2010
Annual Report
of the
Clinical Research Program

Stavroula Osganian, MD, ScD, MPH
Program Director

An interdisciplinary program fostering excellence in clinical research at Children’s Hospital Boston
From the Program Director

The Clinical Research Program (CRP) at Children's Hospital Boston is pleased to share its Annual Report for fiscal year 2010.

As an institutional, academic and service research program, we continue to 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 (including biostatistics, epidemiology, survey methods, and cost effectiveness methods);
- collaboration and consultation on the design, conduct, and analysis of clinical research studies; and
- education on clinical 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 the highest standards of quality and scientific rigor.

As the CRP grows, we continue to forge partnerships and collaborative relationships with Departments and Programs throughout the Hospital and Harvard-wide as well. We have been active contributors to several inter-departmental and institutional projects, working with the Physician’s Organization (PO), Program for Patient Safety and Quality (PPSQ), Clinical and Translational Study Unit (CTSU), Harvard Catalyst, Translational Research Program (TRP), and Research Administration. We also strive to be responsive to the needs and priorities of our institutional leaders and investigators and have spent the past year developing a strategic plan that incorporates valuable feedback from our stakeholders.

Our key accomplishments and activities for FY2010 include:

- Support or consultation on 449 new investigator requests for assistance from 297 researchers in the institution representing an increase of 25% from FY2009.
- Successful collaborations with several CHB investigators and other institutional programs on 75 funded projects and maintenance of significant extramural funding totaling approximately $0.73 million.
- 58 peer reviewed collaborative publications that were co-authored by CRP staff.
- Increases in joint faculty recruits with Departments and Divisions with a corresponding 30% increase in department funding of CRP faculty and staff.
- Newly available, pilot project funding, with a total of $838,112 awarded to 10 CHB investigators over 2 years to support innovative clinical research projects.
- Participation of CRP faculty on key institutional initiatives to promote health care quality and efficiency, including developing an overarching evaluation of the Provider Payer Quality Initiative (PPQI) and the development of a Pediatric Inpatient Experience Survey, which has received national recognition from the National Quality Forum.
- Growth in clinical research education, with 4 new course offerings from the Clinical Research Education Core drawing 141 attendees.
- Growing demand for study coordinators resulting in departmental partnerships with the PDMC Core of the CRP and with the CTSU to recruit, supervise and manage Clinical Research Coordinators (CRCs).
- Support for new, user friendly and robust software tools to more effectively and efficiently collect and store research data, including REDCap and SPSS Data Collection Author.
- Support for new and innovative clinical research informatics tools that will allow researchers to query data in our hospital’s clinical databases and a Clinical Research Coordination System which allows for tracking of study participants.
- Growth in Program faculty and staff, and with the successful recruitment of Dr. Al Ozonoff from the Boston University School of Public Health, new leadership for the Biostatistics Core of the CRP.
- New leadership for the CRP-affiliated Clinical Research Informatics Core with the recruitment of Dr. Jonathan Bickel from the Children’s Hospital of Pittsburgh.

Finally, as the 2010 fiscal year closes, we would like to recognize the support from our collaborators, and we take pride in the collaborative relationships we have established with our colleagues and the work that we have accomplished together. We look forward to another productive year and the opportunity to meet the challenges and needs of the CHB investigator community.

Regards,

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

Acknowledgement: 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.
Leadership and Administration

Jonathan H. Dinsmore, PhD
Associate Director of the CRP

Al Ozonoff, PhD
Director, Biostatistics Core

Jenifer Lightdale, MD, MPH
Director, Education Core

Adam C. Simmons, MPH
Acting Manager, Project & Data Mgmt Core

Jonathan Bickel, MD, MS
Director of Clinical Research Informatics

Sion Kim-Harris, PhD
Director, Survey and Measurement 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 major 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. These Cores work independently as well as in teams to achieve the mission and goals of the Program. In FY2010, the CRP included 38 full-time, and 8 affiliated or part-time faculty and 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 substantial institutional commitment to the Program, which has facilitated its growth and visibility. Institutional support for the Clinical Research Program (CRP) in 2010 totaled $2.419 million. Equally important has been the substantial commitment and funding from departments (totaling $930,484) that support faculty with joint appointments ($884,280 for faculty) and work on specific research projects ($46,204 for projects).

**Table 1: CRP Funding Sources and Expenses in FY10**

<table>
<thead>
<tr>
<th>Source</th>
<th>Budget</th>
<th>Expenses</th>
<th>Unexpended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional****</td>
<td>$2,419,058</td>
<td>$1,845,449</td>
<td>$573,609*</td>
</tr>
<tr>
<td>Departmental (Total)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faculty ($884,280)</td>
<td>$930,484</td>
<td>$930,484</td>
<td>-</td>
</tr>
<tr>
<td>Projects ($46,204)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CGRE</td>
<td>$132,311</td>
<td>$132,311</td>
<td>-</td>
</tr>
<tr>
<td>Extramural**</td>
<td>$729,100</td>
<td>$729,100</td>
<td>-</td>
</tr>
<tr>
<td>Intramural***</td>
<td>$94,588</td>
<td>$94,588</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>$4,305,541</td>
<td>$3,731,932</td>
<td>$573,609*</td>
</tr>
</tbody>
</table>

*Total unexpended institutional funds include position vacancies and recovery from staff charge backs to grants or other funds.
**Catalyst provided $237,841 from extramural funds from NIH for CRP consultations
***Catalyst provided $23,897 from intramural funds from NIH for CRP consultations
****$115,000 returned to hospital for CIMIT initiative

During FY2010, the CRP supported 743 new and ongoing projects and requests for assistance. The majority of these activities (n=668) were not extramurally funded and were hospital, departmental or Catalyst supported consultations. Seventy five of the requests were investigator funded projects and provided a total of $632,051 to fund CRP faculty and staff, with $333,499 funding the Biostatistics Core, $142,691 funding the PDMC Core, $124,972 funding the Survey Core and $9,352 funding the CRIT (Clinical Research Informatics Team).

Table 2 and Figure 1 present the distribution of funding sources for the 75 investigator supported projects. NIH was the primary source of funding for these projects (49%), followed by funding from foundations or associations (19%). Among the NIH funded projects: 12 were funded through R01’s, 3 through K awards, 5 through R21s, and 9 through other funding mechanisms (e.g. U01, H34, P30, and R56). Further, 15 of the 75 funded projects were from collaborations with researchers from the Department of Medicine/Division of GI and Nutrition; 6 from the Department of Medicine/Adolescent Medicine Division; 7 from the Department of Medicine/Endocrine Division; The remainder was from various other departments and divisions in the Hospital including Anesthesiology (7), Hematology/Oncology (7), Developmental Medicine (4), Surgery (3), General Pediatrics (3), Neurology (3), Psychiatry (2), Emergency Medicine (2), Dentistry (2), Cardiology (2), Nephrology (1), Respiratory Medicine (1), Genetics (1), Infectious Disease (1), Pathology (1), Radiology (1) and Nursing (1). CRP faculty were Principal Investigators on 5 of the 75 projects.
Table 2: Sources of Support for 75 Investigator Funded Projects

<table>
<thead>
<tr>
<th>Source</th>
<th>Number</th>
<th>Dollars</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>29</td>
<td>$312,556</td>
<td>49%</td>
</tr>
<tr>
<td>Other Federal</td>
<td>2</td>
<td>$50,293</td>
<td>8%</td>
</tr>
<tr>
<td>Foundation/Association</td>
<td>14</td>
<td>$119,065</td>
<td>19%</td>
</tr>
<tr>
<td>Industry</td>
<td>3</td>
<td>$9,345</td>
<td>2%</td>
</tr>
<tr>
<td>Department</td>
<td>11</td>
<td>$46,204</td>
<td>7%</td>
</tr>
<tr>
<td>Catalyst</td>
<td>4</td>
<td>$45,725</td>
<td>7%</td>
</tr>
<tr>
<td>Internal Awards</td>
<td>12</td>
<td>$48,863</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>75</strong></td>
<td><strong>$632,051</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

*Billings to funds for services totaled $41,623. The remainder was charged as salary support on funds

Figure 1: Sources of Support for 75 Investigator Funded Projects*

*Some projects have multiple funding sources
Utilization of Services

The Clinical Research Program (CRP) provides a range of services (see Appendix E) to assist investigators in the design, conduct, and analysis of their clinical research studies. Through institutional funding for the Program, limited support is provided for guidance to investigators with unfunded studies while greater assistance and involvement on projects is provided for collaborative relationships with investigators on funded projects.

New Requests for Assistance in FY2010

During FY2010, the CRP received 449 new requests for assistance from 297 Children’s Hospital faculty or staff. Overall, this was a 25% increase over the total number of requests received in FY2009. The distribution of requests according to hospital department is shown in Figure 2. The majority of requests were from investigators with appointments in Medicine (n=237) and within the Divisions of Emergency Medicine (34) and GI/Nutrition (n=31), followed by the Departments of Psychiatry (37) and Cardiology (31).

As shown in Figure 3, among the 297 investigators requesting assistance, they were more likely to be at the rank of Instructor (n=73) followed by Assistant Professor (n=48) or Fellow (n=48), Associate Professor (n=33) and Professor (n=19). The Program also provides assistance to a substantial number of non-faculty hospital staff (n=44) engaged in research, as well as residents (n=16) and nurse scientists (n=16).
In FY2010, the CRP received requests for consultation or assistance distributed across the various areas shown in Figure 4. Among the 976 tasks or activities, the majority were for consultation or collaboration on statistical analysis (n=178), power and sample size determination (n=110), development of a statistical analysis plan (n=119), study design (n=67), interpretation of results (n=87), manuscript/presentations (n=86), database development and management (n=73) and survey questionnaire and design (n=39).

Figure 4: Types of Support Provided to Investigators (n=976 tasks)
As shown in Table 3, among the 449 requests for CRP assistance in 2010, 118 (26%) were for assistance with the development of grant applications. Among these 118 applications, the majority were applying to NIH (n=49) or to foundations/associations (n=27). In 2009, CRP assisted with 104 grant application submissions. Follow-up on these 104 grant applications from FY2009 showed that 96 were submitted to the funding agencies, as intended and 20 of those submitted were successfully funded (21% success rate). Among these 96 submissions, 18 applications were in response to the Federal Stimulus Funding to NIH. Among these 18 applications, 4 of them were funded (22% success rate). The total direct costs and indirect costs of these awards to the institution were $7,604,203 and $4,383,987, respectively. These grants allocated $480,370 in funding for the salaries of CRP faculty and staff.

**Table 3: Assistance with Grant Applications**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Number in FY09</th>
<th>Number in FY10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>61</td>
<td>49</td>
</tr>
<tr>
<td>Other Federal</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Foundation/Association</td>
<td>23</td>
<td>27</td>
</tr>
<tr>
<td>Industry</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Philanthropy</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Internal</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Society</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>104</td>
<td>118*</td>
</tr>
</tbody>
</table>

*6 requests are applying to more than one funding source

**Strategic Planning Survey: Your Feedback**

During the past year, the CRP leadership embarked on a strategic planning effort to better understand the priorities and needs of our stakeholders and to incorporate their valuable feedback in our future planning efforts. A web based survey (see Appendix F) was mailed to 53 Institutional Leaders (Chairs/Chiefs/Program Directors) and to 67 Investigators who conduct clinical research. Fourteen leaders responded from the Departments of Cardiology, Medicine, Neurology, Psychiatry and Surgery, CTSA, CTSU, and PPSQ). Among the 41 investigators who responded, 20% were Instructors, 33% were Assistant Professors, 38% were Associate Professors, 3% were full Professors and 8% had no faculty appointment. In addition, 79% were Physician Scientists, 5% were Research Associates and 3% were Psychologists. Mean responses to specific questions by leaders and investigators were as follows:

**Table 4: Responses to importance of CRP services**

<table>
<thead>
<tr>
<th>How important or helpful are each of the following on a scale of 1 to 7 where 1= Not At All and 7=Very</th>
<th>Leaders Mean (SD)</th>
<th>Investigators Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How important are the current CRP services for supporting the successful execution and quality of your clinical research (if investigator) or clinical research in your Dept/Div/Program (if leader)?</td>
<td>5.8 (1.5)</td>
<td>5.4 (1.7)</td>
</tr>
<tr>
<td>How important are the current CRP services in fostering clinical research in the institution?</td>
<td>6.2 (1.5)</td>
<td>5.7 (1.3)</td>
</tr>
<tr>
<td>How helpful do you feel CRP educational activities are in promoting the design and conduct of high quality clinical research?</td>
<td>5.8 (1.4)</td>
<td>5.3 (1.4)</td>
</tr>
</tbody>
</table>
Common themes and key suggestions that emerged from responses to open ended and closed ended questions included the following:

- The CRP was felt to be highly valued and to promote quality in clinical research.
- There was an expressed need for more methodological and technical advising and education.
- The current CRP collaborative model with joint faculty appointments in Departments and Divisions was favored and felt to be working well.
- The challenging funding climate and in particular, the need to support junior faculty identified a need and interest for more hospital-supported work and more opportunities for brief and informal design and analysis consultations.
- Education and brief consulting/advising were more commonly ranked as important for all levels of investigators; whereas, collaboration on research projects was more often favored as important for senior to mid level investigators.
- Growth in more senior faculty in the Program was identified as important.
- There was an interest in having greater CRP faculty and staff participation in investigator research meetings.
- There was an interest in having regular CRP presentations at Division and Department meetings to increase awareness of the CRP and its offerings.
- Suggested strategic areas of growth within the CRP included support for basic science, genomics, statistical genetics, developmental testing, community research, and consortium or multisite studies.

The CRP sincerely thanks those who participated in our survey. We look forward to incorporating many of these suggestions in our longer term strategic initiatives and in next year’s goals and objectives!
Featured Program Activities and Collaborations

Clinical Research Program Grant Funding

In 2009, the Clinical Research Program was very pleased to announce the availability of intramural funds to support clinical research projects at Children’s Hospital Boston through funds made available by the Clinical and Translational Research Executive Committee. The purpose of this funding initiative was to foster and support innovative clinical research at CHB that is consistent with and supports the mission of the Hospital to enhance the health and well-being of children and families. The funding opportunity provided up to two years of support and up to $100,000 in total direct costs. In response to the RFA, thirty-nine letters of intent were submitted by CHB faculty and were reviewed by a multidisciplinary committee of 12 senior scientists at CHB. Twenty-one faculty were invited to submit full applications, which were peer-reviewed in January 2010. Ten talented and deserving recipients were eventually selected for funding and were awarded up to $100,000 each for two years to launch innovative pilot studies with potential to improve treatments and or develop other interventions. The CRP looks forward to another call for applications in the coming year.

Congratulations to the Recipients of 2010 Clinical Research Grants

David Bickham, Research Scientist, Center on Media and Child Health (Children's) and Instructor of Pediatrics (Harvard Medical School), “The Impact of Advergames on Food Choice: Implications for Obesity and Nutrition Interventions.”

Katrina Boyer, Assistant in Neurology (Children's) and Instructor (HMS), “Does Interictal Epileptiform Activity Predict Cognitive and Behavioral Deficits in Benign Childhood Epilepsy with Centro-Temporal Spikes (BCECTS)?”

Jessica Lee, Attending Physician in Pediatric Gastroenterology (Children’s) and Instructor of Pediatrics (HMS), “Gene expression profiling of new-onset pediatric Crohn's disease.”

Nilesh Mehta, Assistant in Critical Care Medicine (Children’s) and Instructor in Anaesthesia (HMS), “Examining and challenging current paradigms in the management of ventilator assisted pneumonia.”

Wanda Phipatanakul, Assistant in Medicine (Children’s) and Assistant Professor of Pediatrics (HMS), “Traffic and Air Pollution in Community Urban Schools and Childhood Asthma (TAPCUS).”

Adrienne Randolph, Senior Associate in Critical Care (Children's) and Associate Professor of Anaesthesia (HMS), “Vitamin D deficiency in critically ill children.”

Erinn Rhodes, Director of the Type 2 Diabetes Program and of Endocrinology Healthcare Research and Quality and Assistant in Medicine (Children's) and Instructor in Pediatrics (HMS), “The Role of Patient/Parent-Provider Communication in Pediatric Weight Management.”

Amy Roberts, Director of the Cardiovascular Genetics Research Program and Associate in Cardiology (Children's) and Instructor of Medicine (HMS), “Learning and Memory in Children and Adolescents with Noonan Syndrome.”
Lydia Shrier, Assistant in Medicine (Children’s) and Assistant Professor of Pediatrics (HMS), “Development of a Real-time, Contextual Intervention Using PDA Technology to Reduce Marijuana Use among Adolescents and Young Adults.”

Colin Sieff, Senior Associate in Medicine (Children’s) and Associate Professor of Pediatrics (HMS), “Basic and Clinical Studies to Identify New Therapeutic Agents for Bone Marrow Failure Disorders.”

Collaborative Projects and Initiatives

Pediatric Myelodysplastic Syndrome (MDS) Registry
The CRP worked closely in this past year to help physicians and research scientists at Children’s Hospital Boston create the Pediatric Myelodysplastic Syndrome (MDS) and Bone Marrow Failure (BMF) Disorder Registry, which is funded by the National Institute of Health (NIH). Children’s Hospital Boston serves as the coordinating center for these efforts and provides both infrastructure and technical support. The registry aims to bring clinicians and researchers interested in pediatric MDS and BMF together, initiate collaborative studies, disseminate information about these rare disorders and serve as a resource. The research database and tissue repository is located at the coordinating study center at Children’s Hospital Boston. The registry, the first of its kind in the United States, is modeled after the European Working Group on MDS (EWOG-MDS), which was founded in 1993 by expert clinicians from Germany, Austria, Denmark, Italy and the Netherlands. The aim is to work together with European colleagues to advance scientific knowledge of MDS and BMF. The Registry was created using the Phase Forward’s InForm™ ITM (Integrated Trial Management) software application which is a Web-based electronic data capture (EDC) and clinical data management system used by research teams to facilitate study data collection, monitoring and analysis. InForm™ is based on open data standards (CDISC ODM, XML, etc.), is designed to facilitate the integration of disparate clinical or bioinformatics services and supports enhanced reporting and integration capabilities. Tracy Antonelli, MPH, Clinical Research Study/Trial Manager, Qiaoli Chen, MS, Data Manager and Moriah Polanco, Research Data Coordinator from the Project and Data Management Core with Leslie Kalish, ScD, Principal Biostatistician, have worked closely with Inga Hofmann, MD, Hematology/Oncology on this project. By creating a centralized patient registry and tissue bank for all pediatric MDS and BMF patients, the Children’s team aims to create a unique platform to accomplish the following goals:

- Improve accuracy of the diagnosis of these rare conditions by using a standardized diagnostic approach.
- Build a tissue repository and database that allows for meaningful longitudinal compilation of clinical outcomes to facilitate research.
- Use new knowledge gained from these observations to develop consensus among national experts and recommend new treatments.
- Gain new insights into causes of MDS and BMF.

The CRP will continue to support the MDS Registry in the upcoming year and looks forward to a successful launch of this collaborative effort.
Uncovering the Genetic Basis of Idiopathic Short Stature
The Children’s Hospital Boston - Waltham site offers space and personnel support for the care of children enrolled in research studies. There are two ambulatory exam rooms, a conference room, phlebotomy and infusion therapy support along with nursing care. The CRP and CTSU has assisted in providing research study support at Waltham, and the study “Uncovering the Genetic Basis of Idiopathic Short Stature” (PI: Andrew Dauber, MD, Endocrinology), has utilized CRP staff (Tracy Antonelli, MPH, Clinical Research Study/Trial Manager and Julie Barenholtz, MSW, Data Manager, both in the Project and Data Management Core -PDMC) to provide a wide range of clinical research activities, from project and data management through implementation in the field. This laboratory and epidemiological study aims to identify novel genetic variants in children with Idiopathic Short Stature (ISS). DNA along with clinical and laboratory information will be collected from 500 subjects and available family members, all during a single CTSU visit. To meet this aggressive recruitment timeline, ISS became the first major study to begin enrolling patients at General Clinical Research at Waltham. The CRP’s involvement with ISS began with PDMC (Lily Chen, MS, and Sarah Krathwohl Steltz, MPH), Biostatistics (Leslie Kalish, ScD and Henry Feldman, PhD), and Clinical Research Informatics Team (Mohamad Daniar, MS) staff working together to design case report forms and develop an Inform database. After a successful launch in the field in Boston, Tracy Antonelli and Julie Barenholtz joined the team to implement the study at the Waltham site, where they perform all clinical research coordination duties and enroll several subjects per week for the study. ISS is an example of the interdisciplinary research work that can be conducted when research teams partner with the CRP.

Children’s Hospital Provider-Payer Quality Initiative (PPQI)
During the past year, CRP faculty, including Drs. Osganian, Graham-Manning, and Ziniel collaborated with colleagues from the Children’s Hospital Provider-Payer Quality Initiative (PPQI) to develop the overarching evaluation design for this innovative partnership. The PPQI is a partnership established between Children’s Hospital Boston and Blue Cross Blue Shield, Tufts Health Plan, Harvard Pilgrim Health Care, and Mass Health that seeks to promote efficiency and quality in the pediatric health care delivery system. This unique, collaborative Provider –Payer model will fund a variety of innovative projects or models of care, tools or technologies that will accelerate the transformation of the pediatric care delivery system to improve or maintain health outcomes while reducing costs. Important outcomes to be assessed across projects include the patient and family experience, provider experience, utilization of health care services, clinical or health related outcome, and/or standardized costs for health care services. This exciting initiative will help to address the current economic challenges of achieving effective health care reform as well as the national imperative to advance health care quality and patient and family-centered care while controlling costs. The PPQI is governed by a Steering Committee that has representation from all stakeholder institutions and chaired by Ms. Sandi Fenwick. Current projects funded by the PPQI include the following:

1. Implementation of Standardized Clinical Assessment and Management Plans in Pediatric Cardiology. SCAMP is a new tool designed to improve patient care in an organized fashion that assesses or manages an identified and diverse patient population in a nearly identical fashion. The purpose of a SCAMP is to reduce clinical practice variability, to analyze the disease-relevant residual sources for practice variability, to improve care, and also to allow the biologic and clinical variability inherent in the patient population to emerge, be identified, and analyzed. Once that occurs, incremental but sustained care improvements are achievable.
2. **Partners in Quality: Headache Collaborative Care Model.** CHB neurologists and HVMA/Atrius PCPs have begun to develop a model of care that will deliver enhanced assessment of headache in the Medical Home; virtual access for PCPs to neurology advice for headache diagnosis (including imaging decision-support) and management; and optimal stable headache management in the primary care setting. This new family-centered process is designed to transform how neurologists and PCPs interact in caring for patients with headache. The goal was to develop an integrated, collaborative care model of headache assessment and management that would build capability in the Medical Home and improve overall access to neurology services.

3. **Radiology Collaborative Support Model (RCSM): Decision Support.** Advances in diagnostic imaging techniques have resulted in dramatically increased utilization of imaging services over the last two decades. Used appropriately, advanced imaging provides earlier and more definitive diagnosis of disease, decreases the number of exploratory or unnecessary surgical procedures, provides intra-operative guidance, and permits monitoring of the response to therapy for many conditions. As a result, diagnostic imaging has become increasingly attractive to patients and referring physicians. The overarching aim of this proposal is to improve radiologic pediatric care and optimize resource utilization by providing increased access to pediatric imaging expertise through processes that support appropriate exam selection, performance and interpretation through the creation of a Radiology Collaborative Support Model (RCSM).

**Harvard Catalyst**

The Harvard Catalyst (NIH-funded Harvard Clinical and Translational Science Center (CTSC)), led by PI and Dean for Clinical and Translational Research, Lee Nadler, MD. Catalyst continues to develop programs and resources aimed at training and educating the next generation of clinical and translational researchers, facilitate translational research (from laboratory-to-bedside and bedside-to-bench) and enable scientists with complementary interests, skills and resources to find each other and to work together. Among the many Harvard Catalyst programs that have been established to support clinical and translational research, the faculty and staff of the CRP are actively participating in Catalyst programs and efforts related to biostatistics and clinical research study coordinator services as described below.

**Catalyst Biostatistical Science Program (BSP)**

One of the valuable resources that the Catalyst provides is core support in Biostatistics. The Catalyst Biostatistical Science Program (BSP), directed by James Ware, PhD, Professor of Biostatistics at the Harvard School of Public Health (HSPH), helps investigators develop their research by assisting on grant and protocol development, study design, education, and analysis advice. The Associate Director representing CHB is Leslie Kalish, ScD, a Principal Biostatistician in the CRP. Other Catalyst biostatisticians in the CRP include Henry Feldman, PhD, Peter Forbes, MA, Chao-Yu Guo, PhD, and Paul Mitchell, MS. At the end of the fiscal year, there were 55 active consults. Catalyst biostatisticians also serve as statistical mentors for Fellows in training programs such as the Clinical Investigator Training Program (CITP) and Scholars in Clinical Science Program (SCSP).

**Study Coordinator Services through the Clinical and Translational Study Unit**

Catalyst continues to provide critical support for inpatient and outpatient clinical research on the Clinical & Translational Study Unit (CTSU) located on 6 East and Pavilion 6 and in the CAT/CR, under the continued direction of Richard Grand, MD, PhD. Clinical research
Coordinator services provided through the CTSU included 2 study coordinators at CHB, and beginning in FY2010, coordinator support was added to the staff at Waltham, where CHB/CTSU hosts a community-based research center. Under the leadership of Adam Simmons, CRP Clinical Study Manager, PDMC staff worked collaboratively with research nursing and CTSU staff to develop the infrastructure for the off-unit study coordinator support, coordination of services and assignments. The two Catalyst coordinators Mark Berry, MS and Emily Webster, BS, supported Catalyst approved clinical investigators working in various areas on campus including the Emergency Department, Neonatal Intensive Care, Cardiology and Newborn Nurseries at CHB, Brigham and Women's and Beth Israel Hospitals. PDMC staff is also assisting in the development of the new clinical research support services in Waltham. Specifically, Tracy Antonelli, MPH, CRP clinical research Study/Trial Manager, now supervises a newly hired CRP Study Coordinator, Julie Barenholtz, MSW who will both work to expand the research support at the CHB Waltham Center. With central training and supervision provided by CRP senior research specialists, services can be provided seamlessly to investigators, across sites, departments and divisions.

Research Electronic Data Capture (REDCap) Support:
REDCap is a novel workflow methodology and software solution designed for rapid development and deployment of electronic data capture tools to support clinical and translational research. Chris Botte, recently employed as a Harvard Catalyst EDC support specialist is responsible for helping investigators adopt REDCap at Children's Hospital, Beth Israel Deaconess Medical Center and The Joslin Diabetes Center. Chris has 10 years of extensive work experience as both a database design specialist and a data analyst and had substantial experience in the design and implementation of small-to-medium scale patient tracking systems and performing advanced analysis of the collected data for management staff. Chris works collaboratively with PDMC staff on database development activities and is available to provide assistance and training in the use of REDCap, which has seen a rapid adoption in use at Children's. To date, REDCap databases are active for 21 studies and under development for an additional 45. Additionally, there is a REDCap Survey tool with 14 surveys in development, 10 in use, with 27 accounts and 16 active users.
Investigator Spotlight: Jessica Lee, MD, MMSc.

The CRP frequently has a formative impact on the careers of promising clinician scientists. Jessica Lee, MD, MMSc, a recipient this year of a CRP research grant exemplifies such a developing investigator. Her work focuses on the integration of basic genetic informatics and translational research to establish whole blood and colonic mRNA expression profiles of newly diagnosed pediatric inflammatory bowel disease (IBD). By linking phenotypic information to key molecular signatures, she hopes to define non-invasive biomarker(s) that can predict the presence of IBD and characterize specific subtypes. A second topic of research for Jessica is to identify genetic profiles for IBD patients with growth failure. Her strong drive and perseverance, previous didactic and hands-on training in basic science and clinical research, incomparable research environment and institutional support, and excellent mentorship by Drs. Isaac Kohane, Richard Grand, and Louis Kunkel will undoubtedly result in a successful outcome for her proposed work. Although her background for genetics and genomics research was minimal at the start of her fellowship, she has been able to carry out a project involving candidate gene analysis in its entirety, to collaborate with other researchers, and to learn to use informatics to analyze genetic data. Jessica started her current research focus back in 2006 stressing basic bench research. However, she knew she wanted to bridge the gap between the basic and clinical research and translate it to clinical practice. Yet, there were no roadmaps to get her where she wanted to go. Enter the CRP and its Introduction to Clinical Research course and Jessica was off and running. From there, she was able to continue pulling together the pieces to advance her work, taking more CRP courses to gain some basic skills in biostatistics and database technologies and then working with CRP statisticians to design her studies, analyze data and become familiar with good clinical practices. Jessica showed grit and determination throughout these years, building her knowledge and skills, working and sharing bench space wherever she could find some, and balancing her clinical responsibilities. Now, with her CRP grant she proudly states that she can afford to purchase her own reagents rather than having to work with what collaborators could spare. Clearly, Jessica's success is a product of her passion for her work and her capacity to search out the resources that were available to her. The CRP congratulates Jessica on her achievements and looks forward to following her promising research.
Staffing

In FY2010 the Biostatistics Core included 10 doctoral level biostatisticians, all holding faculty appointments at Harvard Medical School through CHB departments and divisions, as well as 4 Masters-level biostatisticians, 2 statistical programmers, and an administrative coordinator. Capsule biographies are provided in Appendix A.

Director: Al Ozonoff, PhD
Faculty staff in FY2010 included:
Henry Feldman, PhD, Principal Biostatistician
Leslie Kalish, ScD, Principal Biostatistician
Dionne Graham, PhD, Senior Biostatistician
Matt Gregas, PhD, Senior Biostatistician
Chao-Yu Guo, PhD, Senior Biostatistician
Hongyu Jiang, PhD, Senior Biostatistician
Lin Huang, PhD, Senior Biostatistician
Emily Blood, PhD, Senior Biostatistician
Michael Monuteaux, ScD, Senior Biostatistician

Other statistical and administrative staff included:
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
Robin Walker, MSW, Administrative Coordinator
**Biostatistics Core Mission**

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.

**Biostatistics Services**

The Biostatistics Core provides assistance throughout the lifetime of a research project. In the planning phase, Core members work with investigators to devise study designs, formulate and document statistical analyses, calculate statistical power and sample size, and contribute to the writing of proposals and protocols. During implementation, Core members supervise and participate in database construction, randomization, data-cleaning, quality control, and data and safety monitoring. In the analysis and reporting stage, the Biostatistics Core performs both routine and original statistical analyses, interprets results, and co-authors abstracts, presentations, and journal articles.

**Biostatistics Goals**

- **Scientific Collaboration and Consultation:** To form scientific partnerships with both new and established investigators; to integrate biostatistical reasoning and methods with medical and biological science at an early stage in the development and conduct of research projects; to provide technical guidance, hands-on assistance, or funded effort as appropriate; to demonstrate by the quality of our work that this body of knowledge and technique is integral to the process of rigorous scientific inference and complementary to other aspects of research.

- **Scientific Leadership:** To incorporate innovative biostatistical concepts into every phase of clinical research projects; to raise awareness of such special techniques as statistical genetics, multi-level modeling, and survival analysis; to guide investigators in choosing and performing the most appropriate statistical techniques.

- **Knowledge and Expertise:** To represent a visible and valued source of expertise within the institution; to maintain that role by staying abreast of new developments, acquiring new tools in mathematical theory and computational technique, and promulgating practice standards for the field.

- **Research:** To develop novel and robust approaches to study design and statistical analysis that are generalizable and useful to researchers; to publish and disseminate new methods through professional forums and literature.

- **Professional Development:** To support the professional development and academic advancement of our biostatisticians so that they may develop and enhance their skills and gain recognition for their contributions while carrying out the mission of the Program.

- **Education and Training:** To lead and participate in education and training activities; to recognize and encourage promising young investigators; to ensure that they seek and assimilate adequate training through career-development grants, coursework, and independent study in order to make them sophisticated consumers of biostatistical services and collaborators.

- **Integration:** To demonstrate the value of integrative research through accomplishments that bridge medicine, epidemiology, computational biology, and biostatistics.

- **Growth:** To increase the number of biostatistical faculty and staff dedicated to the above goals through collaborative relationships with Departments and Divisions.
**Biostatistics Progress Report**

Throughout most of FY2010, Dr. Osganian served as acting Director of the Core. In July 2010, the CRP welcomed Dr. Al Ozonoff as the Director of Biostatistics. In this role, Dr. Ozonoff will provide vision, leadership, and oversight of the Biostatistics Core. He will also hold an academic appointment in Division of Emergency Medicine.

**Utilization of Services**

Table 1 shows the number of new requests for Biostatistics Core services during FY2010.

<table>
<thead>
<tr>
<th>Tasks</th>
<th>FY09 Number of Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistance with Existing Database</td>
<td>12</td>
</tr>
<tr>
<td>Data Management</td>
<td>22</td>
</tr>
<tr>
<td>CTSU Biostatistical Review</td>
<td>7</td>
</tr>
<tr>
<td>Grant Application Review/Critique</td>
<td>43</td>
</tr>
<tr>
<td>Interpretation of Results</td>
<td>81</td>
</tr>
<tr>
<td>Manuscripts/Presentations</td>
<td>84</td>
</tr>
<tr>
<td>Power and Sample Size Determination</td>
<td>105</td>
</tr>
<tr>
<td>Randomization</td>
<td>3</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>162</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td>114</td>
</tr>
<tr>
<td>Study Design</td>
<td>56</td>
</tr>
<tr>
<td>Study Protocol/Critique</td>
<td>15</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>709</strong></td>
</tr>
</tbody>
</table>

**Research Collaborations**

The primary activity of the Biostatistics Core is collaboration and consultation with CHB investigators. This leads to involvement in clinical research protocols, grant proposals, and study operations such as subject randomization, data collection, data analysis, data presentation, and ultimate publication in the biomedical literature. These activities have resulted in 45 publications during FY2010. A full list of publications by CRP staff is provided in Appendix B.

**New Research Funding**

An important goal of the CRP is to assist investigators prepare effective funding proposals for submission to NIH, other federal agencies, and medical foundations. The Biostatistics Core plays a critical role in this aspect of the CRP mission: statistical justification, well-designed analytic plans, and adequately budgeted statistical effort are essential for a successful proposal but difficult to achieve without such assistance. CRP activities, seeded by departmental and CRP funds, result in federal and foundation grant support for CRP staff. A list of federal and private research grants active in FY2010 at the CRP is provided in Appendix C.

**Teaching Clinical Investigators**

Biostatistics Core staff 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, of which several are well established and more are in development. Dr. Ji-ang and Mr. Forbes teach *Introduction to Biostatistics with SPSS*, which combines eight lectures on elementary descriptive and inferential statistics with companion computer laboratory sessions. This course has consistently enrolled more than 50 clinical researchers per year, and the course is now available via webcast to address high demand. Dr. Gregas, Ms. Walls, and Mrs. Bacic continued to teach a course with more advanced biostatistical content, first introduced in 2009, titled *Introduction to Regression*. Additionally, Dr. Guo taught a course first introduced in 2008, *Introduction to Statistical Genetics*, which focuses on the application of statistical methods for genetics studies such as family-based and population-based association studies and other designs.

In addition to the CRP short-course program, members of the Biostatistics Core regularly deliver hospital seminars and conduct training at national meetings. Dr. Feldman served for his 13th year as faculty in the American Heart Association Ten-Day Seminar on Epidemiology and Prevention of Cardiovascular Diseases, a post-doctoral training course for preventive cardiology and related professions of which several CHB faculty are graduates. Under the leadership of Dr. Graham, the faculty of the Biostatistics Core continued for the fourth year to provide statistical mentorship to the Harvard Pediatric Health Services Fellowship at their bimonthly Works in Progress sessions. In addition, Dr. Graham provided statistical oversight to several fellows’ projects. Several CRP faculty members presented methodological seminars to this audience throughout the year: “Hierarchical Modeling” (Dr. Gregas), “Tips and Tricks in SAS” and “Using the KID and PHIS Databases” (Dr. Graham), and “The Design and Analysis of Patient Satisfaction Surveys” (Dr. Ziniel).

**Partnerships with Departments and Divisions**

An important organizing principle of CRP is the integration of its faculty with CHB Departments and Divisions, so as to foster creative research collaborations between department-based investigators and CRP-based biostatisticians knowledgeable in the appropriate scientific and medical subject matter. 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 affiliations are in place or planned.

- Mrs. Bacic, Departments of Neurology and Developmental Medicine
- Dr. Blood, Department of Psychiatry and Division of Adolescent Medicine
- Dr. Feldman, Division of Endocrinology
- Mr. Forbes, Department of Psychiatry
- Dr. Graham, Department of Cardiology and Program for Patient Safety and Quality
- Dr. Gregas, Departments of Neurology and Developmental Medicine
- Dr. Huang, Department of Urology
- Dr. Jiang, Division of Gastroenterology and Nutrition
- Dr. Kalish, Division of Hematology/Oncology and Department of Orthopedics
- Mr. Mitchell, Division of Gastroenterology and Nutrition
- Dr. Monuteaux, Division of Emergency Medicine
- Ms. Walls, Division of Adolescent and Young Adult Medicine
- Ms. Zhou, Department of Cardiology and Program for Patient Safety and Quality
- Faculty search in progress, Departments of Radiology and Orthopedics
Staff Changes
FY2010 saw the arrival of the Core Director, Dr. Ozonoff. The Biostatistics Core added a Statistical Programmer, Ms. Ying Feng, who joined CRP with MS degrees from Northeastern University and the Harvard School of Public Health. New faculty member Michael Monuteaux, ScD joined the CRP and the Division of Emergency Medicine from Massachusetts General Hospital. Ms. Courtney Walls changed roles within the Biostatistics Core, assuming the position of Biostatistician. Finally, faculty member Dr. Chao-Yu Guo left the Biostatistics Core after more than four years at CRP. Dr. Guo will be missed by friends, colleagues, and collaborators.
Staffing

FY2010 Education Core staff included the following. Capsule biographies are provided in Appendix A.

Jenifer R. Lightdale, MD, MPH, Director of Clinical Research Education
Stacey Springs BA/BS, Education Coordinator

Education Core Mission

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

Education Services

- Develop, coordinate, arrange for speakers, and participate in courses and seminar series on research methods for faculty, fellows, and residents;
- Develop and offer didactic series on other clinical research special fields of inquiry or advanced topics of interest to the broad research community at Children’s Hospital
- Serve on hospital and university research education-related committees; and
- Develop Web-accessible best practices and educational tools for researchers.
Education Goals

- **Scientific Leadership**: To develop a vision and an agenda to maintain state-of-the-art clinical research education curriculum for the entire clinical research community at Children’s Hospital Boston.
- **Education and Training**: To develop and implement education and training activities on behalf of the CRP.
- **Knowledge and Expertise**: To develop a continuous comprehensive educational plan with useful, scientifically accurate course offerings that range from basic to advanced curriculum for clinical research.
- **Integration**: To promote the integration of educational offerings into daily activities of the entire research community at Children’s Hospital Boston; to effectively communicate CRP course offerings to the research community at Children’s Hospital Boston; to make CRP research education courses available and accessible to the research community at Children’s Hospital Boston.
- **Growth**: To increase enrollment and to consistently introduce relevant new education programming.
- **Professional development**: To promote clinical research faculty development, in part by systematically evaluating and providing feedback to all course directors and lecturers.

Education Progress Report

Under the direction of Dr. Jenifer Lightdale, the Education Core has provided considerable educational opportunities for CHB staff and faculty involved in clinical research. Achievements over the past year and ongoing challenges for 2010 include:

**Infrastructure**

Additional efforts to increase integration include the Core’s expanded use of the online registration and evaluation system and a recent completed redesign of the CRP Education Core intranet site.

**Demand**

Total CRP course enrollment more than doubled from 2006 to 2010 (Table 1). This statistic reflects strong demand for CRP educational offerings from clinical research faculty and staff representing almost all CHB departments and divisions (Figure 1). While we specifically aim to meet the needs of fellow trainees and study coordinators, course attendees also include faculty and represent the spectrum of the CHB Clinical Research Community. Demand for spaces in the CRP courses is often larger than capacity, and we generally reach targeted enrollment within a week or two of opening a course for registration. In order to meet increasing demand for the CRP courses, we have chosen larger venues and increased the frequency of our course offerings.

The Clinical Research Education Core of the Clinical Research Program designs, organizes, and implements a series of hospital-wide CRP sponsored seminars and courses to provide both foundational and advanced knowledge in clinical research. We work closely with the Project and Data Management, Biostatistics and Survey Cores of the CRP to meet the research educational needs of study coordinators, nurses, medical students, fellows, junior faculty, as well as senior faculty involved in clinical research across Children’s Hospital Boston.
Table 1. CRP Course Attendance by Year 2005 - 2010

<table>
<thead>
<tr>
<th>CRP Course</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to Clinical Research</td>
<td>103</td>
<td>100</td>
<td>108</td>
<td>133</td>
<td>126</td>
<td>84*</td>
</tr>
<tr>
<td>Orientation for New Study Coordinators</td>
<td>69</td>
<td>60</td>
<td>73</td>
<td>113</td>
<td>109</td>
<td>111</td>
</tr>
<tr>
<td>Coordinator Rounds</td>
<td>-</td>
<td>75</td>
<td>120</td>
<td>138</td>
<td>159</td>
<td>157</td>
</tr>
<tr>
<td>Introduction to Biostatistics with SPSS</td>
<td>-</td>
<td>62</td>
<td>79</td>
<td>106</td>
<td>105</td>
<td>81</td>
</tr>
<tr>
<td>Power and How to Get It</td>
<td>-</td>
<td>42</td>
<td>30</td>
<td>-</td>
<td>25</td>
<td>-</td>
</tr>
<tr>
<td>Do-It-Yourself Data Management</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>20</td>
<td>21</td>
<td>11</td>
</tr>
<tr>
<td>Beyond Chi-Squares: Drawing Inferences from Tables</td>
<td>-</td>
<td>-</td>
<td>22</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Introduction to Statistical Genetics</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>25</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Statistics for Small Sample Size Studies</td>
<td>-</td>
<td>-</td>
<td>23</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Art and Anatomy of Writing a Career Development Grant</td>
<td>-</td>
<td>-</td>
<td>138</td>
<td>150</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Introduction to Regression Analysis</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>18</td>
<td>25</td>
<td>-</td>
</tr>
<tr>
<td>Focus Groups Workshop</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>16</td>
<td>20</td>
<td>-</td>
</tr>
<tr>
<td>Survey &amp; Questionnaire Design</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>32</td>
<td>-</td>
</tr>
<tr>
<td>Qualitative Research in Clinical Investigation</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>16</td>
<td>35</td>
<td>-</td>
</tr>
<tr>
<td>Passport Series for Clinical and Translational Researchers</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>121</td>
<td>-</td>
</tr>
<tr>
<td>TOTAL REGISTRATION:</td>
<td><strong>172</strong></td>
<td><strong>339</strong></td>
<td><strong>415</strong></td>
<td><strong>718</strong></td>
<td><strong>747</strong></td>
<td><strong>695</strong></td>
</tr>
</tbody>
</table>

*Course offered only once for this year

Figure 1. CRP Course Attendees by Department 2010
Curriculum

Over the past year, the Core continued to work with the Education, Training and Communication subcommittee of the Clinical and Translational Executive Committee (CTREC) at Children’s to develop a continuous comprehensive educational plan with useful, scientifically accurate course offerings that range from basic to advanced curriculum for clinical research.

We have continued to build upon our curriculum by adding 1-2 new courses a year (Table 2). The Core offers an introductory biostatistics course, as well as a curriculum designed to teach junior investigators and fellows the fundamentals of study organization and data management. In 2010, we introduced two new survey methodology courses; Survey & Questionnaire Design and Qualitative Research in Clinical investigation. We also successfully repeated several new courses in advanced biostatistics and survey design introduced in recent years, including Introduction to Regression, Introduction to Statistical Genetics and Focus Groups in Clinical Research.

As part of a multi-disciplinary effort, the Education Core co-sponsored a seminar series with the Translational Research Program and Research Administration to engage and educate clinical and translational researchers. The Passport Series for Clinical and Translational Research held three seminars in 2010;

- 10 Questions Every Investigator Should Ask Before Doing Research on a Drug, Device or Biologic.
- Investigator Responsibilities in FDA regulated research...are you sure you know what you are in for?
- Data and Safety Monitoring: Boards vs. Plans – Which is Right for Your Study?

These inaugural sessions were successfully received and we plan to reprise this series in 2010 to include a fourth lecture on Delegation of Authority on Study Teams.

In 2010, the Education Core plans to renew a collaborative grant writing seminar co-sponsored with Brigham and Women’s Hospital, entitled The Art and Anatomy of Writing a Career Development Grant.

<table>
<thead>
<tr>
<th>Table 2. CRP Course Listings 2004 - 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRP Courses Offered</td>
</tr>
<tr>
<td>Introduction to Clinical Research</td>
</tr>
<tr>
<td>Orientation for New Study Coordinators</td>
</tr>
<tr>
<td>Coordinator Rounds</td>
</tr>
<tr>
<td>Introduction to Biostatistics with SPSS</td>
</tr>
<tr>
<td>Power and How to Get It</td>
</tr>
<tr>
<td>Do-It-Yourself Data Management</td>
</tr>
<tr>
<td>Beyond Chi-Squares: Drawing Inferences from Tables</td>
</tr>
<tr>
<td>Introduction to Statistical Genetics</td>
</tr>
<tr>
<td>Statistics for Small Sample Size Studies</td>
</tr>
<tr>
<td>Art and Anatomy of Writing a Career Development Grant</td>
</tr>
<tr>
<td>Introduction to Regression Analysis</td>
</tr>
<tr>
<td>Focus Groups Workshop</td>
</tr>
<tr>
<td>Survey &amp; Questionnaire Design</td>
</tr>
<tr>
<td>Qualitative Research in Clinical Investigation</td>
</tr>
<tr>
<td>Passport Series for Clinical and Translational Researchers: 10 Questions Ever Investigator Should Ask BEFORE Doing Research with a Drug, Device or Biologic</td>
</tr>
<tr>
<td>Passport Series for Clinical and Translational Researchers: Investigator Responsibilities</td>
</tr>
<tr>
<td>Passport Series for Clinical and Translational Researchers: Data Safety Monitoring &amp; Boards</td>
</tr>
</tbody>
</table>

*** course offered
Faculty
The Education Core supports clinical research faculty development by systematically evaluating and providing feedback to all course directors and lecturers. We continue to modify course content based on the comments of participants and faculty. We are very grateful to all faculty members for contributing to the success of our program, and are fortunate to have hospital support from the CTREC to provide nominal faculty honoraria.

E-Learning
In an effort to promote the integration of educational offerings into the daily activities of the entire research community at CHB, the Education Core has successfully webcasted and recorded several of our past courses using Adobe Breeze: Introduction to Biostatistics with SPSS and the Art and Anatomy of Writing a Career Development Grant. We also have Breeze recorded our signature course: Introduction to Clinical Research. Webcasting of the course lectures provides participants better access to course materials and presentations, and increases flexibility for course attendees.

Leadership
The Education Core values deeply its potential to provide vision and agendas for a comprehensive clinical research education curriculum, not only at Children’s Hospital, but also across the greater Harvard University Community. Collaborations and benchmarking with other clinical research programs at Harvard, as well as outside institutions has allowed us to identify opportunities to expand our curriculum. In FY2009, the Core contributed to the Harvard Catalyst Research Education Advanced Curriculum Compendium. In the coming years, we will continue to embrace opportunities for continued collaboration with Harvard affiliated institutions and enhance the scope and number of CRP educational offerings.
Staffing

FY2010 Project and Data Management staff included the following. Capsule biographies are provided in Appendix A.

Adam Simmons, MPH, CCRC, Clinical Research Study Trial Manager and Acting Manager PDMC
Lucy Abernethy, BA, Clinical Research Coordinator
Tracy Antonelli, MPH, Clinical Research Study Trial Manager
Julie Barenholtz, MSW, Research Data Manager I
Mark Berry, MS, Clinical Research Coordinator II
Aislyn Cangialose, BA, CCRP Clinical Research Coordinator I
Qiaoli Chen, MS, Research Data Manager I
Rajna Filip-Dhima, BS, Clinical Research Specialist I
Susan McDermott, MPH, RN, (Former) Clinical Research Team Leader
Elizabeth Paulsen, BS, Clinical Research Coordinator I
Sarah Steltz, MPH, Clinical Research Specialist II
Moriah Polanco, BS, Research Data Coordinator
Harold T. Thurston, Jr., MA, MAT, Administrative Coordinator
Emily Webster, BS, Clinical Research Coordinator I

Project and Data Management Core Mission

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.

Services

PDMC staff guide clinical investigators and their staff in a number of areas including:
- Study development and implementation activities (e.g., establishment of study timelines, case report form development, study procedure development, study ID assignment and screening logs, randomization protocols, human subjects protection procedures, and data quality and control planning);
- Research study database development and electronic data capture tools;
- Data management (including data capture procedures, document management, data
entry, data cleaning, reporting, extraction of data for statistical purposes, and end user support for database applications):

- Project manager and study coordinator support; and
- Development of Web-accessible best practices and educational tools for researchers.

Clinical Research Coordinator Core (CRC Core) services include:

- Recruitment of study participants
- Screening of research participants for eligibility
- Obtaining informed consent
- Scheduling study participants for study visits
- Assisting the PI during patient visits
- Performs study procedures designated for the study coordinator, including collection and delivery of study specimens*
- Abstracting records from source documents and recording onto Case Report Forms (CRFs)
- Completing data entry
- Maintenance of regulatory binders, updates to the Committee on Clinical Investigations (CCI)
- Assisting the PI in CCI continuing review applications
- Working with study staff to prepare for monitoring and audits by an independent monitor or regulatory authorities

Project and Data Management Core Goals

- **Scientific Collaboration and Consultation:** To partner with CHB clinical investigators to plan implement and manage clinical investigations and to provide organizational, operational and technical guidance and support to implement clinical investigations in compliance with clinical research best practices.
- **Education and Training:** To lead and participate in CRP educational activities offered to members of the CHB clinical research community, including structured courses, one-on-one training and mentoring.
- **Knowledge and Expertise:** To advance CHB research community knowledge of regulatory requirements and operational best practice standards for clinical research pertaining to project management, database security and data management.
- **Research:** To contribute to the expanding field of clinical research best practices, specifically in the area of project and data management, data collection instrument development, research staff training and certification, and quality assurance planning.
- **Integration:** To broaden awareness of CRP services in the CHB Investigator community.
- **Growth:** To enhance the capabilities and quality of PDMC consultative services and to increase the technical capabilities and quality of PDMC project and data management services overall.
- **Professional development:** To support the professional development of PDMC staff so that they may develop their skills and advance their careers, while fulfilling the mission of the Program.

Project and Data Management Progress Report

Table 1 shows the number of requests for some of the Project and Data Management Core services during FY2010.
Table 1. Project and Data Management Core Service Requests

<table>
<thead>
<tr>
<th>Tasks</th>
<th>FY10Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistance with Existing Database</td>
<td>4</td>
</tr>
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<td>2</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>132</strong></td>
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Research Collaborations
Staff provided professional services responding to 132 requests from CHB investigators for project management, study coordination, CRF and database development and/or data management in FY2010: many are ongoing. The CRP staff served as official study members for numerous studies, and costs for staff effort were recovered through extramural grants or hospital departmental funds totaling $269,888.

Clinical Research Coordinator (CRC) Core
The CRC Core expanded to 4 coordinators with an open position to staff a 5th. The efforts for up to 2.0 FTE of coordinator support are funded by The Harvard Catalyst Clinical and Translational Study Award for investigators who apply. Investigators supported by this grant represent the divisions of Emergency Medicine, Infectious Disease, Cardiac Surgery, Nephrology, Nursing/Patient Services and Genetics.

CRC Core also supports ongoing research being conducted in the Emergency Department, funded by both individual investigators and receiving division support. Two research coordinators were hired in April to work specifically on studies being conducted in the Emergency Department.

The Coordinator Services has expanded to support investigators requesting assistance with studies conducted at the CHB Waltham Center.

Clinical Research Database Creation and Support
SciRIS: In FY2010, PDMC in conjunction with CRIT staff provided technical and/or data management support for 11 custom databases developed in earlier years using a proprietary data management systems application, SciRIS, developed by Jason Rightmyer and other CRIT software engineers.

SPSS Data Builder 4.0: CRP staff continues to support the development of SPSS databases in a variety of ways including, direct development, one-on-one tutorials, and CRP Education Core courses. In addition to primary development, SPSS databases developed by CRP Data Managers undergo a routine, comprehensive quality assurance check for all variables and functionality by a second CRP Data Manager prior to release to the study staff; and CRP data managers will serve as the quality control reviewer for programs developed by study staff coached by CRP staff.
REDCap: Research Electronic Data Capture, or REDCap, was introduced in FY2010 as a free, secure, Web-based application. CRP Data Managers provide services of direct development of REDCap databases for study use as well as provide one-on-one tutorials in conjunction with the Harvard Catalyst EDC Specialist. Though new to CRP, Project and Data Managers have developed or guided the development of 90 REDCap databases in FY2010, consisting of approximately 495 data entry forms.

InForm™: CRP continues to utilize the Phase Forward, InForm™ ITM (Integrated Trial Management) software application for development of clinical trial databases for FDA-regulated and complex study protocols. InForm™ is a sophisticated, web-based, electronic data capture (EDC) and clinical data management system used by research teams to facilitate study data collection, monitoring and analysis. InForm™ was added to the package of technology options to address an increasing demand to comply with FDA regulations for studies that involve drug, device or biologics and require an IND application. InForm™ is now the recommended database technology for all FDA regulated, investigator-initiated trials conducted at CHB. In FY2010, CRP Data Managers initiated the development of 9 InForm™ databases.

Randomization
PDMC staff worked closely with Investigators and CRP biostatisticians to develop and deliver randomization schemes and study-specific tools. Randomization schemes were completed for 6 trials and randomization lists and/or envelopes were delivered to investigators. For drug trials, CRP staff work closely with the PI and research pharmacy to develop details of the randomization and blinding procedures; the Master randomization list is delivered to the research pharmacist and investigators receive a blinded list absent the treatment assignments.

Research Practice Guidelines
PDMC staff maintains a collection Research Practice Guidelines published by the CRP and posted on the CRP webpage. The Guidelines provide CHB Investigators with up-to-date best practice recommendations to augment guidance provided by CRP staff during consultations. In addition, Education Core faculty members use the CRP Guidelines as reference to reinforce course content provided during Education Core trainings.

Teaching Investigators and Study Staff
PDMC staff continued to provide investigator and study staff education. Education and teaching activities included one-on-one consultations, hands-on-tutorials, formal education courses offered through the CRP Education Core, and development, maintenance and distribution of Research Practice Guidelines. PDMC staff presenting at the following Education Core sponsored events:

- Orientation for New Study Coordinators
- Introduction to Clinical Research
- 10 Questions Every Investigator Should Ask BEFORE Doing Research with a Drug or Device
- DSMPs vs. DSMBs. What’s the Difference?
Adam Simmons presented at “Elements of a Successful Clinical Research Program” at an event sponsored by the Association of Clinical Research Professionals at Maine Medical Center.

**Staff Development**
PDMC staff serves as resident experts in clinical research methods and it is important for staff to stay current in clinical research best practices and regulations. As such, an important PDMC priority is staff development in areas that support staff, maintain and advance knowledge and skills in clinical research best practices as well as in medical content areas related to the work of the CHB investigators. In FY2010, PDMC staff participated in numerous academic courses, professional conferences and trainings. Members of PDMC attended the Association of Clinical Research Professionals (ACRP) New England Symposium and Global Conference in Tampa Florida. Sarah Steltz also presented at this year’s American Association for Public Opinion Research (AAPOR) Annual Conference.

Aislyn Cangialose was certified by the Society of Clinical Research Professionals as a “Certified Clinical Research Professional”

**Staff Promotions and New Hires**

Promotions:
Adam Simmons, MPH, CCRC, accepted the position of Clinical Research Study Trial Manager and Acting Manager of PDMC

New Hires:
Julie Barenholtz, MSW, joined the CRP in June 2010 as a Clinical Data Manager I
Elizabeth Paulsen, BS, joined the CRP in April, 2010 as a Clinical Research Coordinator I.
Lucy Abernethy, BA, joined the CRP in April 2010 as a Clinical Research Coordinator I.
Emily Webster, BS, joined the CRP in July 2010 as a Clinical Research Coordinator I.

**Highlighted Projects**

*Cytomegalovirus-specific immune responses in breast milk of cytomegalovirus-transmitting and non-transmitting CMV-seropositive mothers of very low birth weight preterm infants* Sallie Permar, MD, PhD. PDMC staff have worked with this project on a variety of aspects from Case Report Form Design and database development in REDCap, to study coordination offered through the CRC Core since May 2009. A poster of the interim results of the study was prepared and presented this spring at the Pediatric Academic Societies Annual Meeting in Vancour, BC and included Aislyn Cangialose, BA, CCRP as a contributor.

**CHB-Connect volunteer registry**

In 2008, a research volunteer registry at CHB was created to assist investigators with recruitment for clinical research studies. The registry was developed and established in collaboration with staff from ISD and CCI. Tracy Antonelli, MPH, of the CRP’s PDMC staff manages the registry and associated web site. The CHB-CONNECT web site allows children and adults to register and volunteer for participation in clinical research at Children’s Hospital Boston. Potential participants can register as healthy volunteers, or for specific medical areas of interest. The CONNECT system also allows CHB principal investigators with IRB-approved protocols to access and search this volunteer registry.
Investigators are required to obtain IRB approval for their protocols prior to searching and downloading volunteer information.

The system consists of two separate web sites:
- A publicly, Internet accessible web site for volunteers
  http://www.childrenshospital.org/connect
- A private CHB-only web site for investigators
  http://crp-apps.tch.harvard.edu/connect

Tables 2 and 3 below show that from the period 10/01/09 to 9/30/10, there have been 1933 views of the homepage, 459 visits to the registration webpage, resulting in a total of 235 human subject registrants. For the internal website, there have been a smaller number of visits (75) as would be expected by the smaller size of the group who have access. To date, the registry had had 44 users and of the 41 research protocols, 11 new protocols were added this year. We encourage investigator utilization of this important resource for clinical trials participant recruitment and seek ways to support its growth and enhance its capabilities.

| Table 2: Number of CHB-CONNECT Public Visitors and Subject Registrants |
|-----------------|---------|----------------------------------|
| Metric          | Number  | Description                       |
| Total Views – Home Page FY 2010 | 1933    | Number of times the CONNECT home page was viewed. |
| Total Views – Registration Form   | 459     | Number of times the CONNECT registration form was viewed. |
| Total Registrants                  | 235     | Number of unique registrants in the system currently. |

| Table 3: Number of Internal Registry Investigator Users |
|-----------------|---------|----------------------------------|
| Metric          | Number  | Description                       |
| Total Hits      | 75      | Number of unique visitors to the site (includes users and anonymous users). |
| Total New Users | 3       | Number of new users (PIs and staff) registered with the system. |
| Total Users to date | 44   | Number of users (PIs and staff) registered with the system |
| Total New Protocols | 11   | Number of new protocols listed. |
| Total Protocols  | 41      | Number of distinct protocols listed. |
Staffing

The Survey and Measurement Core included the following staff. Capsule biographies are provided in Appendix A.

Sion Kim Harris, PhD, CPH, Director and Principal Survey Methodologist
Sonja I. Ziniel, PhD, MA, Senior Survey Methodologist
Yolanda Martins, PhD, Senior Survey Methodologist
Mihail Samnaliev, PhD, Health Economist
Sarah (formerly Krathwohl) Steltz, MPH, Clinical Research Specialist II
Handan Titiz, EdM, Survey Methodologist

The Survey and Measurement Core includes three doctoral level Survey Methodologists, Sion Kim Harris (Core Director), Sonja Ziniel, and Yolanda Martins and one doctoral level health economist, Mihail Samnaliev as well as two research associates Handan Titiz and Sarah Steltz. Dr. Harris stepped down as Core Director at the end of this fiscal year. The CRP wishes to thank Dr. Harris for her leadership and valuable scientific contributions to the Core over the past several years.

Partnerships with Departments and Programs

Sion Kim Harris and Sonja Ziniel hold faculty appointments in the Department of Pediatrics at Harvard Medical School through the Division of Adolescent/Young Adult Medicine. Dr. Ziniel is also supported by and working in the CHB Program for Patient Safety and Quality. Dr. Harris also holds a secondary appointment in the Division of
Developmental Medicine and serves as the Director of Research Methodology and Measurement in the Center for Adolescent Substance Abuse Research. Yolanda Martins joined the CRP in September 2010 and will hold an appointment in the Department of Pediatrics at Harvard Medical School through the Division of General Pediatrics. She is jointly supported by and working with the CRP and Dana Farber Cancer Institute Center for Population Studies, Data Technologies Core. Mihail Samnaliev joined the CRP in September and is supported by the CRP, CHB Program for Patient Safety and Quality, and Physicians’ Organization.

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.

Services

For research protocols and grant proposals:
- Define, review, and clarify study aims
- Ensure that study aims are reflected in the survey through reliable and valid previously established or newly created measures or properly captured in the measurement methods
- Review questionnaire design, select appropriate data collection method, choose sampling procedure and survey implementation features
- Improve survey design and implementation to minimize errors related to coverage, non-response, measurement and processing

For conduct of surveys:
- Provide guidelines and support for survey implementation and quality control measures to ensure adherence to accepted survey standards
- Consult on implementation of questionnaire pre-testing and psychometric testing procedures
- Create and implement Web-based surveys
- Prepare quality-control and survey implementation reports including descriptive tables, graphs and other statistical analyses

For analysis and reporting of survey data:
- Support data analysis and prepare statistical summaries on the survey implementation and data in tabular, narrative, or graphical form
- Develop post-survey adjustments and advise on analysis of complex survey data
- Advise on or conduct cost effectiveness or health economic analyses
- Contribute to abstracts, presentations, and journal articles

For education and training:
- Develop and offer lectures in seminar series, short courses and workshops on qualitative and quantitative methods used in survey research for faculty, fellows, and residents
- Develop CHB Web-based resource pages with examples of good questionnaire design, templates for survey implementation materials, standards used in survey research, and up to date bibliographies on survey research
- Serve on advisory and mentorship committees
Goals

- **Scientific Leadership:** To promote adherence to rigorous standards and procedures in the development of surveys in clinical research; to adapt innovations in survey research methods for use in clinical research; and to guide investigators in choosing or designing the best measurement tools, implementation protocol, and analysis plan.

- **Education and Training:** To provide education and training activities related to survey design, testing, and implementation, and the design of survey-based studies; to recognize and encourage promising young investigators; to ensure that they seek and assimilate adequate training through career-development grants, coursework, and independent study in order to make them sophisticated users and consumers of survey research procedures and data.

- **Scientific Collaboration and Consultation:** To form scientific partnerships with both new and established investigators; to integrate survey research methods into research protocols at an early stage in the development and conduct of clinical research projects; to provide technical guidance and hands-on assistance; to demonstrate by the quality of our work that careful survey design and implementation are critical for valid scientific inference.

- **Research:** To develop or adapt survey methods in clinical research; and to publish and disseminate these methods through professional forums and literature.

- **Knowledge and Expertise:** To represent methodological expertise within the institution; to maintain that role by continuous review of newly developed advances in the field of survey methodology; to adapt advances in survey methods into clinical research settings; and to promote standards of designing, implementing and reporting surveys.

- **Integration:** To broaden awareness of CRP survey services in the CHB investigator community.

- **Growth:** To increase the number of survey methods faculty and staff to meet the growing demand within the CHB community for educational opportunities and survey consultation and collaboration.

- **Professional Development:** To support the professional development and academic advancement of our survey methodologists so that they may develop and enhance their skills and gain recognition for their contributions while carrying out the mission of the Program.

Progress Report

**Utilization of Core Services**

Table 1 shows the types of requests for Survey and Measurement Core services during FY2010. The primary activity of the Survey and Measurement Core is collaboration and consultation with CHB investigators who use surveys or questionnaires in their research. In FY2010, Survey and Measurement Core staff provided assistance on a diverse number of projects, including the design of 22 survey projects, 9 Web-based surveys and 39 survey/questionnaires. A few of these projects are highlighted under Research Collaborations below. A full list of recent publications by Survey and Measurement Core staff is provided in Appendix B.
Table 1. Project and Data Management Core Service Requests

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<thead>
<tr>
<th>Tasks</th>
<th>FY10Requests</th>
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<tbody>
<tr>
<td>Assistance with Existing Database</td>
<td>4</td>
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<td><strong>Total</strong></td>
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</table>

Research Project Collaborations

**CHB Inpatient Experience Survey:** In FY2010, Dr. Ziniel completed the implementation of the pilot-testing of the new CHB Inpatient Experience Survey, which was developed to assess families’ experience of the inpatient care they received at Children’s. Based on the results of the validation, Drs. Ziniel and Harris refined and shortened the survey instrument and baseline data collection started in June 2010. Based on this data, performance benchmarks will be developed with Blue Cross Blue Shield. The shortened survey instrument was also submitted as a pediatric quality improvement measure answering a call by the National Quality Forum. At the end of the summer 2010, the Inpatient Experience Survey was endorsed by NQF for a time-limited period of 1 year, during which a nation-wide validation study will be fielded under the supervision of Dr. Ziniel. In addition, Dr. Ziniel has been spearheading the development of additional patient experience modules to be administered on a rotating basis along with the “core” Inpatient Experience Survey. Such modules will assess the experience of emergency department care, surgical care and psychosocial support services.

**Returning Individual Genetic Research Results to Parents and Children:** Dr. Ziniel is the survey methodologist and the statistician for a NIH-funded project led by Dr. Ingrid Holm in the Department of Genomics. Part of the grant includes a survey that aims at measuring parents’ attitudes and opinions about their participation in DNA research banks. The survey assesses if parents would be hypothetically willing to provide their own and/or their child’s DNA for research purposes and allow researchers to add their medical record information to the DNA bank. In addition, it asks parents how they would like to receive their results. Information gathered from this survey will help inform researchers and clinicians on how to develop and implement patient and family participation in DNA banks for research.

**Young Parents Program Project Connect:** Survey Core staff Handan Titiz, Dr. Kim Harris and Dr. Emily Blood from the Biostatistics Core provide data management and analyses support for this five-year federally funded project led by Dr. Joanne Cox in the Division of General Pediatrics evaluating the outcomes of a teen parent intervention that aims to strengthen teen parents’ parenting and life skills through psycho-educational groups, comprehensive medical care and social services. During FY2010, Ms. Titiz was invited to attend a workshop a federal grantee workshop on how to handle missing data in analyses.
REUNITE Study: Together with Dr. Leslie Kalish from the Biostatistics Core, Dr. Ziniel provides guidance to a team of investigators from the Emergency Department that is part of the Emergency Management Task Force. This team, led by Dr. Sarita Chung, is developing a Web-based tool that will be used in disaster situations to reunite lost children with their parents. Emergency management personnel will take pictures of children that have been separated from their parents and enter them into the REUNITE system. Parents looking for their children can then provide characteristics of their children that are then matched to pictures in the system to help reunite the child with the parents. At this time, there is no existing system that provides an efficient and quick way to reunite children with their parents in disaster situations.

cSBIRT Study: The Center for Adolescent Substance Abuse Research (CeASAR) team, assisted by Sion Kim Harris and directed by Dr. John R. Knight of the Division of Developmental Medicine, recently completed an NIH-funded five-year study of the effects of a new computerized Screening, Brief Intervention, and Referral to Treatment system for addressing adolescent substance abuse in medical office settings. The evaluation was conducted among 12-18 yr old patients of 9 primary care clinic sites throughout New England USA and 10 sites in Prague, Czech Republic. Patients in two study arms (an intervention arm [cSBIRT] and a comparison arm receiving Treatment as Usual [TAU]) completed assessments prior to their clinic visit, immediately post-visit, and then 3- and 12-months later. Initial study results indicate that a brief screening and advice protocol is effective in reducing substance use among adolescents, particularly alcohol use among USA teens, and marijuana use among Czech teens.

iMET study: Through a federal ARRA Challenge Grant (National Institute of Dental and Craniofacial Research), Dr. Harris and the rest of the CeASAR team are developing and pilot-testing a new computerized internet-based Motivational Enhancement Therapy system (iMET) as a brief intervention strategy for adolescent substance use problems. To be used in conjunction with the cSBIRT system described above, the iMET system will offer primary medical and dental care providers a brief intervention tool for treating adolescent substance use issues in the clinical office, once identified through screening. The web-based computer program involves two parts, completed by the patient either in the office or at home, with provider follow-up. The randomized trial will include both medical and dental offices throughout New England and study assessments will be conducted before the visit, immediately post-visit, and 3- and 6-months post-intervention.

Primary Methodological Research

Survey Core staff conducted their own primary survey methodological research in FY2010. Based on this research, three abstracts were submitted to the Annual Meeting of the American Association of Public Opinion Research. The first abstract listed below was selected for a platform publication while Ms. Titiz and Ms. Krathwohl presented posters

Differences in Reliability and Validity Across Mail- and Phone-Administered Surveys
Sonja Ziniel, Harvard Medical School; Children’s Hospital Boston
Nina Rauscher, Children’s Hospital Boston
Jennifer Koch, Children’s Hospital Boston
David Thompson, Children’s Hospital Boston

Parent Proxy and Adolescent Self-Report: Parental Judgment of Adolescent Knowledge and Perceptions of Disease, Treatment, and Medical Care
Laurie Fishman, Harvard Medical School/Children’s Hospital Boston
In addition, Dr. Harris collaborated with Dr. Elizabeth Woods in Adolescent/Young Adult Medicine to develop a new brief Youth Connectedness to Provider (YCP) scale for assessing the degree to which adolescent patients feel connected to their health care provider. This measure was developed for use in provider intervention studies as the level of trust and connection adolescents feel towards their healthcare provider may influence their willingness to disclose sensitive information or to follow recommendations. This 7-item scale, to be completed by adolescents immediately after a visit, was demonstrated to have internal consistency reliability and construct validity in a sample of 1080 adolescent patients attending 9 clinic sites in New England.

Software Acquisition

During the Fiscal Year 2010, the Survey and Measurement Core implemented the REDCap web-based Survey/Database design tool, and purchased a new software license for SPSS Data Collection Author and SPSS Data Collection Interviewer Web. Both are available to users and researchers across the hospital through CRP and CRIT on a per-project basis.

SPSS Data Collection Author helps users create surveys, and allows for deployment in multiple modes, including online, telephone and offline. SPSS Data Collection Author provides an opportunity to deploy surveys in any language as well. In survey creation, an existing IBM SPSS Statistics (.sav) file can be used as a data dictionary, FIPS 140-2 compliance can be processed during installation process, and surveys can be created and deployed in an integrated environment that is suitable to support all phases of a survey project.

The software provides intuitive and visually appealing surveys for the end user and the respondents. SPSS Data Collection Author, with its advanced previewing and testing capabilities, yields responses with minimal need for data cleaning. Ease of use further facilitates the use of this software for CHB investigators. Studies that require a tool to develop and deploy complex surveys and even studies that need an intuitive database for their data that may or may not come from interviews or surveys can use this tool to collect and/or store data.

New Research Funding

Current research grant support for Survey Core staff is included in the full listing of research funding for CRP staff listed in Appendix C. Dr. Ziniel received funding from grants: a NIH grant for a project on “Returning Individual Genetic Research Results to Parents and Children” by Dr. Ingrid Holm, Department of Genomics and a grant for the “REUNITE System” by Dr. Sarita Chung, Department of Emergency Medicine. Dr. Harris is partially supported by 3 NIH grants to Dr. John R. Knight, Division of Developmental Medicine, and a Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Treatment grant to Dr. Sharon Levy, Division of Developmental Medicine.
Teaching Clinical Investigators

The Survey and Measurement Core plays an important role in educating CHB investigators about designing and implementing surveys and developing new measurement tools. Courses taught during FY2010 by Dr. Ziniel included lectures on designing questionnaires and evaluating measures as part of the Introduction to Clinical Research course and other departmental settings. In addition, Dr. Ziniel debuted an intensive multi-lecture workshop on survey methodology and questionnaire design. This course allowed investigators to complete their survey projects and the accompanying IRB application under the guidance of Dr. Ziniel. Due to the positive feedback and demand expressed by participants, Dr. Ziniel has taught a class on the use of focus groups in clinical research.

New Staff

Dr. Yolanda Martins was recruited to Children’s Hospital in September 2010 as part of a joint national search for a Survey Methodologist in the Clinical Research Program and Dana Farber Cancer Institute. Dr. Martins received her PhD in Social Psychology with a specialization in psychological factors affecting food selection and consumption in humans, and statistics and research methods at the University of Toronto (Toronto, Ontario, Canada). She then completed 2 years of postdoctoral training as a fellow at the Monell Chemical Senses Center in Philadelphia, Pennsylvania. After completing training, she held a faculty position in the School of Social Sciences at the Flinders University of South Australia. She has expertise in human eating behavior and in research methods, assessment and measurement. Her work in human eating behavior has increased our knowledge of the motivations underlying individuals’ everyday food rejections. Her research comparing the eating and feeding behaviors in children with Autism to those of typically developing children was the first large-scale study in this area, and her groundbreaking work on pheromones was one of the first to demonstrate that individuals’ sexual orientation plays a role in determining individuals’ responses to pheromones. She has over 12 years of experience conducting and consulting on projects in the areas of consumer behaviour, psychology, medicine, health and wellness, education and environmental issues.

Dr. Mihail Samnaliev was recruited to Children’s Hospital in September, 2010 as part of a joint recruitment with The Program for Patient Safety and Quality (PPSQ) and the Physicians Organization and into the newly created position of Health Economist. Dr. Samnaliev received his PhD in Economics with a Focus on Statistics and Health Economics from the University of Massachusetts at Amherst in 2004 and a Master of Science in Environmental Science from Central European University, Budapest, Hungary in 1999. He was formerly an Instructor in the Department of Family Medicine and Community Health, University of Massachusetts Medical School and Research Associate in the Research Unit, Center for Health Policy and Research, University of Massachusetts Medical School. In these prior roles, he collaborated on several grants studying the health outcomes and costs among Medicaid beneficiaries with co-occurring substance use, mental health and physical disorders. He also studied the quality of care among patients with persistent asthma and conducted several economic evaluations of Medicaid programs and pharmacy benefits. Mihail brings with him valuable skills and experience in health economic evaluations, cost effectiveness research design and statistical analysis, and academic writing. He will be working closely with investigators and hospital stakeholders to advance research on health outcomes, quality, and costs and related hospital-level initiatives.
Staffing

FY2010 Clinical Research Information Technology staff included the following.

Jonathan Bickel, MD, MS, Director of Clinical Research Informatics
Jason Rightmyer, MS, Team Leader
Mohamad Daniar, MS, Senior Applications Developer
James Gregoric, BS, Senior Applications Developer
Joseph Rezuke, BS, Lead Applications Developer and CTSU Informatics Manager
Charles McGow, BS, Applications Developer

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 CHB 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. New services include data warehousing for enhanced analytics as well as content management support to facilitate study Web site creation. Informatics consultation and custom software applications development are also available.

Clinical Research IT Goals

- **Scientific Collaboration and Consultation:** Collaborate with CHB core programs and clinical investigators to plan, implement and manage research projects, as well as provide operational and technical guidance to comply with CHB research policies and procedures.
- **Education and Training:** Provide mentoring and direct training to the research community regarding appropriate use of application software and integration with research operations.
- **Knowledge and Expertise:** Advance community knowledge of best practice standards for IT in clinical research as well as provide strategic advice regarding new technologies and industry trends.
- **Research:** Contribute to the expanding field of research informatics as well as directly support research activities of clinical and epidemiologic research studies.
- **Integration:** Broaden awareness of CRIT and ISD services in the research community.
- **Growth:** Enhance the capabilities and quality of services offered by CRIT. Specifically by expanding the software application portfolio, reducing development time and improving technical support and project management operations.
- **Professional development:** Foster and support the professional development of CRIT staff so that they may develop their skills and advance careers goals, while fulfilling the CHB mission.

Clinical Research IT Progress Report

The CRIT continued to provide its core services and has turned its focus to the development of an innovative product to support clinical research. CRIT also welcomed two new members to the team: Jonathan Bickel as Director, and Charles McGow as applications developer.

**EDC development and use continues to grow using Phase Forward InForm and REDCap FY2010 continued the trend in 2009. The use of EDC (electronic data capture) grows as the institution continues to articulate its vision of gathering clinical research into centralized, supported databases.**

In 2010, the enterprise adopted the 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 45 projects, 21 of which have gone into production. The numbers of users of this tool continues to grow rapidly with current user base of 262 users, 112 of whom are active users.

**The Phase Forward InForm EDC (electronic data capture) is in its second full year of use. The InForm system has continued to allow the enterprise to support major clinical trials. In total, there are 28 active InForm studies. This is clear evidence of the successful adop-**
tion of the product suite and more importantly to the hard work of the CHB InForm users
group.

**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 (CRCS), supports the following features.
- Centralized Patient Enrollment
- Study Scheduling
- Task and Patient Contact Management
- Patient Lab and Demographic Data Export from CDW

**Deployed end-user interface for cohort discovery - i2b2**
The CRIT expanded its service offering in 2010 to include i2b2, a clinical data warehouse. i2b2 is a comprehensive software and methodological framework that enables clinical researcher to accelerate the translation of clinical findings to the development of novel diagnostic, prognostic and therapeutic findings. It also provides a collaborative, organizational and software infrastructure for basic and clinical researchers.

The CRIT team is expanding 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.

**CRIT Web site**
The CRIT has continued to develop its own Web site. The site features a list of supported services, products and solutions. The site is accessible from the Internet and is available through the following Web address.

http://www.childrenshospital.org/crit

**Supported new Web Survey solutions**
The CRIT in close collaboration with the CRP Survey Core helped to deploy a new survey software suite SPSS Data Collection Author. The CRIT continues the support of “Checkbox” survey application as well.

**Supported administrative applications**
The CRIT continued to work closely with the CRP administrative team to revise and support administrative and operating software applications. Specifically, the team supported the ongoing use of the CRP Web-based budget tracking software and enhancing the CRP intake database with new effort tracking functionality and reports through CHQuery.
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<th>Appendix</th>
<th>Description</th>
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<td>Appendix A</td>
<td>Staff Biographies</td>
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<td>Appendix B</td>
<td>Staff Publications</td>
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<td>Appendix C</td>
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<td>Course Agendas</td>
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<td>Appendix F</td>
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APPENDIX A
STAFF BIOGRAPHIES

Program Director

Stavroula Osganian, MD, ScD, MPH
Dr. Osganian is a physician-epidemiologist with considerable experience in the design and conduct of epidemiologic and clinical research studies. Dr. Osganian’s research interests and activities focus on studies of youth health promotion and chronic disease prevention with an emphasis on preventive cardiology. Her present research includes a school nurse delivered smoking cessation intervention for adolescent smokers, a school nurse delivered obesity intervention in adolescents, a structured recess pilot in schools, and a trial of omega 3 fatty acid supplements in adolescents with elevated triglycerides. Dr. Osganian presently serves as Director of the Clinical Research Program at Children’s Hospital Boston and holds an appointment as Associate Professor of Pediatrics at the Harvard Medical School. She is also an attending in the Optimal Weight for Life Clinic at Children’s Hospital Boston.

Program Associate Director

Jonathan H. Dinsmore, PhD
Dr. Dinsmore has spent 17 years in the Biotechnology Industry leading interdisciplinary teams in the areas of clinical research, research and development, clinical manufacturing, regulatory affairs and business operations. He has research and clinical experience in the development of therapeutic products to treat Parkinson’s disease, Huntington’s disease, epilepsy, stroke, spinal cord injury, chronic intractable pain, diabetes, liver disease, cancer, and cardiovascular disease. Prior to his time in industry, Dr. Dinsmore earned a BS in Biology from Boston College in 1983 followed by a PhD in Biology from Dartmouth College in 1988. He then trained four years as a Post-doctoral Research Fellow at the Massachusetts Institute of Technology. His research accomplishments include numerous awarded and pending patents as well as an active publication record in high impact journals.

Biostatistics Core

Al Ozonoff, PhD, Director, Biostatistics Core
Dr. Ozonoff is the Director of the Biostatistics Core and holds an academic appointment in the Division of Emergency Medicine. Before joining CHB, Dr. Ozonoff served as Associate Professor and faculty member of the Department of Biostatistics at the Boston University School of Public Health from 2004-2010. Before that, he was a post-doctoral fellow at the Harvard School of Public Health under the direction of Prof. Marcello Pagano. Dr. Ozonoff collaborates in an ongoing effort to improve oral anticoagulation therapy at Veterans Administration care centers nationwide; he also consults with investigators on several international clinical trials. Dr. Ozonoff is also actively studying the clinical epidemiology of influenza and other respiratory disease; he continues to collaborate with informaticians and public health officials in the design and data analysis of surveillance systems, and consults frequently on statistical matters with public health officials at the local, state, and federal level. He also holds an adjunct appointment at the Harvard School of Public Health where he teaches a course on surveillance methods.
Janine Bacic, MS, Statistical Programmer
Janine Bacic joined the CRP as a statistical programmer in January 2009, bringing Masters of Science degree in statistics from Stanford University and a Bachelor of Arts degree from Boston College in both mathematics and economics. She provides statistical support to the Center for Adolescent Substance Abuse Research, the Developmental Medicine Center, and the department of Neurology.

Emily Blood, PhD, Senior Biostatistician
Dr. Blood joined the CRP in July 2009 and in her collaborative research has focused on design and analysis of all phases of clinical trials. She has experience applying this to several clinical areas including multiple myeloma, breast cancer, nursing research and orthopedic surgery. At Children’s Hospital, she works with the Adolescent/Young Adult Medicine, Psychiatry, and Developmental Medicine divisions. Dr. Blood’s statistical research has focused on the use of Mixed Effects Models and Structural Equation Models (SEM) in the longitudinal data setting.

Henry A. Feldman, PhD, Principal Biostatistician
Henry Feldman joined CRP in 2001, having held research and teaching positions at New England Research Institutes, Harvard School of Public Health, and NIH. His publications span public health, epidemiology, clinical medicine, and biological science on the animal, cellular, and molecular level. Through the Endocrinology Division, Dr. Feldman is co-investigator on numerous studies concentrating on obesity and bone health. He is a regular contributor to CRP educational offerings and actively counsels junior faculty and fellows on development of new protocols.

Ying Feng, MS, Statistical Programmer
Ying Feng joined the CRP as a statistical programmer in November 2009 upon completion of her Master of Science degree at Harvard School of Public Health, where she focused on epidemiology and biostatistics. Her responsibilities include data cleaning, data reporting, and data analysis. Ms. Feng had worked previously as a research assistant II at CHB with the Department of Vascular Biology and the Department of Neurology.

Peter Forbes, MA, Senior Biostatistician
Peter Forbes joined the CRP in 2000, following several years’ experience in the Learning Disabilities Research Center in the Department of Psychiatry. His activities include data cleaning, SAS programming, data analysis, statistical graphics, and participation in the writing of grants and papers. He conducts the computer laboratories for the Introductory to Biostatistics with SPSS course. His areas of interest include statistical software and programming, longitudinal data, sample design, and survey research methods.

Dionne Graham, PhD, Senior Biostatistician
Dionne Graham joined the CRP in 2005, bringing a doctorate in biostatistics from Harvard University and a Master’s degree in biomedical engineering from Johns Hopkins University. She is the Lead Statistician for the hospital’s Program for Patient Safety and Quality, and in this role, she oversees a team of statisticians in assessing the efficacy of various safety and quality initiatives and in developing and monitoring measures of quality of care at the hospital, department, and practitioner level. Dr. Graham also provides statistical support to the Department of Cardiology.

Matt Gregas, PhD, Senior Biostatistician
Matt Gregas joined the CRP in 2007 after completing a post-doc at Harvard School of
Public Health and a doctorate at the University of Minnesota, where he developed methodology for the analysis of neuronal data. He is affiliated with the Department of Neurology, where he works with faculty and fellows on neonatal epilepsy, autism, and the effects of neonatal hypotension on the physiology of the infant brain. Dr. Gregas’s methodological interests include nonparametric function estimation, functional data analysis, and changepoint estimation.

Chao-Yu Guo, PhD, Senior Biostatistician
Chao-Yu Guo joined the CRP in 2007, coming from a faculty position at Boston University Department of Mathematics and Statistics. His research activities have been focused on various statistical methodologies for epidemiological research, longitudinal studies, and statistical genetics using the Framingham Heart Study data. He has special interests in family-based linkage and association studies and missing data patterns in genetic studies. Dr. Guo is affiliated with the Program in Genomics, Department of Medicine and currently working on an autism project.

Lin Huang, PhD, Senior Biostatistician
Dr. Lin Huang joined the CRP in 2009 as a senior biostatistician and faculty member in the Department of Urology. She also serves as senior statistician for the department of Otolaryngology. Dr. Huang has also collaborated with investigators from other areas, such as stroke, breast cancer, and anesthesia. Her methodology research activities have been focused on semi-parametric models in survival analysis and sequential methods in clinical trials and biomedical studies. She also has interests in developing efficient and user-friendly statistical software programs.

Hongyu Jiang, PhD, Principal Biostatistician
Dr. Jiang joined CRP and the GI/Nutrition Program as a faculty member in 2008, bringing long-held interests and extensive collaborative experience in medicine, public health, and biological science. She worked as a faculty member in the Department of Biostatistics at Harvard School of Public Health for 8 years (2001-2008). She taught multiple courses and made significant contribution to methodology research in survival analysis, censored medical cost analysis, genome-wide association analysis for quantitative traits of complex diseases. Dr Jiang also has extensive collaborative research experience through her deep involvement in multiple national and international HIV/AIDS clinical trials. She has published clinical research papers on clinical trial design, antiretroviral treatment studies, viral genomic research, adherence and PK analysis, etc. Now she is actively engaged in GI/nutrition related research at Children’s Hospital Boston.

Leslie A. Kalish, ScD, Principal Biostatistician and Associate Director of Biostatistics for Harvard/Catalyst
Dr. Kalish joined the CRP in 2003, following 10 years at New England Research Institutes and 13 years in the Biostatistics groups at Dana Farber Cancer Institute and Harvard School of Public Health. His professional focus is the design, coordination, and analysis of clinical trials and other clinical research studies. He has collaborated in many areas, including HIV and other infectious diseases, transfusion medicine, alternative medicine, cystic fibrosis, and oncology. Currently, Dr. Kalish is affiliated with Infectious Diseases, Hematology/Oncology, and Orthopedics. He is Associate Director of Biostatistics for the CHB component of the Harvard Catalyst.

Paul Mitchell, MS, Senior Biostatistician
Paul Mitchell came to the CRP in 2007 with over 15 years experience in clinical trials, epidemiology, and survey research. At New England Research Institutes, he carried major
responsibility for statistical programming and analysis in national multi-center trials, including the Child and Adolescent Trial for Cardiovascular Health and the Pediatric Heart Network. Mr. Mitchell serves as statistician for the Gastroenterology/Nutrition Division as well as Harvard’s Clinical and Translational Science Center (Catalyst), providing collaborative assistance on study design, randomization, and data analysis to faculty and fellows. He also co-presents a CRP short-course on statistical power and sample size calculation.

Michael Monuteaux, ScD, Epidemiologist and Senior Biostatistician
Michael Monuteaux joined the CRP in March 2010 as a senior epidemiologist and biostatistician and faculty member in the Division of Emergency Medicine. Dr. Monuteaux is responsible for supporting research projects across a variety of clinical topics relevant to emergency care of children. Collaborating with a wide array of physician investigators, Dr. Monuteaux contributes to the design and analysis of observational cohorts and clinical trials as well as research grant applications. Dr. Monuteaux also participates in teaching biostatistics and research methodology to fellows, and in mentoring fellows and junior faculty.

Courtney Walls, MPH, Statistical Programmer
Courtney Walls joined the CRP in 2008 upon completion of her Master of Public Health degree from Yale University, where she focused on biostatistics. She has prior experience interning in the Department of Preventive and Behavioral Medicine at University of Massachusetts Medical School and with Pfizer Corp. She works predominantly with the Division of Adolescent Medicine.

Jing Zhou, MS, Biostatistician
Jing Zhou joined the CRP in 2006, bringing a Master’s degree in statistics and several years’ experience in trial design, data analysis, and statistical programming at Duke Clinical Research Institute and Brown University Medical School. She currently works with the Department of Cardiology to provide statistical support. She is also a statistician for the Program for Patient Safety and Quality.

Robin Walker, MSW, Administrative Coordinator, Biostatistics Core
Robin Walker, who joined the CRP in 2005, is in charge of financial management and administrative support for the Biostatistics Core. She has spent her professional life working in the non-profit sector, previously working as the administrative coordinator for the Center on Media and Child Health at Children’s Hospital and as the staff and resident education program coordinator for the Department of Anesthesia at Brigham and Women’s Hospital. Ms. Walker holds a Master of Social Work with a concentration in management and planning from Boston University.

Education Core

Jenifer R. Lightdale, MD, MPH, Director
Dr. Lightdale is an attending physician in the Division of Gastroenterology and Nutrition at Children’s Hospital Boston. She completed fellowship training in outcomes research first at the Institute for Health Policy Studies at the University of California, and later in the Harvard Fellowship in Pediatric Health Services Research. Dr. Lightdale received her Master’s degree from the Harvard School of Public Health. She has been on clinical staff at Children’s as a gastroenterologist in the Department of Medicine since finishing her gastroenterology fellowship here in 2001. Dr. Lightdale’s research has focused on improving patient safety for children receiving procedural sedation and analgesia. To date,
she has been supported in her work by a Mentored Career Development Award from the Agency for Healthcare Research and Quality (K08-HS013675), a Risk Management Foundation Patient Safety Award, and the Cook Endoscopy Award from the American Society of Gastrointestinal Endoscopy.

Stacey Springs, BA/BS, Education Coordinator
Ms. Springs joined the CRP as Education Coordinator in February 2009. Ms. Springs provides infrastructure to support all faculty and students involved in courses developed, directed, and organized by the CRP. She is responsible for coordinating and successfully implementing the growing clinical research education curriculum at Children’s. Prior to joining the CRP, Ms. Springs was an instructor and developed medical sciences curriculum for US Education Corporation. She also worked in a research laboratory at Harvard Medical School. Most recently, Ms. Springs served as Program Coordinator for the Melanoma & Sarcoma Clinical Research Team at the University of Arizona College of Medicine where she managed clinical trials and basic science research. She earned a BA in Political Science from the University of Arizona and a BS in Health Promotion from Northern Arizona University.

Project and Data Management Core

Susan McDermott, MPH, RN, CS, Clinical Research Team Leader
Susan McDermott, RN, MPH, joined the CRP in August of 2006 to serve as Team Leader of the Project and Data Management Core. As Team Leader, Susan provides leadership and supervision to the PDMC team and expert advice to CHB investigators for best practice methods in the areas of project and data management. Ms. McDermott also serves as Course Director for the Study Coordinator Orientation, the Study Coordinator Rounds and the Do-It-Yourself Data Management Courses and faculty for the Introduction to Clinical Research Course. Ms. McDermott’s specialties include clinical research team management, proposal development for field methods and budgeting; complex field methods development, deployment, testing and monitoring; data collection tools development; research staff training and certification; quality assurance planning; and development of quality control procedures for clinical research. Ms. McDermott received a BS in Nursing from St. Xavier University in Chicago and an MPH from the University of Hawaii.

Tracy Antonelli, MPH, Clinical Research Trial/Study Manager
Ms. Antonelli joined the CRP in February 2006, to provide assistance on many facets of clinical research, from protocol development through implementation. Ms. Antonelli supports research teams on overall study management, development of case report forms and manuals of operation, data management system development, and recruitment. Ms. Antonelli also provides support to General Clinical Research at Waltham. In this role, she implements protocols in the field and provides oversight of coordinator activities. Ms. Antonelli received her MPH from Boston University. She worked as an Associate Research Scientist at New England Research Institutes managing several multi-site NIH-funded studies and has several years of clinical research coordination experience at a large private urology practice.

Qiaoli (Lily) Chen, MA, Research Data Manager
Ms. Chen joined the CRP in January 2008 to serve as Research Data Manager. She holds a Master’s Degree in Sociology with a minor in Statistics from Iowa State University. Ms. Chen has experience developing data collection forms, building scientific databases, and performing statistical analysis. Her primary responsibilities as a CRP Data Manager
include developing case report forms, surveys and data management system specifications, designing and programming clinical research databases, and preparing scientific databases for statistical analysis, cleaning data and implementing quality assurance procedures.

Rajna Filip-Dhima, MS, Clinical Research Specialist
Rajna Filip-Dhima joined the CRP in March 2004. Ms. Filip-Dhima has completed a MS in Regulatory Affairs for Drugs, Biologics, and Medical Devices from Northeastern University. As Clinical Research Specialist, Ms. Filip-Dhima is responsible for implementing various aspects of a research study, from development of case report forms, specifications, and databases to manual of operations and study specific quality assurance activities. She oversees the overall coordination and data management of a number of studies. She trains study staff on clinical data management systems and works closely with PIs and biostatisticians on preparing databases for analysis. Ms. Filip-Dhima also develops randomization products in collaboration with CRP biostatisticians.

In the past, while completing her undergraduate studies at Northeastern University, she participated in the cooperative education program and worked as a research assistant at MGH, Boston City Hall, and the Laboratory of Social Psychology and Personality at Northeastern University. One of her major projects was a cross-cultural research study she conducted in Albania, where she collected data from 200 participants. She used this data to study cultural differences in emotional and personality styles between the Albanian and American cultures.

Sarah Steltz, MPH Clinical Research Specialist II
Sarah Steltz joined the CRP in 2008. As Clinical Research Specialist II, Ms. Steltz provides research management advice on study design, development of protocols and grant applications, data collection instruments, manuals of operation, and overall study coordination. Ms. Steltz has a Master of Public Health degree from the University of California, Berkeley. Prior to coming to the CRP, she worked at Kaiser Permanente Northern California Division of Research in the San Francisco Bay Area as project manager for a large NIH-funded prospective cohort study of breast cancer survivorship as well as ancillary and related studies. Ms. Steltz also has experience in childhood overweight research through her work at the University of California, Berkeley Center for Weight and Health.

Adam Simmons, MPH, CCRC Clinical Research Study Trial Manager, Acting Manger Clinical Research Operations and Development
Mr. Simmons joined the Children’s in October 2008. His responsibilities include providing support to investigators in the development of clinical research protocols and data management tools, including study manuals of operation, case report forms, and study-specific quality assurance activities. He works to develop and oversee the implementation of best practice guidelines for conducting various clinical research protocols to ensure that quality assurance is met at the hospital, program, state, and federal level. He also prepares training materials on quality assurance as a part of the Clinical Research Program’s educational efforts. Mr. Simmons has a MPH in epidemiology from Emory University. He worked as a clinical research project coordinator through the Department of Orthopaedics at the Emory University School of Medicine managing several industry sponsored trials in orthopaedics, spine, and sports medicine. He has been certified as a clinical research coordinator by the Association of Clinical Research Professionals since 2006. He also serves as a voting member on the Beth Israel Deaconess Medical Center Institutional Review Board.
Mark Berry, BS, MA Clinical Research Coordinator II
Mr. Berry joined the CTSU Clinical Research Coordinator Core (CRC Core) in January 2009 as a Clinical Research Coordinator. He holds a Master’s Degree in Exercise Physiology from the University of North Carolina-Chapel Hill. During his academic career, Mark worked as a research assistant at the University of Massachusetts-Amherst and UNC-CH, which helped to develop his interest and passion for clinical research. As a CRC-II, he is responsible for reviewing incoming protocols requesting CTSU coordinator support, as well as organizing various aspects involved with conducting research studies. His duties include recruiting and enrolling study participants, the maintenance of regulatory binders and source documents, as well as the accurate completion of Case Report Forms.

Emily Webster, BS, Clinical Research Coordinator
Ms. Webster joined the CTSU Clinical Research Coordinator Core (CRC Core) in July 2010 as a clinical research coordinator. After completing her Bachelor’s degree in Health Policy from Providence College, Emily began her professional career at Brigham and Women’s Hospital as research assistant for Pilot and Phase I-IV gastrointestinal related clinical research studies, NIH grants, and investigator-initiated projects. As a clinical research coordinator, Emily’s responsibilities include recruiting and enrolling patients for a variety of clinical trials. She is also responsible for maintaining regulatory binders, source documents and the completion of case report forms.

Lucy Abernethy, BA Clinical Research Coordinator
Lucy Abernethy joined the CRP as a Clinical Research Coordinator in April of 2010. She attended Michigan State University, where she majored in Social Relations and Policy. She has prior experience interning at the National Health Service in London and with the Michigan Senate. She works predominantly in Emergency Medicine.

Harold E. Thurston, Jr., MA, MAT, Administrative Coordinator
Mr. Thurston joined the CRP in March 2006; he provides overall administrative support for the Project and Data Management Core. He has spent his professional life working in the private public health research sector, most recently as the Executive Assistant to the Vice President of Communications and Media for New England Research Institutes, and as a patient information specialist at Caritas St. Elizabeth Medical Center, Boston. Mr. Thurston holds a Master of Arts with a concentration in Design & Environmental Analysis and a Master of Arts in Teaching with a concentration in Program and Curriculum Development from Cornell University.

Julie A. Barenholtz, MSW, Data Manager
Ms. Barenholtz joined the CRP in December 2009. She is responsible for coordinating clinical research studies including recruiting and enrolling study participants, maintaining study documents and patient files, completing case report forms and assisting the Principal Investigator in study procedures for projects in both Waltham and Boston. In her role as Data Manager, she works with study teams to build databases using various technologies, writes CRF specifications, reviews CRF design, and performs quality assurance.

Ms. Barenholtz has a Master of Social Work degree from Boston College. She has worked as a Clinical Research Assistant in the Beetham Eye Institute at Joslin Diabetes Center where she coordinated various clinical research studies related to diabetic eye disease within the Ophthalmology Department.
Survey Core

Sion Kim Harris, PhD, Director, Survey Research Methods Core
Dr. Harris has over 15 years of experience in survey design, implementation, and analysis and she provides consultation throughout Children’s Hospital Boston in the design and implementation of surveys. Dr. Harris also has extensive experience in public health epidemiology, psychometric evaluation of measures, clinical and community-based adolescent health research, program evaluation, and qualitative research methods. She has collaborated in the development and/or psychometric evaluation of numerous instruments for use in adolescent health research. She is currently an investigator in the CHB Center for Adolescent Substance Abuse Research, and holds joint faculty appointments in the Divisions of Adolescent/Young Adult Medicine, and Developmental Medicine.

Sonja Ziniel, PhD, MA, Senior Survey Methodologist
Sonja Ziniel joined the CRP in September 2008 after completing her doctorate in survey methodology at the Institute for Social Research at the University of Michigan. She also holds a Master’s degree in Public Policy and Management from the University of Konstanz, Germany. Dr. Ziniel has substantial experience in designing, implementing and analyzing national surveys. Dr. Ziniel provides consultation in all aspects of survey research throughout the Children’s Hospital Boston. She also directs the validation of the newly developed Inpatient Experience Survey within the Program for Patient Safety and Quality. Her current appointments include a faculty appointment in the Division of Adolescent and Young Adult Medicine and an appointment as an Instructor of Pediatrics at the Harvard Medical School. Among others, one of her research interests is to enhance the application and quality of surveys used in clinical research settings.

Mihail Samnaliev, PhD, Health Economist
Mihail Samnaliev joined the CRP in 2010 as a joint recruitment with The Program for Patient Safety and Quality (PPSQ) and the Physicians Organization. He will be working closely with all three groups to advance research on health outcomes, quality, costs, cost-effectiveness, and related hospital initiatives. Mihail was formerly an Instructor in Department of Family Medicine and Community Health, University of Massachusetts Medical School and Research Associate in the Research Unit, Center for Health Policy and Research, University of Massachusetts Medical School. In these prior roles, he collaborated on several grants studying the health outcomes and costs among Medicaid beneficiaries with co-occurring substance use, mental health, and physical disorders. He also studied the quality of care among patients with persistent asthma and conducted several economic evaluations of Medicaid programs and pharmacy benefits. Mihail received his PhD in Economics with a Focus on Statistics and Health Economics from the University of Massachusetts at Amherst in 2004.

Yolanda Martins, PhD, Senior Survey Methodologist
Dr. Martins joined the CRP in 2010 as a joint recruitment with the Dana-Farber Cancer Institute. Her previous positions include a faculty appointment in the School of Psychology at Flinders University in Australia and Principal Consultant at Inquirus Research Design and Statistics Consulting. She received her PhD in Social Psychology from the University of Toronto, Ontario, Canada in 2001. She has over 12 years of experience developing and conducting survey-based research. Her consultative work to date has focused on research methods, survey design, and statistical analyses for clinical and non-clinical researchers at various universities, and the Province of Ontario. At the CRP, she provides consultation on all aspects of survey design and analyses.
Handan Titiz, EdM, Survey Methodologist
Ms. Titiz joined the CRP in September 2007 as a Research Data Manager. She holds a M.Ed. from Harvard Graduate School of Education. Prior to joining CRP, Ms. Titiz worked at MGH, Harvard University, and the University of Massachusetts. Her current responsibilities include designing and programming case report forms, developing databases and data base specifications, randomizing participants in single and multi-site studies, performing quality assurance checks of the databases for clinical investigations, collaborating with project directors and investigators as a lead consultant or a data manager, and serving as faculty for the Do It Yourself Data Management Course.

Program Administration

Laura Haley, Program Administrative Coordinator
Ms. Haley joined the CRP in July 2003; she provides direct administrative support to the Program Director as well as general Program administration. She has over ten years of administrative experience, primarily in the private sector, in industries as varied as software development, manufacturing, marketing, and telecommunications.

Clinical Research Information Technology

Dr. Jonathan Bickel, Director of Clinical Research Informatics within ISD.
Jonathan comes to CHB from the Children's Hospital of Pittsburgh, where he completed his pediatrics residency, and where he provided direct patient care as Clinical Instructor in the Division of Emergency Medicine since 2007. He also obtained his Master's in Biomedical Informatics from the University of Pittsburgh this past May. He played several important roles in the Pittsburgh Children's rollout of its various HIMSS Level 7-recognized clinical EMR tools, including the design and rollout of Cerner's FirstNet and PowerNote, as well as electronic sign out applications. He also served on the Physician Advisory Committee there since 2007. At CHB, Jonathan will oversee the Clinical Research Informatics Core (CRIC) team, as it serves the clinical research community with IT services and tools to enable cutting edge clinical research.

Jason Rightmyer, MS, Team Leader
Mr. Rightmyer joined the CRP in March 2003, and brings extensive experience in clinical research informatics. As the team leader of applications development, he is responsible for directing all software development activities, including setting standards for data management system design and promoting informatics in clinical research. Mr. Rightmyer holds a graduate degree in Health Informatics from the University of Minnesota. Before joining Children’s Hospital, Mr. Rightmyer served as Project Director and Systems Programmer at New England Research Institutes. There he worked primarily on the co-design and development of a proprietary web-based data management system for clinical and epidemiological research. He has co-authored several NIH Small Business Innovation Research grant proposals and directed a number of additional projects including the development of a computer application for scientific randomization, an evidence-based smoking cessation program, and an expert system for clinical specialists.

Mohamad Daniar, MSIS, Senior Applications Developer
Mr. Daniar joined the CRP in November 2006. He has a Master's in Information Systems and many years of experience as a programmer and applications developer. He has extensive skills and knowledge using a number of database, web, and application technologies, including Microsoft.NET, Java, and SQL Server. He has worked previously for a number of high-tech software companies and is currently a Senior Applications
Developer in the Clinical Research Information Technology group. He is developing a clinical trials data management system for the BASH, Omegaven and several other projects.

James Gregoric, BA, Senior Applications Developer
Mr. Gregoric joined the CRP in April 2008. He has many years of experience as a senior software engineer and project leader. He has extensive skills and experience in the development of software for complex systems, including virtual driver development for automated test systems, a data management subsystem for a mass spectrometer, a physician note-writing system, and a handwriting recognition system. Mr. Gregoric holds a Bachelor’s degree in Philosophy from Lehigh University. He is currently developing web-based server software for the Gene Partnership Program and a database interface layer for the Clinical Research Coordination System.

Joseph Rezuke, BS, Lead Applications Developer and GCRC Informatics Manager
Mr. Rezuke joined the CRP in August 2002. As a Lead Applications Developer, he has designed several systems for clinical studies, including a laboratory inventory and specimen tracking system for the Pulmonary Medicine Tissue Bank project. Mr. Rezuke also serves as the Informatics Manager for the General Clinical Research Center (GCRC). In FY2004, Mr. Rezuke designed and developed an administrative windows based application for the GCRC and Core Lab. In FY2007 Mr. Rezuke developed several advanced reporting procedures for the CRP’s web-based budget tracking software application. In FY2009 Joseph lead a team in the design and development of the HCCRC Resource Review Request web based application for the Harvard Catalyst. This application allows investigators to submit requests for Harvard Catalyst-funded in- and outpatient resources. Investigators may apply for resources at one or more of the HCCRC’s Clinical Research Centers. The submitted application then goes through reviews for both resources and science.


APPENDIX C
COLLABORATIVE PROJECTS

The Clinical Research Program works collaboratively with numerous Children's Hospital Boston investigators from a wide variety of disciplines. The program presently provides such support to the following funded studies (all dollar figures represent Annual Direct Cost).

A. Federal Awards

5 U01 CA81457 (Boyett / CHB subcontract: Poussaint) 04/01/09-03/31/14
NIH/NCI $185,600
Pediatric Brain Tumor Consortium (PBTC)
The primary goal of this project is the establishment of a Neuroimaging Center for the Consortium. The center will develop and coordinate imaging protocols of PBTC trials, collect images, analyze data sets and establish a database of imaging results.

H34 MC10575 (Chung) 09/01/08-08/31/11
NIH/HRSA $250,000
REUNITE: A Novel Imaging System for Children Separated During Disaster
The REUNITE project addresses the difficulty of reuniting unidentified children who are separated from their caretakers after a public health emergency. The system will be developed to provide the functionalities of digital imaging, indexing, archiving, and retrieval of images of the victims of the disaster, with emulation features (digital reconstruction of facial trauma). REUNITE will then be tested in field tests of simulated disasters.

R01 MH087786 (Field) 12/01/09-11/30/14
NIH/NIMH $478,614
Empirical Eating Disorder Classification and Validation Using Prospective Studies
The aim of this study is to collect additional data on eating disorders and treatment from two ongoing cohort studies, the Growing Up Today Study (GUTS) in the United States and the Avon Longitudinal Study of Parents and Children (ALSPAC) in the United Kingdom to empirically create an eating disorder classification scheme.

RC1 DK 086486-01 (Fleming) 09/21/09-07/31/11
NIH/NIDDK $292,398
Hepcidin-based screening for infantile iron deficiency
This grant is a clinical trial to compare the use of a plasma hepcidin assay to other laboratory methods to screen for iron deficiency in infants.

2R44 HD049954-02 (Goldfield) 09/05/08-08/31/11
NIH/NICHD $218,258
Active Bottle for Home Care of Dysphagic Infants Phase II
This SBIR grant develops an advanced version of a new medical device, an active bottle that incorporates a milk flow control algorithm based upon the acoustics of infant swallowing. The bottle is designed to eliminate feeding problems during the home bottle feeding of preterm infants and infants with congenital heart disease.
R01 HD043869 (Gordon) 06/01/06-08/31/10
NIH/NICHD $167,260
Effects of Adrenal and Gonadal Hormone Replacement in Young Women with Anorexia Nervosa
A randomized, controlled trial in young women with anorexia nervosa, designed to measure the effects of an 18-month course of adrenal and gonadal steroid replacement on bone mass, markers of bone turnover, serum levels of IGF-I, and bone strength as assessed through cross-sectional geometric analysis of DXA data.

1R21 HL089659-01A1 (Guinan) 04/01/08-03/31/10
NIH/NIAID $150,000
rBPI21 & Endotoxin-directed Innate Immunity in Stem Cell Transplantation
In Specific Aim 1, we will determine the tolerability and pharmacokinetics of rBPI21 in BPI-deficient HSCT recipients in order to establish an understanding of the dose and schedule that will effectively block LPS mediated toxicity. The effects of rBPI21 infusion on the endotoxin-modulating activity of plasma will be investigated in Specific Aim 2. Specific Aim 3 will focus on determining the effect of rBPI21 infusion on the functional expression of the endotoxin receptor composed of MD-2, TLR4, and mCD14.

1RC1HG005491-01 (Holm) 10/01/09-09/30/11
NIH/NHGRI $287,448
Returning Individual Genetic Research Results to Parents and Children
The goal of this proposal is to understand the attitudes of participants in genomic research towards the return of research results in the setting where the participant is a child and the receiver of the information is the parent.

1R21 DK082661-01A1 (Huh) 07/01/09-06/30/11
NIH/NICHD $203,309
Maternal-Fetal Vitamin D Status and Child Adiposity, Insulin Resistance, and Blood Pressure
The goal of this study is to examine the extent to which maternal and fetal vitamin D status is associated with the development of childhood adiposity, insulin resistance, and blood pressure.

R01 DA018848 (Knight) 09/30/04-10/31/10
NIH/NIDA $427,900
Screening and Brief Advice to Reduce Teen Substance Abuse
The overall goal of this project is to augment the screening/brief advice intervention with educational materials, and then to assess the efficacy of this approach within a network of primary care practices.

R01 DA014553 (Knight) 06/01/04-03/31/11
NIH/NIDA $250,000
A Medical Office Intervention for Adolescent Drug Use
A randomized trial of a brief intervention, developmentally appropriate for adolescents and practical for use in busy clinic settings, designed to test its effect on drug use, engagement in treatment, and other substance-related outcomes. Factors that moderate or mediate the effect of intervention will be identified and measured.
Integrated Epithelial and Mucosal Biology
This is the Harvard Digestive Diseases Center grant, currently in its 24th year. Dr. Lencer is director of the Center.

Reducing Sugar-Sweetened Beverage Consumption in Overweight Adolescents
This project is a long-term, large-scale, multi-site randomized study partnering with six high schools in the greater Boston area. This study has been designed to demonstrate whether or not an intervention focused exclusively on sugar-sweetened beverage consumption is efficacious in the prevention and treatment of obesity in children.

A Novel Diet-Phenotype Interaction Affecting Body Weight
A two-center randomized controlled trial examining the effects of insulin responsiveness on response to weight-loss diets of different composition.

Sugar-sweetened beverages and cardiovascular disease risk: an RCT
A randomized trial comparing the effects of sugar-sweetened beverages, artificially sweetened beverages and unsweetened beverages on cardiovascular disease risk factors over a 1-year period.

Harvard Clinical and Translational Science Center (CTSC)
The Harvard CTSC is designed to: enhance the ability of investigators to identify information and access resources and tools necessary to conceive and successfully complete clinical and translational (C/T) experiments; engage experts from many diverse areas to address challenging questions in C/T research; involve academic disciplines not traditionally engaged in C/T research; provide novel advisory and facilitative human resources to lower the barriers to performing innovative, collaborative, and cross institutional C/T experiments; educate the broader Harvard research community as to the opportunities, challenges, and goals of C/T research; improve the impact of C/T research on underserved populations and communities; and ensure that opportunities in C/T research are equally afforded to all.

Neurocognitive Outcome of Infants of Diabetic Mothers
The major goal of this project is to assess the neurocognitive functioning of school-aged children whose mothers were diabetic during pregnancy.
Placebo Controlled Study of Baclofen for GERD in Children with Cerebral Palsy

The aims of this study are: (1) to gain preliminary evidence of the efficacy of baclofen to treat symptoms of GERD, in comparison to a placebo, in children with CP; (2) to assess the efficacy of baclofen vs. placebo in reducing the number of reflux events; (3) to assess the efficacy of baclofen vs. placebo in reducing the total number of transient lower esophageal sphincter relaxations (TLESRs), and reflux secondary to TLESRs; (4) to assess the safety and tolerability of baclofen administered over a two week period to treat children with CP and intractable GERD.

School Nurse Delivered Smoking Cessation Intervention for Adolescents

The overall aim of the project is to conduct a randomized controlled school-based trial (RCT) to evaluate the effectiveness of a promising four-session school nurse-delivered smoking cessation intervention in an ethnically diverse student population and with longer-term follow-up than in the pilot project.

A School-Nurse Delivered Intervention for Overweight and At-risk Adolescents

This exploratory project will adapt the school nurse-delivered smoking cessation intervention model for the treatment of overweight adolescents, and test its feasibility and potential efficacy in reducing BMI and improving diet, physical activity and sedentary behavior.

Health Literacy and Information Management in ADHD: Designing an Optimal Record

The goal of this project is to develop and evaluate an electronic data-entry tool for parents of children with ADHD, enabling the parents to provide data essential to the child’s treatment regardless of their own level of medical knowledge. The study will include a formative phase for instrument development, a retrospective examination of health literacy and documented ADHD care, and a prospective trial assessing the utility of the instrument.

Cholestasis Prevention (Phase II): Efficacy of IV Fish Oil (IND 73,488)

The major goal of this project is to determine whether parenteral administration of an omega-3 fatty acid based fat emulsion (OmegavenTM) reduces the proportion of patients with cholestasis (direct bilirubin >2 mg/dL for two consecutive weeks after one month of PN) in infants less than 3 months old with surgical gastrointestinal disease, compared to the administration of the conventional fat emulsion (Intralipid®).
**FD-R-003460-01 (Puder)**

**FDA**

$143,596

**Cholestasis Reversal (Phase II): Efficacy of IV Fish Oil (IND 73,488)**

The major goal of this project is to assess the efficacy of parenteral administration of fish oil derived fat emulsion (OmegavenTM) to reverse established PN associated liver disease, when compared to administration of soybean-based fat emulsion (conventional) in patients with surgical gastrointestinal disease.

**1R56Al084011-01A1 (Randolph)**

**NIH/NIAID**

$673,800

**Genetic Epidemiology of Life-Threatening Influenza Infection in Children**

The goal is to identify the inflammatory role of the innate immune response, including genes influencing innate immunity, on disease susceptibility and outcome for children and young adults with life-threatening and fatal influenza infection.

**R01GM085421 (Schachter)**

**NIH/NIGMS**

$185,000

**Preclinical Predictive Markers of Post-Approval Drug Safety**

The goal of this study is to develop and widely distribute preclinical pharmacologic predictive models of post-approval clinical safety.

**1R01 NS066929-01A1 (Soul)**

**NIH/NINDS**

$442,422

**Bumetanide Trial for Neonatal Seizures**

Newborn babies have the highest incidence of seizures, but medications currently used to treat them are relatively ineffective, and their seizures are often associated with serious long-term consequences such as cognitive impairments, cerebral palsy and epilepsy. Recent basic science research shows that the commercially available drug bumetanide is effective in suppressing seizures in newborns through an age-specific mechanism of action. The proposed pilot trial will determine the feasibility of a novel trial design to test new drugs to treat neonatal seizures, and will determine the pharmacokinetics and safety of bumetanide in newborns.

**R01 DC010290 (Tager-Flusberg / CHB subcontract: Nelson)**

**NIH/ NIDCD**

$1,277,053

**Infants at Risk for Autism Spectrum Disorder or Language Impairment**

The major goal of this project is to employ novel home-based methods for collecting frequent, detailed and rich behavioral data during the critical period between 6 and 12 months when the initial signs of language delay or ASD begin to emerge.

**1 RC1 DC010668-01 (Vernacchio)**

**NIH/NIDCD**

$417,533

**Xylitol Syrup for the Prevention of Acute Otitis Media in Otitis-Prone Children**

A randomized placebo controlled trial evaluating the efficacy of xylitol syrup in reducing the recurrence of acute otitis media in children aged 6 months to five years.
B. NIH Career Development Grants

5K12 HL087164-03 (Neufeld) 10/01/06-06/30/11
NIH/NHLBI $368,899
Clinical Hematology Research Career Development Program
The purpose is to develop and evaluate a multidisciplinary career development pro-
gram in non-malignant hematology that will equip new investigators with the knowl-
dge and skills to address complex problems in blood diseases. The program pro-
vides training to encourage promising young physician scientists to choose non-
malignant hematology as a career path, broaden the didactic experience within hema-
tology for graduates of the program, provide structured training in clinical research
methods, and evaluate the outcomes of the training program.

15K24 DK082792-01 (Nurko) 04/01/09-03/31/14
NIH/NIDDK $187,775
Patient Oriented Research in Pediatric Motility and Related Disorders
The purpose of this project is to oversee several ongoing patient-oriented research
projects in pediatric motility and related disorders.

1K23 DK076979-01A1 (Pappa) 09/01/08-08/31/13
NIH/NIDDK $167,000
Optimization of Vitamin D Status and Its Effects on Bone Health of Youth with
IBD
The goal of this project is to determine the appropriate regimens for both the treatment
of hypovitaminosis D and the maintenance of optimal vitamin D status, as well as the
impact of this intervention on the bone health and the disease outcome in young pa-
tients with IBD.

C. Glaser Pediatric Research Network: Design, Analysis and Coordinating
Center

(Feldman) 09/01/02-04/30/10
Glaser Pediatric Research Network $118,211
Design, Analysis, and Coordinating Center (DACC) for the Glaser Pediatric Re-
search Network
The DACC provides leadership in protocol development and statistical design for
GPRN, a consortium of pediatric academic medical centers performing multi-center
research, and conducts training in clinical research methods for the GPRN Fellowship
program.

(Moss/CHB subcontract: Jaksic/DACC: Kalish) 12/01/02-12/31/09
Glaser Pediatric Research Network $16,980
Necrotizing Enterocolitis (NEC) Surgical Database
This study will develop a multi-center prospective data collection process for necrotiz-
ing enterocolitis in order to provide accurate data regarding practice of treatment and
variability of care between different centers.
D. Foundation/Association/Other

(Ebbeling) 03/01/10-02/28/13
Thrasher Foundation $116,557
**Low-glycemic load vs. low-fat diet for treating PCOS in obese adolescents**
A pilot study examining the effects of a low glycemic load diet in the treatment of polycystic ovarian syndrome.

(Emans) 07/01/10-06/30/12
William T. Grant Foundation $12,500
**A Pilot Project to Enhance the Career Development of Promising Interdisciplinary Research Scientists in Adolescent Health**
This is a pilot project to initiate a research forum and mentoring project at the national meeting of the Society for Adolescent Health and Medicine (SAHM).

(Fiebiger) 01/01/08-12/31/10
Gerber Foundation $612,498
**A Prospective, Case-Controlled Study to Identify Novel Biologic Markers Associated with Eosinophilic Esophagitis**
A prospective study to find new non-invasive biomarkers for the evaluation of children with eosinophilic esophagitis.

(Levy) 01/01/07-12/31/09
Dana Foundation $100,000
**Endotoxin-related Innate Immunity in Patients Undergoing Hematopoietic Stem Cell Transplantation**
This study is a pilot clinical trial of rBPI21 administered to patients undergoing myeloablative allogeneic hematopoietic stem cell transplantation (HSCT). HSCT is often complicated by acute graft versus host disease (aGVHD) which is triggered by penetration of endotoxin from the intestines into the bloodstream. The protein rBPI21 is an endotoxin neutralizing agent. This study will investigate the presence of endotoxin and how rBPI21 might alter the body’s inflammatory response to it.

(Nelson) 07/01/09-06/30/12
Simons Foundation $300,000
**Electrophysiological, Metabolic and Behavioral Markers of Infants at Risk for Autism**
The major goals of this project are to a) identify endophenotypes that distinguish infants at high risk for developing autism from those at low risk, and b) predict which infants will eventually be diagnosed with an ASD from early neural and behavioral markers.

(Nurko) 03/01/07-12/31/10
Pappas Foundation $300,000
**Natural History of Eosinophilic Esophagitis**
This grant will be used to establish a registry of patients with eosinophilic esophagitis and GERD that will be used to determine the natural history of the diseases.
(Randolph) 12/01/08-09/30/10
America’s Health Insurance Plans/CDC $594,000
Genetic Epidemiology of Fatal and Life-Threatening Influenza in Children and Young Adults
The major goal of this project is to identify genetic determinants of life-threatening and fatal influenza infection in children and young adults. The cohort includes samples from autopsy specimens collected by the CDC on fatal influenza cases from 2003 onwards (130 subjects) and additional subjects recruited from US and Canadian pediatric ICUs in 2009 (140 subjects).

(van der Velden) 11/01/09-10/31/10
Greenwall Foundation $60,000
Factors Associated with the Withdrawal of Life-Sustaining Treatment in Neurologically Injured Patients in the Pediatric Intensive Care Unit
The aims of this project are: (1) to quantitatively identify predictors of the decision to withdraw life sustaining treatment (LST) in neurologically injured patients in the pediatric ICU; and (2) to hypothetically evaluate how physicians working in pediatric ICUs make recommendations with regard to withdrawal of LST in neurologically injured patients based on factors established in Aim 1.

(Walsh) 10/1/06-3/31/10
Simons Foundation $416,663
Phenotypic and Genotypic Factors in ASD Simplex Families
The major goal of this project is to collect samples for the Simons Foundation repository for research into the phenotype and genotype of autism.

E. Industry

(Bousvaros) 06/20/08-06/19/10
Merck Pharmaceuticals $68,142
Immune Response to Vaccines in Patients with Inflammatory Bowel Disease
The goal of this project is to identify the immune response to the HPV vaccine in children with IBD on immunosuppressive therapy.

(Osganian) 05/01/08-12/31/10
Glaxo Smith Kline $152,000
A Randomized Placebo Controlled Trial of Lovaza in Adolescents with Mild to Moderate Hypertriglyceridemia
This clinical trial will examine the efficacy of Lozava, an omega 3 fatty acid supplement, in lowering triglycerides among adolescents ages 12-19 years old.
### INTRODUCTION TO CLINICAL RESEARCH
#### FALL 2010 COURSE AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:15 - 1:00</td>
<td>Registration and Pick Up Lunch Tote</td>
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<tr>
<td>1:00 - 1:15</td>
<td>Registration and Pick Up Lunch Tote</td>
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<tr>
<td>2:15 - 2:25</td>
<td>Break</td>
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<tr>
<td>2:25 - 3:10</td>
<td>Designing Surveys and Questionnaires</td>
<td>S. Ziniel</td>
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<tr>
<td>3:10 - 3:15</td>
<td>Break</td>
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<tr>
<td>3:15 - 4:00</td>
<td>Evaluating Measures in Clinical Research</td>
<td>S. Ziniel</td>
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<td>4:00 - 4:05</td>
<td>Break</td>
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<tr>
<td>4:05 - 5:00</td>
<td>Descriptive and Univariate Statistics</td>
<td>D. Graham</td>
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</table>

#### Day Two: Wednesday, September 15, 2010

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>12:00</td>
<td>Arrival and Pick Up Tote Lunch</td>
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<tr>
<td>12:15 - 1:15</td>
<td>Observational Study Designs</td>
<td>M. Monuteaux</td>
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<tr>
<td>1:15 - 2:20</td>
<td>Data Collection Best Practices for Clinical Researchers</td>
<td>A. Simmons</td>
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<td>2:20 - 2:30</td>
<td>Break</td>
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<tr>
<td>2:30 - 3:15</td>
<td>Ethics and Integrity in Clinical Research</td>
<td>S. Joffe</td>
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<td>3:15 - 3:20</td>
<td>Break</td>
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<tr>
<td>3:20 - 3:50</td>
<td>Small and Common Study Mistakes Researchers Make with Big Consequences</td>
<td>M. Sueiro</td>
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<td>3:50 - 4:00</td>
<td>Break</td>
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<tr>
<td>4:00 - 5:00</td>
<td>Introduction to Regression Analysis</td>
<td>H. Feldman</td>
</tr>
</tbody>
</table>
# INTRODUCTION TO CLINICAL RESEARCH
## FALL 2010 COURSE AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 - 12:15</td>
<td>Arrival and Pick Up Tote Lunch</td>
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<tr>
<td>12:15 - 1:00</td>
<td>Clinical Trials: Design and Monitoring</td>
<td>E. Neufeld</td>
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<tr>
<td>1:00 - 1:45</td>
<td>Grant Writing 101</td>
<td>J. Lightdale</td>
</tr>
<tr>
<td>1:45 - 2:15</td>
<td>NIH Review</td>
<td>R. Grand</td>
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<tr>
<td>2:15 - 2:20</td>
<td>Break</td>
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<tr>
<td>2:20 - 2:50</td>
<td>10 Questions Every Investigator Should Ask Before Doing a Study with Drugs, Devices or Biologics</td>
<td>M. Wiadowski</td>
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<tr>
<td>2:50 - 3:00</td>
<td>Break</td>
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<tr>
<td>3:00 - 3:30</td>
<td>Translational Research</td>
<td>J. Lee</td>
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<tr>
<td>3:30 - 4:15</td>
<td>Industry and Philanthropy</td>
<td>S. Nurko</td>
</tr>
</tbody>
</table>

**Day Three: Thursday, September 16, 2010**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Instructor</th>
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<tbody>
<tr>
<td>11:45 - 12:00</td>
<td>Arrival and Pick Up Tote Lunch</td>
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<tr>
<td>12:00 - 4:00</td>
<td>Human Subjects and the Institutional Review Board</td>
<td>S. Kornetsky</td>
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<tr>
<td>1:00 - 1:30</td>
<td>The IRB Review Process: An Insider's View</td>
<td>L. Shrier</td>
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<td>1:30 - 1:35</td>
<td>Break</td>
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<tr>
<td>1:35 - 2:35</td>
<td>Writing for Scientific Publication</td>
<td>S.J. Emans</td>
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<td>2:35 - 2:40</td>
<td>Break</td>
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<tr>
<td>2:40 - 3:25</td>
<td>Scientific Presentations</td>
<td>J. Finkelstein</td>
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<tr>
<td>3:25 - 3:30</td>
<td>Break</td>
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<tr>
<td>3:30 - 4:15</td>
<td>Overview of Clinical Research at Children’s Hospital Boston</td>
<td>V. Goganian</td>
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<tr>
<td>4:15 - 4:30</td>
<td>Course Wrap-up</td>
<td>J. Lightdale</td>
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</tbody>
</table>
Introduction to Biostatistics with SPSS

Contact Information:
Instructors
Hongyu Jiang, PhD
Hongyu_jiang@childrens.harvard.edu
8-4748

Peter Forbes, MA
Peter.Forbes@childrens.harvard.edu
8-4715

Coordinator
Stacey Sprins
Stacey.Spinn@childrens.harvard.edu
8-4724

Course Description:
This eight lecture course and companion computer lab sessions will cover the basic principles of biostatistics as well as provide an introduction to SPSS. Topics will include:

- Data Summaries
- Graphical methods
- Mean and Confidence intervals
- Comparing Means
- Non-parametric tests
- Comparing Proportions
- Managing your data
- Statistical analysis with SPSS

Course Learning Objectives:
Upon completion of this course, participants will gain a better understanding of how to:

- Summarize data and present results in graphical and tabular forms
- Calculate and interpret confidence intervals
- Compare means between two or more groups using t-test and ANOVA
- Interpret p-values
- Perform non-parametric tests
- Estimate and compare proportions
- Choose the appropriate statistical test
- Evaluate and interpret the performance of a screening or diagnostic test
- Create and import datasets in SPSS
- Perform data cleaning and create new variables in SPSS
- Use SPSS to perform the statistical methods presented during lecture

Course Target Audience
Junior faculty, fellows, nurse investigators, study coordinators and others who desire further knowledge of introductory biostatistics

Course Schedule
Lecture
Dates: September 28-November 16, 2010 (Tuesdays)
Times: 3:30 PM – 5:00 PM
Location: One Autumn Street, Auditorium B

Lab
Dates: September 30, – November 18, 2010 (Thursdays)
Lab Session A: 2:00 – 3:30 PM
Lab Session B: 3:30 – 5:00 PM
Training Room 8, One Autumn Street

Recommended Texts (not required):
This is an introductory-level book covering the basics of biostatistics. It is more conceptual than mathematical.

A good biostatistics reference book for those with a more quantitative background. Contains more mathematical development of formulas than Pagano and Gauvreau.
# Children's Hospital Boston Clinical Research Program Education Core Course Syllabus

**Introduction to Biostatistics with SPSS**

## Fall 2009 Course Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Topics</th>
<th>Topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 26</td>
<td>Graphical Methods and Summary Statistics</td>
<td>Introductions: Participate in the Course Introductions.</td>
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<tr>
<td></td>
<td></td>
<td>Review: The Syllabus.</td>
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<td><strong>Lecture 1: Graphical Methods and Summary Statistics</strong></td>
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<td></td>
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<td>• Data Types</td>
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<td>• Graphical Display: <strong>Bar Charts, Histograms, Boxplots</strong></td>
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<td>• Summary Statistics: <strong>Measures of Central Tendency, Measures of Spread</strong></td>
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<tr>
<td>September 30</td>
<td>SPSS Lab</td>
<td><strong>Lab 1: Introduction to the SPSS Interface</strong></td>
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<tr>
<td></td>
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<td>• Opening an existing SPSS database</td>
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<td>• Graphical data analysis</td>
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<td>• Descriptive statistics</td>
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<td>• Subsetting data sets</td>
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<tr>
<td>October 5</td>
<td>Estimating the Mean and Confidence Intervals</td>
<td><strong>Lecture 2: Estimating the Mean and Confidence Intervals</strong></td>
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<tr>
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<td>• Normal Distribution</td>
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<td>• Principles of Estimation</td>
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<td>• Estimating the Mean</td>
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<td>• Confidence Intervals for the Mean</td>
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<td>October 7</td>
<td>SPSS Lab</td>
<td><strong>Lab 2: Data set basics</strong></td>
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<tr>
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<td>• Confidence intervals for the mean</td>
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<td>• Introduction to SPSS syntax</td>
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<td>• Descriptive analysis by group</td>
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<td>• Subsetting data sets</td>
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<td>• Creating a new data set from &quot;scratch&quot;</td>
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<tr>
<td>October 12</td>
<td>Hypothesis Testing &amp; Comparing Two Means</td>
<td><strong>Lecture 3: Hypothesis Testing &amp; Comparing Two Means</strong></td>
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<tr>
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<td>• Inference Overview</td>
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<td>• Introduction to Hypothesis Testing</td>
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<td>• Comparing Two Means: <strong>Paired t-test, Two sample t-test</strong></td>
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<td>• Interpreting p-values</td>
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<td>October 14</td>
<td>SPSS Lab</td>
<td><strong>Lab 3: Tests and by-group analysis</strong></td>
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<tr>
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<td>• Two sample t-test</td>
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<td>• Paired t-test</td>
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<td>• More SPSS syntax</td>
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<tr>
<td>October 19</td>
<td>Comparing Three or More Means</td>
<td><strong>Lecture 4: Comparing Three or More Means</strong></td>
</tr>
<tr>
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<td>• Analysis of Variance (ANOVA)</td>
</tr>
<tr>
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<td><strong>Recommended Readings</strong></td>
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*P&G: Sections 2.1-2.3, 3.1-3.2
Rosner: Sections 2.1-2.5, 2.8

*P&G: Sections 7.1, 7.4, 8.1-8.3, 9.1, 9.3
Rosner: Sections 5.1-5.5, 8.1-8.2, 8.5

*P&G: Sections 10.1-10.2, 10.4, 11.1-11.2
Rosner: Sections 7.1-7.3, 8.1-8.2, 8.4, 8.7

*P&G: Sections 12.1-12.2
Rosner: Sections 12.1-12.4
<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Lab Content</th>
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<tr>
<td>October 21</td>
<td>SPSS Lab</td>
<td>Lab 4: More dataset basics and tests</td>
</tr>
<tr>
<td></td>
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<td>- Variable creation and recoding</td>
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<td>- Variable creation and recoding with menus and with syntax</td>
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<td>- ANOVA</td>
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<tr>
<td>October 26</td>
<td>Non-Parametric Tests, Correlation</td>
<td>Lecture 5. Non-Parametric Tests, Correlation</td>
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<tr>
<td></td>
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<td>- Nonparametric Tests: Wilcoxon rank sum: Kruskal-Wallis</td>
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<td>- Correlation</td>
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<tr>
<td>October 28</td>
<td>SPSS Lab</td>
<td>Lab 5. Non-parametric tests and correlation</td>
</tr>
<tr>
<td></td>
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<td>- Wilcoxon and KW tests</td>
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<td>- Correlation</td>
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<tr>
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<td></td>
<td>- Estimating a Proportion</td>
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<tr>
<td></td>
<td></td>
<td>- Confidence intervals for Proportions</td>
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<tr>
<td></td>
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<td>- Comparing Two or More Proportions: Chi-squared test, Fisher's exact test</td>
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<td>November 4</td>
<td>SPSS Lab</td>
<td>Lab 6. Tests for proportions</td>
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<tr>
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<td>- One sample test for proportions</td>
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<td>- Crosstabs</td>
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<td></td>
<td></td>
<td>- Chi squared test</td>
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<tr>
<td></td>
<td></td>
<td>- Fisher's exact test</td>
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<tr>
<td></td>
<td></td>
<td>- Reading data from other data formats</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Risk difference</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Risk ratio</td>
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<tr>
<td></td>
<td></td>
<td>- Odds ratio</td>
</tr>
<tr>
<td>November 11</td>
<td>SPSS Lab</td>
<td>Lab 7. Odds ratios and diagnostic tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Odds ratios</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Sensitivity and specificity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Understanding and using date variables</td>
</tr>
<tr>
<td>November 16</td>
<td>Putting it all together</td>
<td>Lecture 8. Putting it all together</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Picking the right test</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Interpreting the literature</td>
</tr>
<tr>
<td>November 18</td>
<td>SPSS Lab</td>
<td>Lab 8. Additional SPSS features you need</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Tutorials</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Case studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Syntax Reference</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lab wrap-up and discussion</td>
</tr>
</tbody>
</table>
Children's Hospital Boston Clinical Research Program Education Core Course Syllabus

**Introduction to Regression Analysis**

<table>
<thead>
<tr>
<th>Instructor Information</th>
<th>Instructors:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Matt Gregas, Ph.D.</td>
</tr>
<tr>
<td></td>
<td>Janine Bacic, M.S.</td>
</tr>
<tr>
<td></td>
<td>Courtney Walls, M.P.H.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course Coordinator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stacey Springs, BS</td>
</tr>
<tr>
<td>Telephone extension: 84724</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression analysis is the most commonly used statistical methodology. As a broad topic it includes analysis of variance (ANOVA), logistic regression, linear mixed models, and generalized linear models. This course aims to teach the general concepts of regression methods and provide the framework of these methods with the aim improving statistical literacy on this important topic. Specific methods covered will be simple and multiple linear regression, logistic regression, and generalized linear models (GLM). Connections will be made to other topics including the important ANOVA regression connection. A basic approach to statistical model building via regression analysis will be demonstrated. In laboratory sessions participants will learn to implement lecture materials with SAS software.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course Goals:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Learn Basics of Linear Regression.</td>
</tr>
<tr>
<td>Build and interpret regression models.</td>
</tr>
<tr>
<td>Understand limitations and extensions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course Prerequisite:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designed for Faculty, Fellows, and Clinical Research Investigators, participants should have an understanding of basic statistics. A self-assessment is included on the application.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lecture Sessions:</strong> 11:00-12:00 PM</td>
</tr>
<tr>
<td>March 31, 2010: Karp 8</td>
</tr>
<tr>
<td>April 7, 2010: Training Room 8</td>
</tr>
<tr>
<td>April 14, 2010: Karp 8</td>
</tr>
<tr>
<td>April 21, 2010: Karp 8</td>
</tr>
<tr>
<td>April 28, 2010: Karp 8</td>
</tr>
<tr>
<td>May 5, 2010: 21 Autumn Street 2nd Floor Conference Room</td>
</tr>
<tr>
<td>May 12, 2010: Karp 7</td>
</tr>
<tr>
<td>May 19, 2010: Karp 8</td>
</tr>
</tbody>
</table>

| Lab Sessions: |
|               |
| SAS Sessions: 10:00 AM-11:00 AM |
| R Session: 11:00 AM - 12:00 PM |
| April 1, 2010: Training Room 6 |
| April 8, 2010: Training Room 8 |
| April 15, 2010: Training Room 8 |
| April 23, 2010: Training Room 8 |
| April 29, 2010: Training Room 6 |
| May 6, 2010: Training Room 8 |
| May 13, 2010: Training Room 8 |
| May 21, 2010: Training Room 8 |

<table>
<thead>
<tr>
<th>Class Breakdown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture Hours: 8</td>
</tr>
<tr>
<td>Lab Hours: 8</td>
</tr>
<tr>
<td>Total Hours: 16</td>
</tr>
</tbody>
</table>
### Instructor Information:

Sonja I. Ziniel, Ph.D., M.A.
Office Location: 21 Autumn St, Room 204
Phone: 857-218-4738
E-mail: Sonja.Ziniel@childrens.harvard.edu

### Course Description:

This course is an intensive 8-session workshop that will provide an introduction to survey and questionnaire design. Participants will learn important information about the survey process in general and apply what was learned immediately to their own survey project. In addition, participants will also be guided in filling out an IRB application for a research study including a survey. Class discussions and individual meetings with the instructor throughout the course will provide participants with continuous feedback on their projects. At the end of the class, each participant should have a good first draft of the questionnaire to be used in their study ready to be pretested as well as a complete IRB application.

### Course Goals or Course Learning Outcomes:

- Learn general information about survey and questionnaire design
- Create survey questions specific to your own survey project
- Have a first draft of the questionnaire that can be pretested
- Complete an IRB application for your own survey project

### Course Prerequisite

- Plan to conduct a survey in the near future
- Have a good understanding of survey goals
- Know the literature
- Some draft questions of survey to be designed in this workshop
- Meeting with the instructor prior to first session

### Course Schedule

Time: 12-2pm

Dates and Locations:
- October 5, 2010: Karp Building, 8th Floor Conference Room
- October 12, 2010: Karp Building, 8th Floor Conference Room
- October 19, 2010: Karp Building, 8th Floor Conference Room
- October 26, 2010: Karp Building, 8th Floor Conference Room
- November 2, 2010: Karp Building, 8th Floor Conference Room
- November 9, 2010: Karp Building, 8th Floor Conference Room
- November 16, 2010: Karp Building, 8th Floor Conference Room
- November 23, 2010: No class – week of Thanksgiving
- November 30, 2010: Karp Building, 8th Floor Conference Room

### Class Breakdown

<table>
<thead>
<tr>
<th>Category</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture Hours</td>
<td>16</td>
</tr>
<tr>
<td>Meetings with Instructor</td>
<td>2</td>
</tr>
<tr>
<td>Homework (Your Survey)</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total Hours</strong></td>
<td><strong>38</strong></td>
</tr>
</tbody>
</table>
Children's Hospital Boston Clinical Research Program Education Core Course Syllabus

Survey and Questionnaire Design – intensive Workshop

Course Schedule:

<table>
<thead>
<tr>
<th>Module</th>
<th>Topics</th>
<th>Tasks</th>
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</thead>
<tbody>
<tr>
<td>Module 1</td>
<td>Research Question and Hypotheses</td>
<td>• Introduction: Course Introductions and Project Introductions</td>
</tr>
<tr>
<td></td>
<td>Overview of the Survey Process</td>
<td>• Review: The Syllabus</td>
</tr>
<tr>
<td></td>
<td>Total Survey Error Paradigm</td>
<td>• Lecture</td>
</tr>
<tr>
<td></td>
<td>Sampling/Recruiting</td>
<td>• Assignments:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Literature review done?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Check your research questions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Check your hypotheses.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Draft a study plan.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Specify how you will sample/recruit subjects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o If applicable, determine sampling frame (exclusion and inclusion criteria).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o If applicable, address potential coverage error and sampling bias.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Determine sample size (over next 3 weeks).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Complete IRB Application Part A Questions 1-7 and Part B Questions 1-4</td>
</tr>
<tr>
<td>Module 2</td>
<td>Data Collection Mode</td>
<td>• Lecture</td>
</tr>
<tr>
<td></td>
<td>Measurement Process</td>
<td>• Discussion: Project Reports</td>
</tr>
<tr>
<td></td>
<td>Validity</td>
<td>• Assignments:</td>
</tr>
<tr>
<td></td>
<td>Reliability</td>
<td>o Draft cover letter, invitation email, flyers.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o First draft of questionnaire.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Complete IRB Application Part A Questions 8-10 and Part B Question 4f-4l</td>
</tr>
<tr>
<td>Module 3</td>
<td>Informed Consent</td>
<td>• Lecture</td>
</tr>
<tr>
<td></td>
<td>Informed Assent</td>
<td>• Discussion: Project Reports</td>
</tr>
<tr>
<td></td>
<td>Questionnaire Design</td>
<td>• Assignments:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o First draft of survey matrix.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Second draft of questionnaire.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Complete IRB application Part C.</td>
</tr>
</tbody>
</table>
## Module 4: Questionnaire Design
- **Lecture**
- **Discussion:** Project Reports
- **Assignments:**
  - Appointment with instructor
  - Second draft of survey matrix
  - Third draft of questionnaire

## Module 5: Evaluating Survey Questions & Instruments
- **Lecture**
- **Discussion:** Project Reports
- **Assignments:**
  - Outline how you will evaluate your questions and add it to the study design section of the IRB application
  - Third draft of survey matrix
  - Fourth draft of questionnaire

## Module 6: Response Rates, Improving Survey Participation
- **Lecture**
- **Discussion:** Project Reports
- **Assignments:**
  - Set up measuring components of response rates
  - Plan how to improve survey participation and add it to the study design section of the IRB application
  - Complete IRB application Part A Questions 11-10

## Module 7: Study Implementation, Data Processing, Data Coding
- **Lecture**
- **Discussion:** Project Reports
- **Assignments:**
  - Think about your study implementation and anticipate problems
  - Assign codes to data questions and response options
  - Specify data analysis plan
  - Complete IRB application Part A Question 11 and Part B Questions 5-6

## Module 8: Data Analysis
- **Lunch**
- **Discussion:** Project Reports
- **Lecture**
- **Assignments:**
  - Complete IRB application Part D
Coordinator Rounds FY 2010

12/2/09: Source Documentation: Using Electronic Medical Records for Clinical Research Data
          Eunice Newbert

2/3/10: Avoiding Bias in the Research Interview
          Sonja Zimiel, PhD

4/7/10: Randomization, Blinding & Un-blinding
          Henry Feldman
          Cara Ebbeling
          Margaret Lovesky

          The Role of Subject Advocacy
          Enrico Cagliero, MD
          Associate Professor of Medicine
          Harvard Medical School
          Research Subject Advocate
          Harvard Catalyst

8/4/10 Child Development 101
          LaKeisha S. Garcia, MS, CCLS
          Child Life Specialist
          Miranda Guardiano, MS, CCLS
          Child Life Specialist II
# ORIENTATION FOR NEW STUDY COORDINATORS

## COURSE AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:15-8:30</td>
<td>Continental Breakfast</td>
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</tr>
<tr>
<td>8:30 – 8:45</td>
<td>Welcome and Overview</td>
<td>S. Springs</td>
</tr>
<tr>
<td>8:45 - 9:05</td>
<td>Role of the Study Coordinators</td>
<td>T. Antonelli</td>
</tr>
<tr>
<td>9:05 – 9:30</td>
<td>Human Subject Protections / IRB Issues: Before the Research Begins</td>
<td>CCI Staff</td>
</tr>
<tr>
<td>9:30 – 10:00</td>
<td>IRB Issues: During the Research</td>
<td>CCI Staff</td>
</tr>
<tr>
<td>10:00 – 10:15</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>10:15 – 11:15</td>
<td>Informed Consent/Assent/Subject Recruitment</td>
<td>CCI Staff</td>
</tr>
<tr>
<td>11:15 – 11:30</td>
<td>Recruitment Tools from Marketing &amp; Public Affairs</td>
<td>G. Colavecchio</td>
</tr>
<tr>
<td>11:30 – 12:15</td>
<td>Obtaining Informed Consent/Assent: A Practical Approach</td>
<td>V. Turbini</td>
</tr>
<tr>
<td>12:15 – 12:30</td>
<td>Introduction to the Clinical and Translational Study Unit (CTSU)</td>
<td>K. Jordan</td>
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<tr>
<td>12:30 – 1:00</td>
<td>Catered Lunch</td>
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<tr>
<td>1:00 – 1:10</td>
<td>Introduction to the Clinical Trials Office</td>
<td>A. Hannibal</td>
</tr>
<tr>
<td>1:10 - 2:10</td>
<td>Introduction to the Clinical Research Program (CRP)</td>
<td>S. Springs</td>
</tr>
<tr>
<td>1:10 - 2:10</td>
<td>Study Implementation &amp; Timeline Development</td>
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<td></td>
<td>Principles of Data Management</td>
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<td>Case Report Forms</td>
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<td></td>
<td>Manual of Operations</td>
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<tr>
<td>2:10 – 2:20</td>
<td>Break</td>
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<tr>
<td>2:20 – 3:10</td>
<td>Introduction to the Education &amp; Quality Improvement Program (EQuIP)</td>
<td>E. Newbert</td>
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<tr>
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<td>Study Documentation: Common Errors</td>
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<td></td>
<td>Methods of Organizing Study Documents</td>
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<td></td>
<td>Storage of Study Documents and Informed Consent Documents</td>
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</tr>
<tr>
<td>3:10 – 3:26</td>
<td>Wrap-Up &amp; Review</td>
<td>S. Springs</td>
</tr>
</tbody>
</table>
APPENDIX E
PROGRAM DESCRIPTION AND REQUEST FOR ASSISTANCE FORM

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

The CRP at Children's Hospital Boston is an interdisciplinary research program that provides assistance and education to the clinical research community at Children's. The program directly supports one of Children's core mission areas, to be the leading source of research and discovery, and includes the following areas of focus: clinical research methodology (including biostatistics, epidemiology and informatics); collaboration or consultation on the design, conduct and analysis of clinical research studies; and education in clinical research and practice.

ASSISTANCE:
The CRP provides basic consultation and assistance with grant and protocol development and protocol implementation as well as an offering of educational courses aimed at both the experienced and new investigator through hospital support. Beyond this, the CRP offers advanced assistance as funded collaborators on research projects or with reimbursement. A summary of services, cost recovery structure, and budgeting process can be found on the reverse side of this broadsheet. All types of assistance depend on staffing and resources available to the CRP at the time of the request.

CRP AS DATA AND STATISTICAL COORDINATING CENTER:
The CRP provides assistance with data and statistical coordination as well as subject recruitment and data collection for local studies conducted by CHB clinical investigators with site recruitment and data collection. The CRP can only act as an independent data and statistical coordinating center (DSCC) for multi-site studies that have a qualified, doctoral level, CRP statistician serving as Principal Investigator of the DSCC. For studies without an independent DSCC, but with multiple sites for subject recruitment and data collection and where a CHB investigator is the PI, the CRP will consider acting as the central DSCC if a CRP, senior statistician is the lead statistician for the study and if resources and expertise are available.

TIMEFRAMES:
Given the nature of our work and the importance of time for scientific interaction and collaboration, we ask that investigators plan ahead when requesting assistance. We recommend working with us at least 90 days before a grant deadline and require a minimum of 60 days, as well as a first draft of the grant proposal a minimum of 30 days before the deadline. For survey/measure development, we ask that you start working with us a minimum of 90 days before you need a final version of the measure(s) for grant applications or for data collection. For assistance with study implementation, we ask that you begin working with us 6 months in advance of your anticipated start of recruitment. For assistance with analyses for manuscripts, abstracts, and presentations, we recommend working with us 60 to 90 days before any deadline. If these timeframes are not met, we may be unable to fully assist you or meet your deadline.

CRP PUBLICATION RECOMMENDATIONS:
Publications are important measures of the scientific contributions of CRP faculty and staff. In particular, authorship is important to an individual's academic promotion, recognition, and grant support as well as to the scientific stature of the Program. Investigators are asked to recognize CRP collaborators as co-authors on manuscripts when they have contributed to the design, conceptualization or interpretation of the work, and to acknowledge the CRP in all manuscripts where the CRP has provided other meaningful contributions to the work.

AUTHORSHIP:
CRP faculty and staff strive to work collaboratively with investigators resulting in intellectual contributions to the conception, design, analysis and interpretation of data. They also may be involved in the writing and editing of manuscripts. The CRP adheres to the authorship guidelines of Harvard Medical School as described in the HMS Faculty Handbook http://www.hms.harvard.edu/integrity/authorship.html with respect to determination of authorship and order of authorship. Research teams should discuss authorship with CRP faculty or staff frankly and early in the course of work together so as to determine and agree upon appropriate recognition.

ACKNOWLEDGEMENT:
Acknowledgements of the CRP or individual staff of the CRP can vary depending on the amount of space provided and the types of assistance provided. We suggest the following sample language for individual or CRP recognition:

The authors thank <<names of staff>> in the Clinical Research Program at Children's Hospital Boston for their support and assistance with <<list activities>>.

OR

The authors thank the Clinical Research Program at Children's Hospital Boston for its support and assistance with <<list activities>>.
BUDGETING:
Principal Investigators should work with CRP personnel when developing budgets. A significant portion of CRP funding comes from collaborative work with departments/organizations, therefore, timely communication on budgets allows CRP to plan and manage assistance appropriately. The PI is responsible for working with the CRP to estimate project requirements and develop a realistic budget that includes appropriate CRP staff and estimates of effort.

WHAT CAN THE CRP DO FOR YOU?
The table below indicates assistance the CRP provides at no charge and those where cost recovery is requested. To request assistance, complete the Investigator Request Form at [http://crp-areas.bsd.harvard.edu/crp_intake/public/intake_request.aspx](http://crp-areas.bsd.harvard.edu/crp_intake/public/intake_request.aspx).

<table>
<thead>
<tr>
<th>Activities</th>
<th>Consultative Services (Hospital Supported)</th>
<th>Direct Assistance (Investigator Supported)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grants and Study Protocols</td>
<td>• Contributions to the writing of grant proposals and study protocols.</td>
<td>• Case Report Form development, formatting and coding</td>
</tr>
<tr>
<td></td>
<td>• Survey research design</td>
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<tr>
<td></td>
<td>• Study/Clinical Trial design</td>
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<tr>
<td></td>
<td>• Qualitative research methods</td>
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<tr>
<td></td>
<td>• Power and sample size calculations</td>
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<td></td>
<td>• Data Analysis methods</td>
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<tr>
<td></td>
<td>• Data management methods</td>
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</tr>
<tr>
<td></td>
<td>• Critique/review of grants or study protocols</td>
<td></td>
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<tr>
<td></td>
<td>• Cost impact/effectiveness research design</td>
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</tr>
<tr>
<td>Case Report Forms</td>
<td>• Guidance creating/review of case report forms</td>
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<tr>
<td>Survey Instruments</td>
<td>• Guidance creating/review of survey instrument</td>
<td>• Survey instrument development, formatting and coding</td>
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<td></td>
<td></td>
<td>• Administration of web-based surveys</td>
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<tr>
<td>Databases</td>
<td>• Assistance with creation of small, low complexity research study databases</td>
<td>• Development of complex, relational or customized research study databases</td>
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<tr>
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<td></td>
<td>• Database maintenance</td>
</tr>
<tr>
<td>Manuals of Operation</td>
<td>• Guidance/review of Study Manuals</td>
<td>• Writing and assembly of study manuals</td>
</tr>
<tr>
<td>Data Management</td>
<td>• Study ID assignment logs</td>
<td>• Data entry and management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Data conversion/extraction for analyses</td>
</tr>
<tr>
<td>Project Management</td>
<td>• Guidance/review of study timelines, management plans and priorities</td>
<td>• Project Director/Study Coordinator services</td>
</tr>
<tr>
<td>Randomization</td>
<td>• Randomization strategies</td>
<td>• Randomization envelopes</td>
</tr>
<tr>
<td>Data Analyses</td>
<td>• Guidance on data analyses</td>
<td>• Data conversion/analysis file creation</td>
</tr>
<tr>
<td></td>
<td>• Guidance on survey data analyses</td>
<td>• Data set cleaning and verification</td>
</tr>
<tr>
<td></td>
<td>• Guidance on qualitative data analyses</td>
<td>• Data analyses</td>
</tr>
<tr>
<td></td>
<td>• Interpretation of results</td>
<td>• Survey data analyses</td>
</tr>
<tr>
<td></td>
<td>• Critique/review of manuscripts</td>
<td>• Qualitative data analyses</td>
</tr>
<tr>
<td></td>
<td>• Guidance on cost impact/effectiveness data analyses</td>
<td>• Cost impact/effectiveness data analyses</td>
</tr>
<tr>
<td>Mentoring</td>
<td>• Mentoring</td>
<td>• Manuscript writing</td>
</tr>
</tbody>
</table>

CRP CONTACT INFORMATION:
The CRP offices are located at 21 Autumn Street. We can be reached by phone at 857-218-4720 or by e-mail at crp@childrens.harvard.edu.
Investigator Request for Assistance

Instructions: Please complete our Request for Assistance questionnaire to help us better assist you with your project. Submit this Form by emailing it to spgr@childrens.harvard.edu or by faxing it to 617-730-0328. The assigned CRP Project Lead will contact you within ten business days to schedule a meeting.

Principal Investigator:

Last Name: ________________ First Name: ________________ CH ID#: ____________

Title: 

- Prof
- Assoc Prof
- Asst Prof
- Instructor
- Fellow
- Resident
- Nurse
- Psychologist
- Other (specify): __________________________

Department: __________________________ Division: __________________________

Phone/Ext #: __________________________ Email: __________________________

Is this request affiliated with a CHB Program? 

- Yes
- No
- If Yes, what program? __________________________

Research Mentor (if applicable)

Last Name: ________________ First Name: ________________ CH ID#: ____________

Title: 

- Prof
- Assoc Prof
- Asst Prof
- Instructor
- Fellow
- Resident
- Nurse
- Psychologist
- Other (specify): __________________________

Department: __________________________ Division: __________________________

Phone/Ext #: __________________________ Email: __________________________

Requestor: 

- Check if same as name of PI

Last Name: ________________ First Name: ________________ CH ID#: ____________

Title: 

- Prof
- Assoc Prof
- Asst Prof
- Instructor
- Fellow
- Resident
- Nurse
- Psychologist
- Other (specify): __________________________

Department: __________________________ Division: __________________________

Phone/Ext #: __________________________ Email: __________________________

Project Title (same as title on IRB protocol or grant application):

________________________________________

11/18/2010
<table>
<thead>
<tr>
<th>TASKS</th>
<th>CORE SERVICES</th>
<th>REIMBURSEMENT SERVICES</th>
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</table>

Please review grid for services that do not require reimbursement versus those that do require reimbursement.

What do you require assistance with? (check all that apply)
Children’s Hospital Boston

What is the deadline for completion of work for this request?
No deadline ☐ or (MM/DD/YYYY): __ / ___ / ___

Funding Status
a. Is your project currently funded? ☐ Yes ☐ No
b. Are you presently applying for funding? ☐ Yes ☐ No
c. If Yes, what type of application is it? ☐ New Submission ☐ Resubmission
d. What is the deadline for this application?
   No deadline ☐
   (MM/DD/YYYY): __ / ___ / ___

Funding Sources
☐ NIH
   a. Name of Institute / Center: _____________________________
   b. Type of funding mechanism (check one): ☐ F32 ☐ K01 ☐ K07 ☐ K08 ☐ K12
      ☐ K23 ☐ K24 ☐ M01 ☐ NRSA ☐ P01 ☐ P30 ☐ P50 ☐ R01 ☐ R03
      ☐ R18 ☐ R21 ☐ R49 ☐ S07 ☐ SB1R ☐ T32 ☐ U01 ☐ U19 ☐ US4
   c. Is this a response to an announcement? ☐ Yes ☐ No
      i. If Yes, what is the type? ☐ RFA ☐ RFP ☐ PA
      ii. Other Federal Agency: _____________________________
      iii. Foundation / Association: 1) _____________________________
         2) _____________________________
      iv. Industry Sponsor: _____________________________
      v. Internal Award: _____________________________
      vi. Department/Division/Program Funds: _____________________________
      vii. Philanthropic funds: _____________________________
      viii. Other (specify): _____________________________

Does this project have an IND or IDE (i.e. procedures must comply with FDA regulations?) ☐ Yes ☐ No

Will this protocol utilize the CTSU or its resources? ☐ Yes ☐ No

Other Requests/Comments
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

11/18/2010
CRP Strategic Planning Survey

1. Please describe the role the CRP plays in your Department/Division/Program.

2. Please describe the role that you feel the CRP plays in the institution.

Supported by: Clinical Research Program, Children's Hospital Boston
CRP Strategic Planning Survey

Through the support of the institution, the CRP is able to offer some services that are at no cost for CHB researchers. In general, this includes guidance on creating case report forms, surveys, and study manuals, advice on study design and data analysis methods, contributions to grants and study protocols, and educational seminars and workshops. All other direct assistance or scientific collaborations such as project and data management, database programming or data analysis and manuscript writing requires cost recovery or charges that are incurred by the investigators' projects or Department/Division.

1. Keeping in mind that limited resources are available to the CRP, what services do you think should be provided at no charge and equitably to all investigators in the future?

2. How important are the current CRP services for supporting the successful execution and quality of clinical research in your Department/Division/Program?

Not Important At All

<table>
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<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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</thead>
</table>

Very Important

3. How important are the current CRP services in fostering clinical research in the institution?

Not Important At All

| 1 | 2 | 2 | 4 | 5 | 6 | 7 |

Very Important

Supported by: Clinical Research Program, Childrens Hospital Boston

https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true

8/5/2010
CRP Strategic Planning Survey

The CRP works with many investigators of different levels and ranks, however, the majority of those needing or requesting assistance are junior faculty and fellows. Given the limited resources available to the Program, prioritization of use of resources may be required in the future.

1. In your opinion, in what areas should the CRP focus its resources to best support the clinical research of mid to senior level faculty (Associate and Full Professors)?
   Please rank these in order of importance for mid to senior level faculty, using numbers 1-5 where 1 is "most important" and 5 is "least important."
   If you have an "other" suggestion please use numbers 1-6 where 1 is "most important" and 6 is "least important."

   Rank
   Order

   Educational activities such as workshops or seminars

   Brief one-on-one consulting or advising

   Formal mentoring

   Direct assistance using fee for service

   Collaboration on research projects

   Other (please specify below)

1a. Please specify:

2. In your opinion, in what areas should the CRP focus its resources to best support the clinical research of junior faculty (Instructors and Assistant Professors)?
   Please rank these in order of importance for junior level faculty, using numbers 1-5 where 1 is "most important" and 5 is "least important."
   If you have an "other" suggestion please use numbers 1-6 where 1 is "most important" and 6 is "least important."

https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true

8/5/2010
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2a. Please specify:


3. In your opinion, in what areas should the CRP focus its resources to best support the clinical research of fellows? Please rank these in order of importance for fellows, using numbers 1-5 where 1 is “most important” and 5 is “least important.” If you have an “other” suggestion please use numbers 1-6 where 1 is “most important” and 6 is “least important.”

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3a. Please specify:


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https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true 8/5/2010
CRP Strategic Planning Survey

The CRP strives to increase integration with departments and divisions at the hospital and to more effectively collaborate with the investigators in clinical research. Some of the ways we have done this are to have joint faculty appointments with Departments and Divisions, collaborate with other Programs, and work collaboratively on investigators' project teams.

1. Please tell us in what ways you feel the CRP can increase its integration with Departments, Divisions or Programs?

2. Please tell us in what ways you feel the CRP can promote meaningful collaborations with CHB investigators?

Supported by: Clinical Research Program, Children's Hospital Boston

https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true 8/5/2010
**CRP Strategic Planning Survey**

Thinking about all the methodological expertise and services that are needed to conduct high quality clinical research at CHB, which areas of expertise or services do you think are best supported by faculty or staff who are hired and supervised by the CRP, the Department/Division, or the investigators' project team? More than one organizational approach for the types of support listed below may be chosen if you feel it is most appropriate at CHB.

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Please describe:

https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true  
8/5/2010
1. How strongly do you feel that the organizational suggestions you have made will be most effective in supporting and enhancing clinical research at CHB?

Not Strongly At All

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Very Strongly

Supported by: Clinical Research Program, Childrens Hospital Boston

https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true  8/5/2010
CRP Strategic Planning Survey

The CRP is actively involved in planning and providing education and training to junior investigators and other research staff through workshops, talks and courses. These have included the following activities:
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- Focus Groups Workshop
- Grant Writing Course
- Introduction to Clinical Research (3 days sessions)
- Introduction to Biostatistics
- Introduction to Regression
- Introduction to Statistical Genetics
- Setting Up a Clinical Trial @ CHB
- Passport: Data & Safety Monitoring
- Passport: Investigator Responsibilities
- Qualitative Research in Clinical Investigation
- Survey Design & Questionnaires
- Web Survey Design Course

1. How helpful do you feel these educational activities are in promoting the design and conduct of high quality clinical research?

   Not At All Helpful 1 2 3 4 5 6 7 Very Helpful

2. Are there any other training workshops or classes that the CRP should provide in the future?

   

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CRP Strategic Planning Survey

Page 7 of 7

Some of the overarching national and local strategic research directions include clinical translational research, comparative effectiveness research, health outcomes research and health services research.

1. Can you identify any other strategic research directions at CHB that the CRP should support?

2. How can the CRP expand its faculty, staff, and services to best support these strategic research directions?

Finish

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CRP Strategic Planning Survey

Thank you.

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Non-Leaders Survey

Clinical Research Program - Survey Services

CRP Strategic Planning Survey

The Clinical Research Program (CRP) is an institutional program established in 1998 to enhance and support clinical research across the institution. The Program has a broad range of faculty and staff that include Doctoral and Masters' level Biostatisticians, Survey Methodologists/Epidemiologists, Senior Project Directors, Clinical Research Study Coordinators, and Data Managers or Data Coordinators.

1. Please describe the role the CRP plays in your clinical research.

2. Please describe the role that you feel the CRP plays in the institution.

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https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true

8/5/2010
CRP Strategic Planning Survey

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1. Keeping in mind that limited resources are available to the CRP, what services do you think should be provided at no charge and equitably to all investigators in the future?

2. How important are the current CRP services for supporting the successful execution and quality of your clinical research?

   Not Important At All | Very Important
   __1__ | __7__
   __2__ | __6__
   __3__ | __5__
   __4__ | __4__
   __5__ | __3__
   __6__ | __2__
   __7__ | __1__

3. How important are the current CRP services in fostering clinical research in the institution?

   Not Important At All | Very Important
   __1__ | __7__
   __2__ | __6__
   __3__ | __5__
   __4__ | __4__
   __5__ | __3__
   __6__ | __2__
   __7__ | __1__

Next >>

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https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true  8/5/2010
The CRP Strategic Planning Survey

1. In your opinion, in what areas should the CRP focus its resources to best support the clinical research of mid to senior level faculty (Associate and Full Professors)?
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1a. Please specify:

2. In your opinion, in what areas should the CRP focus its resources to best support the clinical research of junior faculty (Instructors and Assistant Professors)?
   Please rank these in order of importance for junior level faculty, using numbers 1-5 where 1 is “most important” and 5 is “least important.”
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2a. Please specify:

3. In your opinion, in what areas should the CRP focus its resources to best support the clinical research of fellows? Please rank these in order of importance for Fellows, using numbers 1-5 where 1 is “most important” and 5 is “least important.” If you have an “other” suggestion please use numbers 1-6 where 1 is “most important” and 6 is “least important.”

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CRP Strategic Planning Survey

Page 4 of 8

The CRP strives to increase integration with departments and divisions at the hospital and to more effectively collaborate with the investigators in clinical research. Some of the ways we have done this are to have joint faculty appointments with Departments and Divisions, collaborate with other Programs, and work collaboratively on investigators’ project teams.

1. Please tell us in what ways you feel the CRP can increase its integration with Departments, Divisions or Programs?

2. Please tell us in what ways you feel the CRP can promote meaningful collaborations with CHB investigators?

Supported by: Clinical Research Program, Children's Hospital Boston
CRP Strategic Planning Survey

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Please describe:

1. How strongly do you feel that the organizational suggestions you have made will be most effective in supporting and enhancing clinical research at CHB?

Not Strongly At All  

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Very Strongly

Supported by: Clinical Research Program, Children's Hospital Boston

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8/5/2010
CRP Strategic Planning Survey

Page 6 of 8

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2. Are there any other training workshops or classes that the CRP should provide in the future?

[Text box for comments]

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https://crp.tch.harvard.edu/survey/Forms/PreviewSurvey.aspx?viewAll=true&print=true 8/5/2010
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Supported by: Clinical Research Program, Children's Hospital Boston

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CRP Strategic Planning Survey

1. Please indicate your position at Children's Hospital Boston.
   - Physician Scientist
   - Research Associate
   - Research Assistant
   - Study Coordinator
   - Medical Student
   - Resident
   - Fellow
   - Nurse Scientist
   - Psychologist
   - Other, please specify: __________

2. What is your faculty rank at Children's Hospital Boston?
   - Instructor
   - Assistant Professor
   - Associate Professor
   - Full Professor
   - Do not have a faculty appointment

Finish

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Thank you.

Next >>

Supported by: Clinical Research Program, Children's Hospital Boston

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8/5/2010