2008
Annual Report
OF THE
CLINICAL RESEARCH PROGRAM
SUBMITTED BY
STAVROULA OSGANIAN, MD, ScD, Director
The Clinical Research Program (CRP) at Children’s Hospital Boston is pleased to share with you its fiscal year 2008 Annual Report.

The CRP is an interdisciplinary, academic and service 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 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 in clinical research methods and practice.

This report summarizes the key accomplishments and 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 more senior faculty as they establish themselves in their field 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. As we reflect on our accomplishments, we wish to recognize the support from and productive collaborations that we have developed with our colleagues, and we take pride in work that we have accomplished together.

Key accomplishments for FY2008 are highlighted below and presented in greater detail in the sections that follow.

- Support or consultation on 324 new investigator requests for assistance from 216 researchers in the institution, a 28% increase in the number of requests for assistance submitted to CRP staff over the past year.
- Successful collaborations with several CHB investigators and other institutional Programs on 83 projects and maintenance of significant funding from such collaborative projects totaling approximately $1.0 million.
- Forty-four peer reviewed collaborative publications that were co-authored by CRP staff.
- An increase in the number of joint faculty recruits with Departments and Divisions with a corresponding 53% increase in department funding of CRP faculty and staff.
- Significant growth in the educational offerings of the Clinical Research Education Core including three additional biostatistics educational seminars and a near doubling of participation in these seminars.
- Establishment of a new core group of services, the Survey Core, which includes two doctoral level survey methodologists, Sion Kim Harris, PhD (Director of the Survey Core) and Sonja Ziniel, PhD.
- Participation of CRP faculty in the newly formed and NIH funded Harvard Catalyst in key leadership roles: Dr. Stavroula Osganian, Co-Director of the Harvard Catalyst Clinical and Translational Studies Training and Mentoring Subcommittee for CHB, Jenifer Lightdale, Harvard Catalyst Director for Clinical and Translational Education Research at CHB and Chair of the Harvard Catalyst Colloquium Series, and Les Kalish, Associate Director of the Harvard Catalyst Biostatistics Program for CHB.
• Development and dissemination of CHB-CONNECT, a research volunteer registry for children and families.
• Participation and leadership on major research initiatives of the Clinical and Translational Executive Committee.

Acknowledgement: We wish to thank Dr. Mandell, CEO, Ms. Fenwick, COO and President, and the hospital leadership for the continued and generous financial support provided to the Program. This support has made it possible for the Program to provide valuable assistance to the investigator community and achieve many of its accomplishments.

Program Leadership and Administration

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

Program Administration
Randi Triant, MFA
Administrative Director

Laura Haley
Program Administrator
Mission, Vision, and Goals

Mission

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

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.

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, 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' 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 professional development of our faculty and staff so that they may develop 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 FY08 the CRP staff included 24 full-time, 4 part-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 other sources of support for the Program are shown in Table 1. There continues to be substantial institutional commitment to the Program, in terms of both space and operating budget, which has facilitated the growth and visibility of the Program. Institutional support for the Clinical Research Program (CRP) now totals $2.365 million. Equally important has been the substantial commitment and funding from departments who support faculty ($532,270). Collaborative relationships with clinical investigators generated approximately $1.1 million in extramural funding to support faculty and staff. In FY08, this resulted in a recovery of $186,758 from the institutional budget.

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Budget</th>
<th>Expenses</th>
<th>Unexpended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional</td>
<td>$2,365,548</td>
<td>$1,479,863</td>
<td>$885,685*</td>
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<tr>
<td>Department</td>
<td>$532,270</td>
<td>$532,270</td>
<td>$0</td>
</tr>
<tr>
<td>Grants</td>
<td>$1,197,051</td>
<td>$1,046,651</td>
<td>$150,400</td>
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<tr>
<td>Billings</td>
<td>$15,984</td>
<td>$14,722</td>
<td>$1,262</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>$4,110,853</strong></td>
<td><strong>$3,073,506</strong></td>
<td><strong>$1,037,347</strong></td>
</tr>
</tbody>
</table>

* Total unexpended institutional funds include position vacancies and recovery from staff charge backs to grants or other funds.
** An additional $43,000 was expended from CGRE for new faculty.

Utilization of Services

The Clinical Research Program (CRP) provides a range of services to assist investigators in the design, conduct, and analysis of their clinical research studies. Limited free support has been provided for guidance to unfunded studies while more support is provided for collaborative relationships with funding. Services include:

- Protocol/Grant Proposal Development
- Study Design
- Sample Size and Power Calculations
- Biostatistical Analysis Methods
- Randomization
- Case Report Form / Survey Design
- Data Management Systems Design
- Data Analysis and Interpretation
- Education and Training
- Mentoring

During FY08, the CRP received 324 requests for assistance (Table 2). The majority of these requests (n=241) did not provide funding for CRP staff. Eighty-three (26%) of these requests funded the CRP staff for a total of $1,578,921.

<table>
<thead>
<tr>
<th>Funding Status</th>
<th>Total</th>
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<tbody>
<tr>
<td># projects</td>
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<tr>
<td>Not Funded</td>
<td>241</td>
</tr>
<tr>
<td>Funded*</td>
<td>83</td>
</tr>
<tr>
<td>Total $</td>
<td>324</td>
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<tr>
<td>Total $</td>
<td>241</td>
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<tr>
<td></td>
<td>83</td>
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<tr>
<td></td>
<td>324</td>
</tr>
</tbody>
</table>

*Includes salary funding from industry, foundation and departments.
**Figure 1** presents the distribution of CRP services funded by the 83 projects during FY08 and the amount of support provided to each area. It should be noted that a single project often funds multiple service areas.

**Figure 1. Direct costs by service area for 83 projects funding CRP in FY08**

*PDMC = Project and Data Management Core*

**Table 3 and Figure 2** present the distribution of funding sources for the 83 projects providing financial support to the CRP. NIH and hospital departments were the primary sources of funding for these projects (32% and 37% of the sources of funded projects, respectively).

<table>
<thead>
<tr>
<th>Funding Source</th>
<th># of Projects</th>
<th>FY08 CRP Funding in dollars</th>
<th>% of Total</th>
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</thead>
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<tr>
<td>NIH</td>
<td>17</td>
<td>$515,717</td>
<td>33%</td>
</tr>
<tr>
<td>Other Federal</td>
<td>5</td>
<td>$46,518</td>
<td>3%</td>
</tr>
<tr>
<td>Foundation/Philanthropy</td>
<td>18</td>
<td>$314,090</td>
<td>20%</td>
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<tr>
<td>Industry</td>
<td>8</td>
<td>$21,586</td>
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<tr>
<td>Departmental Studies</td>
<td>16</td>
<td>$71,657</td>
<td>5%</td>
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<tr>
<td>Departmental Faculty</td>
<td>12</td>
<td>$532,270</td>
<td>34%</td>
</tr>
<tr>
<td>Internal</td>
<td>8</td>
<td>$71,383</td>
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</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>$5,740</td>
<td>&lt;1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>*</td>
<td><strong>$1,578,961</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

*Some projects have multiple funding sources*
Among the 17 NIH funded projects, 6 were funded by R01’s, 5 were K awards, 2 were R21’s, and 4 were other funding mechanisms (e.g. P01, P50, and F32’s). Half (n=42) of the 83 funded projects were from collaborations with researchers from the Department of Medicine. The remainder was from various departments in the Hospital including Cardiology (n=2), Radiology (n=5), Surgery (n=9), and Psychiatry (n=6); and Clinical Research Program faculty were PIs on 6 of the 83 projects.

**New Requests for Assistance in FY08**

During FY08, the CRP received 324 new requests for assistance from 216 Children’s Hospital faculty or staff. Overall, this was a 28% increase over the total number of requests received in FY07. The distribution of requests according to hospital department is shown in Figure 3. The majority of requests were from Investigators with appointments in Medicine (n=163) and within the Divisions of GI/Nutrition (n=36) and Adolescent Medicine (n=24), followed by the Departments of Cardiology (19) and Neurology (19).
As shown in Figure 4, investigators requesting assistance were somewhat more likely to be at the rank of Instructor (n=48) and Assistant Professor (n=38) or Fellow (n=36) as compared to Associate Professor (n=24), Professor (n=17) or Resident (n=9).
In FY08, the CRP received requests for assistance for 930 tasks. As shown in Figure 5 the majority of requests were for consultation on statistical analysis (n=123), manuscript/presentation (n=115), development of a statistical analysis plan (n=102), power and sample size determination (n=92), interpretation of results (n=84), database development and management (n=84), and study protocol review/critique (n=77).

**Figure 5: FY08 Requests by Task**

Among the 324 new requests for CRP resources, 20% (n=68) were applying for funding. Of these 68 applications, the majority (n=58) were new submissions and 10 were resubmissions. Table 4 indicates the agencies to which they were applying.

<table>
<thead>
<tr>
<th>Table 4. Applications for Funding Sources (n=68)</th>
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<tbody>
<tr>
<td>NIH</td>
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<tr>
<td>Foundation</td>
</tr>
<tr>
<td>Internal</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Other Agency</td>
</tr>
<tr>
<td>Industry</td>
</tr>
<tr>
<td>Philanthropy</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>
**Major Program Activities and Collaborations**

**Clinical and Translational Research Executive Committee**

The Clinical Research Executive Committee (CREC) continued to support several strategic initiatives including recruitment of faculty, growth in clinical research infrastructure, and education and faculty career development. In FY08, Dr. David Williams joined Children’s Hospital Boston assuming the role of Chair of the Committee and as Director of the Translational Research Program, broadened the scope of the Clinical Research Executive Committee (CREC) to include translational research (now known as CTREC).

During FY08, CTREC approved the expenditure of funds from the Clinical General Research Endowment for clinical research faculty recruitment ($750K), and funds ($206K) supporting education and faculty development including support of junior faculty clinical research development awards awarded through OFD. Additional funds ($745K) were allocated to the CRP for ongoing staffing and infrastructure support. CTREC also formed the General Clinical Research Center (GCRC) Transition Subcommittee, which was chaired by Dr. Osganian and developed several key recommendations to help ensure a smooth transition of the former GCRC to the Harvard Catalyst (Clinical and Translational Study Center). CTREC approved the allocation of CGRE funds to cover the shortfall ($324K) in ancillary funding between the former GCRC and the PCIR-CTSC, in addition to support for staffing salaries through 2009. The committee developed and announced a Faculty Research Sabbatical Program that will support 3-6 month sabbaticals for Assistant and Associate Professors to devote time to clinical and translational research.

The committee also reviewed applications for the Translational Research Program’s new Investigator Service initiative. Finally, in an effort to improve transparency and understanding of the hospital community to the mission and objectives of CTREC, a website was developed (http://www.childrenshospital.org/ctrec).

The current membership of the CTREC includes:

- David A. Williams, MD  
  Director, Translational Research Program,  
  Chairman, Clinical and Translational Research Executive Committee, Chief of the Division of Hematology/Oncology

- Judith C. Fleming, PhD  
  Executive Secretary, CTREC, Associate Director Translational Research Program

- Carleen A. Brunelli, PhD, MBA  
  VP Research Administration

- S. Jean Emans, MD  
  Chief, Division of Adolescent Medicine; Vice Chair, Clinical Affairs, Dept of Medicine;  
  Director, Office of Faculty Development

- Richard Grand, MD  
  Program Director, Clinical and Translational Study Unit, Harvard Catalyst (CTSA); Director,  
  Center for Inflammatory Bowel Disease

- Tom Jaksic, MD  
  Associate in Surgery

- Margaret McCabe, RN, PNP, DNSc  
  Director of Nursing Research/Medicine Patient Services
Harvard Catalyst

In May 2007, Harvard Medical School (HMS) was awarded a $117.5M grant from NIH for the establishment of the Harvard Clinical and Translational Science Center (CTSC), which will facilitate laboratory-to-bedside translational research. The Harvard CTSC has been renamed the "Catalyst," reflecting its aim of making it easier for researchers from across HMS to collaborate by providing resources which will enable scientists with complementary interests, skills and resources to find each other and to work together. This collaborative effort led by Harvard Medical School includes the entire University community and each of the major Harvard teaching hospitals, Beth Israel Hospital, Brigham and Women’s Hospital, Children's Hospital Boston, Massachusetts General Hospital, Dana Farber Cancer Institute, the School of Dental Medicine, and the Harvard School of Public Health. Among the many Catalyst programs that are being established to support clinical and translational research, the faculty of the CRP are actively participating in programs and efforts related to biostatistics, education and mentoring, and clinical research patient care services.

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 and Dean for Academic Affairs at the Harvard School of Public Health (HSPH), helps investigators develop their research by assisting on grant and protocol development, study design, education, and analysis advice. The Associate Directors of the BSP, representing the Harvard teaching hospitals and HSPH, have been meeting regularly since before the grant was submitted and are now focused on developing policies and systems for managing and tracking the work of the BSP, educational opportunities, and professional development guidelines for biostatisticians across HMS. The Associate Director representing CHB is Leslie Kalish, ScD, a Principal Biostatistician in the CRP. Other Catalyst biostatisticians include Henry Feldman, PhD, Peter Forbes, MA, Chao-Yu Guo, PhD, Paul Mitchell, MS, and Clarissa Valim, ScD. This group was only fully constituted during the last month of FY08, but has already consulted on several projects.

Another core goal of the Catalyst is to create clinical and translational research education programs where none exist and to modify and coordinate meritorious established research

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jane Newburger, MD, MPH</td>
<td>Associate Chief for Academic Affairs, Department of Cardiology</td>
</tr>
<tr>
<td>Stavroula Osganian, MD, ScD, MPH</td>
<td>Director, Clinical Research Program</td>
</tr>
<tr>
<td>Frank Pigula, MD</td>
<td>Associate in Cardiac Surgery</td>
</tr>
<tr>
<td>Scott Pomeroy, MD, PhD</td>
<td>Neurologist-in-Chief</td>
</tr>
<tr>
<td>Tina Young Poussaint, MD</td>
<td>Director, PBTC Neuroimaging Center</td>
</tr>
<tr>
<td>Glenn Saxe, MD</td>
<td>Associate Chief of Psychiatry Research</td>
</tr>
<tr>
<td>Mark Schuster, MD, PhD</td>
<td>Chief of General Pediatrics, Vice-Chair for Health Policy Research</td>
</tr>
<tr>
<td>Patrick Taylor, JD</td>
<td>Deputy General Counsel</td>
</tr>
<tr>
<td>Lynn Susman (ex officio)</td>
<td>VP, Campaign and Major Gifts, Children’s Hospital Trust</td>
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education programs at the Harvard Medical School, the Harvard School of Public Health and the academic health centers. Under the direction of David Golan, MD, Dean for Graduate Medical Education, the Catalyst’s Research Education Program will facilitate new linkages between intellectual disciplines throughout Harvard University and will expand opportunities and training in multidisciplinary clinical and translational research. Jenifer Lightdale, MD, MPH, Director of the CRP’s Clinical Research Education Core, will serve as the Catalyst’s Director for Clinical and Translational Research Education at Children’s Hospital Boston. Working with other institutional Research Education directors, Dr. Lightdale will work to integrate non-degree granting courses that will be open to all investigators across the Harvard campus who are interested in learning more about biostatistics, study design, data management and other aspects of clinical and translational research.

The Catalyst also seeks to provide effective 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. Stavroula Osganian, MD, ScD, MPH, Ellis Neufeld, MD, PhD, and Jean Emans, MD serve 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. Goals for the coming year include piloting a career advising and mentoring program, organizing a network of mentors, and evaluating factors that serve as barriers to the development and advancement of physician scientists in clinical and translational research.

The Catalyst will continue to provide critical support for inpatient and outpatient clinical research on the Clinical & Translational Study Unit (CTSU) (formerly known as the GCRC) located on 6 East and P6 and in the CAT/CR, under the continued direction of Richard Grand, MD, PhD. Support is now also being provided for new programs including “off-unit nursing” support and clinical research assistants. The clinical research assistants will have direct participation in CTSU approved protocols and will be trained and managed through the CRP by Susan McDermott, MPH. By mid 2009, Waltham is also expected to be a site for Catalyst clinical research activities.

Several CHB leaders including Drs. Neufeld (CHB Site Implementation Director), Stavroula Osganian (CRP Director), David Williams, MD (Translational Research Program Director), and Carleen Brunelli, PhD, MBA (Vice President of Research Administration) will be interacting closely as we move forward to ensure successful implementation of the Harvard Catalyst at CHB.

Researchers from CHB can request assistance from the Catalyst either by submitting a Request for Assistance from the CRP web site, contacting Kris Jordan, Administrative Director of the CTSU, or from the Harvard-wide Catalyst web site.

CHB-CONNECT

This past fiscal year, CRP Director, Dr. Osganian led an exciting initiative to create a research volunteer registry at CHB. 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, and Randi Triant, CRP Administrator Director, collaborates with Public Affairs (VP Michelle Davis and Marketing Communications Specialist Gina Collavechio) on the development of communications promoting and marketing the registry (further details are provided below).
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](http://www.childrenshospital.org/connect)
- A private CHB-only web site for investigators  
  [http://crp-apps.tch.harvard.edu/connect](http://crp-apps.tch.harvard.edu/connect)

The CHB CONNECT site was launched on 08/01/2008, and therefore the data below represents only the first three months of web site operation (FY08-Q4). The marketing campaign to date has included Small Talk, Faculty News, a cover article in Clinical Research 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. It should also be noted that although “Find A Trial” (CHB’s clinical trial public web site) is not formally a component of CONNECT, the number of registered protocols on “Find A Trial” has increased from 22 to 79 since CHB-CONNECT’s launch, a 259% increase. The Tables below show that from the period 08/01/08 to 10/31/08, there have been 565 unique visitors to the CHB-CONNECT WEBSITE and 49 human subject registrants.

<table>
<thead>
<tr>
<th>Table 5. Number of CHB-CONNECT Public Visitors to Internet Site and Subject Registrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metric</td>
</tr>
<tr>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Total Visitors</td>
</tr>
<tr>
<td>Total Views – Home Page</td>
</tr>
<tr>
<td>Total Views – Registration Form</td>
</tr>
<tr>
<td>Total Registrants</td>
</tr>
<tr>
<td>Conversion</td>
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</tbody>
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The Bone Team

In the fall of 2008 Dr. Catherine Gordon, MD, MS, Director of the Children’s Hospital Boston Bone Health Program and Associate Professor in the Divisions of Adolescent Medicine and Endocrinology, convened a weekly series of informal research meetings that she dubbed “The Bone Team.” Organized loosely around a dozen ongoing and incipient clinical studies, the meetings provide a forum for Dr. Gordon and her colleagues and staff to exchange news, updates, problems, and speculation on a variety of bone-related research topics. Prominent themes are vitamin D deficiency, radiographic and biochemical measures of bone health, anorexia nervosa, and hormonal derangements with impact on bone quality in children at their critical time of growth.

A regular participant in the Bone Team conferences is Henry Feldman, PhD, a frequent co-investigator and co-author with Dr. Gordon since 2002. Also supporting and collaborating with the group on various studies are Hongyu Jiang, PhD (joined the team in FY09), and Paul Mitchell, MS, Senior Biostatisticians; Courtney Walls, MPH, Statistical Programmer; and Handan Titiz, MEd and Qiaoli Chen, MS, Data Managers. The CRP has taken an active role in all of the studies described below, ranging from statistical planning through forms design, database construction, and analysis, and requiring close cooperation with the Bone Team research assistants Julia Brown, Ashley Quach, and Allison Kutner.

The Bone Team had a virtual existence predating the recent meetings, in the form of multiple clinical research projects spurred by Dr. Gordon. Two major publications appeared in 2008 reporting linked studies of vitamin D deficiency. A survey of 380 infants and toddlers, published in *Archives of Pediatrics and Adolescent Medicine*, showed low vitamin D to be a common condition (12% prevalence) among otherwise healthy young children and pointed to exclusive breast feeding as a risk factor in infants and low milk consumption in older children. The D-deficient children were enrolled in a randomized treatment trial, reported in *Journal of Clinical Endocrinology and Metabolism*, which showed comparable efficacy for daily D2, higher-dose weekly D2, and daily D3. Susanna Huh, MD, Instructor in the Division of Gastroenterology and Nutrition, used the survey data to document a relatively common and apparently benign transient elevation in alkaline phosphatase, which will be reported in 2009 in *Pediatrics*.

Well underway is a similar vitamin D treatment trial, supported by a K23 Mentored Research Award from the National Institutes of Health to Helen Pappa, MD, Instructor in the Division of Gastroenterology and Nutrition, comparing regimens for raising and maintaining vitamin D levels in D-deficient children with inflammatory bowel disease. Just

<table>
<thead>
<tr>
<th>Metric</th>
<th>Number</th>
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<tr>
<td>Total Hits</td>
<td>191</td>
<td>Number of unique visitors to the site (includes users and anonymous users).</td>
</tr>
<tr>
<td>Total Users</td>
<td>48</td>
<td>Number of users (PIs and staff) registered with the system.</td>
</tr>
<tr>
<td>Total Protocols</td>
<td>12</td>
<td>Number of distinct protocols listed.</td>
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<td>Number of user sessions, wherein users downloaded data.</td>
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<td>Conversion</td>
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<td>Percentage of unique visitors converting to registered.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>Total Hits</td>
<td>191</td>
</tr>
<tr>
<td>Total Users</td>
<td>48</td>
</tr>
<tr>
<td>Total Protocols</td>
<td>12</td>
</tr>
<tr>
<td>Total Download Sessions</td>
<td>3</td>
</tr>
<tr>
<td>Conversion</td>
<td>25%</td>
</tr>
</tbody>
</table>
begun is another treatment trial directed by Sarah Pitts, MD, Clinical Fellow in the Division of Adolescent Medicine, comparing regimens for boosting vitamin D in healthy adolescents.

Anorexia nervosa is the object of several Bone Team studies. Amy DiVasta, MD, Instructor in the Division of Adolescent Medicine, has documented an immediate disruption of bone metabolism markers in young anorexic women hospitalized on bed rest and banned from exercise. Following up on those findings, Dr. DiVasta is currently examining their cardiac parameters and has obtained a K23 award to test whether the deleterious effects of bed rest can be reversed with short periods of mechanical stimulation on a vibrating platform. In two additional studies in progress, she is investigating whether the limited fat stores in anorexic women affect vitamin D bioavailability and conducting a randomized trial to compare “add-back” regimens that compensate for estrogen-suppressing therapy in young women with endometriosis.

Nearly finished is Dr. Gordon’s randomized trial comparing two steroid regimens for improving bone quality in 80 anorexic women over an 18-month treatment period. Already the trial has yielded several ancillary publications drawn from baseline data, including evaluation of bone measurement techniques by Dr. DiVasta; an examination of vitamin D levels by Alexandra Haagensen, MD, Instructor in the Division of Endocrinology; and an assessment of oral health and correlation between bone mineral density and tooth width by Brian Shaughnessy, DMD, Clinical Fellow in the Department of Dental Medicine. A newly developing avenue of investigation for Dr. Gordon, with active CRP collaboration and some preliminary data already submitted for presentation at national meetings, is an apparent abnormality of bone-marrow composition in anorexic women, possibly engendered by hormonal shifts.

The involvement of CRP in Dr. Gordon’s Bone Team exemplifies the benefits of a concentrated interaction between methodological experts and a discipline-based research group. The consistency of health and disease patterns, research designs, measurement batteries, and treatment strategies that prevail in this type of partnership provides scientific focus, professional fulfillment, and high productivity for CRP specialists who have the opportunity for such a dedicated collaborative relationship.
In FY08 the Biostatistics Core included 7 doctoral level biostatisticians, all holding faculty appointments at Harvard Medical School through CHB departments and divisions, as well as 4 Masters-level biostatisticians, a statistical programmer, and an administrative coordinator. Capsule biographies are provided in Appendix A.

Acting Director : Stavroula Osganian, MD, ScD, MPH

Faculty staff in FY 2008 included:
Henry Feldman, PhD, Principal Biostatistician
Alka Indurkhya, 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

Other statistical and administrative staff included:
Peter Forbes, MA, Senior Biostatistician
Patrick Johnston, MMath, MSc, Senior Biostatistician
Paul Mitchell, MS, Senior Biostatistician
Courtney Walls, MPH, Statistical Programmer
Jing Zhou, MS, Biostatistician
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 services throughout the lifetime of a research project. In the planning phase, we devise study designs, formulate statistical analyses, calculate sample size, and contribute to the writing of proposals and protocols. During implementation we supervise and participate in database construction, randomization, data-cleaning, quality control, and data and safety monitoring. In the analysis and reporting stage we perform both routine and original statistical analyses, interpret results, and co-author 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 FY2008 while a national search is underway for a new Director.

Utilization of Services

Table 1 shows the number of new requests for Biostatistics Core services during FY08 compared to FY07.

<table>
<thead>
<tr>
<th>Tasks</th>
<th>FY07</th>
<th>FY08</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Requests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Protocol/Critique</td>
<td>740</td>
<td>688</td>
<td>8%</td>
</tr>
<tr>
<td>Study Aims, Hypotheses &amp; Design</td>
<td>3333</td>
<td>3333</td>
<td>0%</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Analysis</td>
<td>111</td>
<td>124</td>
<td>12%</td>
</tr>
<tr>
<td>Randomization</td>
<td>12</td>
<td>17</td>
<td>42%</td>
</tr>
<tr>
<td>Scientific Review</td>
<td>4</td>
<td>4</td>
<td>0%</td>
</tr>
<tr>
<td>GCRC Protocol Review</td>
<td>42</td>
<td>40</td>
<td>-5%</td>
</tr>
<tr>
<td>Grant Application Review/Critique</td>
<td>32</td>
<td>33</td>
<td>3%</td>
</tr>
<tr>
<td>Interpretation of Results</td>
<td>68</td>
<td>84</td>
<td>24%</td>
</tr>
<tr>
<td>Power and Sample Size</td>
<td>90</td>
<td>92</td>
<td>2%</td>
</tr>
<tr>
<td>Presentation/Abstract</td>
<td>27</td>
<td>46</td>
<td>70%</td>
</tr>
<tr>
<td>Manuscript Writing</td>
<td>53</td>
<td>69</td>
<td>30%</td>
</tr>
<tr>
<td>Randomization</td>
<td>12</td>
<td>17</td>
<td>42%</td>
</tr>
<tr>
<td>Scientific Review</td>
<td>4</td>
<td>4</td>
<td>0%</td>
</tr>
<tr>
<td>Grant Application Review/Critique</td>
<td>99</td>
<td>94</td>
<td>-5%</td>
</tr>
<tr>
<td>Study Protocol/Critique</td>
<td>33</td>
<td>33</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>688</td>
<td>740</td>
<td>8%</td>
</tr>
</tbody>
</table>

Research Collaborations

The primary activity of the Biostatistics Core is collaboration and consultation with CHB investigators, leading to involvement in clinical research protocols, grant proposals, randomization and other study operations, data collection, analysis, presentation, and publication in the biomedical literature. These activities have resulted in over forty publications during FY08. A full list of publications by CRP staff is provided in Appendix B.

New Research Funding

An important element of the CRP mission is to help investigators prepare grant-worthy and effective proposals for funding from NIH, other federal agencies, and medical foundations. The Biostatistics Core plays a crucial role in this aspect of the mission because statistical justification, well thought-out analytic plans, and adequately budgeted statistical effort are essential for a successful proposal but difficult to achieve without expert assistance. The fruit of this activity, seeded by departmental and CRP funds, is federal and foundation
grant support for CRP staff. A list of federal and private research grants active in FY08 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 three-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 preparing research proposals. New courses introduced during FY08 included *Introduction to Statistical Genetics*, 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 course on statistical methods for categorical data called *Beyond Chi-Squares: Drawing Inferences from Tables*, taught by Dr. Indurkhya; and *Statistics for Small Sample Size Studies*, taught by Dr. Gregas, which reviews methods that are appropriate for studies with few subjects. Dr. Gregas is also developing a new course offering for FY09 on regression methods.

In addition to the CRP short-course program, members of the Biostatistics Core regularly deliver hospital seminars and conduct training at national meetings. In FY08 Drs. Graham, Indurkhya, Kalish and Feldman contributed to the Research Skills lecture series for the CHB Health Services Research Fellowship. Dr. Feldman served for his eleventh 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. Dr. Valim lectured in a course on design of clinical trials for the Department of Immunology and Infectious Disease, Harvard School of Public Health and also taught a web-based clinical trials course for Harvard Medical School.

**Funding from 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 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.
- Ms. Walls, Division of Adolescent and Young Adult Medicine.
- Ms. Zhou, Department of Surgery and Program for Patient Safety and Quality.
- Faculty search in progress, Division of Emergency Medicine.
- Faculty search in progress, Division of Gastroenterology and Nutrition.
- Faculty search in progress, Department of Radiology.
- Faculty search in progress, Department of Urology.

**New Staff**

During FY08, the Biostatistics Core added a Statistical Programmer, Ms. Courtney Walls, who came to us with an MPH from Yale. Ms. Walls quickly became integrated into the research agenda of the Division of Adolescent and Young Adult Medicine. Two faculty searches were filled shortly after the end of FY08; these new staff will be reported on in our next Annual Report.
The Clinical Research Education Core of the Clinical Research Program plans, 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.

Staffing

FY08 Education Core staff included the following. Capsule biographies are provided in Appendix A.

Jenifer R. Lightdale, MD, MPH, Director of Clinical Research Education
Maya R. Levine, BA, 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 our scientific 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 2008 (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.

<table>
<thead>
<tr>
<th>Table 1. CRP Course Attendance by Year 2005 – 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Course</strong></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 with SPSS Data Entry Builder</td>
</tr>
<tr>
<td>Beyond Chi-Squares</td>
</tr>
<tr>
<td>Statistics for Small Sample Size Studies</td>
</tr>
<tr>
<td>Introduction to Statistical Genetics</td>
</tr>
<tr>
<td>Art and Anatomy of Writing a Career Development Grant</td>
</tr>
<tr>
<td><strong>TOTAL REGISTRATION:</strong></td>
</tr>
</tbody>
</table>
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 2008, we introduced three biostatistics short courses: *Beyond Chi-Squares*, *Statistics for Small Sample Size Studies* and *Introduction to Statistical Genetics* and a collaborative grant writing seminar co-sponsored with Brigham and Women’s Hospital, *The Art and Anatomy of Writing a Career Development Grant*. In 2009, the Education Core plans to launch 4 new courses in collaboration with both the CRP’s Survey and Biostatistics Cores.
Table 2. CRP Course Listings 2004 – 2009

<table>
<thead>
<tr>
<th>CRP Course</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to Clinical Research</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
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<td>***</td>
</tr>
<tr>
<td>Orientation for New Study Coordinators</td>
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<td>***</td>
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<tr>
<td>Coordinator Rounds</td>
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<td>***</td>
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<td>***</td>
<td>***</td>
<td>***</td>
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<tr>
<td>Introduction to Biostatistics with SPSS</td>
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<td>***</td>
<td>***</td>
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<tr>
<td>Power and How to Get It</td>
<td>***</td>
<td>***</td>
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<td>***</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Do-It-Yourself Data Management</td>
<td>***</td>
<td>***</td>
<td>***</td>
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<td>***</td>
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<tr>
<td>Beyond Chi-Squares: Drawing Inferences from</td>
<td>***</td>
<td>***</td>
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<td>***</td>
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<td>***</td>
</tr>
<tr>
<td>Tables</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introduction to Statistical Genetics</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Statistics for Small Sample Size Studies</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Art and Anatomy of Writing a Career Development Grant</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Introduction to Regression Analysis</td>
<td>***</td>
<td>***</td>
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<td>***</td>
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<tr>
<td>Introduction to Focus Groups</td>
<td>***</td>
<td>***</td>
<td>***</td>
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<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Introduction to Survey Design</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Survey Design Practicum</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</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*. 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 expanded use of the online registration and evaluation system and a recent completed redesign of the CRP Education Core intranet site.

Leadership
The Education Core values deeply its potential to provide vision and agendas for a comprehensive clinical research education curriculum, not only at Children’s Hospital, but also across the greater Harvard University Community. Collaborations and benchmarking with other clinical research programs at Harvard, as well as outside institutions has allowed us to identify opportunities to expand our curriculum. In FY08, the Core contributed to Harvard’s successful CTSA application. In the coming years, Harvard Catalyst will provide many opportunities for continued collaboration with affiliated institutions and enhance the scope and number of CRP educational offerings.
Staffing

FY08 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
Laura Boger, AB, Research Data Coordinator
Qiaoli Chen, MS, Research Data Manager
Rajna Filip-Dhima, BS, Research Data Manager
Jui Haker, MD, MPH, Epidemiologist, Project Director
Maggie McCarthy, MS, MPH, Project Director
Handan Titiz, EdM, Research Data Manager
Harold T. Thurston, Jr., MA, MAT, Administrative Coordinator

Project and Data Management Core Mission

The mission of the core is to promote excellence in clinical research practice and data quality through provision of guidance and direct staff services to investigators for project and data management of clinical research initiatives and studies conducted by CHB investigators.

Project and Data Management Services

The staff of the PDMC assists clinical investigators with study management and
coordination, regulatory document filing, data form design and development, database development, randomization plans with lists and envelopes, data management, staff training and certification and development of quality control procedures. The principal work of the PDMC is to provide hands-on support and expert consultation to CHB clinical investigators in best practice project and data management procedures for planning and implementing clinical research studies at CHB. In FY08, the PDMC staff provided assistance to investigators on 160 requests that ranged from providing advice to extensive hands-on efforts and deliverables.

**Project and Data Management 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 methods 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. To increase the technical capabilities and quality of PDMC project and data management services overall.
- **Professional development:** To support the professional development of PDMC faculty and 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 FY08 compared to FY07.

<table>
<thead>
<tr>
<th>Tasks</th>
<th>FY 07 Requests</th>
<th>FY08 Requests</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistance with Existing Database</td>
<td>24</td>
<td>20</td>
<td>-17%</td>
</tr>
<tr>
<td>Case Report Form Development</td>
<td>37</td>
<td>33</td>
<td>-11%</td>
</tr>
<tr>
<td>Database Development</td>
<td>49</td>
<td>58</td>
<td>18%</td>
</tr>
<tr>
<td>Data Entry</td>
<td>5</td>
<td>6</td>
<td>20%</td>
</tr>
<tr>
<td>Data Management</td>
<td>11</td>
<td>8</td>
<td>-27%</td>
</tr>
<tr>
<td>Manual of Operations</td>
<td>1</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>Project Management</td>
<td>Info not available</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Randomization</td>
<td>12</td>
<td>17</td>
<td>42%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>139</strong></td>
<td><strong>148</strong></td>
<td><strong>6%</strong></td>
</tr>
</tbody>
</table>
Research Collaborations
PDMC staff provided professional staff services for project coordination and/or data management to CHB investigators for 18 projects in FY08; most are ongoing. The CRP staff served as official study staff members and costs for staff effort was recovered through extramural grant funds or hospital departments.

Research Consultations
The staff of the PDMC also provided expert consultation to investigators and their staff. Specific areas of consultation included proposal development, best practices for study start-up, case report form design and development, database development including variable coding and programming specifications, and development of web surveys. Most of these investigators are new to clinical research with limited resources to support their investigations, i.e. new physician attendings, nurses, research fellows, medical residents.

In response to an increase in requests for assistance with database development for patient clinical registries, CRP staff worked with physicians and nurses to design clinical registries to track epidemiological, sociodemographic and service metrics from special disease clinics and programs. Development of databases for the clinical registries is completed by the staff of ISD Knowledge Management.

Complex Databases using CRIT protocol data management application, SciRIS
In FY08, PDMC and CRIT staff developed 4 complex databases using a CRIT developed protocol data management systems application, SciRIS. With the adoption of InForm™ technology (see below), SciRIS will no longer be used for database development for new studies.

Complex Databases using InForm Technology
With financial support from the CTREC, the CRP adopted a new clinical trial database technology in January 2008, i.e. Phase Forward’s InForm™ ITM (Integrated Trial Management) software application. 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 pharmaceutical industry standards for FDA regulated research. InForm™ is now the recommended database technology for all FDA regulated, Investigator-initiated and sponsored trials conducted at CHB.

Since February of 2008, PDMC staff invested over 400 hours in formal InForm™ training and mentoring sessions. With the adoption of InForm™ our long-term goal is to transfer database development duties (for complex and/or FDA regulated studies) from the CRIT engineering team to the CRP Data Managers for all but the most sophisticated programming functions. This ‘duties transfer’ process was initiated in FY08 and continues in FY09. In FY08, CRP Data Managers initiated development of 4 InForm™ databases; 1 was completed and moved to the study production environment and data entry and data management training were completed for the study staff. At the end of FY08, there were 9 studies in queue for InForm™ database development and 7 studies were pending extramural funding.

Development of SPSS Databases
CRP staff 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 27 investigations in FY08 by PDMC staff or under their guidance. Programs were written and developed for more than 127 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.

Web Surveys
PDMC staff also developed interactive, electronic surveys for research questionnaires distributed via computer or the internet. Six electronic web surveys were developed in FY08. CRP staff also provided project and data management services during the survey distribution phase of the study for 3 of the 6 web surveys completed in FY08.

Randomization
PDMC staff worked closely with Investigators and CRP biostatisticians to develop and deliver randomization schemes and products. Randomization schemes were completed for 17 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 assignment.

Teaching Investigators and Study Staff
Another important priority for the PDMC staff is in the area of 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, contributions to the CRP newsletter and development and distribution of Research Practice Guidelines.

Research Practice Guidelines
In FY08, PDMC staff added a new Research Practice Guideline to the 14 already posted on the CRP web page, i.e. “Clinical Research Project and Data Management Best Practice Procedures.” The new Guideline offers recommendations for best practice procedures for project management including data collection and data management in clinical research. PDMC staff review all 14 Guidelines annually and revise accordingly to be certain all are current.

CRP Education Core Courses
Coordinator Rounds Seminar Series
PDMC staff served as director and faculty for the Study Coordinator Orientation program for clinical research coordinators sponsored by the CRP Education Core. Study Coordinator Orientation was offered 8 times in FY08. The day long orientation introduces new coordinators to the basic elements of clinical research and to the key clinical research staff, resources and services provided by various CHB departments.

Coordinator Rounds Seminar Series
PDMC Team Leader, Ms. McDermott, serves as director for The Coordinator Rounds Series. A Coordinator Rounds program was offered 6 times in FY08. The hour long program provides a forum for group review and discussion of common logistical challenges, proven operational strategies, and important updates in the field of clinical research. The Rounds allows a more in depth discussion of topics than is possible in the Orientation program. A list of the topics presented in FY08 appears in Appendix D.
Do-It-Yourself Data Management Course
The Do It Yourself Data Management Course was offered in June of 2008 and 18 investigators and research staff attended. The 3-session course was substantially improved in FY08 with the addition of a database programming component and a hands-on lab computer session. The course included an introduction to ICH Good Clinical Practice Guidelines; preparing for a QC review; and development of study timelines, case report forms, and corresponding databases.

Participation in Educational Offerings at other HMS affiliated Hospitals
In September 2008, Susan McDermott served as faculty for the Brigham and Woman’s Hospital annual flagship course, “Introduction to Clinical Research.” Ms. McDermott presented the lecture, “Collecting and Managing Clinical Research Data.” The course is offered to medical fellows and junior faculty. More inter-hospital collaboration is planned for FY09 under the auspices of the Harvard Catalyst.

Staff Development
Another important PDMC priority is staff development. In FY08, PDMC staff participated in a number of on-site and off-site trainings. The most notable were those pertaining to FDA regulation, InForm training, and Survey Research Methods.

- Brigham and Women’s Sponsored, “Essentials of Good Clinical Practice.”
  (7 staff attended in January 2008)
- SoCRA sponsored, “FDA Clinical Trial Requirements, Regulations, Compliance and GCP Conference”
  (4 staff attended in May 2008)
- SoCRA sponsored, “SOP Development and Implementation Conference”
  (1 member attended in July 2008)
- Phase Forward sponsored, “InForm Site and Sponsor End User Training”
  (7 staff attended in February 2008)
- Phase Forward sponsored, “Central Designer Basic Database Programming”
  (5 members attended in April - September 2008)
- Phase Forward sponsored, “Central Designer Advanced Designer Programming”
  (7 staff attended in April 2008)
- CRP sponsored In-Service, “Research Survey Development,” a two-session training provided by Sion Harris, CRP Survey Methodologist
  (7 staff attended in May 2008).

New Staff Hires
Qioli (Lily) Chen, MS, joined the CRP in January of 2008 as a Data Manager.
Staffing

Survey Core staff in FY08 included the following faculty. Capsule biographies are provided in Appendix A.

Sion Kim Harris, PhD, Director, Survey Research Methods Core
Sonja I. Ziniel, PhD, MA, Survey Methodologist

The newly founded Survey Core includes two doctoral level survey methodologists, Sion Kim Harris and Sonja Ziniel. Both hold faculty appointments in the CHB Division of Adolescent/Young Adult Medicine and Harvard Medical School. Dr. Harris serves as the Director of the Core.

Survey Core Mission

The mission of the Survey 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 Core staff are supported by CRP and departmental funds, the CHB Program for Patient Safety and Quality, and federal and foundation research grants.

Survey 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, nonresponse, 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; 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.

Survey 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.
Survey Progress Report

Utilization of Core Services
Table 1 shows the number of requests for survey core services during FY08 compared to FY07.

Table 1: Survey Core Service Requests

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<th>Task</th>
<th>FY07 Requests</th>
<th>FY08 Requests</th>
<th>Percent Change</th>
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<tbody>
<tr>
<td>Survey/Questionnaire Design</td>
<td>18</td>
<td>36</td>
<td>100%</td>
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Research Collaborations
The primary activity of the Survey 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), and other survey-related activities. The Survey Core also assists with analyzing survey data, and presentation and publication of results. In FY08, Survey Core staff provided assistance on 36 projects, a few of which are highlighted below. A full list of recent publications by Survey Core staff is provided in Appendix B.

- **CHB Patient Experience Surveys:** As part of the CHB Program for Patient Safety and Quality’s (PPSQ) efforts to improve the performance of the tools currently being used to assess patient and family experience of care, Dr. Harris provided leadership in the revision of the hospital’s two main patient experience surveys, the Inpatient survey and the Ambulatory Care survey. Dr. Ziniel is currently leading the implementation of the pilot-testing of the Inpatient survey.

- **Withdrawal Assessment Tool:** Dr. Harris collaborated with nursing researchers (Martha Curley and Linda Franck) to examine the reliability and validity of the newly developed Withdrawal Assessment Tool-1 which is used to assess the severity of pediatric patient withdrawal from opioid and benzodiazepine medication.

- **Active Where? Survey:** As part of a multi-city study (San Diego, Cincinnati, Boston), Dr. Harris worked with Nefertiti Durant (former CHB Adolescent Medicine fellow and current faculty at University of Alabama at Birmingham) to evaluate the psychometric properties of the new Active Where? Survey designed to assess environmental factors that influence youth physical activity and food intake.

- **Brief Multidimensional Measure of Religiousness/Spirituality (BMMRS):** Dr. Harris collaborated with investigators in the Center for Adolescent Substance Abuse Research (CeASAR) to evaluate the psychometric properties of the BMMRS among adolescents and to examine the relationship between various aspects of adolescent religiousness/spirituality and substance use behavior.

- **Parent Alcohol Screening in the Pediatric Office:** Dr. Harris assisted Dr. Celeste Wilson, a pediatrician and associate investigator in CeASAR, in the development of a survey to assess parents’ attitudes about, and preferences for, alcohol screening by their child’s pediatrician during a pediatric office visit.

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. New in FY08 is a large multi-center NIH/NHLBI R01 grant entitled “Sedation Management in Pediatric Patients with Acute Respiratory Failure” (M.A. Curley, PI), on which Dr. Harris serves as the measurement expert. This study examines the effects of a sedation management protocol for pediatric patients supported on mechanical ventilation in pediatric intensive care units, and assesses its impact on care outcomes such as days on mechanical ventilation, hospital length of stay, and cost of care.
Teaching Clinical Investigators
The Survey Core plays an important role in educating CHB investigators about designing and implementing surveys. Courses taught during FY08 include the following:

- **The Use of Surveys in Medical Education**
  Children's Hospital Boston Academy Retreat

- **Being Survey Savvy: Design Tips for More Effective Surveys**
  Children's Hospital Boston Department of Cardiology Clinical Research Course

- **Writing for Scientific Publication**
  CHB Office of Faculty Development/Office of Fellowship Training

- **Being Survey Savvy: Design and Implementation Tips for More Effective Surveys**
  Dartmouth Medical Libraries, Annual October Conference for New England Academic Librarians

In the coming year, several new courses will be offered by Dr. Ziniel. She will teach a short course on focus groups and offer a multi-lecture introduction to survey research. In addition, an intensive workshop, the “Survey Practicum,” is planned allowing participants to develop a survey and an IRB protocol with guidance at every step within a two-month period.

**Funding From Departments and Divisions**
Both Dr. Harris and Dr. Ziniel are funded by departments. Dr. Harris is funded by the Division of Adolescent/Young Adult Medicine; Center for Adolescent Substance Abuse Research; Program for Patient Safety and Quality; and Department of Cardiology. Dr. Ziniel is funded by the Program for Patient Safety and Quality.

**New Staff**
Dr. Ziniel was the first full-time faculty person to join the Survey Core after its founding this year. Dr. Sonja Ziniel completed her Ph.D. in Survey Methodology at the University of Michigan Institute for Survey Research in 2008 and brings extensive experience and expertise in all aspects of survey research from designing questionnaires and implementing surveys to analyzing complex survey data.
Staffing

FY2008 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, BA, 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 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.

**Implemented Phase Forward InForm Enterprise Adoption**
The CRIT partnered with several business and IT service teams to complete the CHB enterprise adoption of Phase Forward’s electronic data capture system titled InForm ITM. This product is the hospital’s preferred full-featured solution to collect, manage and analyze data for clinical trials and research studies. The enterprise adoption team installed, trained and successfully qualified the InForm system for use on all eligible studies. Since the summer of 2008, the implementation team has designed 11 large trials with 4 in production.

**Developed and Deployed CHB-CONNECT Volunteer Registry**
The CRIT collaborated with several CHB teams to design and develop the CONNECT Volunteer Registry. The collaboration included members from the ISD Web team, CRP, CCI and Public Relations. The CONNECT Registry allows children and adults to register and volunteer for participation in clinical research at CHB. The system also allows CHB principal investigators with IRB-approved protocols to access and search this volunteer registry. See: Page 14 for more information on CHB-CONNECT.

**Participating Member of FDA Working Group**
The CRIT is now a participating member of the CHB FDA guidelines working group. The
team consists of members from the EQuIP group, Regulatory Affairs and CRP. The working group was established to identify and publish guidelines related to FDA regulatory issues. These issues include topics such as Good Clinical Practice as well as guidelines on electronic records and digital signatures.

**Started Design of a New Clinical Research Coordination System**
The CRIT has initiated the development of a new enterprise software application that will be used by study teams to coordinate daily research activities. The product, titled the Clinical Research Coordination System, will support features such as centralized patient enrollment, study scheduling, automated data transfers and direct-to-patient communication capabilities (email, text messaging, etc.).

**Developed Central Data Repository for GPP/PGD**
The CRIT collaborated with clinical investigators from the Developmental Medicine Center (DMC) and Children's Hospital Informatics Program (CHIP) on the Gene Partnership Program. Specifically, the CRIT provided 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 will provide clinical investigators with a central registry of genotype and phenotype data that may be analyzed for new associations and promote scientific discovery.

**Supported initial I2B2 implementation and SHRINE demonstration**
The CRIT provided support and project coordination of the initial deployment of the I2B2 and SHRINE systems at CHB. The I2B2 project is a Web-based application that facilitates secure access to data stored in Clinical Data Warehouse. It is based on open source software developed by an NIH-funded National Center for Biomedical Computing grant. The goal of I2B2 is to develop a scalable informatics framework to manage data collected for clinical research.

The I2B2/SHRINE system will allow CHB clinical investigators to identify patient populations for clinical studies. The tool provides users with a graphical drag-and-drop interface that permits them to select medical concepts and build complex queries that incorporate both inclusion and exclusion criteria. In addition, the SHRINE system allows researchers at participating academic medical centers to query aggregate data across multiple institutions.

**Developed New GCRC/CTSC Protocol Review Process Using Sharepoint 2007**
The CRIT developed a new protocol review application using Microsoft Sharepoint Services 2007. This new application permits GCRC/CTSC administrators to centrally manage the protocol document review, approval and promotion process. Protocol reviewers are automatically notified of document changes and are sent friendly email reminders by the system to complete workflow tasks.

**Created New Service for Clinical Data Warehouse Requests**
In cooperation with the ISD Business Intelligence team, the CRIT assumed full responsibility for handling IRB-approved requests to obtain data from the Clinical Data Warehouse (CDW). This new level of cooperation and coordination eliminates a level of bureaucracy between the research community and clinical data warehousing facilities. Requests for research data and data warehouse capabilities may now be placed directly through the CRIT.
Supported the Development of EDC and Web Survey Solutions
The CRIT in close collaboration with the CRP Data Management Core developed and deployed many new large-scale data management systems in 2008. Specifically, the CRIT helped to implement new systems for use in Orthopaedics, Cardiology, Surgery and Oncology. The CRIT now provides ongoing support to over 25 large-scale systems in the field.

Supported the Development of Administrative Applications
The CRIT worked closely with the CRP administrative team to revise and redesign several of its administrative software applications. Specifically, the team added features and reports to the CRP Web-based budget tracking software. In addition, the team revamped the CRP intake database with new technologies and functionality. This new intake system now supports online request submissions, automated email workflow, and ad hoc reporting through CHQuery.
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APPENDIX A
STAFF BIOGRAPHIES

Program Director

Stavroula Osganian, MD, ScD, MPH
Dr. Osganian is a physician-epidemiologist with considerable experience in the design and conduct of epidemiologic and clinical research studies. Dr. Osganian's research interests and activities focus on studies of youth health promotion and chronic disease prevention with an emphasis on preventive cardiology. Her present research includes a 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 the CHB Co-Director of the Clinical Translational Studies Subcommittee of the NIH-funded Harvard Catalyst. She holds an appointment as Assistant Professor of Pediatrics at the Harvard Medical School and is an attending in the Optimal Weight for Life Clinic at Children's Hospital Boston.

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

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.

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.

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.

Maya Levine, BA, Education Coordinator
Ms. Levine joined the CRP as Education Coordinator in January 2007. Ms. Levine provides administrative support to all faculty and students involved in courses directed and organized by the CRP. She provides the infrastructure by which to best coordinate and successfully implement a growing clinical research education curriculum at Children’s. Prior to joining the CRP, Ms. Levine held administrative positions at several non-profit organizations in the United States and Ecuador. She received her Bachelor’s degree from Bates College in 2003.

Project and Data Management Core

Susan Mc Dermott, MPH, RN, CS, Clinical Research Team Leader
Susan Mc Dermott, 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. Mc Dermott 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. Mc Dermott’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. Mc Dermott 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), an NIH clinical trial implemented at 10 U.S. sites.

**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**

**Randi Triant, MFA, Administrative Director**
Ms. Triant joined the CRP in January of 2006 as Administrative Director. She has over twenty-five years of administrative and management experience, particularly in public health research. Prior to joining the CRP she was the Vice President of Communications and Media for New England Research Institutes. She also served as Principal Investigator or Project Director of fourteen NIH-funded SBIR grants, developing and evaluating multi-media programs and hand-held devices.

**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.


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).

**Federal Awards**

5 U01 CA81457 (Boyett / CHB subcontract: Poussaint) 04/01/04-03/31/09  
NIH/NCI $297,440  
**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.

5R01AI068119-02 (Crosby / CHB subcontract: Shrier) 06/15/06-05/31/11  
NIH/NIAID $96,456  
**Do Condoms Protect from Non-viral Sexually Transmitted Infections?**  
The major goal of this study is to determine the protective value of condoms against the acquisition of three common sexually transmitted infections: Chlamydia, gonorrhea, and trichomoniasis.

R21 HD056009 (du Plessis) 09/01/07-09/08/09  
NIH/NINDS $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 infant. Insights gained and techniques developed during the proposed research will facilitate the development of a much-needed cerebrovascular monitoring device, and ultimately to rational brain-oriented management of the critically-ill infant.

R21-DK073130A (Field) 01/15/06-12/31/07  
NIH/NIDDK $54,742  
**Weight Cycling and Mortality in Women**  
This project assesses the relationship between weight cycling and mortality among 77021 middle-aged and older women in the Nurses’ Health Study. The goals are: (1) to evaluate whether independent of net weight gain during adulthood, which is known to increase risk of death, weight cycling is associated with an increased risk of mortality; (2) to assess the association of weight cycling due to intentional weight losses, as well as cycling due to unintentional weight losses; (3) to assess whether weight variability, which includes both intentional and unintentional weight losses and gains, increases mortality risk.

R01 MH65877 (Galler / CHB subcontract: Waber) 05/01/04-02/28/08  
NIH/NIMH $51,821  
**30 Year Follow-up of Mental Health Outcomes Following Childhood Malnutrition**  
The goal of this project is to assess the long-term cognitive and mental health...
consequences of infant malnutrition in adulthood. Individuals who were followed from infancy through late adolescence will now be re-evaluated as adults in order to determine whether and how effects that persisted through adolescence may be evident among adults, and if so, what their consequences are for those individuals regarding mental health and adaptation.

R01 HD043869 (Gordon) 06/01/06-08/31/10
NIH/NICHD $167,260
Effects of Adrenal and Gonadal Hormone Replacement in Young Women with Anorexia Nervosa
This is a randomized, controlled trial in young women with anorexia nervosa, designed to measure the effects of an 18-month course of adrenal and gonadal steroid replacement on bone mass, markers of bone turnover, serum levels of IGF-I, and bone strength as assessed through cross-sectional geometric analysis of DXA data.

1R21 HL089659-01A1 (Guinan) 04/01/08 – 03/31/10
NIH/NHLBI $150,000
rBPI21 & Endotoxin-directed Innate Immunity in Stem Cell Transplantation
The aims of this study are: (1) to 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; (2) to investigate the effects of rBPI21 infusion on the endotoxin-modulating activity of plasma; and (3) to determine the effect of rBPI21 infusion on the functional expression of the endotoxin receptor composed of MD-2, TLR4, and mCD14.

R01 5U01DK067767 (Jonas) 09/01/05-08/31/08
NIH/NIDDK $10,345
PEDS-C Trial
This is a Phase II randomized, blinded placebo trial to compare safety and efficacy of PEG-2a plus placebo versus PEG-2a plus riavirin in children chronically infected with Hepatitis C virus.

R01 DA018848 (Knight) 09/01/04-08/31/09
NIH/NIDA $528,250
Screening and Brief Advice to Reduce Teen Substance Abuse
The overall goal of this project is to augment the screening/brief advice intervention with educational materials, and then to assess the efficacy of this approach within a network of primary care practices.

R01 DA014553 (Knight) 06/01/04-03/31/09
NIH/NIDA $250,000
A Medical Office Intervention for Adolescent Drug Use
This is a randomized trial of a brief intervention, developmentally appropriate for adolescents and practical for use in busy clinic settings, designed to test its effect on drug use, engagement in treatment, and other substance-related outcomes. Factors that moderate or mediate the effect of intervention will be identified and measured.

R01 EB01998 (Levine / CHB subcontract: Estroff) 07/01/03-05/31/09
NIH/BIDMC $200,079
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).

Glycemic Load and Infant Birth Weight in Pregnant, Glucose Intolerant Women

A randomized trial testing whether a low-glycemic load diet during the third trimester of pregnancy will reduce the risk of high birth weight in offspring of women who are glucose-intolerant.

General Clinical Research Center

The major goal of this project is to provide the clinical research infrastructure for medical scientists who conduct patient-oriented research.

Harvard Clinical and Translational Science Center

The HCTSC is a clinical and translational research program that provides support to investigators with funded sponsored research support, to facilitate patient-oriented research. Investigations carried out in the HCTSC include studies of normal and abnormal physiology and studies of the cause, prevention, progression, control, and cure of diseases that afflict individuals of all ages and ethnic backgrounds. The HCTSC also provides a unique environment for mentored training of health professionals in issues related to patient-oriented research.

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.

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

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

d-Penicillamine Chelation in Lead Poisoned Children
This study is a Phase II/III randomized, placebo-controlled clinical trial to evaluate the effectiveness of d-penicillamine in 50 children ages 6 months to 16 years with blood lead levels of 15-25 mcg/dl.
Mood and HIV Risk in Depressed Adolescents
The goal of this project is to evaluate the association between mood and sexual activity using handheld computers in depressed adolescents.

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.

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 5 sites in East and West Africa.

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.

NIH Career Development Grants

Academic Career Award in Adolescent Alcohol Abuse
The major goals of this project are to develop new knowledge, skills and experience in alcohol treatment research.

Clinical Hematology Research Career Development Program
The purpose of this grant 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.
Residency Training in General and Pediatric Dentistry
This project aims to improve awareness, knowledge and practice of oral health in pediatricians by training the next generation of practicing pediatricians. At the same time, pediatric dental residents will gain context in working with high risk populations which will sustain their patient care practice beyond their years of training. Finally, access to needed dental care, including early preventative dental care for young children, will increase as a result of this project.

Health Values and Treatment of Pediatric Type 2 Diabetes
The goals of this award is to provide training in health services research, and to develop expertise in research methods and disciplines that will be used to develop health promotion and disease strategies for children with, and at risk for, type 2 diabetes. The study proposed will evaluate the role of health preferences in the treatment of type 2 diabetes in children.

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

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 among different centers.

Massachusetts Healthy Choices Evaluation
Scientific oversight, study design, statistical analysis, and interpretation of data for evaluation of a program in Massachusetts middle schools promoting cardiovascular health through increased physical activity, increased fruit and vegetable consumption, and limited TV and computer time.
(Bennett) 07/07/04-12/31/07
St. Giles Foundation $125,000
**Genetic Modifiers of Childhood Chronic Immune Thrombocytopenic Purpura (ITP)**
This study has two specific aims: 1) to collect precise and detailed phenotypic data from the North American Pediatric Chronic ITP Registry to study a large cohort of patients with chronic ITP in a prospective manner, and 2) to analyze the association of candidate genes to the clinical severity of chronic ITP and its response to therapy.

(Chirnomas) 03/01/08-02/28/10
Cooley’s Anemia Foundation $60,000
**Mechanism of Inadequate Response to Deferasirox**
This study has two specific aims: 1) to investigate the biological mechanism of deferasirox in a cohort of patients with poor response as compared to controls, and 2) to investigate the risk factors for inadequate response to deferasirox.

(Ericson) 07/01/06-06/30/08
Cystic Fibrosis Foundation $100,000
**A Six Month Open Label Study of Amiloride Solution for Inhalation and Tobramycin Solution for Inhalation for the Eradication of Burkholderia dolosa in Patients with Cystic Fibrosis**
The primary goal of this clinical trial is to determine the ability of multiple doses of amiloride solution for inhalation (ASI) and tobramycin solution for inhalation (TSI) to eradicate Burkholderia dolosa respiratory tract infection in patients with cystic fibrosis.

(Levy) 01/01/07-12/31/09
Dana Foundation $100,000
**Endotoxin-related Innate Immunity in Patients Undergoing Hematopoietic Stem Cell Transplantation**
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.

047191 (Mooney) 10/01/04-10/31/07
Robert Wood Johnson Foundation $8,472
**Injury Free Coalition for Kids of Boston**
The purpose of this grant is for funding the Injury Free Coalition for Kids of Boston site. The planned interventions were based upon the needs expressed by the community and data concerning injuries to children. Surveys indicated that families perceived home, fire, and pedestrian safety as their top three concerns. Interventions include a home safety program, a community safety program, and a pedestrian safety program.

CDHNF-06-004 (Pappa) 11/15/06-11/14/08
NASPghAN $50,000
**Optimization of Vitamin D Status and Its Effects on Bone Health and Disease Outcomes in Young Patients 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 and the impact of this intervention on the bone health and the disease outcome in young patients with IBD.
Efficacy of Omega-3 Enriched Fat Emulsion and Prevention of Parenteral Nutrition Induced Liver Injury in Infants

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

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.

Pilot Study of Immunogenicity and Tolerability to the Quadrivalent HPV L1 VLP Vaccine (Gardasil) Among IBD Patients on Immunosuppressive Therapy Compared to Healthy Children and Young Females

This study will compare antibody response to the quadrivalent HPV L1 VLP vaccine (Gardasil) in children and young adult females with IBD who are on immunosuppressive therapy to IBD patients on salicylates and to healthy patients. It will also compare the number and type of vaccine-associated side effects in children and young adult females with IBD on immunosuppressive therapy compared to IBD patients on salicylates and to healthy patients, as well as evaluate disease activity and flare-ups before and after vaccination with Gardasil. Thirdly, the study will analyze factors associated with strength of the antibody response to each HPV type, including socio-demographics, disease severity/activity, medications, etc. among patients with IBD.

Oral Health Needs Assessment of Children with Special Health Care Needs in Massachusetts

HRSA national studies have found that dental care was the service most commonly reported needed, but not received for children with special health care needs. A convenience sample dental survey was used to further characterize these children’s access to dental care, dental needs, and barriers to care in Massachusetts.

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.
APPENDIX D
COURSE AGENDAS

Introduction to Clinical Research Agenda
March 10 – 13, 2008

Monday, March 10, 2008
Design and Analysis

1:00 – 1:15  Introduction and Overview
            Jenifer Lightdale, MD, MPH

1:15 – 2:15  Observational Study Designs
            Alison Field, ScD

2:15 – 2:30  BREAK

2:30 – 3:30  Good Measures and Good Tests
            Clarissa Valim, MD, ScD

3:30 – 3:45  BREAK

3:45 – 4:30  Designing Surveys and Questionnaires
            Erinn Rhodes, MD, MPH

4:30 – 5:30  Statistics in Clinical Research: An Overview
            Henry Feldman, PhD

Tuesday, March 11, 2008
Institutional Approval, Study Implementation and Investigator Responsibilities

1:00 – 1:15  Overview of Research Administration: Organization & Resources
            Richard Fleck, MBA

1:15 – 2:15  Human Subjects and Institutional Review Board
            Susan Kometsky, MPH, CIP

2:15 – 2:30  BREAK

2:30 – 3:00  The IRB Review Process: An Insider’s View
            Lydia Shrier, MD, MPH

3:00 – 3:30  EQuIP: Top Ten Review Findings
            Eunice Yim Newbert, MPH

3:30 – 4:00  Collecting and Managing Clinical Research Data, Part I
            Susan M. McDermott, MPH, RN, CS

4:00 – 4:15  BREAK
4:15 – 4:45  Collecting and Managing Clinical Research Data, Part II  
Susan M. McDermott, MPH, RN, CS

4:45 – 5:30  Data Fraud and Authorship  
Sadath Sayeed, MD, JD

Wednesday, March 12, 2008
Grants and Protocol Development

1:00 – 1:30  The NIH Review  
Dick Grand, MD

1:30 – 2:30  Writing for Scientific Publication  
Laurie Fishman, MD

2:30 – 2:45  BREAK

2:45 – 3:30  Industry and Philanthropy  
Samuel Nurko, MD, MPH

3:30 – 4:00  The General Clinical Research Center  
Kristine Jordan

4:00 – 4:15  BREAK

4:15 – 5:30  Introduction to Statistics  
Dionne Graham, PhD

Thursday, March 13, 2008
Design, Manuscripts and Presentation

1:00 – 1:45  Clinical Trials: Design and Monitoring  
Jane Newburger, MD, MPH

1:45 – 2:30  Scientific Presentations  
Michael Rich, MD, MPH

2:30 – 2:45  BREAK

2:45 – 3:30  Grant Writing 101  
Jenifer Lightdale, MD, MPH

3:30 – 3:45  BREAK

3:45 – 4:45  Introduction to Regression  
Dionne Graham, PhD

4:45 – 5:00  The CRP Course Wrap-Up  
Jenifer Lightdale, MD, MPH

5:00 – 5:30  The NIH & CTSA: An Update  
Ellis Neufeld, MD, PhD
# Introduction to Clinical Research Agenda

**September 15-19, 2008**

### Monday, September 15, 2008

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<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
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<tr>
<td>1:00–1:15</td>
<td>Introduction and Overview</td>
<td>Jenifer Lightdale, MD, MPH</td>
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<td>1:15–2:15</td>
<td>Observational Study Designs</td>
<td>Voula Osganian, MD, MPH</td>
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<td>2:15–2:25</td>
<td><strong>BREAK</strong></td>
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<td>3:25–3:35</td>
<td><strong>BREAK</strong></td>
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<td>3:35–4:10</td>
<td>Scientific Presentations</td>
<td>Jonathan Finkelstein, MD, MPH</td>
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<td>4:10–5:10</td>
<td>Statistics in Clinical Research: An Overview</td>
<td>Henry Feldman, PhD</td>
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### Tuesday, September 16, 2008

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<tr>
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<tr>
<td>1:00–1:15</td>
<td>Overview of Research Administration: Organization &amp; Resources</td>
<td>Paula Roth, MEd</td>
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<tr>
<td>1:15–2:30</td>
<td>Introduction to Statistics</td>
<td>Dionne Graham, PhD</td>
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<td>2:30–2:45</td>
<td><strong>BREAK</strong></td>
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<td>The IRB Review Process: An Insider’s View</td>
<td>Lydia Shrier, MD, MPH</td>
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<tr>
<td>3:15–3:45</td>
<td>Small and Common Study Mistakes</td>
<td>Eunice Yim Newbert, MPH</td>
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<td>3:45–4:15</td>
<td>Collecting and Managing Clinical Research Data – Part I</td>
<td>Susan M. McDermott, MPH, RN, CS</td>
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<tr>
<td>4:15–4:30</td>
<td><strong>BREAK</strong></td>
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<tr>
<td>4:30–5:00</td>
<td>Collecting and Managing Clinical Research Data – Part II</td>
<td>Susan M. McDermott, MPH, RN, CS</td>
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<tr>
<td>5:00–5:45</td>
<td>Grant Writing 101</td>
<td>Jenifer Lightdale, MD, MPH</td>
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<tr>
<td>Time</td>
<td>Session</td>
<td>Speaker(s)</td>
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<tr>
<td>1:00 – 1:30</td>
<td>NIH Review</td>
<td>Dick Grand, MD</td>
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<td>1:30 – 1:45</td>
<td>The Clinical and Translational Study Unit (CTSU)</td>
<td>Kristine Jordan</td>
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<td>1:45 – 2:00</td>
<td>BREAK</td>
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<tr>
<td>2:00 – 3:00</td>
<td>Introduction to Regression Analysis</td>
<td>Henry Feldman, PhD</td>
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<tr>
<td>3:00 – 4:00</td>
<td>Writing for Scientific Publication</td>
<td>S. Jean Emans, MD</td>
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<td>4:00 – 4:15</td>
<td>BREAK</td>
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<tr>
<td>4:15 – 5:00</td>
<td>Industry and Philanthropy</td>
<td>Sam Nurko, MD, MPH</td>
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<tr>
<td>5:00 – 5:45</td>
<td>Clinical Trials: Design and Monitoring</td>
<td>Jane W. Newburger, MD, MPH</td>
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<td></td>
<td><strong>Thursday, September 18, 2008</strong></td>
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<tr>
<td>1:00 – 1:45</td>
<td>Evaluating Measures in Clinical Research</td>
<td>Henry Feldman, PhD</td>
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<tr>
<td>1:45 – 2:30</td>
<td>Designing Surveys and Questionnaires</td>
<td>Erinn Rhodes, MD, MPH</td>
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<tr>
<td>2:30 – 2:45</td>
<td>BREAK</td>
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<tr>
<td>2:45 – 3:15</td>
<td>Drug &amp; Devices: Investigator-initiated Trials in Which You are the Sponsor (as Opposed to a Company, Foundation or Consortium as Sponsor) that May Fall under FDA Regulations</td>
<td>Jay Kaplan, JD</td>
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<tr>
<td>3:15 – 3:25</td>
<td>Marketing and Public Affairs Department: Options for Recruitment</td>
<td>Gina Colavecchio, MBA</td>
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<tr>
<td>3:25 – 4:10</td>
<td>Data Fraud and Authorship</td>
<td>Sadath Sayeed, MD, JD</td>
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<tr>
<td>4:10 – 4:25</td>
<td>The CRP Course Wrap-up</td>
<td>Jenifer Lightdale, MD, MPH</td>
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<tr>
<td>Date</td>
<td>Lecture</td>
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<tr>
<td>September 23</td>
<td>Lecture 1: <strong>Graphical Methods and Summary Statistics</strong></td>
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<tr>
<td></td>
<td>- Data Types</td>
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<td></td>
<td>- Graphical Display: <em>Bar Charts, Histograms, Boxplots</em></td>
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<td></td>
<td>- Summary Statistics: <em>Measures of Central Tendency, Measures of Spread</em></td>
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<tr>
<td>September 30</td>
<td>Lecture 2: <strong>Estimating the Mean and Confidence Intervals</strong></td>
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<tr>
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<td>- Normal Distribution</td>
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<td>- Principles of Estimation</td>
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<td>- Estimating the Mean</td>
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<td>- Confidence Intervals for the Mean</td>
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<td>October 7</td>
<td>Lecture 3: <strong>Hypothesis Testing &amp; Comparing Two Means</strong></td>
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<tr>
<td></td>
<td>- Inference Overview</td>
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<td></td>
<td>- Introduction to Hypothesis Testing</td>
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<td></td>
<td>- Comparing Two Means: Paired t-test, Two sample t-test</td>
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<td>- Interpreting p-values</td>
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<td>October 14</td>
<td>Lecture 4: <strong>Comparing Three or More Means</strong></td>
<td></td>
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<tr>
<td></td>
<td>- Analysis of Variance (ANOVA)</td>
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<td>October 21</td>
<td>Lecture 5: <strong>Non-Parametric Tests, Correlation</strong></td>
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<tr>
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<td>- Nonparametric Tests: Wilcoxon rank sum; Kruskal Wallis</td>
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<td></td>
<td>- Correlation</td>
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<td>October 28</td>
<td>Lecture 6: <strong>Estimating and Testing Proportions</strong></td>
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<tr>
<td></td>
<td>- Estimating a Proportion</td>
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<td>- Confidence Intervals for Proportions</td>
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<td>- Comparing Two or More Proportions: Chi-squared test, Fisher’s exact test</td>
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<tr>
<td>November 4</td>
<td>Lecture 7: <strong>Comparing Two Proportions – Measures of Effect</strong></td>
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<td></td>
<td>- Risk difference</td>
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<td>- Risk ratio</td>
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<td>- Odds ratio</td>
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<tr>
<td>November 11</td>
<td>VETERANS DAY – NO CLASS</td>
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<tr>
<td>November 18</td>
<td>Lecture 8: <strong>Putting it all together</strong></td>
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<td></td>
<td>- Picking the right test</td>
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<td></td>
<td>- Interpreting the literature</td>
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</table>
Introduction to Biostatistics with SPSS Lab Agenda
September - November 2008

September 25 Lab 1: *Introduction to the SPSS Interface*
- Opening an existing SPSS database
- Graphical data analysis
- Descriptive statistics
- Subsetting data sets

October 2 Lab 2: *Data set basics*
- Confidence intervals for the mean
- Introduction to SPSS syntax
- Descriptive analysis by group
- Subsetting data sets
- Creating a new data set from "scratch"

October 9 Lab 3: *Tests and by-group analysis*
- Two sample t-test
- Paired t-test
- More SPSS syntax

October 16 Lab 4: *More dataset basics and tests*
- ANOVA
- Wilcoxon and KW tests
- Variable creation and recoding
- Correlation
- Variable creation and recoding with menus and with syntax

October 23 Lab 5: *Tests for proportions*
- One sample test for proportions
- Crosstabs
- Chi squared test
- Fisher’s exact test
- Reading data from other data formats

October 30 Lab 6: *Odds ratios and diagnostic tests*
- Odds ratios
- Sensitivity and specificity
- Understanding and using date variables
- Exporting SPSS output to Word or PowerPoint

November 6 Lab 7: *Additional SPSS features you need*
- Tutorials
- Case studies
- Syntax Reference
- Lab wrap-up and discussion
Do It Yourself Data Management Agenda  
*June 16, 17, 19 & 24, 2008*

**SESSION 1 – 6/16**
2:00pm – 2:20pm  *Welcome and Introductions*

2:20pm – 2:25pm   **Course Overview**  
Susan McDermott, RN, MPH

2:25pm – 3:15pm   **LECTURE 1:**  *Developing a Manual of Operations*  
Susan McDermott, RN, MPH

3:15pm – 3:45pm   **LECTURE 2:**  *EQUIP (Education and Quality Improvement Program)*  
Eunice Newbert, MPH

**SESSION 2 – 6/17**
2:00pm – 2:30pm  **LECTURE 3:**  *Thinking About Your Variables*  
Tracy Antonelli, MPH

2:30pm – 2:40pm  **Variable List Review**  
Handan Titiz, EdM

2:40pm – 3:25pm  **LECTURE 4:**  *CRP Case Report Form Standards*  
Tracy Antonelli, MPH

3:25pm – 3:35pm  **LECTURE 5:**  *Timelines*  
Tracy Antonelli, MPH

3:35pm – 3:45pm  **Review of Timeline Handout**  
Susan McDermott, RN, MPH

3:45pm – 4:15pm  **LECTURE 6:**  *Writing Form Specs*  
Handan Titiz, EdM

**LAB A – 6/19**
2:00pm – 4:30pm  **SPSS Data Builder Workshop**  
Handan Titiz, EdM

4:30pm – 4:45pm  **Closing: Intakes & Evaluations**  
Susan McDermott, RN, MPH

**LAB B – 6/24**
2:00pm – 4:30pm  **SPSS Data Builder Workshop**  
Handan Titiz, EdM

4:30pm – 4:45pm  **Closing: Intakes & Evaluations**  
Susan McDermott, RN, MPH
Do It Yourself Data Management Agenda
June 16, 17, 19 & 24, 2008

SESSION 1 – 10/27
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 – 10/29
2:00pm – 2:10pm  Variable List Review
Handan Titiz, EdM
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)
Eunice Newbert, MPH
3:35pm – 4:05pm  LECTURE 6: Writing Form Specs
Handan Titiz, EdM

LAB A – 10/31
2:00pm – 4:15pm  SPSS Data Builder Workshop
Handan Titiz, EdM
4:15pm – 4:30pm  Closing: Intakes & Evaluations
Susan McDermott, RN, MPH

LAB B – 11/3
2:00pm – 4:15pm  SPSS Data Builder Workshop
Handan Titiz, EdM
4:15pm – 4:30pm  Closing: Intakes & Evaluations
Susan McDermott, RN, MPH
CRP Biostatistics Short Courses 2008

Beyond Chi-Squares: Drawing Inferences from Tables
Course Agenda 2008
Alka Indurkhya, PhD
Lead Biostatistician

LECTURE 1 – 2/25/08:  Mostly about 2x2 Tables
LECTURE 2 – 2/26/08:  Correlated and Stratified 2 x 2 Tables and R x C Tables
LECTURE 3 – 2/27/08:  Miscellany

Statistics for Small Sample Size Studies
Course Agenda 2008
Matt Gregas, PhD
Senior Biostatistician

LECTURE 1 – 4/8/08:  Non Parametric Methods
LECTURE 2 – 4/9/08:  One Sample Location Problems: Sign Tests and Rank Sign Tests as Alternatives to the t-test
LECTURE 3 – 4/15/08:  Two Sample Location Problems: Wilcoxon Rank Sum, Hodges-Lehman Estimator & Kolmogorov-Smirnov
LAB 1 – 4/16/08  LAB

Introduction to Statistical Genetics
Course Agenda 2008
Chao-Yu Guo, PhD
Senior Biostatistician

LECTURE 1 – 5/8/08:  Introductions
• Genetics
• Hardy-Weinberg Equilibrium
• Heritability
• SOLAR
LECTURE 2 – 5/15/08:  Linkage Analysis
• easyLinkage
LECTURE 3 – 5/21/08:  Population based association study
• the HapMap Consortium
• Haploview
LECTURE 4 – 5/29/08  Family based association study
• FBAT, PBAT
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><strong>Rochelle P. Walensky, MD, MPH</strong></td>
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<td>2:55 – 3:15</td>
<td>Specific Aims</td>
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<td><strong>Voula Osganian, MD, ScD, MPH</strong></td>
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<td>3:15 – 3:45</td>
<td>Background &amp; Preliminary Studies</td>
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<td><strong>John R. Knight, MD</strong></td>
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<td>3:45 – 3:55</td>
<td>BREAK</td>
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<td>3:55 – 4:25</td>
<td>Research Plan</td>
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<td><strong>Ellen W. Seely, MD</strong></td>
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<td>4:25 – 4:45</td>
<td>Data Analysis Plan</td>
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<td><strong>Henry Feldman, PhD</strong></td>
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<td>4:45 – 5:00</td>
<td>Panel Q &amp; A Session</td>
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</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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<td><strong>Jenifer R. Lightdale, MD, MPH</strong></td>
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<td>1:10 – 1:30</td>
<td>Identifying Funding Sources;</td>
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<td><strong>Liam O’Connor, MEd</strong></td>
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<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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<td><strong>Grace Chang, MD, MPH</strong></td>
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<td>1:50 – 2:10</td>
<td>NIH 101</td>
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<td><strong>Jordan Kreidberg, MD, PhD</strong></td>
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<td>Time</td>
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<tr>
<td>2:10 – 2:20</td>
<td>BREAK</td>
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<tr>
<td>2:20 – 2:40</td>
<td>The Review Process</td>
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<td>2:40 – 3:10</td>
<td>30 Art of Grantsmanship</td>
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<tr>
<td>3:10 – 3:30</td>
<td>Panel Q &amp; A Session</td>
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<tr>
<td>3:30 – 3:35</td>
<td>Concluding Remarks</td>
</tr>
</tbody>
</table>
Orientation for New Study Coordinators Schedule 2008

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
    A. Abend
    • Funded Research
    • Patient Care Costs
  • Introduction to the General Clinical Research Center (GCRC)
    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/Bowling
  • Study Documentation: Common Errors
    Newbert/Bowling

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

3:10 – 3:25  Wrap-up, Review, Evaluations
  S. McDermott
Coordinator Rounds 2008

2/13/08  
**EQuIP Regulatory Binders**

Eunice Yim Newbert, MPH  
Manager  
Education and Quality Improvement Program (EQuIP)  
Children’s Hospital Boston

Kristin Bowling, MPH  
Quality Improvement Specialist  
Education and Quality Improvement Program (EQuIP)  
Children’s Hospital Boston

4/2/08  
**The Progeria Clinical Trial: A Coordinator’s Perspective**

William Fletcher  
Clinical Research Coordinator  
Children’s Hospital Boston & Dana-Farber Cancer Institute

Angela Kraybill  
Clinical Research Assistant  
Children’s Hospital Boston

Kyra Johnson  
Clinical Research Coordinator  
Progeria Research Foundation

8/6/08  
**FDA Regulation Procedures at CHB**

Kristin Bowling, MPH  
Quality Improvement Specialist  
Education and Quality Improvement Program (EQuIP)  
Children’s Hospital Boston

Jay Kaplan, JD  
Regulatory Affairs Specialist  
Clinical Trials Office (CTO), Children’s Hospital Boston

Susan McDermott, MPH, RN, CS  
Clinical Research Team Leader  
Project and Data Management Team, Clinical Research Program (CRP) Children’s Hospital Boston

Jason Rightmyer, MS  
Team Leader & Applications Developer  
Clinical Research Information Technology (CRIT), Children’s Hospital Boston
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
Clinical Research Program
Request For Assistance

Program Description and Application

Mission:
The mission of the Clinical Research Program is to enhance the quality of clinical research at Children's Hospital by providing to members of the research community scientific support, education, and collaborative assistance in the design, conduct, and analysis of clinical research. We also closely interact with the Children’s Hospital Clinical and Translational Study Unit - CTSU (formerly General Clinical Research Center - GCRC) and provide some support to CTSU-funded studies.

CRP Personnel:
- Directors: Senior clinical researchers with extensive experience in conducting clinical research studies.
- Biostatisticians: Skilled in protocol and grant development, study design, and data analysis.
- Survey Epidemiologists: Skilled in the design and analysis of surveys.
- Clinical Research Specialists: Skilled in the design of case report forms and questionnaires, quality assurance procedures, and the development of manuals of operations.
- Applications Specialists: Skilled in data management system design, including database and Web application development.

Funding Sources:
The CRP receives a portion of its support from the hospital as part of the institution's commitment to clinical research. A significant amount of funding also comes from departments/divisions, federal, foundation, and other awards that are obtained by either our staff or the investigators with whom we collaborate. As we plan our role in your research, we will estimate your requirements and a realistic budget will be developed to formalize our collaboration. We also strongly encourage investigators to consider seeking CTSU support for their clinical studies wherever possible. All types of assistance depend on staffing and resources available to the CRP at the time of the request.

Types of Assistance:
Please review the CRP Services Grid on the Investigator Request for Assistance form for services which do not require reimbursement (i.e., hospital-supported services) versus services that must be reimbursed. Please also adhere to the deadlines for assistance described on the next page under Timeframes.

Assistance Procedures:
To be eligible for CRP assistance, you must have an appointment at Children's Hospital or be a Children's Hospital employee. For assistance with any aspect of study implementation or with data analyses, you must have a written study protocol with IRB approval to conduct the research.

- For each request, complete the CRP Investigator Request for Assistance form by clicking the start button at the bottom of the screen. If you have trouble submitting the form on-line, you can also submit a paper copy through interoffice mail or by e-mail: crp@childrens.harvard.edu. We will respond within 10 business days to schedule an initial planning meeting.
- You will receive an email informing you of the assigned CRP Project Lead. Please email to this designated Project Lead all pertinent background materials (including a draft of your research aims, draft protocol or grant proposal, guidelines for submission of the grant application, draft data


1/16/2009
forms, etc.). These materials should be sent to the CRP at least one week before your meeting.

- At the initial planning meeting, CRP staff will meet with you (and your mentor, if applicable) to assess your request. At the initial planning meeting we will begin to discuss feasibility and resources. This includes an evaluation of tasks to be performed, assignment of responsibilities, and the need for budgetary support.
- At a follow-up meeting, we will develop a mutually agreed-upon written plan of action and an estimate of costs, when needed.
- Work will proceed according to an agreed-upon timeframe.

**Timeframes:**
Grant proposal applications as well as study protocols vary in complexity and length. Most National Institutes of Health (NIH) applications (R01’s, K23’s and other funding mechanisms) as well as applications to major foundations require significant time and effort to prepare. Most studies also require 6 to 12 months of planning and development prior to the start of recruitment of subjects. Similarly, data analyses require sufficient time for data cleaning, statistical programming, interaction with the investigators, and writing and review of manuscripts. Furthermore, the CRP provides assistance to many investigators at any given time. Therefore, we ask that investigators adhere to the following timeframes when requesting assistance from the CRP.

- For grant applications, we recommend beginning to work with us at least 90 days before the submission deadline or due date and require a minimum of 60 days. We also require a complete first draft of the grant proposal or study protocol and preliminary budget a minimum of 30 days before the submission deadline or due date. If this timeframe is not met or we feel there is not adequate time to assist you, we may recommend delaying submission to the next cycle.
- For assistance with study implementation, we ask that you begin working with us at least 6 months in advance of your anticipated start of recruitment.
- For assistance with data analyses, including manuscript preparation, abstracts, and presentations, we recommend beginning to work with us 60 to 90 days before any deadline, depending on the scope and complexity of the analyses.

**CRP Contact Information:**

- The CRP Offices are located at 21 Autumn Street. We can be reached by phone at 857-228-4720 or by e-mail at crp@childrens.harvard.edu.

Print Paper Version | Start Request Online


1/16/2009
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 ☐ U18 ☐ U54  
  c. Is this a response to an announcement? ☐ Yes ☐ No  
     i. If Yes, what is the type? ☐ RFA ☐ RFP ☐ PA

☐ Other Federal Agency: ______________________________________________________________________________________________
☐ Foundation / Association: 1) ______________________________________________________________________________________________
  2) ______________________________________________________________________________________________
☐ Industry Sponsor: ______________________________________________________________________________________________
☐ Internal Award: ______________________________________________________________________________________________
☐ Department/Division/Program Funds:
☐ Philanthropic funds ______________________________________________________________________________________________
☐ 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 GCRC or its resources? ☐ Yes ☐ No

Other Requests/Comments ______________________________________________________________________________________________
__________________________________________________________________________________________________________________________________________

12/9/2008
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>
<thead>
<tr>
<th>TASKS</th>
<th>CORE SERVICES NO CHARGE</th>
<th>REIMBURSED SERVICES CHARGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRANTS OR STUDY PROTOCOL</td>
<td>Contributions to the writing of grant proposals &amp; study protocols, including limited preliminary data analysis. Requires a 90-day lead-time.</td>
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<tr>
<td></td>
<td>Development of aims and hypotheses</td>
<td>Case Report Form development, formatting, and coding</td>
</tr>
<tr>
<td></td>
<td>Study design</td>
<td>Survey development, formatting, and coding</td>
</tr>
<tr>
<td></td>
<td>Power and sample size calculations</td>
<td>Development of custom research database applications</td>
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<td></td>
<td>Analysis methods</td>
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<tr>
<td></td>
<td>Data management methods</td>
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<td></td>
<td>Critique/review of grants or study protocols</td>
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</tr>
<tr>
<td>CASE REPORT FORMS</td>
<td>Guidance/review of case report forms</td>
<td>Development &amp; writing of study manuals</td>
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<tr>
<td>SURVEYS</td>
<td>Guidance/review of surveys</td>
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<tr>
<td>RESEARCH DATABASES</td>
<td>Development of CRP research databases</td>
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<td>Development of database for Web-based surveys</td>
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<tr>
<td>STUDY MANUALS OF OPERATION</td>
<td>Guidance/Review of Study Manuals</td>
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<tr>
<td>DATA MANAGEMENT</td>
<td>Study ID assignment logs</td>
<td>Data entry and management</td>
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<td>Administration of web-based surveys</td>
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<tr>
<td>PROJECT MANAGEMENT</td>
<td>Guidance/review of study timelines and management plans and priorities</td>
<td>Project Director/Study Coordinator support</td>
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<tr>
<td>RANDOMIZATION</td>
<td>Randomization Strategies</td>
<td>Randomization envelopes</td>
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<td>DATA ANALYSIS</td>
<td>Descriptive 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>Critique/review of manuscripts</td>
<td>Data analyses for manuscripts, abstracts and presentations</td>
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<td></td>
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<td>Manuscript Writing</td>
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</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
      _________________________________
□ Other Federal Agency: _________________________________
□ Foundation/Association: 1) _________________________________
   2) _________________________________
□ Industry Sponsor: _________________________________
□ Internal Award: _________________________________
□ Department/Division/Program Funds: _________________________________
□ Philanthropic funds: _________________________________
□ 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 GCRC or its resources? □ Yes □ No

Other Requests/Comments
__________________________________________________________________________________

_________________________ 1/28/2008
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<th>Tasks</th>
<th>Assigned Staff</th>
<th>Task Status*</th>
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<tbody>
<tr>
<td>Grant Proposal/Protocol Development</td>
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<tr>
<td>DSMB/Interim Analysis Plan</td>
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<td>Grant Application Review/Critique</td>
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<td>Power and Sample Size Determination</td>
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<td>Statistical Analysis Plan</td>
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<td>Study Aims and Hypotheses</td>
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<td>Study Protocol Review/Critique</td>
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<td>Assistance with Existing Database</td>
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<td>Case Report Form Development</td>
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<td>Survey/Questionnaire Design</td>
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1/14/2009
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*Task Statuses:
Pending, Active, Complete