quality, independent research.

#### 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 (faculty, residents, fellows, study nurses and, study coordinators and, research assistants) on clinical research methods and study implementation best practices.
- Scientific Collaboration and Consultation: To serve as active scientific collaborators in support of others' clinical research initiatives and provide consultation services on the design, conduct, analysis and reporting of clinical research studies.
- Research: To conduct independent research that serves to promote innovative and robust approaches in statistical design and analysis, survey and data collection methods, electronic data capture methods, and clinical research information technology.
- Knowledge and Expertise: To be knowledgeable in and foster the use of best practices in the design, conduct, analysis and reporting of clinical research studies.
- Integration: To provide a formal interdisciplinary home that links faculty members from the Program to various Departments and Divisions throughout the Hospital.
- Growth: To assist Departments and Divisions throughout the Hospital in recruiting and nurturing faculty members who are engaged in clinical research.
- Professional development: To support the development of our staff so that they may augment their skills and advance their careers, while fulfilling the mission of the Program.

#### **Organizational Structure, Staffing and Space**

The CRP is an institutional Program, reporting into the CEO and COO, and organized into four functional cores, the Biostatistics Core, Clinical Research Education Core, Project and Data Management Core, and Survey and Measurement Core. The Cores interact closely with the affiliated Clinical Research Information Technology Team located in the Information Systems Department. In FY2011, the CRP included 40 faculty and professional staff and occupied approximately 4000 square feet of space located in 21 Autumn Street.



#### **Financial Resources and Expenditures**

Institutional, extramural and departmental sources of support for the Program are shown in **Table 1**. There continues to be a substantial institutional commitment, totaling \$2,398,436 million in FY2011, which facilitates its growth and visibility. Equally important has been the funding from departments, totaling \$1,386,583, with \$1,278,559 supporting jointly hired faculty and professional staff and \$108,024 supporting work on specific research projects.

Table 1: CRP Funding Sources and Expenses in FY11

Source	Budget	Expenses	Unexpended
Institutional	\$ 2,398,436	\$2,013,230	\$385,206*
Departmental (Total) Faculty (\$1,278,559) Projects (\$108,024)	\$ 1,386,583	\$ 1,386,583	-
CGRE	\$ 268,491	\$ 268,491	-
Catalyst support for Staff	\$ 278,436	\$ 278,436	
Extramural Projects**	\$ 547,587	\$ 547,587	-
Intramural Projects***	\$ 100,022	\$ 100,022	-
Total	\$4,979,556	\$4,594,350	\$385,206*

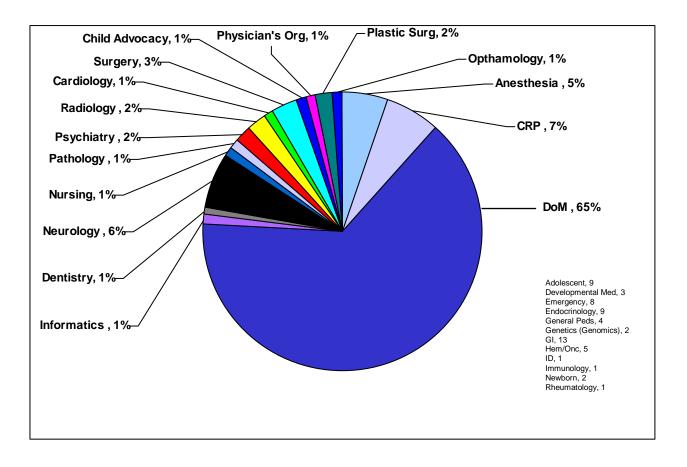
<sup>\*</sup>Total unexpended institutional funds include position vacancies and recovery from staff charge backs to grants or other funds.

Ninety-five (95) investigator projects provided financial support to CRP faculty and staff in FY2011 **(Table 2 and Figure 1).** The majority (n=61) were funded through collaborations with researchers in the Department of Medicine. NIH was also the primary source of funding for these projects (35%), followed by funding from departments (20%) and foundations (17%). Among the 33 NIH funded projects, 15 were funded through R01's mechanisms.

Table 2: Funding Sources for 95 Investigator Projects supporting CRP Faculty and Staff

Source	Number	Dollars	Percent
NIH	33	\$ 342,609	35%
Other Federal	4	\$ 83,334	4%
Foundation/Association	16	\$ 98,239	17%
Industry	4	\$ 23,405	4%
Department Projects	19	\$ 108,024	20%
Catalyst Pilot Projects	5	\$ 30,389	5%
Internal Awards	14	\$ 69,633	15%
Total	95	\$ 755,634*	100%*

Figure 1: Distribution of Departments for the 95 Investigator Projects supporting CRP Faculty and Staff



#### **Utilization of Services**

NEUROLOGY, 25

The Clinical Research Program (CRP) 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 FY2011, the CRP received **495 new requests for assistance** from 331 Children's Hospital faculty or staff. In comparison to FY2010, this was a 10% increase in the number of requests and an 11% increase in the number of faculty and staff requesting assistance. 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=254) and within the Divisions of Developmental Medicine (44), Adolescent Medicine (35) and Gl/Nutrition (n=33), followed by the Departments of Cardiology (35) and Psychiatry (33).

PHYSICIAN'S ORGANIZATION, 2-CHILD ADVOCACY, 3 ADMINISTRATION, 2 UROLOGY, 18-SURGERY, 16-ANESTHESIA, 23 RADIOLOGY, 14-CLINICAL RSCH PROGRAM, 12 PSYCHIATRY, 33 CARDIOLOGY, 35 PPSQ. 2-DENTISTRY, 4 PATHOLOGY, 5-OTOLARYNGOLOGY, 8 ORTHOPEDIC SURGERY, 19 OPHTHALMOLOGY, 6-M FDICINE, 254 NURSING, 11-Adolescent Med. 35 Dev. Med., 44 NEUROSURGERY, 3 Emergency Med, 26 Endocrinology, 21 GI/Nutrition, 33 General Pediatrics, 22

Figure 1: Distribution of 495 New Requests for Assistance

7

Genetics, 15 Hem/Onc, 17 Immunology, 11

Infectious Diseases, 8 Newborn Med, 6 Respiratory, 3 As in past years, the 331 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).

Number of Investigators Non Facility Hospital State No. Scientis, Resident Professor Resident Instructor.

Figure 2: Distribution of Rank of 331 Investigators requesting CRP services

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

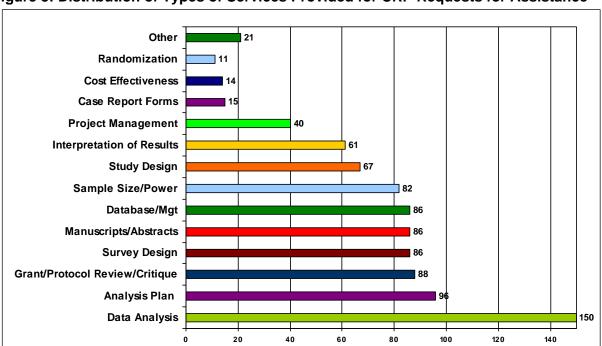


Figure 3: Distribution of Types of Services Provided for CRP Requests for Assistance

Assistance with grant applications and success in securing funding for research is central to the mission of the CRP (Figures 4 and 5). In 2010, the CRP assisted with 117 grant applications, with 101 of these being submitted to the funding agency, and of those submitted, 35 being funded (35% overall success rate). Among these, 56 applications were to federal agencies and 13 of them were funded (23% success rate). The total direct costs and indirect costs of these awards across all years to CHB were \$12,268,037 and \$5,868,025 respectively, with \$504,952 allocated to support CRP faculty and staff efforts on these projects.

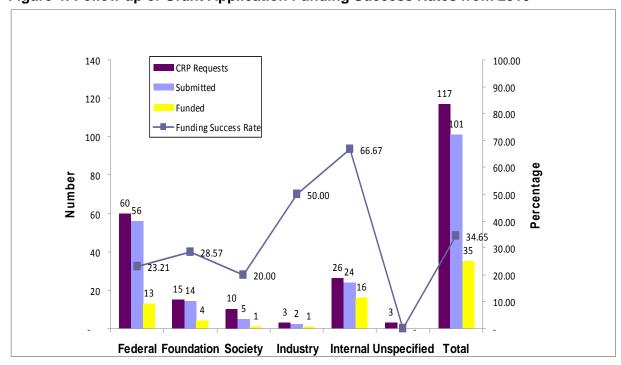
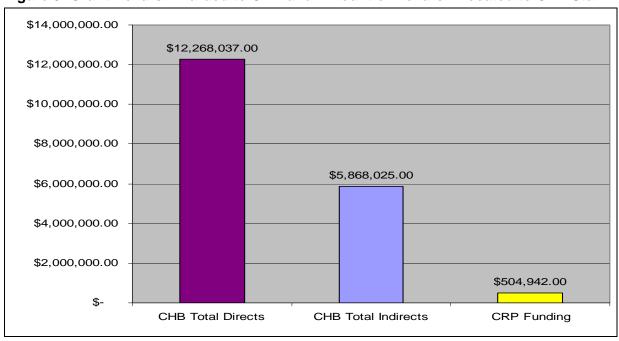


Figure 4: Follow up of Grant Application Funding Success Rates from 2010





#### **CRP User Feedback Survey**

Annually, we conduct a survey of CHB investigators and staff that have collaborated with the CRP, requested services, or participated in its courses to gather valuable feedback on the impact of our assistance and educational efforts (Table 1). Among the 175 respondents (26% of those surveyed), 62% worked with CRP faculty or staff on research projects, 46% attended an educational seminar or talk, and 24% had done both. About 60% were doctoral prepared scientists (MD, PhD, ScD) and 29% were study coordinators or research assistants. 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 CRP faculty and staff was knowledgeable, professional and responsive, and they were also highly likely to request assistance from the CRP again. These results were consistent across faculty rank and Core and reinforce the valuable contributions of the Program to the education, functional mentoring and collaborative assistance provided to the CHB clinical research community.

Table 1: Responses to CRP Survey

Statement	N	Mean (SD)	Median
The assistance I received from the CRP was valuable in terms of enhancing the <b>quality of the science and methods of my study</b> .	103	4.49(0.93)	5.0
After receiving assistance from the CRP, I feel more knowledgeable confident in <b>designing a research study</b> .	90	4.16(0.99)	4.0
After receiving assistance from the CRP, I feel more knowledgeable in <b>implementing a research study</b> .	86	4.14(1.00)	4.0
After receiving assistance from the CRP, I feel more knowledgeable in <b>reporting results from a research study</b> .	84	4.08(1.02)	4.0
The education I received was valuable in terms of enhancing the quality of the science and methods of my research.	79	4.13(0.85)	4.0
The education I received helped me to feel more knowledgeable in <b>designing research studies</b> .	74	4.04(0.93)	4.0
The education I received helped me to feel more knowledgeable in <b>implementing research studies</b> .	73	4.04(0.92)	4.0
The education I received helped me to feel more knowledgeable in reporting results of research studies.	63	3.95(0.94)	4.0
The faculty and staff of the CRP worked with me in a <b>responsive</b> and professional manner.	107	4.52(0.89)	5.0
The majority of the CRP staff with whom I interacted was <b>knowledgeable</b> about the services that I requested.	107	4.44(0.87)	5.0
I received assistance in a timely manner.	106	4.19 (1.01)	4.5
I am likely to request assistance from the CRP in the future.	106	4.65 (0.76)	5.0

<sup>\*1 =</sup>strongly disagree to 5 =strongly agree

#### **CRP CORE REPORTS**

#### **Biostatistics Core**



#### **Biostatistics Core Staffing**

Al Ozonoff, PhD, Director Robin Walker, MSW, Administrative Coordinator

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 Michael Monuteaux, ScD, Senior Biostatistician and Epidemiologist

Caterina Stamoulis, PhD, Senior Biostatistician

Peter Forbes, MA, Senior Biostatistician Paul Mitchell, MS, Senior Biostatistician Jing Zhou, MS, Biostatistician Courtney Walls, MPH, Biostatistician Janine Bacic, MS, Statistical Programmer Ying Feng, MS, Statistical Programmer

FY11 saw the arrival of **Dr. Stamoulis**, who joins CRP and the Departments of Radiology and Neurology, arrives from Beth Israel Deaconess Medical Center with a doctorate in acoustics and applied mathematics from the Massachusetts Institute of Technology. **Dr. Liu**, a faculty Bioinformatician with the Children's Hospital Informatics Program, began spending a portion of her time with the Biostatistics Core to strengthen CRP bioinformatics capabilities. CRP also saw two of its valued staff depart at the end of FY11. Statistical Programmer **Ms. Feng** and Biostatistician **Mrs. Bacic** will be missed by their friends and colleagues at CRP.

#### **Biostatistics Core Mission**

In support of the overall mission of the CRP, the mission of the Biostatistics Core is to furnish biostatistical expertise, methodological resources and scientific leadership, and to promote excellence in the design and conduct of clinical research.

#### **FY11 Highlight of Activities**

The Biostatistics Core 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.

FY11 was another successful and productive year for the Biostatistics Core. 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. Blood was awarded funds from the Aerosmith Foundation to continue her methodological research. The one-year project, titled "Analyzing the temporal relationships between affective states and condom non-use in depressed adolescents using structural equation modeling", has grown out of Dr. Blood's ongoing work with her colleague Dr. Lydia Shrier in the Division of Adolescent Medicine.
- Dr. Feldman began a new study with his longtime collaborator in the Department of Endocrinology Dr. Catherine Gordon to support a randomized trial comparing the effectiveness of two treatments for young women with anorexia nervosa. This work is funded by the National Institutes of Health and will continue for the next four years.
- Dr. Monuteaux presented results of his research; a collaboration with colleagues in Emergency Medicine Dr. Mark Newman and Division Chief Dr. Rich Bachur, at the American Academy of Physicians annual meeting. This work was later published in the prestigious journal *Pediatrics* under the title "Prediction of pneumonia in a pediatric emergency department".
- Dr. Stamoulis, in joint work with Dr. Rebecca Betensky at the Harvard School of Public Health, published an important methodological paper in the high-impact journal *Bioinformatics* titled "A novel signal processing approach for the detection of copy number variations in the human genome".

Biostatistics Core 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 CRP. The yearly *Introduction to Clinical Research*, a two-day overview for fellows and junior faculty, features seven hours of statistical material taught by three Core faculty (Drs. Feldman, Graham and Monuteaux). The introductory course generates demand for more advanced short courses, some of which are well established while others are in development. Dr. Jiang and Mr. Forbes teach *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 a more advanced course titled *Introduction to Regression*. Dr. Blood successfully introduced a new course, *Introduction to Longitudinal Analysis*, which focuses on the appropriate methods for studies that measure outcomes repeatedly over time. In addition to the CRP 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 FY11:

- Dr. Feldman served for his 14th year as faculty in the American Heart Association Ten-Day Seminar on Epidemiology and Prevention of Cardiovascular Diseases, a postdoctoral training course for preventive cardiology and related professions of which several CHB faculty are graduates.
- Dr. Feldman also participated in the inaugural offering of a weekly year-long Harvardwide course titled "Harvard Catalyst Certificate in Biostatistics", where he contributed eight lectures on topics related to study design, grant and protocol development, and presentation of manuscript results.
- Under the continued leadership of Dr. Graham, the faculty of the Biostatistics Core
  provided its fifth 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.
- CRP faculty members presented methodological seminars to the Health Services Fellowship throughout the year: "Hierarchical Modeling" (Dr. Gregas); "Using Propensity Scores to Adjust for Bias in Observational Studies", "Tips and Tricks in SAS", and "Using the KID and PHIS Databases" (Dr. Graham).

An important organizing principle of CRP is the integration of its faculty with CHB Departments and Divisions, which provide academic appointments and/or funding, so as to foster creative research collaborations between department-based investigators and CRP-based biostatisticians. All of the Core masters-level statisticians are also funded by CHB 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 biostatistician 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. Gregas, Instructor, Departments of Neurology and Developmental Medicine
- Dr. Huang, Department of Urology
- Dr. Jiang, Instructor, Division of Gastroenterology and Nutrition
- Dr. Kalish, Associate Professor, Division of Hematology/Oncology and Department of Orthopedics
- Dr. Monuteaux, Assistant Professor, Division of Emergency Medicine
- Dr. Stamoulis, Assistant Professor, Department of Radiology and Department of Orthopedics
- Mrs. Bacic, Departments of Neurology and Developmental Medicine
- Mr. Forbes, Department of Psychiatry
- Mr. Mitchell, Division of Gastroenterology and Nutrition
- Ms. Walls, Division of Adolescent and Young Adult Medicine
- Ms. Zhou, Department of Cardiology and Program for Patient Safety and Quality





#### **PDMC Staffing**

Adam C Simmons, MPH, CCRC, Manager Harold T. Thurston, Jr., MA, MAT, Administrative Coordinator

Lucy Abernethy, BA, Clinical Research Coordinator
Ed Anderson, BA, CCRP, Clinical Research Coordinator
John A Andrea, BS, Clinical Research Coordinator
Tracy Antonelli, MPH, Clinical Research Study Manager
Julie Barenholtz, MSW, Research Data Manager
Mark Berry, MS, MA, CCRC, Senior Clinical Research Specialist
Qiaoli (Lily) Chen, MS, CCDM, Senior Research Data Manager
Rajna Filip-Dhima, MS, Clinical Research Specialist
Audrey Gill, BA, Clinical Research Coordinator
Jisun Jang, MA, Statistical Programmer
Prajakta Mangeshkar, MSc, MS, Senior Clinical Research Specialist
Jessica Oribabor, MS, Clinical Research Coordinator
Elizabeth Paulsen, BS, Clinical Research Specialist
Emily Webster, BA, Clinical Research Coordinator

The Core welcomed the hires of Prajakta Mangeshkar, MSc, MS as a joint hire with the *Division of Developmental Medicine*, Ed Anderson, BA with the *Rheumatology Program*, John Andrea, BS with the *Division of Emergency Medicine*, Audrey Gill, BA and Jessica Oribabor, BS with the support of *Harvard Catalyst* and Jisun Jang, MS. In addition Mark Berry, MS, CCRC accepted a position as senior clinical research specialist as a joint hire with the *Division of Emergency Medicine*.

#### **PDMC Mission**

In support of the overall mission of the CRP, the mission of the Project and Data Management Core is to provide leadership and guidance in clinical research practice, data management and data integrity for CHB clinical investigators.

#### **FY11 Core Highlights**

The project and data management core had a busy and successful year. The PDMC supported project management for a number of NIH, foundation and industry sponsored trials including a multicenter drug trials, *A Double Blind Phase II Trial of a mTOR inhibitor in neurocognition in individuals with tuberous sclerosis complex with* Mustafa Sahin of the Department of Neurology and Pharmacological *Treatment of Rett Syndrome by Stimulation of Synaptic Maturation with IGF-1* with Omar Khwaja also from the Department of Neurology. The PDMC also supported project management of research projects coordinated by the *New Balance Foundation Obesity Prevention Center*.

As in years past, the PDMC offered coordinator staffing to support the Harvard Catalyst Clinical Research Center. In 2011, the PDMC supported nine different investigators across clinical departments including Cardiology, Medicine and Patient Services. This year marked the successful completion of projects by Margaret McCabe and Sallie Permar with Dr. Permar's study being published in the Journal of Infectious Diseases with contributions from co-author and CRP study coordinators, Emily Webster. (Ehlinger EP, Webster EM, Kang HH, Cangialose A, Simmons AC, Barbas KH, Burchett SK, Gregory ML, Puopolo KP, Permar SR. Maternal cytomegalovirus-specific immune responses and symptomatic postnatal cytomegalovirus transmission in very low-birth-weight preterm infants. J Infect Dis. 2011 Dec;204(11):1672-82)

PDMC staff also play significant leadership roles and participate in CRP educational offerings including the *Orientation for Study Coordinators*. Sarah Steltz and Prajakta Mangeshkar both served as course directors and presenters this year for the bi-monthly orientation available to all new CHB clinical research staff. PDMC staff lead sessions during the orientation in *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* as well as presenting that same talk for the *Harvard Catalyst Introduction to Clinical Investigation*.

As part of our initiative to provide high quality clinical research support and promote best practices, all senior PDMC Core staff are pursuing certification by a professional clinical research society. This past year Mark Berry was Certified as a Certified Clinical Research Coordinator (CCRC) by the Academy of Clinical Research Professionals (ACRP), Ed Anderson was certified as a Certified Clinical Research Professional (CCRP) by the Society of Clinical Research Associates (SoCRA) and Lily Chen was certified as Certified Clinical Data Manager (CCDM) by the Society for Clinical Data Management (SCDM).

In addition to supporting REDCap™, Inform™ (22 InForm studies were put into production) and IBM® Data Collection Author databases and web surveys, the PDMC, in collaboration with *Clinical Research Informatics* and Biostatistics core worked to develop common libraries and data standards using *CDISC standards*. The PDMC also worked to develop new brochures and training materials for educating investigators on best-fitted technologies for their research and quality improvement projects. These helpful materials can be found on our website.

PDMC staff served on a number of committees in the Children's Hospital and Harvard community. Sarah Steltz and Rajna-Filip Dhima serve on the *Harvard Catalyst Data Protection Sub-Committee*, a committee that looks at how electronic research data is protected across Catalyst institutions. Tracy Antonelli continues to serve at the CRP representative to the *Children's Committee on Clinical Investigation*, and for the third year Sarah Steltz and Adam Simmons have served as voting members on the Beth Israel *Committee on Clinical Investigation*.

#### **Education Core**



## Education Core Staffing Jenifer Lightdale, MD, MPH, Director Stacey Springs, Education Coordinator Chau Tran, Education Coordinator

In 2011, the Education Core underwent a staff change, introducing **Chau Tran**, MA, MPH as the new Education Program Coordinator, replacing valued staff member, Ms. Stacey Springs. We wish to thank **Ms. Springs** for her important contributions to the successful planning and implementation of the many seminars and workshops sponsored by the Core.

#### **Education Core 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 Children's Hospital Boston.

#### **FY11 Core Highlights**

The Education Core continues to deliver a range of services to the Children's Hospital Boston 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 Children's Hospital
- Serving on hospital and university research education-related committees; and
- Developing Web-accessible best practices and educational tools for researchers.

Under the direction of Dr. Jenifer Lightdale, the Education Core has consistently provided considerable educational opportunities for CHB staff and faculty involved in clinical research. Core achievements over the past year include the expansion and integration the Core's use of online registration and evaluation systems, as well as the development of a new internally accessible online repository for course materials.

Total CRC course enrollment from 2006 to 2011 continues to expand annually reflecting 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 2011, we introduced the advanced biostatistics course; Introduction to Longitudinal Analysis and helped launch the Program for Research Assistant Development and Achievement (PRADA), a new informal biweekly program for research assistant and study coordinator career development, centered on promoting professional skills and collaboration. Additionally, we have been successful in repeating many courses introduced in recent years, including Introduction to Regression and Focus Groups in Clinical Research. Finally, as part of a multi-disciplinary effort, the Education Core co-sponsored a second rendition of a seminar series with Brigham and Women's Hospital, entitled The Art and Anatomy of Writing a Career Development Grant. With these new staff changes, the Education Core plans on expanding our infrastructure and programs for the fiscal year of 2012. In the coming year, we also plan on 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. Agendas for our longstanding and regularly featured Introduction to Clinical Research and Orientation for Study Coordinators sessions are shown in the Appendix.

Table 1. CRP Course Attendance by 2004-2011

CRP Course Registration							
CRP Course	2005	2006	2007	2008	2009	2010	2011
Introduction to Clinical Research	103	100	108	133	128	84	86
Orientation for New Study Coordinators	69	60	73	113	109	111	103
Coordinator Rounds		75	120	138	159	157	74
Introduction to Biostatistics with SPSS		62	79	106	105	81	62
Do-It-Yourself Data Management			5	20	21	11	
Introduction to Statistical Genetics				25	16	18	
Art and Anatomy of Writing a Career Development Grant				138	150		188
Introduction to Regression Analysis					18	25	38
Survey and Measurement Research Education					16	20	43
Survey & Questionnaire Design						32	25
Introduction to Longitudinal Analysis							41
Beyond Chi-Squares: Drawing Inferences from Tables				22			
Statistics for Small Sample Size Studies				23			
Qualitative Research in Clinical Investigation					16	35	
Passport Series for Clinical and Translational Researchers						121	

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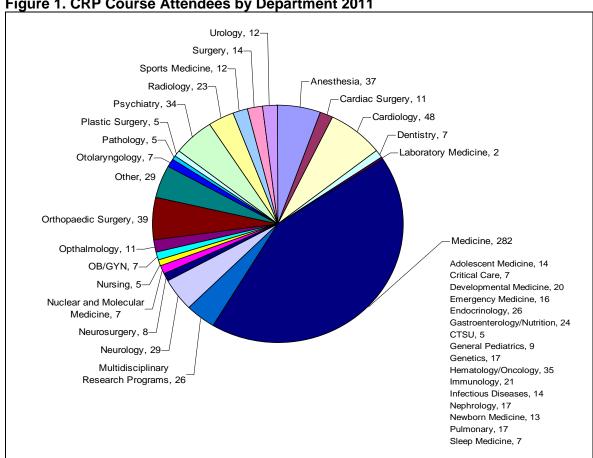


Figure 1. CRP Course Attendees by Department 2011

Table 2. CRP Course Listings 2004-2011

CRP Courses Offered	2004	2005	2006	2007	2008	2009	2010	2011
Introduction to Clinical Research	***	***	***	***	***	***	***	***
Orientation for New Study Coordinators	***	***	***	***	***	***	***	***
Coordinator Rounds	***	***	***	***	***	***	***	***
Introduction to Biostatistics with SPSS			***	***	***	***	***	***
Do-It-Yourself Data Management				***	***	***	***	
Introduction to Statistical Genetics					***	***	***	
Art and Anatomy of Writing a Career Development Grant						***		***
Introduction to Regression Analysis						***	***	***
Survey and Measurement Research Education						***	***	***
Survey & Questionnaire Design							***	***
Program for Research Assistant Development and Achievement							***	***
Introduction to Longitudinal Analysis								***
Beyond Chi-Squares: Drawing Inferences from Tables					***			
Statistics for Small Sample Size Studies					***			
Qualitative Research in Clinical Investigation							***	
Passport Series for Clinical and Translational Researchers							***	
cou	rse offere	ed ***	·					



#### **Survey and Measurement Core Staffing**

Stavroula Osganian, MD, ScD (acting director) Harold Thurston, Administrative Coordinator

Yolanda Martins, PhD, senior survey methodologist Sonja Ziniel, PhD, senior survey methodologist Mihail Samnaliev, PhD, Health Economist Kelly Burmeister, MS, survey methodologist

The Survey and Measurement Core welcomed Kelly Burmeister, survey methodologist who joined the Clinical Research Center in May 2011, after completing her master's degree at the University of Michigan. Kelly replaced valued staff member, Ms. Handan Titz in FY11, who departed to pursue doctoral studies at Columbia University. We wish to thank **Ms. Titz** for her important contributions to the successful design and implementation of the many survey projects administered by the Core.

#### **Survey and Measurement Core Mission**

In support of the overall mission of the CRP, the mission of the Survey and Measurement Core is to promote excellence at CHB in the design, implementation and analysis of surveys in clinical research through the provision of methodological expertise and leadership, educational offerings, and links to additional resources.

#### **FY11 Highlights**

During the past year, the Survey and Measurement Core contributed to numerous research and health economics investigations. Some key contributions are as follows:

- Dr. Yolanda Martins, with support from Ms. Titz and Ms. Burmeister collaborated with Dr. Joanne Cox and her team to develop the methodology, interview guide and coding scheme for a study comparing teenage mothers who experience another pregnancy within a year of the birth of their first child and those who do not. The goal of this study is to explore the personal, social and environmental factors that impact the motivations and planning for another child. Dr. Martins also consulted on the design of the methodology and survey instrument for Dr. Izabela Gasior's study, which focused on understanding why some parents consent to clinical research while others do not. Working with Dr. John Meara, they developed the methodology and collected data that allowed them to assess the time involved in each stop of the cleft palate repair process among the Main and Waltham campuses.
- Health economist Mihail Samnaliev, PhD collaborated with Office of Child Advocacy's Deborah Dickerson, Urmi Bhaumik and Shari Nethersole, MD to conduct a cost-effectiveness analysis of 'Fitness in the City', a community based program, aimed at reducing childhood obesity. The research team developed an economic model to estimate the lifetime medical cost savings, the increase in quality of life and in life expectancy associated with decreased obesity. From a methodological perspective, this study was an example of how internal data can be combined with external datasets from the Centers of Disease Control and Prevention, the Agency of Healthcare Research and Quality and published research—to develop useful economic evaluations.
- Dr. Sonja Ziniel collaborated with Dr. Ingrid Holm on her NIH funded grant that aimed to measure parents' attitudes and opinions about their participation in DNA research banks. Information gathered from this survey will inform researcher and clinicians on how willing patients would be to provide their DNA for research purposes and how they would feel with regard to getting research results back. Dr. Sonja Ziniel also collaborated with Dr. Elizabeth Blume as survey methodologist and statistician on a project eliciting parental perspectives on end of life care in children with advanced heart disease. In her role as survey methodologist for PPSQ, Dr. Ziniel led a national validation of the Pediatric Inpatient Experience Survey that she developed and validated at CHB with colleagues.

As in previous years, the Core was active in teaching CHB faculty and staff in the *Introduction into Clinical Research Course as* well as various workshop series. Dr. Ziniel offered workshops on how to conduct focus groups and qualitative research methods. Dr. Ziniel also presented two lectures on Designing Surveys and Questionnaires and Evaluating Measures in Clinical Research and Dr. Samnaliev presented a lecture on Cost Effectiveness Analyses *in the Introduction into Clinical Research Course*. The Core also developed a Grand Round Series on Survey and Economic Measurement that will be offered in the next year.

In addition to lectures and presentations, the Core staff has developed several teaching and educational materials that are available to investigators on the CRP website. Some of these helpful tools include best practices on How to Design a Survey and a compilation of information on "best available measures" to assess various self-reported psychosocial and behavioral factors in children and adolescents.

Finally, because of her interest in increasing researcher's access to assistance, Kelly has piloted **walk-in consulting hours** in the main hospital for brief, accessible survey design consultations. These hours are posted on our website and on the hospital's television systems.

The Survey and Measurement Core faculty also have appointments in the various CHB Departments and Divisions in order to foster research collaborations with investigators and support CRP faculty's scholarly activities and academic advancement.

- Yolanda Martins, PhD, Instructor, Division of General Pediatrics
- Sonja Ziniel, PhD, Instructor, Division of Adolescent and Young Adult Medicine
- Mihail Samnaliev, PhD, Instructor, Division of General Pediatrics

#### **APPENDIX**

#### **Staff Publications**

#### 2011 Published

- 1. Aarabi S, Sidhwa F, Riehle KJ, **Chen Q**, Mooney DP. Pediatric appendicitis in New England: epidemiology and outcomes. J Pediatr Surg. 2011 Jun;46(6):1106-1114.
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#### **Course Agendas**

#### INTRODUCTION TO CLINICAL RESEARCH FALL 2011 COURSE AGENDA

AM	Day One: Tuesday, September 13, 2011	
7:45-8:00	Registration & Check-in	
8:00-8:15	Introduction and Overview	J. Lightdale
8:15-9:15	Statistics in Clinical Research: An Overview	H. Feldman
9:15-9:25	Break	
9:25 - 10:10	Designing Surveys and Questionnaires	S. Ziniel
10:10-10:20	Break	
10:20-11:05	Evaluating Measures in Clinical Research	S. Ziniel
11:05-11:15	Break	
11:15-12:00	Introduction to Cost Effectiveness Analysis	M. Samnaliev
12:00-12:45	Lunch	
12:00-12:45 PM	Lunch Day One: Tuesday, September 13, 2011	
12.00	Landi	E. Neufeld
РМ	Day One: Tuesday, September 13, 2011	E. Neufeld
PM 12:45-1:30	Day One: Tuesday, September 13, 2011  Clinical Trials: Design and Monitoring	E. Neufeld  M. Wladkowski
PM 12:45-1:30 1:30 - 1:40	Day One: Tuesday, September 13, 2011  Clinical Trials: Design and Monitoring  Break  10 Questions Every Investigator Should Ask Before doing a	
PM 12:45-1:30 1:30 - 1:40 1:40 - 2:10	Day One: Tuesday, September 13, 2011  Clinical Trials: Design and Monitoring  Break  10 Questions Every Investigator Should Ask Before doing a Study with Drugs, Devices or Biologics	
PM 12:45-1:30 1:30 - 1:40 1:40 - 2:10 2:10-2:20	Day One: Tuesday, September 13, 2011  Clinical Trials: Design and Monitoring  Break  10 Questions Every Investigator Should Ask Before doing a Study with Drugs, Devices or Biologics  Break	M. Wladkowski
PM  12:45-1:30  1:30 - 1:40  1:40 - 2:10  2:10-2:20  2:20-3:05	Day One: Tuesday, September 13, 2011  Clinical Trials: Design and Monitoring  Break  10 Questions Every Investigator Should Ask Before doing a Study with Drugs, Devices or Biologics  Break  Industry and Philanthropy	M. Wladkowski
PM  12:45-1:30  1:30 - 1:40  1:40 - 2:10  2:10-2:20  2:20-3:05  3:05-3:15	Day One: Tuesday, September 13, 2011  Clinical Trials: Design and Monitoring  Break  10 Questions Every Investigator Should Ask Before doing a Study with Drugs, Devices or Biologics  Break  Industry and Philanthropy  Break	M. Wladkowski S. Nurko





#### INTRODUCTION TO CLINICAL RESEARCH FALL 2011 COURSE AGENDA

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AM	Day Two: Friday, September 16, 2011	
7:45-8:00	Arrival/ Check In	
8:00-9:00	Observational Study Designs	M. Monuteaux
9:00-9:05	Break	
9:05-10:20	Descriptive and Univariate Statistics	D. Graham
10:20-10:25	Break	
10:25- 11:25	Collecting and Managing Clinical Research Data	A. Simmons
11:25-11:55	Common Study Documentation Errors & Best Practices	E. Newbert
11:55-12:35	Lunch	
PM	Day Two: Friday, September 16, 2011	
12:35-1:30	Introduction to Regression Analysis	H. Feldman
1:30-1:35	Break	
1:35 - 2:20	Human Subjects and the Institutional Review Board	S. Kornetsky
2:20-2:50	The IRB Review Process: An Insider's View	L. Shrier
2:50-3:00	Break	
3:00 - 3:45	Ethics and Integrity in Clinical Research	S. Joffe
3:45-4:30	Scientific Presentations	J. Finkelstein
4:30-4:35	Break	
4:35-4:40	Wrap-Up	J. Lightdale
4:40-5:25	Overview of Clinical Research at Children's Hospital	V. Osganian





### ORIENTATION FOR NEW STUDY COORDINATORS COURSE AGENDA

9:00 - 9:15	Welcome and Overview	S. Steltz
9:15 - 9:35	Role of the Study Coordinators	S. Stell2
9:35 – 9:55	Human Subject Protections IRB Issues: Before the Research Begins	M. Stafford & R. Dominguez
9:55 – 10:20	IRB Issues: During the Research	
10:20 - 10:30	Break	
10:30 – 11:15	Informed Consent/Assent/Subject Recruitment	M. Stafford & R. Dominguez
11:15 - 11:30	Break	
11:30 – 12:15	Obtaining Informed Consent/Assent: A Practical Approach	M. Berry
12:15 – 12:45	Catered Lunch	
12:45 - 1:40	Introduction to the Education & Quality Improvement Program (EQuIP)	M. Sueiro & E. Newbert
	Study Documentation: Common Errors	
	Methods of Organizing Study Documents	
	Storage of Study Documents and Informed Consent Documents	
1:40 – 1:45	Break	
1:45 – 1:55	Introduction to the Clinical Trials Office	A. Hannibal
1:55-2:45	Introduction to the Clinical Research Program (CRP)	
	Study Implementation & Timeline Development	4.61
	Principles of Data Management	A. Simmons
	Case Report Forms & Manual of Operations	
2:45 - 3:00	Wrap-Up & Review	S. Steltz



