2009 Annual Report
OF THE CLINICAL RESEARCH PROGRAM
SUBMITTED BY STAVROULA OSGANIAN, MD, ScD, Director

Children’s Hospital Boston
The Clinical Research Program (CRP) at Children's Hospital Boston is pleased to share with you its fiscal year 2009 Annual Report.

The CRP is an interdisciplinary, academic and collaborative research program that provides assistance and education to the clinical research community at Children's Hospital. The program directly supports one of the Hospital’s core mission areas, 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 informatics);
- collaboration or consultation on the design, conduct, and analysis of clinical research studies; and
- education on clinical research methods and practice.

This annual report summarizes the key accomplishments of the Program in 2009 and the work of the many talented and committed faculty and staff who strive to support the mission of the Program and the Hospital. In support of its mission, our faculty and staff serve as institutional leaders, mentors, teachers, and valued 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 and important research questions that relate to the diagnosis, prevention, and treatment of childhood illnesses into practice with the highest standards of quality and scientific rigor. The CRP has experienced growing success in forging partnerships and collaborative relationships with Departments and Programs across the Hospital and Harvard-wide and is an active and important contributor to several cross-departmental and institutional projects, including works with the Patient Safety and Quality (PPSQ), Clinical and Translational Study Unit (CTSU) and Harvard Catalyst, Research Administration and the Translational Research Program (TRP). Reflecting on our accomplishments, we wish to recognize the support from collaborators and the productive collaborative relationships that we have established with our colleagues, and we take pride in the work accomplished together.

Key accomplishments for FY2009 include:

- Support or consultation on 360 new investigator requests for assistance from 238 researchers in the institution representing an increase of 12% from FY2008.
- Successful collaborations with several CHB investigators and other institutional programs on 68 funded projects and maintenance of significant extramural funding totaling approximately $1.0 million.
- Thirty-eight peer reviewed collaborative publications that were co-authored by CRP staff.
- Continued increase in the number of joint faculty recruits with Departments and Divisions with a corresponding 35% increase in department funding of CRP faculty and staff.
- Continued growth in the educational offerings of the Clinical Research Education Core including a new Biostatistics course offering, “Intro to Linear Regression”, and a new Survey Methodology course offering, “Focus Group Workshops”.
- Successful integration and increased productivity of and demand for assistance from the recently formed Survey Core.
- Newly available, competitive pilot project funds to support the clinical research of CHB investigators.
• Continued support of CHB-CONNECT, a research volunteer registry for children and families.
• Collaboration with the CTSU to supervise and manage clinical research study coordinator support through Harvard Catalyst resources.
• Collaboration with CRIT to provide researcher’s with the tools to more effectively collect, store, and protect clinical research data.
• Participation and leadership on major research initiatives of the Clinical and Translational Executive Committee (CTREC).
• Continued participation and collaboration of CRP faculty in the NIH funded Harvard Catalyst activities.

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.

Program Leadership and Administration

Program Leadership:
Stavroula Osganian, MD, ScD, MPH
Program Director of the CRP

Jonathan H. Dinsmore, Ph. D.
Associate Director of the CRP

Program Administration:
Laura Haley
Program Administrative Coordinator
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, the Clinical Research Education Core, the Project and Data Management Core, and the Survey Core. The Cores interact closely with the affiliated Clinical Research Information Technology team located in the Information Systems Department. These functional cores work independently as well as in teams to achieve the mission and goals of the Program and Cores. In FY09 the CRP staff included 30 full-time, and 4 associated staff organized into four major cores 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 2009 totaled $2.648 million. Equally important has been the substantial commitment and funding from departments (totalling $710,465) that support faculty with joint appointments ($679,485 for faculty) and work on specific research projects ($30,980 for projects).

Table 1: CRP Funding Sources and Expenses in FY09

<table>
<thead>
<tr>
<th>Source</th>
<th>Budget</th>
<th>Expenses</th>
<th>Unexpended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional</td>
<td>$2,648,043</td>
<td>$1,606,967</td>
<td>$1,041,076*</td>
</tr>
<tr>
<td>Departmental (Total)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faculty ($679,485)</td>
<td>$710,465</td>
<td>$710,465</td>
<td>-</td>
</tr>
<tr>
<td>Projects ($30,980)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CGRE</td>
<td>$158,587</td>
<td>$158,587</td>
<td>-</td>
</tr>
<tr>
<td>Extramural**</td>
<td>$1,012,506</td>
<td>$1,012,506</td>
<td>-</td>
</tr>
<tr>
<td>Intramural</td>
<td>$31,619</td>
<td>$31,619</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>$4,561,220</td>
<td>$3,520,144</td>
<td>$1,041,076*</td>
</tr>
</tbody>
</table>

*Total unexpended institutional funds include position vacancies and recovery from staff charge backs to grants or other funds.
**Catalyst provided $246,612 from extramural funds from NIH for CRP consultations.

During FY09, the CRP supported 681 new and ongoing projects and/or requests for assistance. The majority of these activities (n=613) were not extramurally funded and were hospital, departmental or Catalyst supported consultations. Sixty eight of the 681 requests (10%) were investigator funded projects and provided a total of $828,432 to fund CRP faculty and staff (Table 2), with $617,132 funding the Biostatistics Core, $203,744 funding the PDMC Core, $5,232 funding the Survey Core and $2,324 funding the CRIT (Clinical Research Informatics Team). Table 2 and Figure 1 present the distribution of funding sources for the 68 investigator supported projects. NIH was the primary source of funding for these projects (54%), followed by funding from foundations or associations (23%). Among the funded projects, 30 were NIH funded: 8 funded through R01’s, 2 through K awards, 6 through R21s, and 14 through other funding mechanisms (e.g. U01, H34, P30, and U58). Further, 13 of the 68 funded projects were from collaborations with researchers from the Department of Medicine/Division of GI and Nutrition; 9 from the Department of Medicine/Adolescent Medicine Division; 8 from the Department of Medicine/Endocrine Division; The remainder was from various other departments and divisions in the Hospital including Surgery (5), Radiology (5), Hematology/Oncology (5), Psychiatry (4), Emergency Medicine (3), Developmental Medicine (3), Dentistry (2), Anesthesiology (1), General Pediatrics (1), Nephrology (1), Orthopedics (1), Neurology (1), Urology (1), Plastic Surgery (1) and Cardiology (1). Clinical Research Program faculty were PIs on 3 of the 68 projects.
Table 2: Sources of Support for 68 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>30</td>
<td>$452,342</td>
<td>54%</td>
</tr>
<tr>
<td>Other Federal</td>
<td>5</td>
<td>$107,603</td>
<td>13%</td>
</tr>
<tr>
<td>Foundation/Association</td>
<td>15</td>
<td>$189,111</td>
<td>23%</td>
</tr>
<tr>
<td>Industry</td>
<td>3</td>
<td>$16,777</td>
<td>2%</td>
</tr>
<tr>
<td>Department</td>
<td>6</td>
<td>$30,980</td>
<td>4%</td>
</tr>
<tr>
<td>Internal Awards</td>
<td>9</td>
<td>$31,619</td>
<td>4%</td>
</tr>
<tr>
<td>Total</td>
<td>68</td>
<td>$828,432</td>
<td>100%</td>
</tr>
</tbody>
</table>

*Billings to funds for services totaled $29,310; The remainder was charged as salary support on funds.

Figure 1: Sources of Support for Investigator Funded Projects*

Utilization of Services

The Clinical Research Program (CRP) provides a range of services (see Appendix F) 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 FY09

During FY09, the CRP received 360 new requests for assistance from 238 Children’s Hospital faculty or staff. Overall, this was a 12% increase over the total number of requests received in FY08. 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=168) and within the Divisions of GI/Nutrition (n=31) and Endocrinology (33) followed by the Departments of Cardiology (32) and Neurology (15).

As shown in Figure 3, investigators requesting assistance were somewhat more likely to be at the rank of Instructor (n=51) and Assistant Professor (n=52) or Fellow (n=40) as compared to Associate Professor (n=33), Professor (n=20) or Resident (n=5).
In FY09, the CRP received requests for consultation distributed across the various areas shown in Figure 4. Among the 852 consultation activities, the majority was for consultation on statistical analysis (n=126), power and sample size determination (n=102), development of a statistical analysis plan (n=100), study design (n=84), interpretation of results (n=69), manuscript/presentation (n=61), database development and management (n=60) and survey questionnaire and design (n=51).
As shown in Table 3, among the 360 requests for CRP assistance in 2009, 21% (n=75) were for assistance with the development of grant applications. Among these 75 applications, the majority were applying to NIH (n=46) or to foundations (n=14). In 2008, CRP assisted with 68 Grant application submissions. Follow-up on these 68 grant applications from FY2008 showed that 55 were submitted to the funding agencies, as intended and 20 of those submitted were successfully funded resulting in a 36% success rate. The total direct costs and indirect costs of these awards to the institution were $4,736,354 and $1,494,489, respectively. These grants provided $110,312 in funding for CRP faculty and staff.

<table>
<thead>
<tr>
<th>Agency</th>
<th>Number in FY08</th>
<th>Number in FY09</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>28</td>
<td>46</td>
</tr>
<tr>
<td>Other Federal</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Foundation/Association</td>
<td>26</td>
<td>14</td>
</tr>
<tr>
<td>Industry</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Philanthropy</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Internal</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>68</td>
<td>75</td>
</tr>
</tbody>
</table>

CRP User Survey

The CRP annual survey of CHB investigators and staff who have collaborated with the CRP, requested services or participated in its courses continues to provide valuable feedback on the impact of our assistance and educational efforts and the needs of the investigator community (Table 4). Among the 191 respondents (25% of the total surveyed), 53% worked with CRP faculty or staff on research projects, 46% attended an educational seminar or talk, and 18% had done both. About 60% were doctoral prepared scientists (MD, PhD, ScD) and 29% were study coordinators or research assistants. After working with the CRP faculty and staff on their research projects, respondents reported fairly high levels of confidence in their understanding of how to design, implement, and analyze and report results of their research study and felt the CRP faculty and staff were knowledgeable, professional and responsive. Most were also very likely to collaborate or request assistance from the CRP again. Similarly, among those who took CRP educational offerings, respondents reported high levels of knowledge and confidence on clinical research design and methods and implementation practices. Furthermore, these results were consistent across faculty rank and Core activity and reinforce the valuable contributions of the Program to the education, functional mentoring, and collaborative assistance provided to the CHB clinical research community.
Table 4: Responses to CRP Survey

<table>
<thead>
<tr>
<th>Statement</th>
<th>N</th>
<th>Mean (SD)</th>
<th>%≥5</th>
</tr>
</thead>
<tbody>
<tr>
<td>The assistance I received from the CRP was valuable in terms of enhancing the quality of the science and methods of my study.</td>
<td>81</td>
<td>5.80 (1.23)</td>
<td>88%</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more knowledgeable in clinical research methods.</td>
<td>75</td>
<td>5.49 (1.45)</td>
<td>79%</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more confident in designing a research study.</td>
<td>66</td>
<td>5.19 (1.49)</td>
<td>67%</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more confident in implementing a research study.</td>
<td>61</td>
<td>5.43 (1.43)</td>
<td>75%</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more confident in analyzing data from a research study.</td>
<td>65</td>
<td>5.54 (1.21)</td>
<td>83%</td>
</tr>
<tr>
<td>After receiving assistance from the CRP, I feel more confident in reporting results from a research study.</td>
<td>66</td>
<td>5.49 (1.52)</td>
<td>77%</td>
</tr>
<tr>
<td>The faculty and staff of the CRP worked with me in a responsive and professional manner.</td>
<td>85</td>
<td>6.23 (1.67)</td>
<td>92%</td>
</tr>
<tr>
<td>The majority of the CRP staff with whom I interacted was knowledgeable about the services that I requested.</td>
<td>87</td>
<td>6.21 (1.13)</td>
<td>93%</td>
</tr>
<tr>
<td>I am likely to request assistance from the CRP in the future.</td>
<td>88</td>
<td>6.39 (0.98)</td>
<td>93%</td>
</tr>
<tr>
<td>The education I received was valuable in terms of enhancing the quality of the science and methods of my research.</td>
<td>82</td>
<td>5.39 (1.35)</td>
<td>81%</td>
</tr>
<tr>
<td>The education I received helped me to feel more knowledgeable in clinical research methods.</td>
<td>80</td>
<td>5.58 (1.31)</td>
<td>81%</td>
</tr>
<tr>
<td>The education I received helped me to feel more confident in designing research studies.</td>
<td>74</td>
<td>5.19 (1.26)</td>
<td>70%</td>
</tr>
<tr>
<td>The education I received helped me to feel more confident in implementing research studies.</td>
<td>78</td>
<td>5.46 (1.08)</td>
<td>77%</td>
</tr>
<tr>
<td>The education I received helped me to feel more confident in analyzing data from research studies.</td>
<td>74</td>
<td>5.12 (1.28)</td>
<td>66%</td>
</tr>
<tr>
<td>The education I received helped me to feel more confident in reporting results of research studies.</td>
<td>75</td>
<td>5.17 (1.20)</td>
<td>71%</td>
</tr>
</tbody>
</table>

*1 = strongly disagree to 7 = strongly agree
Major Program Activities and Collaborations

Clinical Research Program Funding Opportunity

This past year, 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 is 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 provides for 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 reviewed by a multidisciplinary committee of 12 senior scientists at CHB. Twenty-one faculty have been invited to submit full applications, which will be peer-reviewed in January 2010. The number of awardees will be determined by the quality of the proposals and the funds available. The full announcement can be found in the Appendix of this report.

The “Challenge Grant” challenge

The announcement in the spring of 2009 that federal research awards were available from the National Institute of Health under the American Recovery and Reinvestment Act (also known as “Challenge” or “Stimulus” grants) brought numerous prospective applicants to CRP seeking help with clinical research proposals. After an intense month of consultation and collaboration with faculty from all corners of the Children’s research world, including Psychiatry, Surgery, Endocrinology, Gastroenterology/Nutrition, Pathology, Urology, Adolescent Medicine, General Pediatrics, Developmental Medicine, Pulmonary, and Emergency Medicine, CRP faculty were named as co-investigators in 15 submitted proposals, of which four, described below, received funding.

Xylitol syrup for the prevention of acute otitis media in otitis-prone children. Dr. Louis Vernacchio, a member of the Division of General Pediatrics, won a two-year award to conduct a clinical trial of a novel agent for preventing recurrent ear infections in children. Xylitol is a naturally occurring sugar alcohol with known antibacterial properties, which Dr. Vernacchio hypothesizes can fend off infection if taken orally in a viscous form, adhering to the throat long enough to deliver an adequate preventive dose. Besides Dr. Vernacchio, who is Director of Research and Analysis for Pediatric Physicians’ Organization at Children’s (PPOC), the study team includes Dr. Henry Feldman, Principal Biostatistician at CRP, as well as epidemiologists, study coordinators, and data-management staff at Slone Epidemiology Center, Boston University. With consultation from Susan McDermott, Leader of the CRP Project and Data Management Core, a randomization scheme was developed at CRP for assigning treatment or placebo to 450 children at 50-60 clinical sites, drawn from the PPOC network in eastern Massachusetts and the nationwide Slone Center Office-Based Research network.

Dental and medical office iMET to reduce substance use. Dr. John R. Knight, Associate Professor in the Division of Developmental Medicine, and his colleagues in the Center for Adolescent Substance Abuse Research (CeASAR) received funding for a two-year study to develop and pilot an Internet/Intranet-based Motivational Enhancement Therapy (iMET) program for use with adolescent medical and dental patients that targets tobacco, alcohol, and drug use. Building on results of a previous CeASAR study where MET was found to be significantly better than treatment-as-usual in reducing alcohol and
drug use among teens in an outpatient substance abuse treatment population, the team will now adapt this proven intervention to include tobacco use and to be largely self-administered on the computer. The intervention will then be tested as part of a comprehensive screening and brief intervention protocol in a primary care population of adolescents coming for routine medical and dental care. Dr. Sion Kim Harris, Director of the CRP Survey Core, serves as the measurement expert on this project.

**Hepcidin based screening for infantile iron deficiency.** In this two-year study, Dr. Mark Fleming, Associate Professor in the Department of Pathology, will evaluate a new diagnostic test based on measuring serum hepcidin, as a screen for iron deficiency (ID) in infants. With a prevalence of 9% in US toddlers, ID is a common nutritional deficiency in infants and puts the child at risk for neurodevelopmental deficits. If detected, ID is easily treated with oral iron supplements. Guidelines suggest screening for ID during the first year of life but there are limitations to the available screening tests. The most sensitive test, based on cellular hemoglobin of the reticulocytes, is also the most invasive and most costly, whereas the least invasive and least costly test, based on a finger-stick hemoglobin test, is also the least sensitive. In addition to evaluating serum hepcidin as a screening test, the project has a genetic component. The study will test the hypothesis that variants in the gene encoding TMPRSS6, a protein that modulates hepcidin production, confers resistance or susceptibility to infantile ID. These aims will be accomplished via a relatively simple design -- collection of blood samples from 500 9-12 month old infants at the time of routine ID screening in the primary care setting, and abstraction of minimal clinical data from the infants' medical records. Dr. Leslie Kalish, a Principal Biostatistician in the CRP, will collaborate on the design and analysis of the study.

**Maternal-fetal vitamin D status and child adiposity, insulin resistance, and blood pressure.** Dr. Susanna Huh, Instructor in the Division of Gastroenterology and Nutrition, won funding for a two-year study of vitamin D and cardiovascular risk factors in the 1300 women and children of Project Viva, a longitudinal cohort drawn from the patient population of Harvard Pilgrim Health Care and designed to identify pre- and postnatal factors affecting child health. Dr. Huh will have access to maternal vitamin D levels in the second trimester of pregnancy as well as in the children from birth thru age 7 and will examine prospectively the relation of vitamin D to childhood adiposity, blood pressure, insulin and glucose levels, and other factors predisposing to insulin resistance and heart disease later in life. The study team includes Dr. Henry Feldman, Principal Biostatistician at CRP, as well as the staff of Project Viva under the leadership of Dr. Matthew Gillman in the Department of Population Medicine of Harvard Medical School (formerly Ambulatory Care and Prevention).

**Health Services Research**

"Health services research is the investigation of how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and quantity and quality of life." Health services research is multidisciplinary and important to all medical specialties. As such, it involves many researchers across CHB, including members of the CRP faculty and staff.

The Program for Patient Safety and Quality sponsors CHB’s and CRP’s participation in the Pediatric Health Information Systems (PHIS) database. This large administrative database contains over five years of data on all inpatient discharges, outpatient surgeries, and ED encounters at 42 free-standing children’s hospitals in the United States. Access to the database can be obtained by contacting Dr. Dionne Graham, a CRP biostatistician working with the Program. In addition to patient demographics, diagnoses, and procedures, PHIS
contains detailed resource utilization data (e.g. charges for pharmaceuticals, laboratory tests, imaging studies, etc), thereby providing a rich source of information for various health services research projects. Dr. Graham has collaborated with health services researchers from many CHB departments and divisions on studies using the PHIS database of which recent examples include:

A study by Complex Care Service physician Jay Berry, MD in which he described the long-term health outcomes and resource use for children following tracheotomy and identified patient characteristics that correlate with poor health outcomes and increased resource use. The findings, which were recently published in Pediatrics, showed that neurologic impairment was associated with increased total hospital days and higher 5 year mortality rates in this population.

A paper, to appear in Pediatrics, by Jon Routh, MD from the Department of Urology which described the variation in surgical management of vesicoureteral reflux and shows that even after adjusting for patient risk factors, there is marked variation in the choice of endoscopic injection over ureteral reimplantation by hospitals across the United States.

A study by hematologist, Amy Sobota, MD reporting wide hospital variation in the use of corticosteroids for acute chest syndrome in children hospitalized with sickle cell disease. This work will appear in the American Journal of Hematology.

CRP also supports health services research at CHB by providing biostatistics mentorship to the Harvard Pediatric Health Services Research Fellowship. The primary goal of the Fellowship is to provide training and development to junior investigators whose research will ultimately improve the healthcare of children. CRP faculty members provide biostatistical feedback at the fellowship’s bi-monthly Works in Progress sessions and serve as research mentors to the fellows. Additionally, during FY09, several members of the CRP faculty presented lectures during the Fellowship’s Research Seminars: Voula Osganian and Clarissa Valim “Confounding and Effect Modification”, Chao-Yu Guo “Overview of Statistical Genetics,” and Dionne Graham “Tips and Tricks in SAS”.

Harvard Catalyst Activities and Updates

The Harvard Catalyst is the name given to the NIH-funded Harvard Clinical and Translational Science Center (CTSC), one of now 50 CTSA grantees nationwide. Catalyst comprises a central management core 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, education and mentoring, and clinical research study coordinator services as described below. Several CHB leaders including Drs. Neufeld (CHB Site Implementation Director and CHB Principal Investigator), Richard Grand (CTSU Program Director), Jean Emans (OFD Director), Stavroula Osganian (CRP Director), and Carleen Brunelli, PhD, MBA (Vice President of Research Administration) are interacting closely as we move forward to ensure successful implementation of the Harvard Catalyst at CHB.
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. Over the past year, Dr. Ware and the Associate Directors of the BSP, representing the Harvard teaching hospitals and HSPH, have established a consulting program and have developed policies and systems for managing and tracking the work of the BSP. 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, Paul Mitchell, MS, and Clarissa Valim, ScD. In the most recent satisfaction survey of BSP clients, covering consults initiated September 2008 through April 2009, 100% of respondents who worked with a CRP biostatistician reported being “satisfied” or “very satisfied” with their consultation.

Education and Mentoring through the Harvard Catalyst.

The Catalyst also seeks to provide effective education and mentoring for the medical students, fellows, and junior faculty who are seeking to build careers in clinical and translational research or who need assistance on the development of clinical and translational studies. Last year, Stavroula Osganian, MD, ScD, MPH, Ellis Neufeld, MD, PhD, and Jean Emans, MD served as CHB Co-Directors on the Clinical and Translational Studies Training and Mentoring Subcommittee chaired by Dr. Ellen Seely from Brigham and Women’s Hospital. One of the important goals for the last year was to piloting a career and research advising program and organizing a network of mentors for CHB faculty conducting or wishing to conduct clinical and translational research. Eight faculty participated in this pilot at CHB and the majority found the experience to be very helpful in increasing knowledge and awareness of resources to support their research and career development. As a result, CHB plans to move forward with an ongoing service for career and research advising and a formal community of advisors to support this initiative. As a member of the Education Subcommittee, Dr. Jen Lightdale worked with the Harvard Catalyst to develop clinical and translational (C/T) research education offerings that could support clinical and translational investigators of all levels at Children’s Hospital. Through the Education Core, the Clinical Research Program is committed to coordinating meritorious research education programs developed through Catalyst with those that we are offering at Children’s. Catalyst support for hospital-based education and mentoring in C/T research ended in Sept 2009, and a new centralized model was put in place. Because this model can serve only a small fraction of the overall number of fellows and junior faculty at each hospital, our CHB members, named above plan to continue this effort at CHB in FY10 and beyond.

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) (formerly known as the GGRC) located on 6 East and Pavilion 6 and in the CAT/CR, under the continued direction of Richard Grand, MD, PhD. Clinical research services provided through the CTSU were expanded considerably this year to include study coordinator support. Two study coordinators and
two part-time research nurses have been hired this year to support such studies. In addition, in year 2 of Catalyst (beginning in FY10 at CHB), support is provided for increased staff at Waltham, where CHB/CTSU host a community-based research center.

PDMC staff worked collaboratively with research nursing and staff of the CTSU to develop the infrastructure for the off-unit study coordinator support CRP Clinical Research Specialist, Adam Simmons, MPH, coordinates services and assignments for the study coordinators. The two Catalyst coordinators added to the CRP team this year include Mark Berry, MS and Aislyn Cangialose, BA. Mark and Aislyn currently support 12 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 project director, now supervises a newly hired CRP Study Coordinator, Julie Barenholz, MSW who will be assigned to the Waltham Center. Julie joins the Waltham Catalyst clinical research team including research nurse, medical assistant and administrative assistant. Study Coordinators services include case finding and eligibility screening, consent procedures, study measurements, medical record abstraction, case report form completion and general study coordination. With central training and supervision provided by CRP senior research specialists, services can be provided seamlessly to investigators, across sites, across departments and across divisions.

**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

The CHB CONNECT site was launched on 08/01/2008, and the data below represent the new and cumulative activity since its creation. The marketing campaign to date has included Small Talk, Faculty News, an Intranet posting, direct mailings to investigators and coordinators, and flyers for distribution by study coordinators in hospital clinics. Further promotional efforts will include direct listings on clinical department web sites, an article published in Pediatric Views, and posters for pediatrician offices. The CRIT and CRP are working with the ISD Web team to enhance monitoring capabilities of the public Internet site. **Tables 5 and 6** below show that from the period 08/01/08 to 9/30/09, there have been 2317 views of the homepage, 711 visits to the registration webpage, resulting in a total of 84 human subject registrants. For the internal website, there have been a smaller number...
of visits (137) as would be expected by the smaller size of the group who have access. The fiscal year 2009 has seen the addition of 7 new users bringing the total users to 42. Of the 30 listed research protocols, 19 new protocols were added this year. We look forward to seeing continued growth and utilization of this important resource for clinical trials participant recruitment.

Table 5. Number of Public Visitors and Subject Registrants

<table>
<thead>
<tr>
<th>Metric</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Views – Home Page</td>
<td>2317</td>
<td>Number of times the CONNECT home page was viewed.</td>
</tr>
<tr>
<td>Total Views – Registration Form</td>
<td>711</td>
<td>Number of times the CONNECT registration form was viewed.</td>
</tr>
<tr>
<td>Total Registrants</td>
<td>84</td>
<td>Number of unique registrants in the system currently.</td>
</tr>
</tbody>
</table>

Table 6. Number of Internal Registry Investigator Users

<table>
<thead>
<tr>
<th>Metric</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hits</td>
<td>137</td>
<td>Number of unique visitors to the site (includes users and anonymous users).</td>
</tr>
<tr>
<td>Total New Users</td>
<td>7</td>
<td>Number of new users (PIs and staff) registered with the system.</td>
</tr>
<tr>
<td>Total Users to date</td>
<td>42</td>
<td>Number of users (PIs and staff) registered with the system</td>
</tr>
<tr>
<td>Total New Protocols</td>
<td>19</td>
<td>Number of new protocols listed.</td>
</tr>
<tr>
<td>Total Protocols</td>
<td>30</td>
<td>Number of distinct protocols listed.</td>
</tr>
<tr>
<td>Total Download Sessions</td>
<td>17</td>
<td>Number of user sessions, wherein users downloaded data.</td>
</tr>
</tbody>
</table>
In FY09 the Biostatistics Core included 9 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.

Acting Director: Stavroula Osganian, MD, ScD, MPH
Faculty staff in FY 2009 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
Clarissa Valim, MD, ScD, Senior Biostatistician
Hongyu Jiang, Ph. D., Senior Biostatistician
Lin Huang, Ph. D., Senior Biostatistician
Emily Blood, Ph. D., Senior Biostatistician

Other statistical and administrative staff included:
Peter Forbes, MA, Senior Biostatistician
Patrick Johnston, MMath, MSc, Senior Biostatistician
Paul Mitchell, MS, Senior Biostatistician
Jing Zhou, MS, Biostatistician
Courtney Walls, MPH, Statistical Programmer
Janine Molino, 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, promoting 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, CRP members work with investigators to devise study designs, formulate statistical analyses, calculate sample size, and contribute to the writing of proposals and protocols. During implementation CRP supervises and participates in database construction, randomization, data-cleaning, quality control, and data and safety monitoring. In the analysis and reporting stage, CRP performs both routine and original statistical analyses, interprets results, and co-authors abstracts, presentations, and journal articles.

**Biostatistics Goals**

- **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.

- **Education and Training:** To lead and participate in education and training activities of the Program; 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.

- **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, providing 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.

- **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.

- **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.

- **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.

- **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.

**Biostatistics Progress Report**

Dr. Osganian served as acting Director of the Core during FY2009 while a national search is underway for a new Director.
Table 1 shows the number of new requests for Biostatistics Core services during FY09.

<table>
<thead>
<tr>
<th>Tasks</th>
<th>FY09 Number of Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistance with Existing Database</td>
<td>13</td>
</tr>
<tr>
<td>DSMB Participation</td>
<td>4</td>
</tr>
<tr>
<td>CTSU Biostatistical Review</td>
<td>22</td>
</tr>
<tr>
<td>Grant Application Review/Critique</td>
<td>38</td>
</tr>
<tr>
<td>Interpretation of Results</td>
<td>64</td>
</tr>
<tr>
<td>Manuscripts/Presentations</td>
<td>59</td>
</tr>
<tr>
<td>Power and Sample Size Determination</td>
<td>98</td>
</tr>
<tr>
<td>Randomization</td>
<td>2</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>114</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td>94</td>
</tr>
<tr>
<td>Study Design</td>
<td>76</td>
</tr>
<tr>
<td>Study Protocol/Critique</td>
<td>23</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>614</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 over forty publications during FY09. 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 thought-out 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 results in federal and foundation grant support for CRP staff. A list of federal and private research grants active in FY09 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 twice-yearly Introduction to Clinical Research, a two-day overview for fellows and junior faculty, features seven hours of statistical material. The introductory course generates demand for more advanced short courses, of which several are well established and more are in development. Dr. Graham and Mr. Forbes teach Introduction to Biostatistics with SPSS yearly, combining 8 lectures on elementary descriptive and inferential statistics with companion computer laboratory sessions. Even allowing enrollment of 50 per offering, this course has been consistently over-subscribed in its four-year history and the course is now available via webcast to address the high demand. Dr. Feldman has developed a three-session course on Statistical Power and How to Get It: Sample Size for Clinical Research, including a computer laboratory session led by Mr. Mitchell, aimed at investigators prepar-
ing research proposals. Additionally, a course, first introduced in 2008, *Introduction to Statistical Genetics*, was taught by Dr. Guo, which focuses on the application of statistical methods for genetics studies such as family-based and population-based association studies and other designs. A new course introduced in 2009, *Introduction to Regression*, was taught by Dr. Gregas and Ms. Walls.

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 twelfth 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.

**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 our 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 based in the department. 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.

- Dr. Feldman, Division of Endocrinology.
- Mr. Forbes, Department of Psychiatry.
- Dr. Graham, Department of Cardiology and Program for Patient Safety and Quality.
- Dr. Guo, Program in Genomics.
- Dr. Gregas, Departments of Neurology and Developmental Medicine.
- Mr. Johnston, Division of Emergency Medicine and Department of Otolaryngology.
- Dr. Kalish, Division of Hematology/Oncology.
- Mr. Mitchell, Division of Gastroenterology and Nutrition.
- Dr. Valim, Department of Surgery.
- Dr. Jiang, Division of Gastroenterology and Nutrition.
- Dr. Huang, Department of Urology.
- Dr. Blood, Division of Adolescent and Young Adult Medicine.
- Ms. Walls, Division of Adolescent and Young Adult Medicine.
- Ms. Molino, Division of Emergency Medicine and Department of Neurology.
- Ms. Zhou, Department of Surgery and Program for Patient Safety and Quality.
- Faculty search in progress, Division of Emergency Medicine.
- Faculty search in progress, Department of Radiology and Department of Orthopedics.

**New Staff**

During FY09, the Biostatistics Core added a Statistical Programmer, Ms. Janine Molino, who came to us with an MS from Stanford University. Three new faculty were recruited: Hongyu Jiang, Ph. D. joined the CRP and Division of Gastroenterology and Nutrition and came from the Harvard School of Public Health, Department of Biostatistics where she was an Assistant Professor of Biostatistics; Lin Huang, Ph. D. joined the CRP and Department of Urology after graduating from the Columbia University, Biostatistics Graduate Program; and Emily Blood, Ph. D. joined the CRP and Division of Adolescent and Young Adult Medicine after graduating from Boston University, Biostatistics Graduate Program.
Staffing

FY09 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 short courses and seminar series on research methods for faculty, fellows, and residents;
- Develop and offer short didactic series on other clinical research special fields of inquiry or advanced topics of interest to the broad research community at Children’s Hospital Boston;
- Serve on hospital education-related committees; and
- Develop Web-accessible best practices and educational tools for researchers.
**Education Goals**

- **Scientific Leadership:** To develop the vision and agenda for a state-of-the-art clinical research education curriculum for community.
- **Education and Training:** To develop and implement education and training activities of the Program.
- **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 the 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 to the research community at Children’s Hospital Boston both in person and on-line.
- **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 2009 include:

**Demand**

Total CRP course enrollment more than doubled from 2006 to 2009 (Table 1). This statistic reflects strong demand for CRP educational offerings from clinical research faculty and staff representing most CHB departments and divisions (Figure 1). While we specifically aim to meet the needs of fellow trainees and study coordinators, course attendees also 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.
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 2009, we introduced two new short courses: *Introduction to Focus Groups* and *Introduction to Regression Analysis*. We also successfully repeated a new advanced biostatistics course introduced the year prior, *Introduction to Statistical Genetics* and designed and implemented a collaborative grant writing seminar co-sponsored with Brigham and Women’s Hospital, *The Art and Anatomy of Writing a Career Development Grant*. In 2010, the Education Core plans to launch 4 new educational offerings in collaboration with both the CRP’s Survey and Biostatistics Cores, as well as the Office of Faculty Development and the Translational Research Program at Children’s Hospital Boston.

<table>
<thead>
<tr>
<th>Table 2. CRP Course Listings 2004 – 2009</th>
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</thead>
<tbody>
<tr>
<td>CRP Course</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>
</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 successfully webcasted two recent courses using Adobe Breeze: *Introduction to Biostatistics with SPSS* and the *Art and Anatomy of Writing a Career Development Grant*. We also have continued to Breeze record 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. Additional efforts to increase integration include the Core’s ex-
expanded use of the online registration and evaluation system and a recent completed re-
design of the CRP Education Core intranet site.

Leadership
The Education Core values deeply its potential to provide vision and agendas for a com-
prehensive 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 al-
lowed us to identify opportunities to expand our curriculum. In FY08, the Core contributed
to Harvard’s successful CTSA application. In the coming years, we will continue to em-
brace opportunities for continued collaboration with Harvard affiliated institutions and en-
hance the scope and number of CRP educational offerings.
Staffing

FY09 Project and Data Management staff included the following. Capsule biographies are provided in Appendix A.

Susan McDermott, MPH, RN, Clinical Research Team Leader
Tracy Antonelli, MPH, Project Director
Mark Berry, MS, Clinical Research Coordinator
Aislyn Cangialose, BA, Clinical Research Coordinator
Qiaoli Chen, MS, Research Data Manager
Rajna Filip-Dhima, BS, Research Data Manager
Jui Haker, MD, MPH, Epidemiologist, Project Director
Sara Krathwohl, MPH, Clinical Research Specialist
Moriah Polanco, Research Data Coordinator
Marina Shishova, BA, Research Data Coordinator
Adam Simmons, MPH, CCRC, Clinical Research Specialist
Handan Titiz, EdM, Research Data Manager
Harold T. Thurston, Jr., MA, MAT, Administrative Coordinator

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 procedures 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.

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

**Utilization of Services**

Table 1 shows the number of requests for some of the Project and Data Management Core services during FY09.
Research Collaborations
Staff provided professional services responding to 129 requests from CHB investigators for project management, study coordination, CRF and database development and/or data management in FY09; 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 $290,242.

New Study Coordinator Services Program
Early in FY09, the CRP collaborated with staff of the CTSU and research nursing to design, develop and implement a new service program funded by the Catalyst and provided through the CTSU. The new program, called the “Off-Unit” clinical research program provides clinical research nursing and study coordinator support to investigators beyond the CTSU (i.e. “Off-Unit”). CRP hired and supervises the study coordinators who provide a variety of services consistent with the role of the clinical research study coordinator. A similar program was approved for the CHB’s Waltham Center at the end of FY09. CRP will select and will supervise a Study Coordinator to provide services from the CHB Waltham Center.

Clinical Research Database Creation and Support
SciRIS: In FY09, 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: 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. SPSS data entry / data management programs were developed for 25 investigations in FY09 by PDMC staff or under their guidance. Programs were written and developed for more than 83 case report forms in these investigations collectively. In addition to primary development, SPSS databases developed by CRP Data Managers undergo a routine, comprehensive QC check of 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 QC reviewer for programs developed by study staff coached by CRP staff.

InForm™: CRP continues to utilize the Phase Forward, InForm™ ITM (Integrated Trial Management) software application for development of clinical trial databases for FDA

<table>
<thead>
<tr>
<th>Table 1. Project and Data Management Core Service Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tasks</strong></td>
</tr>
<tr>
<td>Assistance with Existing Database</td>
</tr>
<tr>
<td>Case Report Form Development</td>
</tr>
<tr>
<td>Database Development and Management</td>
</tr>
<tr>
<td>Grant Application Review/Critique</td>
</tr>
<tr>
<td>Manual of Operations</td>
</tr>
<tr>
<td>Project Management</td>
</tr>
<tr>
<td>Randomization</td>
</tr>
<tr>
<td>Study Design</td>
</tr>
<tr>
<td>Study Review/Critique</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>
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 FY09, CRP Data Managers initiated development of 5 InForm™ databases; 3 were completed and deployed, with 2 studies still in technical development.

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 11 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.

Participation in Educational Offerings at other HMS affiliated Hospitals
This year, PDMC Team Leader, Susan McDermott served as faculty for clinical research educational programs at the Massachusetts General Hospital and Brigham and Woman’s Hospital. Ms. McDermott presented a lecture entitled “Research Data Management” for the MGH educational series, “Essentials of Clinical Research Coordination”, and a lecture entitled “Collecting and Managing Clinical Research Data” at the Brigham and Woman’s Hospital annual flagship course, “Introduction to Clinical Research”. This BWH course is offered annually to medical fellows and junior faculty.

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 FY09, PDMC staff participated in numerous academic courses, professional conferences and trainings.

Staff Promotions and New Hires
Promotions:
Handan Titiz, EdM, formerly Clinical Data Manager was promoted to Survey Methodologist
in the CRP Survey Core
Rajna Filip-Dhima, BS, formerly PDMC Clinical Data Manager was promoted to PDMC Clinical Specialist I

New Hires:
Adam Simmons, MPH, CCRC, joined the PDMC in October, 2008 as Clinical Research Specialist II
Sara Krathwohl, MPH, joined the PDMC in November, 2008 as Clinical Research Specialist II
Mark Berry, MS, joined the CRP in January, 2009 as Clinical Research Coordinator
Aislyn Cangialose, BA, joined the CRP in March, 2009 as Clinical Research Coordinator
Moriah Polanco, joined the CRP in July, 2009 as Research Data Coordinator
Staffing

The Survey and Measurement Core in FY09 included the following staff. Capsule biographies are provided in Appendix A.

Sion Kim Harris, PhD, CPH, Director and Principal Survey Methodologist  
Sonja I. Zniel, PhD, MA, Senior Survey Methodologist  
Handan Titiz, EdM, Survey Methodologist

The Survey and Measurement Core includes two doctoral level Survey Methodologists, Sion Kim Harris and Sonja Zniel, who both hold faculty appointments in the CHB Division of Adolescent/Young Adult Medicine and Harvard Medical School. Dr. Harris also holds a faculty appointment in the CHB Division of Developmental Medicine. In addition, a new Survey Methodologist, Handan Titiz, joined the Survey Core during FY09.

Survey and Measurement Core Mission

The mission of the Survey and Measurement Core is to promote excellence at CHB in the design, implementation, and analysis of surveys and other measurement tools in clinical research and evaluations of patient care quality and medical education through the provision of methodological expertise and leadership, educational offerings, and links to additional resources. Survey and Measurement Core staff are supported by CRP and departmental funds, the CHB Program for Patient Safety and Quality, and federal and foundation research grants.
Services

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

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; and
- 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; and
- 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; and
- 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 number of requests for Survey and Measurement Core services during FY09.

<table>
<thead>
<tr>
<th>Task</th>
<th>FY09 Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistance with Existing Database</td>
<td>3</td>
</tr>
<tr>
<td>Database Development (On-Line Survey)</td>
<td>20</td>
</tr>
<tr>
<td>Interpretation of Results</td>
<td>5</td>
</tr>
<tr>
<td>Manuscripts/Presentations</td>
<td>2</td>
</tr>
<tr>
<td>Power and Sample Size Determination</td>
<td>4</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td>6</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>12</td>
</tr>
<tr>
<td>Study Design</td>
<td>7</td>
</tr>
<tr>
<td>Study Review/Critique</td>
<td>6</td>
</tr>
<tr>
<td>Survey/Questionnaire Design</td>
<td>31</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>96</strong></td>
</tr>
</tbody>
</table>

**Research Collaborations**

The primary activity of the Survey and Measurement Core is collaboration and consultation with CHB investigators who use surveys or questionnaires in their research. Such assistance includes development of grant proposals, survey and questionnaire design, data collection (qualitative and quantitative), programming and implementation of Web-based surveys, and other survey-related activities. The Survey and Measurement Core
also assists with analyzing survey data, and presentation and publication of results. In FY09, Survey and Measurement Core staff provided assistance on a diversity of projects (Table 1), including 20 Web-based surveys. A few of these projects are highlighted below. A full list of recent publications by Survey and Measurement Core staff is provided in Appendix B.

- **CHB Inpatient Experience Survey:** In FY09, Dr. Ziniel led 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. For the pilot phase, 477 patient families were recruited during their hospital stay to complete the survey either by mail or phone interview. Of the 477, 353 to date have completed the survey a second time for test-retest reliability. Dr. Ziniel is currently supervising the data analysis, report of findings, and refinement/shortening of the survey for full implementation in spring 2010. In addition, Dr. Ziniel is spearheading the development of additional 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.

- **CHCA Whole System Measure of Patient Satisfaction:** Together with Nina Rauscher, the Executive Director of the Program for Patient Safety and Quality, Dr. Ziniel led a group of service excellence specialists to develop one measure on patient satisfaction, called the Whole System Measure. The hospitals that will report on this measure are all participating hospitals in the Child Health Corporation of America. Reporting this measure on a regular basis will enable hospitals to compare themselves among each other and set benchmarks for comparisons across time.

- **Youth Connectedness to Provider (YCP) Scale:** In collaboration with Dr. Elizabeth Woods in Adolescent Medicine, Dr. Harris developed and conducted a psychometric evaluation of a brief measure of the degree to which teens feel connected to their health care provider. We developed this 7-item scale for use in clinical intervention studies where the effectiveness of a clinician-delivered intervention may be modified by the quality of the adolescent patient-provider relationship. The scale consists of items that assess how much adolescents feel that the provider cares, listens, is someone they can talk to about their problems, does not judge, etc. This scale was administered immediately post-visit to over 2,000 adolescent primary care patients as part of a clinical trial evaluating a brief substance use screening and advice protocol for adolescent primary care. We found the scale to have good reliability and construct validity as demonstrated by its association with the number of prior visits with the provider, satisfaction with the visit, and willingness to follow the provider’s advice.

- **Screening and Brief Advice for Adolescent Substance Use in Primary Care:** Dr. Harris serves as the measurement expert for the Center for Adolescent Substance Abuse Research in the Division of Developmental Medicine, of which Dr. John Knight is the director. FY09 was the final year for two five-year NIH-funded clinical trials and data analyses are currently being conducted to assess the effects of a screening and brief advice protocol to address teen substance use in the primary care office, and of motivational enhancement therapy in the treatment of adolescent substance abuse problems.

- **Young Parents Program Project Connect:** Survey Core staff (Handan Titiz and Sion Kim Harris) 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.
• **End of life decision making in neurologically injured patients in a pediatric ICU:**
  Dr. Ziniel provides consulting around focus group research, analysis of qualitative data, and survey design for a study led by Dr. Meredith Giglia van der Velden. The study aims to identify factors that influence the decision making process of doctors evaluating when to take neurologically injured patients off life support. The study will address personal factors, case factors as well as institutional factors and will be the first of its kind to examine the influences of physician recommendations regarding withdrawal of life support.

• **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.

**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. Newly awarded in FY09 is an NIH Challenge Grant entitled “Dental and Medical Office iMET to Reduce Teen Substance Use.” (PI, John R. Knight) on which Dr. Harris is a co-investigator. The goal of this two-year project is to develop and pilot test an Internet/Intranet-based Motivational Enhancement Therapy (iMET) intervention for adolescents, which targets tobacco, alcohol, and drug use. Dr. Ziniel received funding from two grants: a CDC grant for the “Community Asthma Project” by Dr. Elizabeth Woods, Department of Adolescent/Young Adult Medicine, and a grant for the “REUNITE System” by Dr. Sarita Chung, Department of Emergency 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 FY09 by Dr. Ziniel include the following: Lectures on designing questionnaires and evaluating measures as part of the Introduction to Clinical Research course and other departmental settings. In addition, Dr. Ziniel offered for the first time a class on the use of focus groups in clinical research.

In the coming fiscal year, several new courses will be offered by Dr. Ziniel. She will teach a short course on web surveys and an introduction to survey research. A more intensive multi-lecture workshop on survey methodology and questionnaire design will also be offered. This course allows investigators to complete their survey projects and the accompanying IRB application under the guidance of Dr. Ziniel. Also, the courses offered in FY09 will again be offered in the coming year due to the positive feedback and demand expressed by participants.

**Partnerships with Departments and Divisions**
Both Dr. Harris and Dr. Ziniel are funded by CHB Departments/Divisions. Dr. Harris is funded by the Divisions of Adolescent/Young Adult Medicine and Developmental Medicine in the Department of Medicine. Both Dr. Harris and Dr. Ziniel are funded by the Program for Patient Safety and Quality.
New Staff
Handan Titiz joined the Survey and Measurement Core in the spring of 2009. Ms. Titiz worked previously in the Project and Data Management Core and completed her Masters in Education at the Harvard Graduate School of Education. She has extensive experience in programming Web-based surveys, and database development and management. Ms. Titiz provides Web-based survey programming and oversees implementation, provides consultation on all aspects of survey design and research methods, and conducts survey data analyses.
Staffing

FY2009 Clinical Research Information Technology staff included the following. Capsule biographies are provided in Appendix A.
Jason Rightmyer, MS, Team Leader
Mohamad Daniar, MS, Senior Applications Developer
James Gregoric, BS, Senior Applications Developer
Joseph Rezuke, BS, Lead Applications Developer and GCRC Informatics Manager

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 a wide variety of clinical investigators, core program and administrative teams. 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 initiated, led and participated in a variety of informatics activities throughout the fiscal year. A summary of these accomplishments are provided below.

*Doubled EDC development using Phase Forward InForm*

The enterprise adopted the use of Phase Forward InForm EDC (electronic data capture) system on all new large-scale clinical trial databases in 2008. During its first full year of employment, the InForm system has allowed the enterprise to increase dramatically the number of supported projects. The InForm design tools allow the enterprise to expanding the number of database designers and reducing bottlenecks in the build process.

Prior to adopting the Phase Forward product suite, the institution relied exclusively on the CRIT to design and implement systems. The CRIT is a very small team and during its best single year the team developed eight large-scale systems. In 2009, the InForm team developed 17 new studies, doubling enterprise productivity in its inaugural year. This is clear evidence of the successful adoption 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 developed and deployed a new enterprise software application that is used by
study teams to coordinate daily research activities. The product, titled the Clinical Re-
search Coordination System, supports the following features.

- Centralized Patient Enrollment
- Study Scheduling
- Task and Patient Contact Management
- Patient Lab and Demographic Data Export from CDW

**Released the GPP/PGD into production**
The CRIT collaborated with clinical investigators from the Developmental Medicine Center
(DMC) and Children's Hospital Informatics Program (CHIP) on the Gene Partnership Pro-
gram. The CRIT provided continued applications development for the Program’s core data
repository named the Phenotype Genotype Database (PGD). This repository functions as
a central store for data collected via the DMC clinic, patient surveys, genetic samples and
medical records system. This translational research application provides clinical investiga-
tors with a central registry of genotype and phenotype data that can be analyzed for new
associations and promote scientific discovery. The GPP enrolled its first patient in 2009.

**Added new Research Study Extranet service**
The CRIT expanded its services offering in 2009 to include a Sharepoint 2007 extranet.
This “research studies” extranet system is accessible from the Internet and can be used to
manage study communications and share documents for multi-site collaborative studies.

**Created and Deployed CRIT Web site**
The CRIT developed and deployed 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 Web address [http://www.childrenshospital.org/crit](http://www.childrenshospital.org/crit).

**Supported legacy EDC and new Web Survey solutions**
The CRIT in close collaboration with the CRP Survey Core helped to develop and deploy
many new small and large-scale surveys in 2009. The CRIT has now provided support to
over 100 surveys in the field. In addition, the CRIT continued support of 20 legacy EDC
systems developed prior to InForm adoption.

**Supported the development of administrative applications**
The CRIT worked closely with the CRP administrative team to revise and support several
of its administrative and operating software applications. Specifically, the team assisted in
revising features in the CRP Web-based budget tracking software and enhancing the CRP
intake database with new effort tracking functionality and reports through CHQuery.
| Appendix A | Staff Biographies |
| Appendix B | Staff Publications |
| Appendix C | Collaborative Projects |
| Appendix D | Course Agendas |
| Appendix E | CRP Research Grant Program |
| Appendix F | Program Description & Request for Assistance Form |
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 trial of Metformin for weight loss in obese adolescents, a school nurse delivered smoking cessation intervention for adolescent smokers, a school nurse delivered obesity intervention in adolescents, 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 Assistant 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, Ph.D.
Dr. Dinsmore has spent the last 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 B.S. in Biology from Boston College in 1983 followed by a Ph.D. 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.

Clinical Research Faculty

Christopher Duggan, MD, MPH
Dr. Christopher Duggan is a pediatric gastroenterologist and nutrition physician whose research interests include the nutritional management of acute diarrhea, short bowel syndrome and persistent diarrhea, clinical trials of micronutrient supplementation, and general aspects of nutritional support in catabolism. Dr. Duggan has an active research program in collaboration with colleagues in Tanzania and India. He is an Associate Professor of Pediatrics at Harvard Medical School, an Associate Professor of Nutrition at the Harvard School of Public Health, and Director of the Clinical Nutrition Service at Children’s Hospital Boston.

Biostatistics Core

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.

**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 Manning, PhD, Senior Biostatistician**

Dionne Graham Manning 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 devotes substantial effort to the Program for Patient Safety and Quality, assessing the efficacy of safety and quality initiatives and developing measures for monitoring hospital performance. Dr. Graham Manning also provides statistical support to the Department of Cardiology and delivers a popular introductory biostatistics course under CRP auspices.

**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, Senior 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.

Patrick Johnston, MS, Senior Biostatistician
Patrick Johnston joined the CRP in 2006. He holds degrees in mathematics and economics and has wide interests in theoretical and applied statistics, ranging from Bayesian, likelihood, and frequentist approaches to inference, through parametric and semiparametric models, to solving practical problems in design and analysis by simulation. He has devoted substantial effort to a study of necrotizing enterocolitis sponsored by the Glaser Pediatric Research Network and provides statistical support and collaboration to medical researchers in various departments, serving particularly as statistician for the Otolaryngology Department and Emergency Medicine Division.

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. Dr. Kalish is affiliated with the Infectious Disease and Hematology/Oncology Divisions and is Associate Director of Biostatistics for the CHB component of the newly formed 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.

Janine Molino (Bacic), MS, Statistical Programmer
Janine Molino joined the CRP as a statistical programmer in January, 2009. Her responsibilities include data cleaning, data reporting, and data analysis. Ms. Molino holds a Masters of Science degree in statistics from Stanford University and a Bachelor of Arts degree from Boston College in both mathematics and economics.

Clarissa Valim, MD, ScD, MSc, SM, Senior Biostatistician
Clarissa Valim has a multidisciplinary background, with graduate studies in medicine, epidemiology, and biostatistics leading to her joining CRP in 2003. Her methodological research interests are in the area of survival methods, particularly in studies with censoring due to outcome-related mortality, and in predictive models for functional outcomes in longitudinal studies. She is affiliated with the Department of Surgery, collaborating on protocol development, conduct of trials, and data analysis. Dr. Valim lectures in the CRP educational program and is a biostatistician for the NIH-funded Severe Malaria in African Children clinical research network.

Courtney Walls, MS, 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 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 Surgery 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, Project Director
Ms. Antonelli joined the CRP in February 2006 to serve as Project Director for the BASH
study and staff consultant. Her primary responsibility is to serve as Project Director for the
BASH study, a large multi-site NIH-funded trial with the Obesity Research Group, including
study oversight, development of case report forms and manuals of operation, data
management system specifications, recruitment, and implementation of the protocol in the
field. She also supports development of Education Core courses and Research Practice
Guidelines. 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 also has several years of clinical research experience in a
large private urology practice.

Laura Boger, AB, Research Data Coordinator
Ms. Boger joined the CRP in October 2006 to serve a Research Data Coordinator. She
received an AB in Development Studies from Brown University and worked after
graduation for a non-profit health and human rights organization and served as a Peace
Corps volunteer in Guyana, South America.
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 surveys, 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, building and preparing scientific databases for statistical analysis, cleaning data and implementing quality assurance procedures.

Rajna Filip-Dhima, BS, Research Data Manager
Ms. Filip-Dhima joined the CRP in March 2004 after earning a Bachelor of Science degree in Psychology from Northeastern University. While completing her undergraduate studies, Ms. Filip-Dhima participated in the University’s cooperative education program working as a research assistant at MGH, Boston City Hall, and Northeastern’s Laboratory of Social Psychology and Personality. As CRP Data Manager, Ms. Filip-Dhima works on multiple research studies, both large and small. As such, she develops case report forms and surveys, writes programming specifications and builds databases in SPSS and InForm™, implements quality control procedures for databases and data management, trains study staff in data management procedures, creates randomization products and develops web surveys.

Jui Haker, MD, MPH, Epidemiologist, Project Director
Dr. Jui Haker joined the Clinical Research Program (CRP) in January 2007 as an Epidemiologist / Biostatistician. She is a physician from India, where she completed a residency in Preventive and Social Medicine. She also graduated from the Harvard School of Public Health with a Master of Public Health degree. As part of the PDMC, Dr. Haker serves as a protocol manager and/or project lead for multiple studies; she collaborates with investigators for study planning and implementation, and oversees the development of case report forms, data management systems and web surveys. Prior to joining the CRP, Dr. Haker worked as a researcher in the Department of Radiology at the Brigham and Women's Hospital, where she was actively involved in a number of NIH funded studies as an Investigator.

Maggie McCarthy, MS, MPH, Project Director
Ms. McCarthy joined the CRP in April 2002. She earned a MPH from Harvard School of Public and a Master of Clinical Immunology from Hahnemann University in Philadelphia. At CRP, Ms. McCarthy served as Project Director for the Glaser Pediatric Research Network, assisting in protocol development, development of case report forms, manuals of operation, and database specifications for the Network’s data management systems. Prior to joining the CRP, Ms. McCarthy served as Data Coordinating Center Project Director for the multi-site study, Hepatitis C Antiviral Long Term Treatment against Cirrhosis (HALT-C), a NIH clinical trial implemented at 10 U.S. sites.

Sarah Krathwohl, MPH Clinical Research Specialist II
Sarah Krathwohl joined the CRP in 2008. As Clinical Research Specialist II, Ms. Krathwohl provides research management advice on study design, development of protocols and grant applications, data collection instruments, manuals of operation, and overall study coordination. Ms. Krathwohl 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. Krathwohl also has experience in childhood
overweight research through her work at the University of California, Berkeley Center for Weight and Health.

Marina Shishova BS, Data Coordinator I
Marina Shishova joined the CRP in 2008 as a Research Data Coordinator after completing her Bachelor’s degree in Statistics from Mount Holyoke College. Ms. Shishova served as Data Coordinator for multiple studies supported by the CRP. Her primary responsibilities included research document file management, data entry, edit query resolution and provision of general data management support to study staff. Ms. Shishova left the CRP in the summer of 2009.

Adam Simmons, MPH Clinical Research Specialist II
Adam Simmons joined the CRP in 2008. Mr. Simmons supports CHB investigators in the development of clinical research protocols including study implementation and data management tools, e.g., study procedures manuals, case report forms, and study-specific quality assurance activities. He works to develop and oversee the implementation of best practice procedures for conducting regulated clinical trials to insure compliance with hospital, state and federal regulations. Mr. Simmons also prepares training materials on quality assurance as a part of the CRP’s educational efforts. Mr. Simmons earned an MPH in epidemiology from Emory University where he also worked as a clinical research coordinator in the Department of Orthopaedics in the 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.

Handan Titiz, EdM, Data Manager
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.

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.

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, 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.

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

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 hand-writing 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 FY07 Mr. Rezuke developed several advanced reporting procedures for the CRP’s web-based budget tracking software application.


Richmond TK, **Walls CE,** Gooding H, Field A. Television viewing is not predictive of Body Mass Index in Black and Hispanic young adult females. Obesity. 2009 Oct 29 [Epub ahead of print].


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

5U01 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.

R21 HD056009 (du Plessis) 09/09/07-09/08/09
NIH/NICHD $125,000
Continuous Monitoring for Cerebral Pressure-Passivity in Premature Infants
The overall aim of this study is to characterize the systemic and cerebral hemodynamic antecedents of germinal matrix-intraventricular hemorrhage (GM-IVH), the principal form of hemorrhagic injury in the preterm.

5R01 DC007127-03 (Goldfield) 04/01/05-03/31/10
NIH/NIDC $187,740
Videofluoroscopy of Preterm Infant Swallowing
This project examines the contributions of sensory and motor processes to swallowing of preterm infants. Computer motion analysis is conducted on recorded videofluoroscopic images of swallowing thin-consistency and honey-thick solutions of barium sulfate.

2R44 HD049954-02 (Goldfield) 09/05/08-08/31/10
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.
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.

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.

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.

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.

MRI of Fetal Ventriculomegaly: Morphology and Outcome

Comparison of magnetic resonance imaging to ultrasound for prenatal diagnosis, pregnancy management, and prediction of newborn cognitive, motor, and psychosocial development in cases of ventriculomegaly.

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.
Popular Diets, Metabolism, and CVD Risk
A three-period, randomized, crossover feeding trial in obese adults following weight loss, designed to evaluate the impact on resting energy expenditure of three prevalent diets: low fat, low glycemic index, and very low carbohydrate (Atkins-type).

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 (Omegaven™) 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®).

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 (Omegaven™) to reverse established PN associated liver disease, when compared to administration of soybean-based fat emulsion (conventional) in patients with surgical gastrointestinal disease.

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.

d-Penicillamine Chelation in Lead Poisoned Children
This study evaluates in a Phase II/III randomized, placebo-controlled clinical trial, the effectiveness of d-penicillamine in 50 children ages 6 months to 16 years with blood lead levels 15-25mcg/dl.
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<th>Project ID</th>
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<th>Grant Details</th>
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**Affect and Marijuana Use in Adolescents and Young Adults**

The major goal of this study is to test an affect regulation model for marijuana use among adolescents and young adults who are frequent marijuana users.

**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.

**Redefining Cerebral Malaria: Can Eye Findings Improve the Diagnosis**

This study aims to assess new criteria to diagnose cerebral malaria and sequestration – ocular fundus finding and brain smear. More specifically, the study aims to assess the accuracy of ocular fundus finding to diagnose cerebral malaria and evaluate the prognostic significance of ocular fundus to predict death in patients with clinical cerebral malaria. Additionally, the accuracy of brain smear as a predictor of cerebral sequestration will be investigated. The study will be carried out within the Severe Malaria in African Children (SMAC) Network, which includes five sites in East and West Africa.

**Harvard Clinical Nutrition Research Center**

The goal of this project is to assess liver function using a 13-C methionine breath test in children with intestinal failure.

**Bioinformatics Tools for Multi-Center Diagnostic Trials**

This proposal aims to develop a novel and general statistical validation methodological framework based on accuracy, reliability, and reproducibility metrics to evaluate the diagnostic performance of imaging findings, against a statistically best-available gold standard.

**REACH Community Action Project**

The goal of this grant is to address health disparities for children with asthma served by the Community Asthma Initiative who live in the Jamaica Plain and Roxbury communities of Boston.
### B. NIH Career Development Grants

**5K12 HL087164-03 (Neufeld)**
- **NIH/NHLBI:** $368,899
- **Period:** 10/01/06-06/30/11

**Clinical Hematology Research Career Development Program**

The purpose is to develop and evaluate a multidisciplinary career development program in non-malignant hematology that will equip new investigators with the knowledge and skills to address complex problems in blood diseases. The program provides training to encourage promising young physician scientists to choose non-malignant hematology as a career path, broaden the didactic experience within hematology for graduates of the program, provide structured training in clinical research methods, and evaluate the outcomes of the training program.

**1K23 DK076979-01A1 (Pappa)**
- **NIH/NIDDK:** $167,000
- **Period:** 09/01/08-08/13/13

**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 patients with IBD.

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

**(Feldman)**
- **Period:** 09/01/02-09/30/10

**Glaser Pediatric Research Network**

$118,211

**Design, Analysis, and Coordinating Center (DACC) for the Glaser Pediatric Research 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)**
- **Period:** 12/01/02-12/31/09

**Necrotizing Enterocolitis (NEC) Surgical Database**

This study will develop a multi-center prospective data collection process for necrotizing enterocolitis in order to provide accurate data regarding practice of treatment and variability of care between different centers.

### D. Foundation/Association/Other

**(Bae)**
- **Period:** 01/01/09-12/31/10

**American Society of Surgery of the Hand**

$10,000

**Randomized Trial of Bivalved and Circumferential Casting for Displaced Forearm Fractures in Children**

This study aims to compare the efficacy of bivalved and circumferential casts to prevent loss of fracture reduction in children with forearm fractures. Loss of fracture reduction will be primarily defined as a loss of reduction that requires remanipulation and/or surgical intervention at 6 weeks post-randomization. Also, this study aims to compare the tolerability of bivalved and circumferential casts, as measured by the frequency of compartment syndrome or neurovascular compromise, and of saw burns and/or lacerations.
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.

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.

Improving the Safety of Gastrointestinal Endoscopy through Simulation

This study will test the use of simulation-based training at increasing clinical competence by improving teamwork and communication, reducing patient pain and decreasing the incidence of adverse events during GI endoscopy. It will also test whether endoscopic simulation predicts actual procedural performance.

Electrophysiologiocal, 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.

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.

Efficacy of Omega-3 Enriched Fat Emulsion and Prevention of Parenteral Nutrition Induced Liver Injury in Infants

The goals of this project are to: 1) determine whether the parenteral administration of an omega-3 fatty acid based fat emulsion reduces the proportion of cholestasis in infants; 2) describe biochemical tests of liver function profiles over time in the two treatment groups; 3) assess the safety and tolerability of an omega-3 fatty acid based fat emulsion (Omegaven™) as opposed to a conventional fat emulsion (Intralipid®).
(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).

(Richmond) 01/01/07-12/31/08
Charles H. Hood Foundation Child Health Research Grant $75,000
Do School Physical Activity Programs Contribute to Racial/Ethnic Disparities in Adolescent Physical Activity and Obesity?
The goal of this project is to determine whether school programs, specifically physical education classes and/or interscholastic sports, contribute to racial/ethnic disparities in adolescent physical activity and/or obesity.

(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

**Tuesday, March 17, 2009**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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</table>
| 8:00 – 8:15 | **Introduction and Overview**                      | Jenifer Lightdale, MD, MPH  
Director, Education Core  
Clinical Research Program  
Gastroenterology/Nutrition  
Children’s Hospital Boston |
| 8:15 – 9:15 | **Observational Study Designs**                    | Voula Osganian, MD, MPH  
Program Director  
Clinical Research Program  
Endocrinology  
Children’s Hospital Boston |
| 9:15 – 9:25 | **BREAK**                                          |                                                                              |
| 9:25 – 10:25 | **Statistics in Clinical Research: An Overview**   | Henry Feldman, PhD  
Lead Biostatistician  
Clinical Research Program  
Children’s Hospital Boston |
| 10:25 – 10:35 | **BREAK**                                         |                                                                              |
| 10:35 – 11:35 | **Human Subjects and the Institutional Review Board** | Susan Kornetsky, MPH, CIP  
Director, Clinical Research Compliance  
Committee on Clinical Investigation  
Children’s Hospital Boston |
| 11:35 – 11:50 | **Overview of Research Administration: Organization & Resources** | Jessica Moran  
Administrative Manager  
Research Administration  
Children’s Hospital Boston |
| 11:50 – 12:45 | **LUNCH BREAK**                                   |                                                                              |
| 12:45 – 1:15 | **The IRB Review Process: An Insider’s View**      | Lydia Shrier, MD, MPH  
Director of Clinic-based Research  
Division of Adolescent/Young Adult Medicine |
1:15 – 1:45 **Small and Common Study Mistakes**
Eunice Yim Newbert, MPH
Manager, Education and Quality Improvement Program
Children’s Hospital Boston

1:45 – 1:50 **BREAK**

1:50 – 2:15 **Collecting and Managing Clinical Research Data – Part I**
Susan M. McDermott, MPH, RN
Team Leader, Data Management Core
Clinical Research Program
Children’s Hospital Boston

2:15 – 2:30 **BREAK**

2:30 – 3:00 **Collecting and Managing Clinical Research Data – Part II**
Susan M. McDermott, MPH, RN

3:00 – 3:15 **Marketing and Public Affairs Department: Options for Recruitment**
Gina Colavecchio, MBA
Marketing Communications Specialist
Marketing Department
Children’s Hospital Boston

3:15 – 3:25 **BREAK**

3:25 – 4:40 **Descriptive and Univariate Statistics**
Dionne Graham, PhD
Senior Biostatistician, Clinical Research Program
Statistician for the Program for Patient Safety and Quality
Research Faculty in the Department of Cardiology
Children’s Hospital Boston
Instructor, Harvard Medical School

4:40 – 4:45 **BREAK**

4:45 – 5:30 **Industry and Philanthropy**
Sam Nurko, MD, MPH
Director, Center for Motility and Functional Gastrointestinal Disorders
Children’s Hospital Boston
Associate Professor, Harvard Medical School
INTRODUCTION TO CLINICAL RESEARCH

Friday, March 20, 2009

8:00 – 8:45  Grant Writing 101
Jenifer Lightdale, MD, MPH
Director, Education Core
Clinical Research Program
Gastroenterology/Nutrition
Children's Hospital Boston

8:45 – 9:15  NIH Review
Richard Grand, MD
Program Director
General Clinical Research Center
Gastroenterology/Nutrition
Children's Hospital Boston
Professor of Pediatrics, Harvard Medical School

9:15 – 9:20  BREAK

9:20 – 9:35  The Clinical and Translational Study Unit (CTSU)
Kristine Jordan
Administrative Director
Clinical and Translational Study Unit (CTSU)
Children's Hospital Boston

9:35 – 10:20  Clinical Trials: Design and Monitoring
Jane W. Newburger, MD, MPH
Associate Chief for Academic Affairs, Department of Cardiology
Children's Hospital Boston
Professor of Pediatrics, Harvard Medical School

10:20 – 10:30  BREAK

10:30 – 11:30  Introduction to Regression Analysis
Henry Feldman, PhD
Lead Biostatistician
Clinical Research Program
Children's Hospital Boston

11:30 – 11:40  BREAK

11:40 – 12:15  Scientific Presentations
Jonathan Finkelstein, MD, MPH
Associate Professor, Departments of Ambulatory Care and Prevention and Pediatrics
Harvard Medical School
Director, Center for Population Health Education

12:15 – 1:00  LUNCH
1:00 – 2:00  
**Writing for Scientific Publication**  
Marjorie Beeghly PhD  
Assistant Professor of Pediatrics  
Children’s Hospital Boston

Sion Harris PhD, CPH  
Children's Hospital Boston Clinical Research Program  
Survey Research Methodology Core  
Division of Adolescent/Young Adult Medicine  
Division of Developmental Medicine  
Center for Adolescent Substance Abuse Research

2:00 – 2:15  
**Translational Research at Children's Hospital Boston**  
Judy Fleming PhD  
Associate Director  
Translational Research Program  
Children's Hospital Boston

2:15 – 3:00  
**Evaluating Measures in Clinical Research**  
Sonja Ziniel PhD, MA  
Survey Methodologist  
Clinical Research Program  
Children’s Hospital Boston

3:00 – 3:10  
**BREAK**

3:10 – 3:55  
**Designing Surveys and Questionnaires**  
Sonja Ziniel PhD, MA

3:55 – 4:00  
**BREAK**

4:00 - 4:15  
**Clinical & Translational Services Unit (CTSU) Off-Unit Services**  
Adam Simmons MPH, CCRC  
Clinical Research Specialist  
Manager, CRC Core  
Clinical Research Program  
Children’s Hospital Boston

4:15 – 4:30  
**The CRP Course Wrap–up**  
Jenifer Lightdale, MD, MPH  
Director, Education Core  
Clinical Research Program  
Gastroenterology/Nutrition  
Children’s Hospital Boston
INTRODUCTION TO CLINICAL RESEARCH

Tuesday, September 22, 2009

8:00 – 9:00  Observational Study Designs
Voula Osganian, MD, MPH
Program Director
Clinical Research Program
Endocrinology
Children’s Hospital Boston

9:00 – 9:10  BREAK

9:10 – 9:20  Introduction and Overview
Jenifer Lightdale, MD, MPH
Director, Education Core
Clinical Research Program
Gastroenterology/Nutrition
Children’s Hospital Boston

Henry Feldman, PhD
Principal Biostatistician
Clinical Research Program
Children’s Hospital Boston

10:20 – 10:25  BREAK

10:25 – 11:25  Writing for Scientific Publication
S. Jean Emans, MD
Chief, Division of Adolescent Medicine
Vice Chair Clinical Affairs, Dept. of Medicine
Director, Office of Faculty Development
Children’s Hospital Boston

11:25 – 11:40  Overview of Research Administration: Organization & Resources
Jessica Moran
Administrative Manager
Research Administration
Children’s Hospital Boston

11:40 – 12:25  LUNCH BREAK

Lydia Shrier, MD, MPH
Director of Clinic-based Research
Division of Adolescent/Young Adult Medicine
Member, Committee on Clinical Investigation
Children's Hospital Boston
Assistant Professor, Harvard Medical School
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:55 – 1:25</td>
<td>Common Study Documentation Errors and Best Practices</td>
<td>Kristin Bowling, MS&lt;br&gt;Quality Improvement Specialist&lt;br&gt;Education and Quality Improvement Program&lt;br&gt;Children’s Hospital Boston</td>
</tr>
<tr>
<td>1:25 – 1:35</td>
<td>Translational Research at Children’s Hospital Boston</td>
<td>Judy Fleming, PhD&lt;br&gt;Associate Director&lt;br&gt;Translational Research Program&lt;br&gt;Children's Hospital Boston</td>
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<tr>
<td>1:35 - 1:45</td>
<td>BREAK</td>
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<tr>
<td>1:45 – 2:15</td>
<td>Regulatory Affairs</td>
<td>Matt Wladkowski, MS&lt;br&gt;Regulatory Affairs Coordinator&lt;br&gt;Translational Research Program&lt;br&gt;Children's Hospital Boston</td>
</tr>
<tr>
<td>2:15 – 2:20</td>
<td>BREAK</td>
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<tr>
<td>2:20 – 3:05</td>
<td>Clinical Trials: Design and Monitoring</td>
<td>Jane W. Newburger, MD, MPH&lt;br&gt;Associate Chief for Academic Affairs, Department of Cardiology&lt;br&gt;Children's Hospital Boston&lt;br&gt;Professor of Pediatrics, Harvard Medical School</td>
</tr>
<tr>
<td>3:05 – 3:15</td>
<td>BREAK</td>
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</tr>
<tr>
<td>3:15 - 4:15</td>
<td>Descriptive and Univariate Statistics</td>
<td>Dionne Graham, PhD&lt;br&gt;Senior Biostatistician, Clinical Research Program&lt;br&gt;Statistician for the Program for Patient Safety and Quality&lt;br&gt;Research Faculty in the Department of Cardiology&lt;br&gt;Children’s Hospital Boston&lt;br&gt;Instructor, Harvard Medical School</td>
</tr>
<tr>
<td>4:15 – 4:20</td>
<td>BREAK</td>
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<tr>
<td>4:20 – 5:05</td>
<td>Introduction to the Responsible Conduct of Research</td>
<td>Sadath Sayeed, MD, JD&lt;br&gt;Instructor, Division of Medical Ethics&lt;br&gt;Harvard Medical School&lt;br&gt;Assistant in Medicine&lt;br&gt;Division of Newborn Medicine&lt;br&gt;Children's Hospital Boston</td>
</tr>
</tbody>
</table>
INTRODUCTION TO CLINICAL RESEARCH

Friday, September 25, 2009

8:00 – 8:10
Day Two Opening Thoughts
Jenifer Lightdale, MD, MPH
Director, Education Core
Clinical Research Program
Gastroenterology/Nutrition
Children's Hospital Boston

8:10 – 8:55
Grant Writing 101
Jenifer Lightdale, MD, MPH

8:55 – 9:20
NIH Review
Richard Grand, MD
Program Director
Clinical and Translational Study Unit (CTSU) Gastroenterology/Nutrition
Children's Hospital Boston
Professor of Pediatrics, Harvard Medical School

9:20 – 9:35
The Clinical and Translational Study Unit (CTSU)
Kristine Jordan
Administrative Director
Clinical and Translational Study Unit (CTSU)
Children's Hospital Boston

9:35 – 9:40
BREAK

9:40 – 10:05
Collecting and Managing Clinical Research Data – Part 1
Susan M. McDermott, MPH, RN
Team Leader, Project and Data Management Core
Clinical Research Program
Children's Hospital Boston

10:05 – 10:10
BREAK

10:10 – 10:40
Collecting and Managing Clinical Research Data – Part 2
Susan M. McDermott, MPH, RN

10:40 – 11:40
Introduction to Regression Analysis
Dionne Graham, PhD
Senior Biostatistician, Clinical Research Program
Statistician for the Program for Patient Safety and Quality
Research Faculty in the Department of Cardiology
Children's Hospital Boston
Instructor, Harvard Medical School

11:40 – 11:45
BREAK
11:45 – 12:20  *Scientific Presentations*  
Jonathan Finkelstein, MD, MPH  
Associate Professor, Departments of Population Medicine and Pediatrics  
Harvard Medical School and Harvard Pilgrim Health Care Institute  
Director, Center for Population Health Education

12:20 - 12:40  *Harvard Catalyst/CTSA*  
Ellis Neufeld, MD, PhD  
Associate Chief, Division of Hematology/Oncology  
Children’s Hospital Boston  
Professor of Pediatrics, Harvard Medical School

12:40 – 1:40  *LUNCH – break out session*

1:40 – 2:40  *Human Subjects and the Institutional Review Board*  
Susan Kornetsky, MPH, CIP  
Director, Clinical Research Compliance  
Committee on Clinical Investigation  
Children’s Hospital Boston

2:40 – 2:45  *BREAK*

2:45 – 3:30  *Designing Surveys and Questionnaires*  
Sonja Ziniel PhD, MA  
Survey Methodologist  
Clinical Research Program  
Children’s Hospital Boston

3:30 – 3:35  *BREAK*

3:35 – 4:20  *Evaluating Measures in Clinical Research*  
Sonja Ziniel PhD, MA

4:20 – 4:25  *BREAK*

4:25 – 5:10  *Industry and Philanthropy*  
Sam Nurko, MD, MPH  
Director, Center for Motility and Functional Gastrointestinal Disorders  
Children’s Hospital Boston  
Associate Professor, Harvard Medical School
COORDINATOR ROUNDS FY 2009

10/1/08  **Assenting: Challenging Ethical Issues in Assenting Research Patients**
Maya Mundkur Greer MSN, FNP-BC  
Program Manager, Advanced Fetal Care Center  
previously Research Subject Advocate, GCRC  
Children’s Hospital Boston

  Brianna J Matney, MS, CCLS  
  Child Life Specialist  
  6 East/Clinical and Translational Study Unit  
  Children’s Hospital Boston

12/3/08  **Rolling the Dice: Randomization in Clinical Trials**
Henry Feldman, PhD  
Senior Biostatistician  
Clinical Research Program  
Children’s Hospital Boston

  Amy DiVasta, MD, MMSc  
  Staff Physician, Adolescent Medicine/Gynecology  
  Children’s Hospital Boston  
  PI of the Endometriosis/Add Back Trial

  Ashley Quach  
  Research Study Coordinator  
  Adolescent Medicine  
  Children’s Hospital Boston

2/4/09  **Strategies for Successful Recruitment**
Gina Colavecchio, MBA  
Marketing Communications Specialist  
Department of Marketing and Public Affairs  
Children’s Hospital Boston

  Meredith Beard  
  Optimal Weight for Life Research Program  
  Children’s Hospital Boston

  Sarah Krathwohl, MPH  
  Clinical Research Specialist  
  Clinical Research Program  
  Children’s Hospital Boston

  Rebecca Hansen  
  Recruitment Coordinator  
  Labs of Cognitive Neuroscience

4/1/09  **CCI Update**
Matt Stafford, CIP  
Manager, Committee on Clinical Investigation (CCI)  
Children’s Hospital Boston
6/16/09  **Preparing for an FDA Audit**  
Eunice Newbert MPH  
Manager, Education & Quality Improvement Program  
Children’s Hospital Boston  

Jean Connors DNS, RN, CPNP  
Department of Cardiology  

Heidi Moses M.Ed.  
Department of Cardiology  

8/5/09  **Child Development 101**  
Brianna J Matney, MS, CCLS  
Child Life Specialist  
6 East/Clinical and Translational Study Unit  
Children’s Hospital Boston  

LaKeisha Ruley MS, CCLS  
Child Life Specialist  
10 East; Infant/Toddler Surgical  
Children’s Hospital Boston
# The Anatomy and Art of Writing a Career Development Grant

## Course Agenda

**October 15, 2008 & October 17, 2008**

### 10/15/08 SESSION ONE: Anatomy of a Career Development Grant

**Brigham and Women’s Hospital, 2:30pm – 5:00pm**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
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<tbody>
<tr>
<td>2:30 – 2:35</td>
<td>Welcome and Introduction</td>
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<tr>
<td>2:35 – 2:55</td>
<td>Career Development Plans</td>
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<td></td>
<td><em>Rochelle P. Walensky, MD, MPH</em></td>
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<tr>
<td>2:55 – 3:15</td>
<td>Specific Aims</td>
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<td><em>Voula Osganian, MD, ScD, MPH</em></td>
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<tr>
<td>3:15 – 3:45</td>
<td>Background &amp; Preliminary Studies</td>
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<td><em>John R. Knight, MD</em></td>
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<tr>
<td>3:45 – 3:55</td>
<td><strong>BREAK</strong></td>
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<tr>
<td>3:55 – 4:25</td>
<td>Research Plan</td>
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<tr>
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<td><em>Ellen W. Seely, MD</em></td>
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<tr>
<td>4:25 – 4:45</td>
<td>Data Analysis Plan</td>
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<td><em>Henry Feldman, PhD</em></td>
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<tr>
<td>4:45 – 5:00</td>
<td>Panel Q &amp; A Session</td>
</tr>
</tbody>
</table>

### 10/17/08 SESSION TWO: The Art of Grantsmanship

**Children’s Hospital Boston, 1:00pm – 3:30pm**

**Enders Auditorium**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
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<tbody>
<tr>
<td>1:00 – 1:10</td>
<td>10 Boiler Plate 101: Human subjects/animal protection, etc.</td>
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<tr>
<td></td>
<td><em>Jenifer R. Lightdale, MD, MPH</em></td>
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<tr>
<td>1:10 – 1:30</td>
<td>Identifying Funding Sources;</td>
</tr>
<tr>
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<td><em>Liam O’Connor, MEd</em></td>
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<tr>
<td>1:30 – 1:50</td>
<td>Budget (Constructing a budget, direct vs. indirect vs. fringe, K vs. Independent Scientist Awards, etc)</td>
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<tr>
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<td><em>Grace Chang, MD, MPH</em></td>
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<tr>
<td>1:50 – 2:10</td>
<td>NIH 101</td>
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<td><em>Jordan Kreidberg, MD, PhD</em></td>
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</table>
2:10 – 2:20  BREAK

2:20 – 2:40  The Review Process  
Grace Chang, MD, MPH

2:40 – 3:10  30 Art of Grantsmanship  
Jenifer R. Lightdale, MD, MPH

3:10 – 3:30  Panel Q & A Session

3:30 – 3:35  Concluding Remarks

Focus Groups in Patient Oriented Clinical Research: An Introductory Workshop  
8/25/09 10:00AM - 1:00 PM

Sonja Ziniel, Ph.D.  
Senior Survey Methodologist  
Survey Core, Clinical Research Program

Workshop Outline:  
Characteristics and purpose of focus groups  
Planning focus groups  
Development of moderator guides  
Moderating focus groups  
Analyzing data collected by focus groups
Orientation for New Study Coordinators  
Karp 8th Floor Conference Room  

Hosted by CHB Clinical Research Program  

8:15 – 8:30  Continental Breakfast  

8:30 – 8:45  Welcome and Overview  
S. McDermott  

8:45 – 9:05  Overview of Responsibilities of Study Coordinators  
S. McDermott  
• Study Coordinator’s Central Role in Clinical Research  

9:05 – 9:30  Human Subject Protections IRB Issues: Before the Research Begins  
CCI Staff  
• Introduction/Why are we here?  
• Training Requirements  
• Protocol Submissions  

9:30 – 10:00  IRB Issues – During the Research  
CCI Staff  
• Continuing Renewals  
• 3 Year Re-writes  
• Amendments / Revisions  
• Adverse Events  
• Violations/Deviations  

10:00 – 10:15  Break  

10:15 – 11:15  Informed Consent / Assent and Subject Recruitment  
CCI Staff  
• Writing Informed Consent / Assent  
• Research Subject Recruitment  
• Communication/Shared Responsibility  

11:15 – 11:30  Recruitment Tools from Marketing and Public Affairs Department  
G. Colavecchio  

11:30 – 12:15  Obtaining Informed Consent / Assent – A Practical Approach  
V. Turbini  

12:15 – 12:45  Catered Lunch
12:45 – 1:30 Resources for Conducting Clinical Research
- Introduction to the Clinical Trials Office J. Kaplan
- Introduction to Research Budgets and Study Tracking Sheets K. Jordan
  Funded Research
  Patient Care Costs
- Introduction to the Clinical and Translational Study Unit (CTSU) K. Jordan
- Introduction to the Clinical Research Program (CRP) S. McDermott
- Good Clinical Practices for Clinical Research Professionals S. McDermott

1:30 – 2:10 Study Implementation S. McDermott
- Planning Phase
- Timelines
- Case Report Forms
- Manual of Operations
- Implementation Phase

2:10 – 2:20 Break

2:20 – 2:55 Introduction to the Education and Quality Improvement Program (EQuIP) Newbert
  Study Documentation: Common Errors Newbert

2:55 – 3:10 Methods of Organizing Study Documents Newbert
- Storage of Study Documents and Informed Consent Documents

3:10 – 3:25 Wrap-up & Review S. McDermott
### Introduction to Biostatistics with SPSS Lecture Agenda
**September - November 2009**

<table>
<thead>
<tr>
<th>Date</th>
<th>Lecture Title</th>
<th>Content</th>
</tr>
</thead>
</table>
| Sept. 29  | Lecture 1: Graphical Methods and Summary Statistics | Data Types  
|         |                                                    | Graphical Display: *Bar Charts, Histograms, Boxplots*  
|         |                                                    | Summary Statistics: *Measures of Central Tendency, Measures of Spread* |
| Oct. 6  | Lecture 2: Estimating the Mean and Confidence Intervals | Normal Distribution  
|         |                                                    | Principles of Estimation  
|         |                                                    | Estimating the Mean  
|         |                                                    | Confidence Intervals for the Mean |
| Oct. 13 | Lecture 3: Hypothesis Testing & Comparing Two Means | Inference Overview  
|         |                                                    | Introduction to Hypothesis Testing  
|         |                                                    | Comparing Two Means: Paired t-test, Two sample t-test  
|         |                                                    | Interpreting p-values |
| Oct. 20 | Lecture 4: Comparing Three or More Means         | Analysis of Variance (ANOVA) |
|         |                                                    | Correlation |
| Nov. 3  | Lecture 6: Estimating and Testing Proportions     | Estimating a Proportion  
|         |                                                    | Confidence Intervals for Proportions  
|         |                                                    | Comparing Two or More Proportions: Chi-squared test, Fisher’s exact test |
| Nov. 10 | Lecture 7: Comparing Two Proportions – Measures of Effect | Risk difference  
|         |                                                    | Risk ratio  
|         |                                                    | Odds ratio |
| Nov. 17 | Lecture 8: Putting it all together                | Picking the right test  
|         |                                                    | Interpreting the literature |

### Introduction to Biostatistics with SPSS Lab Agenda
**September - November 2009**

<table>
<thead>
<tr>
<th>Date</th>
<th>Lab 1: Introduction to the SPSS Interface</th>
<th>Content</th>
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</table>
| Oct. 1 |                                           | Opening an existing SPSS database  
|         |                                           | Graphical data analysis  
|         |                                           | Descriptive statistics  
<p>|         |                                           | Subsetting data sets |</p>
<table>
<thead>
<tr>
<th>Date</th>
<th>Lab: Data set basics</th>
<th>Lab: Tests and by-group analysis</th>
<th>Lab: More dataset basics and tests</th>
<th>Lab: Non-parametric tests and correlation</th>
<th>Lab: Tests for proportions</th>
<th>Lab: Odds ratios and diagnostic tests</th>
<th>Lab: Additional SPSS features you need</th>
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<tr>
<td>Oct. 8</td>
<td>Oct. 15</td>
<td>Oct. 22</td>
<td>Oct. 29</td>
<td>Nov. 5</td>
<td>Nov. 12</td>
<td>Nov. 19</td>
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<tr>
<td></td>
<td>Lab 2: Data set basics</td>
<td>Lab 3: Tests and by-group analysis</td>
<td>Lab 4: More dataset basics and tests</td>
<td>Lab 5: Non-parametric tests and correlation</td>
<td>Lab 6: Tests for proportions</td>
<td>Lab 7: Odds ratios and diagnostic tests</td>
<td>Lab 8: Additional SPSS features you need</td>
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<tr>
<td></td>
<td>Confidence intervals for the mean</td>
<td>Two sample t-test</td>
<td>Variable creation and recoding</td>
<td>Wilcoxon and KW tests</td>
<td>One sample test for proportions</td>
<td>Odds ratios</td>
<td>Tutorials</td>
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<tr>
<td></td>
<td>Introduction to SPSS syntax</td>
<td>Paired t-test</td>
<td>Variable creation and recoding</td>
<td>Correlation</td>
<td>Crosstabs</td>
<td>Sensitivity and specificity</td>
<td>Case studies</td>
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<tr>
<td></td>
<td>Descriptive analysis by group</td>
<td>More SPSS syntax</td>
<td>with menus and with syntax</td>
<td>Correlation</td>
<td>Chi squared test</td>
<td>Understanding and using date variables</td>
<td>Syntax Reference</td>
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<tr>
<td></td>
<td>Subsetting data sets</td>
<td></td>
<td>ANOVA</td>
<td>Correlation</td>
<td>Fisher’s exact test</td>
<td>Exporting SPSS output to Word or PowerPoint</td>
<td>Lab wrap-up and discussion</td>
</tr>
<tr>
<td></td>
<td>Creating a new data set from “scratch”</td>
<td></td>
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<td></td>
<td>Reading data from other data formats</td>
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</table>
CRP Biostatistics Short Courses 2009

Power & How to Get It
Course Agenda 2009
Henry Feldman, PhD
Principal Biostatistician, CRP
Paul Mitchell, MS
Senior Biostatistician, CRP

Lecture 1 - 1/27/09
- Review of key concepts: precision, standard error, inferential error
- Definition of power and detectable effect
- Relation to sample size, study design, Type I & Type II error
- Catalogue of formulas for various study designs

Lecture 2 - 1/29/09
- Take-home exercise: Real-life design scenarios
- In-class presentation and discussion

Lab - 1/30/09
- Introduction to Power and Samples Size program
- Examples - Continuous and Binary variables

Introduction to Statistical Genetics
Course Agenda 2009
Chao-Yu Guo, PhD
Senior Biostatistician

Lecture 1 – 4/23/09: Introductions
- Genetics
- Hardy-Weinberg Equilibrium
- Heritability
- SOLAR

Lecture 2 – 4/30/09: Linkage Analysis
- easyLinkage

Lecture 3 – 5/7/09: Population based association study
- the HapMap Consortium
- Haploview

Lecture 4 – 5/14/09: Family based association study
- FBAT, PBAT
# DO IT YOURSELF DATA MANAGEMENT AGENDA

**June 1, 3, 4 & 5, 2009**

## Session 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>2:00pm – 2:20pm</td>
<td>Welcome and Introductions</td>
<td></td>
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<tr>
<td>2:20pm – 2:25pm</td>
<td>Course Overview <em>Susan McDermott, RN, MPH</em></td>
<td></td>
</tr>
<tr>
<td>2:25pm – 3:15pm</td>
<td>Lecture 1: Developing a Manual of Operations <em>Susan McDermott, RN, MPH</em></td>
<td></td>
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<tr>
<td>3:15pm – 3:45pm</td>
<td>Lecture 2: EQUIP (Education and Quality Improvement Program) <em>Eunice Newbert, MPH</em></td>
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## Session 2

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<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>2:00pm – 2:30pm</td>
<td>Lecture 3: Thinking About Your Variables <em>Tracy Antonelli, MPH</em></td>
<td></td>
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<tr>
<td>2:30pm – 2:40pm</td>
<td>Variable List Review <em>Handan Titiz, EdM</em></td>
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<tr>
<td>2:40pm – 3:25pm</td>
<td>Lecture 4: CRP Case Report Form Standards <em>Tracy Antonelli, MPH</em></td>
<td></td>
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<tr>
<td>3:25pm – 3:35pm</td>
<td>Lecture 5: Timelines <em>Tracy Antonelli, MPH</em></td>
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<tr>
<td>3:35pm – 3:45pm</td>
<td>Review of Timeline Handout <em>Susan McDermott, RN, MPH</em></td>
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<tr>
<td>3:45pm – 4:15pm</td>
<td>Lecture 6: Writing Form Specs <em>Handan Titiz, EdM</em></td>
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## LAB A

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<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>2:00pm – 4:30pm</td>
<td>SPSS Data Builder Workshop <em>Handan Titiz, EdM</em></td>
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<tr>
<td>4:30pm – 4:45pm</td>
<td>Closing: Intakes &amp; Evaluations <em>Susan McDermott, RN, MPH</em></td>
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## LAB B

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<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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<tr>
<td>2:00pm – 4:30pm</td>
<td>SPSS Data Builder Workshop <em>Qiaoli Chen/Handan Titiz, EdM</em></td>
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<tr>
<td>4:30pm – 4:45pm</td>
<td>Closing: Intakes &amp; Evaluations <em>Susan McDermott, RN, MPH</em></td>
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</table>
DO IT YOURSELF DATA MANAGEMENT AGENDA  
**November 12, 13 & 16, 2009**

**Session 1**

2:00pm – 2:30pm  Welcome and Introductions

2:30pm – 2:40pm  Course Overview and Introduction to CRP  
*Susan McDermott, RN, MPH*

2:40pm – 2:55pm  Lecture 1: Introduction to Best Practices  
*Susan McDermott, RN, MPH*

2:55pm – 3:10pm  Lecture 2: Timelines  
*Tracy Antonelli, MPH*

3:10pm – 3:20pm  BREAK

3:20pm – 4:00pm  Lecture 3: Thinking About Your Variables (with BASH slides)  
*Tracy Antonelli, MPH*

**Session 2**

2:00pm – 2:10pm  Variable List Review  
*Qiaoli Chen*

2:10pm – 2:55pm  Lecture 4: CRP Case Report Form Standards  
*Tracy Antonelli, MPH*

2:55pm – 3:05pm  BREAK

3:05pm – 3:35pm  Lecture 5: EQUIP (Education and Quality Improvement Program)

3:35pm – 4:05pm  Lecture 6: Writing Form Specs  
*Qiaoli Chen*

**LAB A**

2:00pm – 4:15pm  SPSS Data Builder Workshop  
*Qiaoli Chen*

4:15pm – 4:30pm  Closing: Intakes & Evaluations  
*Susan McDermott, RN, MPH*
The Clinical Research Program (CRP) is pleased to make funds available to support clinical research projects at Children’s Hospital Boston. The CRP is an interdisciplinary, academic and service research program that provides methodological assistance and education to the clinical research community at Children’s. The Program directly supports one of Children’s core missions to be the leading source of research and discovery through three primary areas of focus:

- clinical research methodology (including biostatistics, epidemiology, survey methods, and informatics);
- collaboration or consultation on the design, conduct, and analysis of clinical research studies; and
- education in clinical research methods and practice

In accordance with our mission of promoting excellence and best practices in clinical research, the Program aims to enable investigators to conduct high quality and meaningful clinical research.

1. **Purpose:** The purpose of this funding initiative is 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.

2. **Eligibility:** Applications will be accepted from CHB faculty at the levels of Instructor through Associate Professor (Full Professors are not eligible) who hold advanced degrees (M.D., Ph.D., M.D.-Ph.D., or equivalent). Applicants at the level of Associate Professor must demonstrate that the proposed research represents a new area of investigation for them with a strong potential for future extramural funding. Applicants will not be considered eligible if they are within the first 3 years of a 5 year NIH K-award or have a CHB OFD award at the time that funding of this grant would begin or if the proposed research overlaps with any other current funding. All applicants should also demonstrate that the proposed research supports obtaining pilot data or additional data.
that will allow them to successfully compete for an R01 or other extramural funding. Finally, the proposed research must meet the following definition of clinical research. “Research conducted with human subjects or on identifiable material of human subjects such as tissues, specimens, or cognitive phenomena for which the investigator or a colleague directly interacts with the human subject.” Projects proposing only secondary data analysis of existing data sets are not eligible for this award.

3. **Level of support:** These grants are for two years of support. The maximum allowable budget in direct costs is $50,000/year. The number of awardees will be determined by the quality of the proposals, the total amounts of the requested budgets of sufficiently meritorious proposals, and the available funds. It is anticipated that anywhere from 5-10 awards may be made.

4. **Allowable Use of Funds:** Funds should be requested to support the research to be conducted and may include faculty salaries, research staff salaries, laboratory tests and procedures, supplies, and patient incentives. Costs for equipment and travel to meetings should not be requested.

5. **Process:** The initial application will consist of a 1 to 2 page Letter of Intent (LOI). The LOI will be screened to confirm the eligibility of the applicant and determine whether the proposed research project meets the goals of this initiative. The screening process will be performed by a multidisciplinary committee representing established researchers at CHB and chaired by the Director of the Clinical Research Program. Following the initial screening, an invitation will be sent to selected investigators to submit the full application.

6. **Letter of Intent (LOI):** The LOI consists of a 1-2 page description that includes a statement on how the proposed project meets the eligibility criteria, the specific aims and hypotheses of the project, and a brief description of the research design and methods. The LOI should also include the principal investigator’s name, rank, CHB ID, and primary CHB department or division affiliation. LOI applications must be submitted as a pdf to CRP@childrens.harvard.edu. An email confirmation of receipt will be returned to the applicant. **The LOI must be received by 9/15/09.**

7. **Invited Full applications:**
   Full applications must be submitted in single spaced text, one-half inch margins, and no smaller than an 11-point font. Arial or Helvetica typeface is preferred. The primary applicant’s name must appear in the upper right hand corner of each page, and page numbers inserted at the bottom right corner of each page. **The Research Aims and Plan must be limited to five pages (including figures but excluding references).** Standard PHS 398 forms for the budget, biosketch, other support, may be used.

   **Required format:** Applications must be submitted electronically (ideally, this also includes electronic versions of the letters of support). Send a PDF file of the assembled proposal to CRP@childrens.harvard.edu no later than December 23, 2009.

   **Required Content:**
   a. Face page (PI name, CHB ID number, rank, and department/division affiliation; names, titles, and affiliation of all other investigators; Title of Research Project, Dates of Proposed Research, Direct Costs Requested for each Year, and Signatures of PI and Investigators)
b. Abstract (200 words or less)
c. Table of contents
d. Budget (use PHS 398 forms)
e. Budget justification
f. Biosketch(es) of PI and co-investigators (PHS 398 form)
g. Other support of PI and co-investigators (PHS 398 form)
h. Research Aims and Plan
   a. Specific Aims and Hypotheses
   b. Background and Significance with a statement of impact of research on scientific field
   c. Prior Studies/Preliminary Results (if available)
   d. Research Design and Methods (should include study design, study population and recruitment methods, data collection, intervention methods or treatments (if relevant), power and sample size, analysis plan, limitations)
i. Human Subjects Protection
j. Resources: Plans to utilize any relevant CHB resources such as CHB Lab Cores, CRP Cores, or CTSU/Catalyst resources
k. Literature cited
l. Consortium/Contractual Arrangements (if applicable)
m. Letter of support from Department Chair/Division Chief (required)
n. Letter of support from Research Mentor (if applicable)
o. Letters of support from collaborators or consultants (if applicable)

8. Associate Professors: Associate Professors should also provide an additional one page explanation of how the proposed research represents a new area of investigation for them with a strong potential for future extramural funding.

9. Letters of Support: Full applications must include a letter of support from the primary applicant’s department chair or division chief. The letter of support must include a statement demonstrating the priority or importance of the research to the department or division and a statement of the impact of the research on the applicant’s career development and on future ability to get extramural funding. Applicants at the rank of instructor must also have a letter of support from their Research Mentor that includes a statement demonstrating the impact of the research to the field and to the career development of the applicant as well as a statement demonstrating the commitment of the mentor to support the research.

10. Signatures: The signature of the principal investigator is sufficient on the Letter of Intent. The signatures of all investigators are required for the full application.

11. Evaluation Criteria:
   a. Significance. Does this study address an important problem? How will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
   b. Approach. Are the conceptual or clinical framework, design, methods, and analyses adequately developed and appropriate to the aims of the project? Is the project feasible?
   c. Innovation. Is the project original and innovative? Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
d. Investigators. Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project?

e. Resources and Environment. Are the resources and environment in which the work will be done adequate to support the success of the project?

f. Institutional Support: Is there strong evidence of support from the Department Chair or Division Chief and mentor where appropriate?

g. Human Subjects Protection: Have the risks and benefits of the research and protection of human subjects been adequately addressed?

12. Reporting Requirements: Progress reports are required of all awardees after the first year of the project. The PI may be asked to present results to the Clinical and Translational Executive Committee. Funding for the second year is contingent upon first-year progress. A final report and expense summary is due at the end of the two-year project period. Carry-forwards of unexpended funds and no-cost extensions are contingent upon study progress and the corresponding justification. Should the PI leave CHB at any time during the funding period of the award, the remainder of the award will be forfeited unless approval is granted for it to be transferred to a qualified collaborating investigator in at CHB.
APPENDIX E
PROGRAM DESCRIPTION
AND REQUEST FOR ASSISTANCE FORM

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 on-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 30 days as a first draft of the grant proposal. For survey/measurement 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 various activities.

**BUDGETING:**
Principal Investigators should work with CRP personnel when developing budgets. A significant portion of CRP funding comes from collaborative work with departments/divisions, 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-apps.hs.harvard.edu/crp.intake/public/intakeresquest.aspx](http://crp-apps.hs.harvard.edu/crp.intake/public/intakeresquest.aspx).

<table>
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<tr>
<th>Collaborative Activities</th>
<th>Consultative Services (Hospital Supported)</th>
<th>Direct Assistance (Investigator Supported)</th>
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<tr>
<td>Case Report Forms</td>
<td>Guidance creating/review of case report forms.</td>
<td>Survey Report Form development, formatting and coding.</td>
</tr>
<tr>
<td>Surveys</td>
<td>Guidance creating/review of surveys.</td>
<td>Survey development, formatting and coding. Administration of web-based surveys.</td>
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<tr>
<td>Study Databases</td>
<td>Assistance with creation of small, low complexity databases.</td>
<td>Development of complex, relational or customized databases. Database maintenance.</td>
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<tr>
<td>Study Manuals of Operation</td>
<td>Guidance/review of Study Manuals.</td>
<td>Writing and assembly of study manuals.</td>
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<tr>
<td>Data Management</td>
<td>Study ID assignment logs.</td>
<td>Data entry and management. Data conversion/file creation for analysis.</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>
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**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.
Children’s Hospital Boston

Clinical Research Program
21 Autumn Street
Phone: 617-219-4720 / fax: 617-730-0828
cro@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 cro@childrens.harvard.edu or by faxing it to 617-730-0828. 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):

__________________________________________

4/27/2009
Children’s Hospital Boston

What do you require assistance with? (check all that apply)
Please review grid for services that do not require reimbursement versus those that do require reimbursement.

<table>
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<tr>
<th>TASKS</th>
<th>CORE SERVICES</th>
<th>REIMBURSED SERVICES</th>
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<tr>
<td>Grants or Study Protocol</td>
<td>Contributions to the writing of</td>
<td>Case Report Form development,</td>
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<td>grant proposals &amp; study protocols</td>
<td>formatting, and coding</td>
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<td>Development of aims and hypotheses</td>
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<td></td>
<td>Study design</td>
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<td>Power and sample size calculation:</td>
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<td></td>
<td>Analysis methods</td>
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<td>Data management method:</td>
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<td></td>
<td>Critique/ review of grants or study protocols</td>
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<tr>
<td>Case Report Forms</td>
<td>Guidance/ review of case report forms</td>
<td>Survey development, formatting, and coding</td>
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<tr>
<td>Research Databases</td>
<td>Development of CRP research databases</td>
<td>Development of relational or custom research databases</td>
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<td>Guidance/ Review of study manuals and materials</td>
<td>Development &amp; writing of study manuals and materials</td>
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<td>Administration of web-based surveys</td>
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<td>Guidance/ review of study timelines and management plan</td>
<td>Project Director/ Study Coordinator support</td>
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<td>Randomization</td>
<td>Randomization Strategies</td>
<td>Randomization envelopes</td>
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<td></td>
<td>Randomization assignment logs</td>
<td></td>
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<tr>
<td>Data Analysis</td>
<td>Guidance on data analyses</td>
<td>Data Conversion/ Analysis file creation</td>
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<td>Interpretation of results</td>
<td>Data set organization &amp; cleaning</td>
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<td></td>
<td>Critique/ review of manuscripts</td>
<td>Data analyses</td>
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<tr>
<td>Mentoring</td>
<td>Mentoring</td>
<td>Manuscript Writing</td>
</tr>
</tbody>
</table>
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 □ U54
   c. Is this a response to an announcement? □ Yes □ No
      i. If Yes, what is the type? □ RFA □ RFP □ PA
   d. Other Federal Agency: _______________________________________________
   e. Foundation / Association: 1) _________________________________________
      2) _________________________________________
   f. Industry Sponsor: ___________________________________________________
   g. Internal Award: _____________________________________________________
   h. Department/Division/Program Funds: ___________________________________
   i. Philanthropic funds _________________________________________________
   j. 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 _______________________________________________

4/27/2006