Children's Hospital Boston

The Clinical Research Center

Life-changing care, World-changing research

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The Clinical Research Center
Who We Are

Vision
To be a state-of-the-art, dynamic, and integrated clinical research center that provides leadership, infrastructure, and resources to support patient-oriented studies.

Mission
The mission of The Clinical Research Center 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.

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 on clinical research methods and study implementation best practices.
- **Scientific Collaboration and Consultation**: To serve as active scientific collaborators with 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 develop their skills and advance their careers,

Values
The Clinical Research Center is committed to ensuring standardized and consistent best practices in clinical research methods, study conduct, data integrity, and the design of ethical protocols for all human subjects.

The Clinical Research Center is committed to providing a positive and motivational work environment that fosters teamwork, mutual respect, integrity, responsiveness and concern for each project, with creative interaction at the interface between areas of science.

The Clinical Research Center is committed to fostering a culture of collaborative, interdisciplinary research of the highest quality, respecting the priorities of each contributing discipline while placing priority on excellence in the joint effort.

The Clinical Research Center
Accessing Resources

Available Support
The CRC has four Cores with the following areas of focus:

- ***Design & Analysis***: provide biostatistical expertise, methodological resources, scientific leadership while promoting excellence in the design and conduct of clinical research
- ***Development & Operations***: provide collaboration or consultation on the design, conduct, and analysis of clinical research studies and promote excellence in clinical research practice
- ***Education***: provide integrated, useful, scientifically accurate education curriculum in clinical research methods and practice to enhance the quality of clinical research
- ***CTSU (Clinical & Translational Study Unit)***: provide state-of-the-art clinical research facilities and expertise to faculty who conduct human studies with the goal of translating scientific knowledge into new therapies for pediatric conditions.

Accessing Support
For assistance from The CRC, complete an intake request online at http://crit-apps/crp.intake/Public/IntakeRequest.aspx. If you have any questions, please call 857-218-4720.

Requirement for Consultation
It is expected that all projects supported by The CRC will require an initial consultation with the Center's staff. The requirement for a consultation may be waived at the discretion of Center staff.

What to Expect at an Initial Consultation
Investigators should expect to meet with one of our experienced staff members, during which time we will conduct a project review and a comprehensive needs assessment. For faculty without significant research experience, including those who have not previously been a PI on an R01 or similar project, and for trainees, we request that they be accompanied by an experienced researcher who is acting as the mentor or preceptor. At the end of the initial meeting, a written plan of support and timeline will be developed and will be communicated within 5 business days.

Timeline/Work Scope
After requesting support, a Center staff manager will make outreach to the requestor and PI within 2 business days to confirm the request and begin the triage process. Within 3 business days and after the request confirmation, a Center project lead will be assigned and the triage process will begin, i.e. an initial consultation is scheduled.

If the request is for review of a protocol, manuscript or grant, initial review will usually occur within 2 weeks of the initial contact. For analyses or other more detailed needs, a timeline/work scope will be established at the initial consultation that will be scheduled by the Center project lead.

Because there are always competing demands on support, investigators are expected to work with us to help meet their deadlines. Any timelines/work scopes set up for providing data, protocol drafts or otherwise disseminating necessary information must be strictly adhered to, or a revised timeline/work scope will need to be established.

It remains the responsibility of the investigator to ensure that all activities move forward with the timeline/work scope required for the project. The Center staff will endeavor to satisfy investigators' needs, but may not be able to satisfy unrealistic deadlines.

It is recommended that investigators plan ahead for requests that require significant contributions from Center staff, ideally submit request for services at least 3 months in advance of grant application and manuscript/presentation deadlines and 6 months in advance of when a study is expected to start recruiting.

Center staff are available to meet with investigators Monday through Friday from 8:30am to 5:00pm. On rare occasion, extenuating circumstances may require a meeting/work performed outside of normal business hours but should be scheduled at a mutually convenient time. We ask for flexibility from investigators when this is required.

Tracking and Review of Projects

It is The CRC's policy to track all research projects through a database and project management software system maintained by the Center. Time and activities spent on a project are tracked, as well as periodic QA assessments evaluating the efficiency and the quality of the Center's work. On completion of projects, the record is archived.

User Surveys and Feedback

To meet reporting requirements and to maximize support, all investigators will be asked to provide feedback about the support they received from The CRC during the course of their project. For most, this will be a phone or email conversation with the Core Director/Manager.

In addition to formal evaluations, users are encouraged to provide any feedback, either positive or constructive. This can be done confidentially by contacting Colette Hendricks (Colette.hendricks@childrens.harvard.edu). Grievances or concerns will initially be addressed by the Co-Chiefs of the Center and, if they remain unresolved, will be addressed by The CRC Executive Committee.

Paying for Support/Billing Plans

The Center is able to offer one hour free per project per Core of consultative support with exceptions for Trainees with Scholarship Requirements and Applications for Extramural Funding as described in our Billing Plan Policy. See page 5 for more details regarding our billing plans. See page 10-11 for our Cost Recovery Policy and current FY11 rates.

Acknowledging Support: Publications, Authorship, Acknowledgements/Citations

See page 9 for more details.

Prioritization

In general, consultation services will be provided on an as needed, first come, first served basis, facilitated by the Center staff. However, higher priority will be assigned to those consults for investigators developing applications for funded research. Fee-for-service work conducted by the Center will receive higher priority than consultative services if there are competing deadlines and limited resources. Up to one hour of free consultation will be given for all CHB faculty, nurse scientists, other professional research staff, and trainees without scholarship requirements.

Services provided by co-funded Center staff will be prioritized in consultation with the department's or division's leadership in order to meet their specific research goals and priorities.

The Clinical Research Center
Billing Plans, as of March 2012

CHB HOSPITAL SUPPORTED ACTIVITIES

CHB Research Faculty

Departments/Divisions/Programs that co-fund CRC staff

- Up to one hour free per project per Core of consultative support (not including Core of co-funded staff)
- Work scope and budget created for any future work, i.e. beyond 1 hour
- Training/Extramural scholarship fee waived if co-fund PhD statistician
- Extramural grant application support fee waived if the application would fund relevant CRC faculty and staff

Departments/Division/Programs that do not co-fund CRC staff

- Up to one hour free per project per Core of consultative support
- Work scope and budget created for any future work, i.e. beyond 1 hour
- Extramural grant application support fee waived if the application will fund relevant CRC faculty/staff

Non-Faculty/Hospital Staff

- Up to one hour free per project per Core of consultative support (not including Core of co-funded staff)
- Work scope and budget created for any future work, i.e. beyond 1 hour
- Extramural Grant Application support
  - Basic plan: free, up to 2 hours
  - Intermediate plan: $500, maximum of 10 hours
  - Custom plan: cost determined on case-by-case basis; chief approval required; work scope and budget created

***Note: if your department/division co-funds a CRC staff member, please consult with your chair/chief.*

Trainees with Scholarship Requirements (e.g. Residents and Fellows)

- $500 per trainee (~15-20 hours) for advising on research design, study start-up and implementation needs, and analyses

***Note: if your department/division co-funds a CRC staff member, please consult with your chair/chief.*

All Hospital Faculty and Staff

- Educational seminars: attendance is free for all CRC-sponsored seminars and courses

HARVARD CATALYST GRANT SUPPORTED ACTIVITIES

Study Coordinator

- 200 “free” hours, then investigator pays hourly rate; only Junior investigators are eligible: Assistant Professor and Instructors

Nurse Coordinator

- Tiered-level plan—TBD, “free” hours offered or investigator pays hourly rate

Biostats Consults

- Postdoctoral fellows and faculty members eligible; services include: design consultation for IRB or grant submission; analysis planning & advice; response to scientific review. Typical consults require less than 10 hours and are completed within 3 months; separate budget and work scope are required for longer consultations

CTSU Core Patient Care

- Basic Nursing, Nutrition and Lab Processing (For lab: $30 Senior/$60 Junior Investigators subsidy)

SOFTWARE TECHNOLOGY VIA CLINICAL RESEARCH INFORMATION TECHNOLOGY (CRIT)

SPSS Data Collection

- $500/per study

INFORM

- $2,000 for first-time, Junior Investigator user
- $4,000 all others for Non-Industry Funded studies (per study/per year)
- $10,000 for Industry Funded studies (per study/per year)

The Clinical Research Center
Services Menu

Activities	Services Offered
Grants and Study Protocols	• Survey research design • Study/Clinical Trial design • Qualitative research design methods • Power and sample size calculations • Data Analysis methods • Data management methods • Contributions/Critique/review of grant proposals, grants or study protocols • Cost impact/effectiveness/Health Economics research design
Case Report Forms	• Case Report Form development, formatting and coding
Survey Instruments	• Survey instrument development, formatting and coding • Administration of web-based surveys
Databases	• Development of simple/complex, relational or customized research study databases • Database maintenance
Manuals of Operation	• Review/Writing and/or assembly of study manuals
Data Management	• Study ID assignment logs • Data entry and management • Data conversion/extraction for analyses
Project Management	• Review of study timelines, management plans and priorities • Project Director/Study Coordinator services
Randomization	• Randomization strategies • Randomization logs • Randomization envelopes
Data Analyses	• Interpretation of results • Data conversion/analysis file creation • Data set cleaning and verification • Data analyses • Survey data analyses • Qualitative data analyses • Cost impact/effectiveness/Health Economics data analyses • Critique/Review/Writing of manuscripts
Mentoring	• Mentoring
Patient Care	• Protocol design and implementation • Nursing, Nutrition and Specimen processing • Off-unit Research Nurse Coordinator support
Education*	• Seminars that meet the current educational needs of the CHB clinical research community

*Hospital-supported service

Note: Effective March 1, 2012, The Center is able to offer one hour free per project per Core of consultative support with exceptions for Trainees with Scholarship Requirements and Applications for Extramural Funding as described in our Billing Plan Policy.

The Clinical Research Center
Other Resources

Publications
Publications are important measures of the scientific contributions and productivity of CRC faculty and staff. In particular, authorship is important to the individual's academic promotion, recognition, and grant support as well as to the reputation of the Center. Investigators are asked to recognize CRC collaborators as co-authors on manuscripts when CRC faculty or staff have made substantial intellectual contributions to the work, or to acknowledge the CRC or its staff in all manuscripts where the CRC has provided other significant contributions to the work.

Authorship
CRC faculty or staff often work collaboratively with investigators and make substantial intellectual contributions to the work through contributions to conception and design, analysis and interpretation of data, and writing and editing of the manuscript. The CRC adheres to the authorship guidelines of Harvard Medical School as described in the HMS Faculty Handbook http://www.hms.harvard.edu/integrity/authorship.html with respect to determination of authorship and order of authorship. As explained in these guidelines, authorship is an explicit way of assigning responsibility and giving credit for intellectual work. When determining authorship, all authors should have made substantial intellectual contributions and participated in writing the manuscript by drafting sections and/or reviewing drafts, and by approving the final version. Research teams should discuss authorship with CRC faculty or staff frankly, early in the course of their work together to determine and agree upon their appropriate recognition.

Acknowledgements/Citations
Acknowledgements of the CRC or individual staff of the CRC can vary depending on the amount of space provided and the types of assistance provided. We suggest the following sample language for individual or Center recognition, respectively:

The authors thank <<n*ames of staff*>> in the Clinical Research Center at Children's Hospital Boston for their support and assistance with << *list activities*>>:

Or

The authors thank the Clinical Research Center at Children's Hospital Boston for its support and assistance with <<*list activities*>>.

Or

The CRC is also funded in part by the National Institutes of Health Clinical and Translational Science Award (CTSA). All projects supported by the Center that receive Catalyst support that are being disseminated for public review must include the following text:

> *This work was conducted with support from Harvard Catalyst | The Harvard Clinical and Translational Science Center (NIH Award #UL1 RR 025758 and financial contributions from Harvard University and its affiliated academic health care centers). The content is solely the responsibility of the authors and does not necessarily represent the official views of Harvard Catalyst, Harvard University and its affiliated academic health care centers, the National Center for Research Resources, or the National Institutes of Health.*

Cost Recovery Policy
The CRC uses two methods of cost recovery for work conducted by its staff and faculty on grants, contracts or other departmentally or externally funded projects:

1. Charging staff salary directly to grants or contracts through the hospital's salary allocation procedures (Employee Change Form, ECF).
2. Billing or invoicing for staff time on an hourly basis

In the case of departmental funding and most foundation grants, CRC generally prefers method 1, because it facilitates planning, staffing, and cost recovery, and because it is most consonant with the professional level of contributions that CRC staff typically make.

In the case of federal grants, strict rules apply. CRC staff effort must be charged through an ECF change (method 1) if any of the following applies:

- the CRC staff member is listed as key personnel; or
- the CRC staff member will be making significant scientific contributions to the project; or
- the CRC staff member is expected to be co-author on manuscripts.

Invoicing or billing for faculty or staff on federal grants (method 2) is allowed only under limited circumstances:

- none of the above conditions is met; and
- one of the following applies:
    - the CRC staff member has a short, concentrated period of time for the work to be completed (typically less than one year); or
    - the CRC staff member will work for less than 100 hours during any one-year period.

Current FY2011 Rates

ESTIMATED BILLING RATES FOR THE CLINICAL RESEARCH CENTER
February 2012 Update

These rates are for informational purposes only.
The following are the current average hourly billing rates for CRC staff. Hourly rates for specific staff will vary with level and experience of personnel. You MUST obtain a formal budget quote from The CRC for utilization of services before including CRC resources in a budget. Rates are subject to change at any time without prior notice.

	Average Hourly Rate Includes Fringe Benefit rate of 33%
BIOSTATISTICAL SERVICES	
PRINCIPAL BIOSTATISTICIAN (PhD)	$90
SENIOR BIOSTATISTICIAN (PhD)	$70
BIOSTATISTICIAN (Masters)	$53
STATISTICAL PROGRAMMER	$35
DATA MANAGEMENT SERVICES	
CLINICAL RESEARCH PROJECT MANAGER	$50
DATA MANAGER	$35
CLINICAL RESEARCH COORDINATOR	$30
CTSU OFF-UNIT NURSING / STUDY COORDINATOR SERVICES*	
NURSE	$85
STUDY COORDINATOR	$30
SURVEY SERVICES:	
SENIOR SURVEY METHODOLOGIST (PhD)	$63
SURVEY RESEARCH METHODS ASSOCIATE (Masters)	$38
CLINICAL RESEARCH INFORMATICS TEAM SERVICES:	
APPLICATION DEVELOPERS	$59
SOFTWARE TECHNOLOGY FEES	
SPSS DATA COLLECTION (per study)	$500
INFORM: NON-INDUSTRY FUNDED (per study/per year)	$2,000 for first-time, Junior Investigator $4,000 all others
INFORM: INDUSTRY FUNDED (per study/per year)	$10,000

*CTSU Off-unit study/nurse coordinator rates are actual, i.e. not average.