**Resources and Environment for Clinical Investigation**

The Harvard Catalyst is a pan-Harvard University enterprise dedicated to improving human health. Harvard Catalyst works with Harvard schools and the academic healthcare centers (hospitals) to build and grow an environment where discoveries are rapidly and efficiently translated to improve human health. Harvard Catalyst was founded in May 2008. The resources of the Harvard Catalyst are available to all faculties at Harvard regardless of their institutional affiliation or academic degree.

The Center for Clinical Investigation (CCI) at Brigham and Women's Hospital provides inpatient and outpatient units for clinical research, in addition to other resources.  The inpatient unit is located on the ninth floor of the Hospital Towers, (6,000 square feet).  The inpatient facility includes the Nutrition Core, Nursing Services, Specimen Processing and Phlebotomy, Intensive Physiologic Monitoring Unit and Standard Bed Units. In addition, there are resources in the Neonatal Intensive Care Unit, located in the Center for Women and Newborns.

There are three Ambulatory research units associated with the CCI.  The Ambulatory Clinical Center is located at 221 Longwood Avenue, (2,400 square feet) and is open 7:30 AM-4:00 PM on weekdays.  This location includes a waiting room, 5 examination rooms, a phlebotomy chair, staff workstation area, a metabolic kitchen, patient dining room, conference area, and a specimen processing laboratory with options for short term sample storage.

The Clinical Trial Center is located on the fourth floor of the original Peter Bent Brigham Hospital, (1,800 square feet) and is open from 7:00 AM-6:00 PM on weekdays. This space includes a reception area, four exam rooms, phlebotomy chair, and a specimen processing laboratory with long-term -80 freezer storage space.  There is also an Infusion Center with four rooms equipped to deliver controlled-rate intravenous infusions to patients with appropriate hemodynamic monitoring.

The Clinical Trials Hub is located on the third floor of the Hale Building for Transformative Medicine (1,466 square feet) and is open from 7:30 AM-4:00 PM on weekdays. This space includes a reception area, three exam rooms, a consult room, an infusion suite, and a laboratory for processing and storing specimens on a short-term basis.  There is also an Infusion Suite with three bays equipped to deliver controlled-rate intravenous infusions to patients with appropriate hemodynamic monitoring.

There is a network of over 25 computers that make up the C-SMART system used on the Intensive Physiologic Monitoring Unit.  The focus of the Informatics Core is to provide 24-hour availability of all user files, network programs, and data files to the Informatics Core, Core Lab, Dietary, Nursing, and Administration.

“The Nutrition and Metabolic Core operates nutrition services seven days per week, allowing continuous research support for all studies from 7:00 a.m. – 3:30 p.m.  The nutrition staff, which includes 3 full-time registered and licensed (in the Commonwealth of MA) Dietitians, are highly experienced in meeting the rigorous precision of the assessment and control of the dietary intake including: (1) controlled meal provision during both ambulatory and in-laboratory visits (2) detailed nutritional analysis and interpretation of meal intake; and (4) anthropometric measurements and questionnaire administration. The metabolic kitchen services both inpatient and outpatient studies, providing over 700 meals calculated and weighed meals per month.

The Biostatisticians provide statistical collaboration by performing the analyses and writing the methods and results sections of manuscripts, and answering any questions that arise in the editorial review process.  Informal consultations are also available. Areas of expertise include (but are not limited to) categorical data analysis, computational statistics, generalized linear models, longitudinal and dependent data analysis, multivariate data analysis, power analysis and design, randomization, regression diagnostics, and survival analysis. Each biostatistician has one computer with Microsoft Office 2010 (Word, Excel, PowerPoint, Outlook) and SAS, in addition to access to various other statistical packages. Further, all biostatisticians have access to REDCap v8.5.28 for data collection.

The Research Coordinator Network (RCNet) provides investigators with a source for reliable and experienced research coordinators for clinical investigation. Coordinators are on hand to work simultaneously on a variety of protocols throughout the hospital, on a part- or full-time basis.

There are three centralized clinical trials services devoted to initiating and conducting trials: The Data Management Core (DMC), Data Coordinating Center (DCC), and Clinical Trials Coordinating Center (CTCC). The DMC is a fee-for-service hourly model which includes case report form (CRF) development, data export services, data management, and database consultation. The DCC is a percent effort model as this requires a significant and continued effort through the entire life of the trial - from prior to study start until publication and includes the following services: database build, CRF development, data integration with other systems, data management, database documentation, report development and generation, data exports. The CTCC offers all of the DCC services but a host of other essential functions including site feasibility and selection, document development and maintenance (i.e., protocol, informed consent form, manual of operations, data management plan, data monitoring plan), regulatory oversight for multi-center trials, IND submission and reporting, trial master file development and maintenance, site activation, site training, study closeout, collaboration with biostatistics, data monitoring, establishing and managing committees (i.e., Steering Committee, Data and Safety Monitoring Board), and publication management.

The Center for Clinical Investigation (CCI) is a core service at Brigham and Women’s Hospital which offers extensive laboratory resources to investigators carrying out research. The CCI has three separate, fully equipped outpatient laboratories, as well as one fully equipped inpatient laboratory which is available to collect, process, ship, and store samples 24 hours a day 7 days a week. Each laboratory location houses both a refrigerated and room temperature centrifuge. Each location contains both a -80 freezer as well as a -20 freezer for short term sample storage. There is a 4C mini fridge available for short term storage as needed. The CCI also provides options for long term sample storage with two dedicated -80 freezers that are available to investigators upon request. All laboratory locations are fully stocked with dry ice and basic supplies which can be used for both sample processing and shipment as needed.

CCI lab facilities and processing equipment are available for study team use, however, the CCI can also provide personnel support with four experienced, certified phlebotomists on staff who can collect, process, store or ship samples as per the study team’s direction. In addition to simple processing, dedicated laboratory technicians also provide advanced support for PBMC processing as needed. At the inpatient lab facility CCI technicians can also support glucose analysis using YSI and Hemocue equipment.