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We are delighted to share with you the Fiscal Year (FY) 2014 annual report of The Clinical Research Center (CRC) at Boston Children’s Hospital. Over the past year, we have strived to work efficiently and seamlessly with investigators and successfully meet the goals of our Center and the mission of our Institution. The Center directly supports a core mission of the hospital, to be the leading source of research and discovery and make significant contributions to the improvement of children’s health through CRC’s four primary areas of focus:

- clinical research methodology,
- assistance on research project initiation and implementation,
- resources for the conduct of clinical research visits and ancillary services, and
- education on clinical research methods and practice.

Our key accomplishments and activities for FY2014 include:

- Services provided for 171 new requests for assistance from 127 researchers and 101 consultations from 82 researchers broadly distributed across 28 Departments and Divisions of the Hospital.
- Successful collaborations with BCH investigators on 123 funded projects, totaling $1,103,040 in direct support of CRC from extramural awards and internal grants.
- Strong support from and integration with Departments and Divisions with 24 shared faculty and staff and with funding totaling $1,449,282.
- Appreciation for the value of skilled research nursing, project management and study coordination resulting in 2989 CTSU ambulatory visits and 21 junior investigator projects supported by Harvard catalyst.
- Continued demand for clinical research education, with 13 courses or seminar offerings drawing 1262 registrants across 26 departments
- Scholarly productivity with 90 peer-reviewed publications that were co-authored by CRC faculty and staff.
- Growth in staff, resources, and much more to support clinical and translational research (See “What’s New” on pages6 and 7)

As the 2014 fiscal year closes, we would like to recognize the support from our collaborators and take pride in the work we have accomplished together.

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

Take pride in how far you have come. Have faith in how far you can go!

Michael Josephson
The Center seeks to be a state-of-the-art, dynamic, and integrated clinical research program that provides leadership, infrastructure, and resources to support patient-centered studies.

Its mission is to promote excellence and quality in clinical research methods, to encourage best practices in clinical study implementation, and to empower investigators to conduct high quality independent research.

**Scientific Leadership:** To provide scientific leadership and expertise on the design, conduct, analysis, and reporting of clinical research studies.

**Education and Training:** To provide education, training and mentoring to the clinical researcher community on clinical research methods and study implementation best practices.

**Scientific Collaboration and Consultation:** To serve as active scientific collaborators on hospital research initiatives and provide consultation services and/or collaboration in support of the design, conduct, analysis and reporting of clinical research studies.

**Research:** To conduct independent research that serves to innovate and advance methodology in statistical design and analysis, survey and data collection methods, electronic data capture methods, and clinical research information technology.

**Integration:** To provide a formal interdisciplinary home that links faculty members from the Center with various Departments and Divisions throughout the Hospital.

**Growth:** To assist Departments and Divisions throughout the Hospital in recruiting and mentoring faculty members who are engaged in clinical research.

**Professional Development:** To support the professional development of our faculty and staff so that they may cultivate their skills and advance their careers.
The CRC is an institutional Center organized into four functional teams: the Design & Analysis Core (DAC), Education Core, Development & Operations Core (DOC), and Clinical and Translational Study Unit (CTSU). The teams work together to assist investigators in conducting all phases of clinical research from design to implementation to analysis and reporting of results.

Institutional support is provided for limited guidance to investigators who have unfunded studies, while greater involvement is provided for collaborative relationships and funded projects. Requests for consultations or services can be made online at http://www.childrenshospital.org/research-and-innovation/research/clinical/clinical-research-center
The clinical and translational research enterprise saw many new important initiatives as well as increases in staff and resources both internally and externally to the Center. These important efforts continue to support investigators conduct innovative, safe, and high quality clinical and translational research at BCH.

- The CTSU expanded its room capacity, hours and staffing: 2 existing consult rooms have been equipped to serve as either consult rooms or exam rooms; 2 FTE’s of additional nursing staff was hired to accommodate the volume and complexity of study visits that require research nursing support; and hours of operation have been extended to 6 pm on Monday through Thursday and 2 Saturdays each month. Fast track phlebotomy service is now available by appointment or drop-in with minimal to no wait time.

- The CTSU introduced a new scheduling system that allows study teams to independently schedule CTSU visits for study subjects.

- The CTSU nutrition team has joined a combined Harvard Catalyst nutrition research rotation for Dietetic Interns. This past year more than 30 Dietetic Interns spent a day under the mentorship of the Nutrition Research Manager at Boston Children’s Hospital.

- Harvard Catalyst launched the Medical Research Officer Program at each site designed to help both new and established researchers navigate the process of finding clinical research collaborators, conducting cross-institutional research, and obtaining medical oversight for tests and procedures that require a credentialed provider.

- The Center expanded its weekly “triage” meetings to include Biostatistics, Research Nursing, Project management, and Clinical Research Informatics teams in the review of all requests for assistance and consultations.

- The Center added 2 FTE’s of nurse project managers provide research management services to interventional studies.

- The interactive Clinical Research Map was launched on the internal web landing page to help investigators navigate the complex landscape of services and administrative infrastructure at Boston Children’s.
The Center for Human Cell Therapy laboratory was expanded to serve as the Translational Lab. The Trans Lab conducts laboratory assays and process and product development (PPD) of assays and biological reagents for clinical trials.

The Center developed a proposal to increase space available for high volume, low intensity studies. More to come in FY15.

The Center recovered significant unspent CTSA grant funding to provide additional resources and staff for clinical research.

Access to study protocols was expanded to nurses caring for patients enrolled in interventional trials with drugs or devices in order to improve their understanding of drug, dose, route, and potential adverse effects as well research laboratory specimen acquisition requirements.

The hospital increased support for use of InForm technology, which eliminated the investigator user fee and provided 1 FTE of a dedicated programmer for InForm.

The Clinical Research Informatics Team has made available increased capabilities of REDCap, which can now connect directly to the Enterprise Data Warehouse to extract and save selected data directly into research databases.

A senior faculty advisory committee was assembled to help guide the goals and activities of the Center. Members are Drs. Scott Pomeroy, Jane Newburger, Rick Malley, Pedro del Nido, and Mark Schuster.
The Center received financial support from multiple sources totaling $5,677,778 with strong commitments from the Institution, Departments and Harvard Catalyst (NIH Funded, Clinical and Translational Science Award).

**FY 14 Center Funding Sources and Expenses**

Funding from extramural grants, industry and internal awards totaled $1,103,040 and supported CRC staff on **123 projects**. Among the **123 projects**, NIH/Federal grants (n=51) were the primary source of funding, followed by funding from Foundations (n=32) and Internal Awards (n=27) and Industry (n=13).
During FY2014, the Design and Analysis Core and Development and Operations Core received 171 new requests for services and 101 requests for brief consultations from 127 and 82 Boston Children’s Hospital faculty or staff, respectively distributed across all ranks of faculty. The requests were broadly distributed across 28 hospital departments and divisions.
The Clinical and Translational Study Unit had 133 active and enrolling protocols from 18 different Departments and Divisions in FY 2014 with nearly 3000 ambulatory visits. More than half (56%) of the investigators receiving services were Junior Investigators.

The CTSU Nutrition Team has provided a variety of services including preparing double-blind, placebo-controlled food challenges, measuring resting energy expenditure via indirect calorimetry, and measuring body composition with Bioelectrical Impedance Analysis (BIA) and skinfold measurements. In collaboration with the GI/Nutrition department, the CTSU offers body composition measurement using air displacement plethysmography with the new BOD POD machine; over 65 tests were performed in the last year. The team has also analyzed more than 700 food recalls for several nutrition protocols.
The Clinical Research Education Core hosted 13 courses and seminars with 1262 registrants designed to teach the fundamentals of study design, analysis, and management as well as more advanced analysis methods. Attendees were from 26 departments and divisions across the hospital. The first annual CRC Poster Day was held during the Introduction to Clinical Research Course. CRC staff had an opportunity to showcase their work to attendees.

The Education Core was also proud to continue to host the Clinical Research Center Grand Rounds, a monthly session featuring speakers from across the hospital. The goal of Grand Rounds is to provide a series of state of the art sessions at the cutting edge of clinical and translational research, with the goal of educating and inspiring the clinical research community.

### Title Number

- **Introduction to Clinical Research**: 71
- **Orientation for New Study Coordinators**: 103
- **Coordinator Rounds**: 171
- **Introduction to Biostatistics with SPSS**: 101
- **Introduction to Regression Analysis**: 29
- **Introduction to Longitudinal Analysis**: 18
- **REDCap Information Session**: 86
- **i2b2 Information Sessions**: 37
- **Art and Anatomy of a Career Development Grant**: 152
- **CRC Grand Rounds**: 407
- **REDCap How To: Building a Database**: 27
- **Economic Evaluation in Healthcare Research**: 38
- **Survey Development and Validation**: 22
- **Total Registrations**: 1262

### Distribution of Number of Course Attendees

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**Surgery**: 41
- **Psychiatry**: 17
- **Orthopedics**: 15
- **Nuclear Medicine**: 10
- **Neurology**: 65
- **Med-Pulmonary**: 15
- **Med-Newborn**: 15
- **Med-Nephrology**: 10
- **Med-Infectious Diseases**: 9
- **Med-Heme/Onc**: 20
- **Med-Gastroenterology**: 28
- **Med-General Pediatrics**: 14
- **Med-Gastroenterology**: 28
- **Med-Genetics**: 32
- **Critical Care**: 12
- **Cardiology**: 46
- **Anesthesia**: 36
- **Urology**: 41
- **PT/OT**: 4
- **Lab Medicine**: 7
- **Med-Adolescent**: 11
- **Med-Developmental**: 35
- **Med-Emergency**: 19
- **Med-Endocrinology**: 15
- **Med-General Pediatrics**: 14
- **Med-Immunology**: 21
- **Med-Heme/Onc**: 20
- **Med-Gastroenterology**: 28
- **Med-Genetics**: 32

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Special Thanks to all the CRC Grand Rounds Speakers from FY14

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Agus, MD</td>
<td>Designing Multicenter Interventional Trials in the Pediatric ICU</td>
</tr>
<tr>
<td>Christopher Duggan, MD, MPH</td>
<td>Maternal and Child Health in India</td>
</tr>
<tr>
<td>Chris Landrigan, MD, MPH</td>
<td>Building a Better Academic Healthcare System</td>
</tr>
<tr>
<td>Walter Kaufmann, MD</td>
<td>Clinical Trials in Neurodevelopmental Disorders</td>
</tr>
<tr>
<td>Douglas Perrin, PhD</td>
<td>3D Echocardiography: Fast Frame Rate Technology</td>
</tr>
<tr>
<td>Jonathan Mansbach, MD MPH</td>
<td>The Pathway From Bronchiolitis to Wheezing &amp; Asthma</td>
</tr>
<tr>
<td>Kenneth Mandl, MD MPH</td>
<td>The Power of Shared Data</td>
</tr>
<tr>
<td>Susan Kornetsky, MPH</td>
<td>The Boston Children’s Hospital Institutional Review Board</td>
</tr>
<tr>
<td>Caleb Nelson, MD, MPH</td>
<td>UTI Screening Tests</td>
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</tbody>
</table>

CRC POSTER DAY

![CRC POSTER DAY Image 1](image1)

![CRC POSTER DAY Image 2](image2)
Harvard Catalyst targets junior investigators by subsidizing up to 200 hours of project management and/or study coordinator services to help get their projects started and running smoothly. Study Coordinators and Project Managers perform a wide variety of services, including recruitment of patients, case report form development, and data entry/management. Development and Operations Core staff provided this valuable support to the following 21 Investigators from 11 departments and divisions.

<table>
<thead>
<tr>
<th>PI</th>
<th>Title</th>
<th>Dept/Division</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blum, Richard</td>
<td>Simulation Assessment of Performance of First Year Anesthesia Residents to Ensure Minimum Competence</td>
<td>Anesthesia</td>
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<tr>
<td>Maleki, Nasim</td>
<td>Understanding the Role of Puberty in Migraine Evolution in Girls: Neuroendocrine, Neuroanatomical and Neurofunctional Interactions</td>
<td>Anesthesia</td>
</tr>
<tr>
<td>Wu, Fred</td>
<td>Improving Functional Capacity in Fontan patients through inspiratory muscle training</td>
<td>Cardiology</td>
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<tr>
<td>Fida, Zameera</td>
<td>An Analysis of School Time Missed Due to Dental Care</td>
<td>Dentistry</td>
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<tr>
<td>Duncan, Christina</td>
<td>Collection of Mobilized Peripheral Blood Stem Cells from Adult Volunteer Donors</td>
<td>Heme/Onc</td>
</tr>
<tr>
<td>Grace, Rachael</td>
<td>ICON1: Physician Treatment Decisions for Idiopathic Thrombocytopenia Purpura</td>
<td>Heme/Onc</td>
</tr>
<tr>
<td>Biddinger, Sudha</td>
<td>Assessing the pathogenesis of Dyslipidemia in Diabetes: A comparison of PCSK9 levels in Youth with Type 1 and Type 2 Diabetes</td>
<td>Endocrinology</td>
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<tr>
<td>Huang, Stephen</td>
<td>Modified Shirmir Test for Long-term Sequelae of Radio-iodine Therapy</td>
<td>Endocrinology</td>
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<tr>
<td>Swartz, Jonathan</td>
<td>Whole Exome Sequencing and Genomics in Disorders of Sex Development</td>
<td>Endocrinology</td>
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<td>Thaker, Vidhu</td>
<td>Genetics of Early Childhood Obesity</td>
<td>Endocrinology</td>
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<tr>
<td>Uluer, Ahmet</td>
<td>Urinary Biomarkers in Early Detection of Nephrotoxicity in Pediatric and Adult Cystic Fibrosis Patients</td>
<td>Endocrinology</td>
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<tr>
<td>Berry, Jay</td>
<td>Prototyping a Mobile, Web-based Integrated Care Plan Application</td>
<td>General Pediatrics</td>
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<td>Russell, George</td>
<td>Fecal Microbiota Transplant (FMT) for the Treatment of Pediatric Active Ulcerative Colitis/Crohn's Colitis</td>
<td>Gastroenterology</td>
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<tr>
<td>Rhein, Lawrence</td>
<td>Oxygen Wearing Recorded Home Oximetry to Optimize Oxygen Wearing in Premature Infants</td>
<td>Pulmonary</td>
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<tr>
<td>Loddenkemper, Tobias</td>
<td>Rufinamide Add-on Therapy for Epileptic Seizures</td>
<td>Neurology</td>
</tr>
<tr>
<td>Spence, Sarah</td>
<td>Treatment of epileptiform discharges in children with ASD</td>
<td>Neurology</td>
</tr>
<tr>
<td>Simons, Laura</td>
<td>Screening for pediatric chronic pain prognostic indicators and severity</td>
<td>Psychiatry</td>
</tr>
<tr>
<td>DeGrazia, Michele</td>
<td>Brain Characteristics Prior to and Following Treatment of Right-sided Deformational Plagiocephaly with a Helmet</td>
<td>Pt Care/ Nursing</td>
</tr>
<tr>
<td>Freiberger, Dawn</td>
<td>How Does Pre-Transplant Physical Condition Correlate with Post Lung Transplant?</td>
<td>Pt Care/ Nursing</td>
</tr>
<tr>
<td>Kulik, Lynda</td>
<td>Predicting Pressure Ulcer Risk</td>
<td>Pt Care/ Nursing</td>
</tr>
<tr>
<td>McCabe, Margaret</td>
<td>Fatigue and Tiredness in Hospitalized Children: Does environment matter?</td>
<td>Pt Care/ Nursing</td>
</tr>
</tbody>
</table>
The **Behavior Core**, Directed by Deborah Waber, Ph.D. and co-directed by Michelle Bosquet, Ph.D., supports behavioral science studies, providing cost efficient data collection, scoring and data basing, as well as written feedback to families. It also provides consultation to investigators who are planning protocols and grants that include behavioral outcome measures. The service is especially helpful for investigators who are participating in multi-site trials but do not have dedicated staff with expertise to perform the behavioral component of the protocol. Last year the Core supported 34 patient visits from 5 multi-site trials, as well as 2 consultations.

**AFFILIATED CORES**

**STAFF RECOGNITION**

**Tanya Logvinenko** (as first author) was awarded the Prize for Best Clinical Science at the Society for Pediatric Urology Fall Congress in 2014 (coauthored by Dr. Caleb Nelson and Dr. Jeanne Chow).

**Caterina Stamoulis** was awarded a Brain EAGER grant from the National Science Foundation for transformative research in Neuroscience. The project aims to characterize neural dynamics in the developing human brain during the first 3 years of life.

**Stavroula Osganian** was awarded a grant from the Milton Foundation to support the collection of biopsychosocial data and establish a biospecimen repository for the POOL Research Registry, a registry of obese and overweight youth from BCH.
Annually, we survey BCH investigators and staff who requested services or participated in its courses to gather valuable feedback on the value and quality of our efforts. The overall response rate was 23% (172 respondents) and included a broad representation of various positions including research faculty (47.1%), trainees (6.4%), research assistants (13.4%) study coordinators (20.3%) and other research staff (15.2%). The percentage of respondents who strongly agreed or agreed with each statement below reinforce the value-added of the Center services and highlight the responsiveness of the staff as well the need to improve processes for accessing services. In addition, 74% responded “yes” that they are likely to use the CRC in the future, while 20% may do so in the future.

- The assistance was valuable in terms of enhancing the quality of the science and methods of my study: 86%
- The process for receiving assistance was clear and well organized: 67%
- The faculty and staff worked with me in a responsive and professional manner: 87%
- I received assistance in a timely manner: 83%
The Center welcomed Dr. David A. Williams as Director of Clinical and Translational Research for BCH, Dr. Judy Fleming, as administrative director for the Center, and Dr. Lise Nigrovic as Director of the Clinical Research Education Core. Other new faculty and staff included two new DAC members: Dr. David N. Williams and Dr. Kosuke Kawai; three new CTSU members: Eorna Maguire, Clinical Assistant, Karen Jones, Staff nurse and Maggie Malsch, Research Nurse Project Manager and three new DOC members: Tess Buccigrosso, Lindsay Toto and Ann Bailey.

The Center bid a fond farewell to its co-Chief, Dr. Ellis Neufeld and Dr. Robert Fuhlbrigge, MD, PhD, who served as the CTSU’s Medical Director. Colette Hendricks, CRC administrative director took a new position at Harvard Medical School as Director of Operations for Harvard Catalyst. Dr. Andrew Dauber, who served as Assistant Medical Director of the CTSU relocated to Cincinnati where he accepted a faculty position at Cincinnati Children’s Hospital Medical Center. Dr. Jennifer Lightdale, who served as the Clinical Research Education Director took the position of Director of Gastroenterology in the Department of Pediatrics at UMASS Medical Center. Our warmest thanks go out to all of them for their contributions to the Center and our best wishes for success in their new endeavors.
Center Leadership and Administration
Stavroula Osganian, MD, ScD, MPH, Chief
Judy Fleming, PhD, Interim Administrative Director
Christina DeFranceaux, MS, Program Coordinator

Clinical and Translational Study Unit
David Williams, MD, Interim CTSU Program Director
Cindy Williams, DNP, MSN, RN, PNP, NE-BC, Nurse Director, CTSU
Judy Fleming, PhD, Administrative Director CTSU
Voula Osganian, MD, ScD, MPH, Medical Research Officer
Nicole Quinn, MS, RD, LDN, Nutrition Manager
Ivy Dang, Staff nurse
Joanna Sullivan, Staff nurse
Kyla Almeida, Staff nurse
Courtney Jordan, Staff nurse
Karen Jones, Staff nurse
Eorna Maguire, Clinical Assistant
Laura Feloney, Laboratory Technician
Stephanie Patriarca, Clinical Assistant
Tina Kim, Administrative Associate
Chelsea Tyler, Administrative Associate
Kayla Arouchon, Diet Technician

Development and Operations Core
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Edwin Anderson, BA, Clinical Research Specialist
Ann Bailey, BS, Clinical Research Specialist
Tess Buccigrosso, BA, Clinical Research Coordinator
Kimberly Chin, BA, Clinical Data Manager
Erica Denhoff, MPH, Clinical Research Specialist II
Gloria Faboyede, MPH, Clinical Research Coordinator
Hana Gragg, MPH, Clinical Trial Manager
Andrea Hale, RN, Nurse Project Manager
Prajakta Mangeshkar, MSc, MS, Clinical Research Specialist II
Molly McDonald, BA, Clinical Research Coordinator
Kara McLaughlin, BA, Clinical Research Coordinator
Emily Pariseau, BA, Clinical Research Coordinator
Lindsay Toto, BS, Clinical Research Specialist

Clinical Research Education Core
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Erin Deneen, Education Program Coordinator

Design and Analysis Core
Michael Monuteaux, ScD, Scientific Director
Henry Feldman, PhD, Principal Biostatistician
Peter Forbes, MA, Senior Biostatistician
Jisun Jang, MA, Biostatistician
Leslie Kalish, ScD, Principal Biostatistician
Kush Kapur, PhD, Senior Biostatistician
Kosuke Kawai, PhD, Senior Biostatistician
Heather Litman PhD, , Senior Biostatistician
Tanya Logvinenko, PhD, Senior Biostatistician
Carly Milliren, MPH, Biostatistician
Paul Mitchell, MS, Senior Biostatistician
Carter Petty, MS, Senior Biostatistician
Mihail Samnaliev, PhD, Health Economist
Georgios Sideridis, PhD, Survey Methodologist
Caterina Stamoulis, PhD, Senior Biostatistician
Matthew White, PhD, Senior Biostatistician
David Williams, PhD, Senior Biostatistician
Kathryn Williams, MS, Senior Biostatistician


