ICTR Resources and Support for Commercially Sponsored Studies

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ICTR Research Navigator Service
Objectives

- Provide a general introduction to the ICTR
- Highlight ICTR resources that will promote study success
- Demonstrate the steps in accessing ICTR programs and services
- Established in 2007

- Member of the Clinical and Translational Science Awards (CTSA) program of the NIH National Center for Advancing Translational Sciences (NCATS)

- Working to improve the way biomedical research is conducted across the country.
The ICTR has more than 50 programs, services and resources available to support both investigator-initiated and commercially sponsored research. This is an overview of select resources from several of the ICTR cores that may be of interest to those doing research with corporate sponsors.
Center for Clinical Data Analysis (CCDA)

This center provides exploratory data access, data extraction, and development support to the clinical research community.

- Capable of providing clinical & administrative data from a variety of data sources
- Works with client to ensure appropriate data stewardship (IRB approval, data quality/relevancy)
- Manages the security of delivered data
- Services are rendered on an hourly charge basis after an initial no-charge consultation

I2B2 (currently in beta testing)

Provides researchers access to de-identified EPIC clinical data for use in projecting enrollment and determining feasibility of reaching target populations and recruitment goals.

- accelerate study recruitment planning
- develop queries to assess the feasibility of reaching target population & recruitment goals
- Upcoming workshop 4/17/15!
Clinical Research Management System (CRMS)

CRMS is a web-based enterprise-wide application designed to organize and streamline clinical research data.

**CRMS supports:**
- electronic eligibility checklists
- interfaces and integrates with e-IRB and EPIC
- tracks signed consent forms
- store subject enrollment information in a secure location
- run real-time reports
Epic for Clinical Research

Epic is the electronic medical record and primary clinical care system for Johns Hopkins.

Researchers use Epic in many ways including:
• Scheduling and registering patients for a research visit
• Research charge handling
• Research meds
• Study registries
Human Subjects Research Core
Study Coordinator Apprenticeship and Mentoring Program (SCAMP)

The ICTR Study Coordinator Apprenticeship and Mentoring Program (SCAMP) is a two year internship program that trains inexperienced individuals to become study coordinators.

- Structured training program (education component)
- Shadow experienced study coordinators and get hands-on training experience
- Study coordinating assignments under the supervision of SCAMP Manager
- Available for hire to JHU faculty (resource component)
  - One time 50 hours free service followed by fee-for-service $33/hour
- At the end of 2 year internship, SCAMPS sit for their SOCRA certification
Research Coordinator Support Service (RCSS)

After internship completion, SCAMPS who wish to do so may enter Research Coordinator Support Service pool of study coordinators available for hire on a part time basis by Johns Hopkins faculty.

- a pool of experienced study coordinators (RCSS) available to be hired on a part time basis by Johns Hopkins faculty
- $33/hour fee-for-service
- Currently two coordinators in the RCSS pool

NOTE: 50 free hours of support is offered one time per investigator utilizing the SCAMP program and does not extend to hiring of SCs from the RCSS pool
Research Coordinator Support Service (RCSS)

- Currently a total of 10 SC’s within RCSS (including SCAMP apprentices)
- Due to program popularity, they are expanding the SCAMP and bringing on an additional cohort of 4 hires this month.
- These individuals will be available to start taking assignments in June 2015.
- The fall cohort of 4 will be able to start assignments in late December.
- Submit requests for Study Coordinator support as early as possible.
Clinical Research Units

The ICTR's Clinical Research Units (CRUs) can provide clinical resources needed to accomplish clinical research. The CRUs offer inpatient beds, outpatient clinic space, and dedicated research nursing staff at both the Johns Hopkins Hospital and the Bayview Medical Center.

- Pediatric Clinical Research Unit (PCRU - Inpatient & Outpatient)
- Bayview Clinical Research Unit (Bayview CRU - Inpatient & Outpatient)
- East Baltimore Campus Adult Clinical Research Units (Inpatient & Outpatient)
- Neurobehavioral Research Unit (NBRU-KKI Kirby Center)

- Use of any of the Clinical Research Unit facilities requires an application and approval separate from the JHM/JHSPH IRBs via the CRU Online system.

- Trials with commercial sponsors will be charged a protocol review fee as well as fees for ancillary testing, nursing time, phlebotomy services and room charges. Contact CRUs@jhmi.edu for associated fees when preparing your study budget.
Exercise Physiology/ Body Composition Lab (JHBMG, GSS, EBMC)

• DEXA measurements for body fat, muscle and bone composition
• Stress testing
• Anthropometric and body composition studies

Cardiovascular Imaging Laboratory (CRU)

• Echocardiogram
• Brachial reactivity studies
• Carotid IMT (intima-medial thickness)

Neurobehavioral Research Unit (NBRU)-KKI Kirby Center

• Functional MRI
• Motion Analysis Laboratory
• Neuroimaging
• Neuropsychological Testing

And more....
Research Participant and Community Partnerships Core (RPCP)
Research Participant Recruitment and Community Engagement Programs

The Research Participant Recruitment Program is designed to facilitate the recruitment and retention of study participants into research activities throughout the Johns Hopkins Medical Institutions.

- Developing a recruitment plan
- Developing a concise description of a target population
- Reaching out to target populations
- Reaching out to minority or underserved populations
- Budgeting for recruitment and retention efforts
- Marketing and advertising
- Tracking recruitment and retention
- Participant incentives
- Assistance identifying potential community partners
‘Ask a Navigator’ Service

Assists investigators, research teams, and staff with identification of resources needed for successful completion of research projects, such as:

- Information about and referral to other ICTR sponsored programs and events
- Application of institutional policies and guidelines for approval and implementation of research
- Navigation of the eIRB, CRU online, and JHSPH IRB systems
- Identification of available support and possible funding sources
ICTR Home Page:
http://ictr.johnshopkins.edu/
ICTR

How to Access ICTR Services & Resources

Connection Request System
Log in with JHED ID and password
Choose from the list of ICTR resources
CLINICAL RESEARCH MANAGEMENT SYSTEM (CRMS)

CRMS is a web-based tool designed to organize and streamline clinical research management. It is designed to improve communication among study team members, store subject enrollment information in a secure location, and run real-time reports.

Accessible by JHED ID, CRMS supports electronic eligibility checklists, integrates with eIRB, and tracks signed consent forms. It allows for electronic eligibility checklists, integrates with eIRB, and tracks consents signed. It is designed to improve communication among study team members, store subject enrollment information in a secure location, and run real-time reports.

If you are already a CRMS user, you can access the software at https://research.jhmi.edu.

CONTACT

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News

Tailored Recruitment Workshop: April 17
Recruitment & i2b2: A Hands on Introductory Workshop...
Cloud Storage Security Flaw Uncovered
CTSA Tool Shop Webinar July 18: The Murdock Study
Memory Formation

Section Pages

Clinical Resources
Human Subjects Research Core
ICTR Home Page:  
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For questions or more information about any ICTR research resources, please submit an ICTR Connection Request to the ‘Ask a Navigator’ service