Johns Hopkins Institute for Clinical and Translational Research
A CTSA Program
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Vice Dean for Clinical Investigation

Translational Pathway

- Basic Discovery
- Mechanistic Studies
- Initial Human Testing
- Proof of Efficacy
- Proof of Effectiveness
- Diffusion to All Health Care Settings
Institute for Clinical and Translational Research

Influence on Scientific Discovery

Research Education and Training

- Enhancing Observation
- Formulation of Scientific Question
- Creation of Research Team
- Development of Study Protocol
- Conduct of Study
- Analysis of Study Data
- Publication Impact Study

Institute Programs

- Advisory Boards
- Protocol Review
- Translational Science Forums
- Science Cores
- Innovation Groups
- Biostatistical Support
- Regulatory Support
- ATIP
- Research Ethics
- Clinical Research Units
- Clinical Research Participant Core
- Data/Safety Monitoring
- Community Engagement Program
- Biomedical Informatics
- Navigator Program

Deputy Directors of the Institute for Clinical and Translational Research

- Dr. Karen Bandeen-Roche
- Dr. Cheryl Dennison Himmelfarb
- Dr. Stephen Desiderio
- Dr. Charles Flexner
- Dr. Elizabeth Jaffee
- Dr. Pete Miller
- Dr. Pamela Ouyang
- Dr. Jeffrey Rothstein
- Dr. Darius Tandon
- Dr. Pamela Zeitlin
**Johns Hopkins ICTR**  
**Participating Schools**

- School of Business  
- School of Engineering  
- School of Medicine  
- School of Nursing  
- School of Public Health

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**Research Education, Training, and Career Development**

**Leaders:** Pete Miller, Franklin Adkinson, Ebony Bouleware, Mary Catherine Beach, Jeri Allen

- Coordinates clinical and translational research training throughout Johns Hopkins  
- Administers formal degree granting programs in clinical research (Graduate Program in Clinical Investigation, Clinical Epidemiology Program)  
- Administers predoctoral (TL), postdoctoral (KL) and junior faculty (KL) training awards in clinical and translational research  
- Coordinates summer and elective experiences in clinical and translational research for medical and nursing students  
- Curriculum design, innovation and development of problem/case and/or team based modules in clinical research  
- Provides technical assistance on study design, study implementation, data collection, data management and data analysis to clinical and translational research trainees in the formal program
### Clinical Research Units

**Leaders:** Pamela Ouyang (Bayview), Charles Flexner (JHH Broadway), Pamela Zeitlin (Pediatrics), Michael Cataldo (Neurobehavioral KKI)

- Continue to provide the “laboratory” in which over 260 active clinical research protocols currently being accomplished
- Inpatient and Outpatient facilities on the Broadway and Bayview campuses (both adult and pediatric); sleep units (Pediatric at Broadway, Adult at the Bayview campus)
- Emphasis on investigator-initiated protocols
- Provide thorough peer review prior to study initiation
- Support investigators with trained research nurses, phlebotomists, and interviewers
- Support investigators with computing (including system manager), full nutrition staff and consultations.
- Support investigators by funding limited laboratory and imaging costs

### Clinical Research Units

- Provide specialized services such as exercise (Bayview/GSS), body composition, CV imaging (Bayview), and a Core Laboratory for research immunoassays, mucociliary clearance laboratory, flexible bronchoscopy, BAL and infant lung function laboratory (Pediatrics)
- Provide specimen processing
- Neurobehavioral CRU (Kennedy Krieger) with functional MRI facilities is also available to researchers
## Translational Research Navigators

**Leader:** Daniel Ford

- Experienced research coordinators available to research teams to help develop a plan for efficiently moving protocols through regulatory offices
- Assist research teams in completing appropriate applications and taking advantage of all science opportunities

## Biostatistical Support

**Leaders:** Karen Bandeen Roche and Rick Thompson

- Johns Hopkins Biostatistics for Clinical and Translational Research (Biostats CenTeR)
- Center coordinates biostatistics support to Johns Hopkins translational research teams
- Provides practical advice on study design and biostatistics questions
- Encourages consultation at study design phase and before data collection has been initiated
Advanced Translation Incubator Program - ATIP

**Leader:** Jeffrey Rothstein

- Research teams can apply for pilot grant funds to support translational projects
- Investigators need to describe a “deliverable” product at the end of funding
- Program includes a new focus on strict timelines with rapid turnaround
- Can apply for up to $100,000 over two years
- New investigators, interdisciplinary teams, and research teams with trainees are priorities

Clinical Research Management System - CRMS

**Leaders:** Diana Gumas, Daniel Ford, Stuart Ray, Kerry Stewart

- Application to register and follow research participants
- Linked to eIRB and EPR
- Document eligibility and produce CRF
- Web-based secure system
- Form Builder
Clinical Research Management System

Biomedical Informatics

Leaders: Harold Lehmann, Kerry Stewart

- Have programs responsible for knowledge management, clinical research informatics, biospecimen informatics, and bioinformatics
- Piloting use of caTISSUE for managing biospecimens
- Prioritizing development of new biomedical informatics applications
- SciVal/Collexis for searching researchers at Johns Hopkins
- Center for Computational Genomics – Sarah Wheelan
Center for Clinical Data Analysis (CCDA)

**Leader:** David Thiemann

- Jointly sponsored by ICTR and the Johns Hopkins Medicine Center for Information Services (JHMCIS)
- Provides “one-stop shopping” and database expertise for researchers who need data from enterprise clinical systems (EPR, Amalga, Sunrise, Datamart, IDX, Pathology)
- Acts as trusted intermediary for data queries and ensures that data release conforms to IRB terms
- Services include sample-size estimates for grant planning and statistical analysis, case-finding for research, and one-time or periodic data extracts for research analysis.

Research Participant Retention and Recruitment Office

**Leader:** Cheryl Dennison Himmelfarb

- Develop tools to monitor the success of various recruitment and retention approaches used within Johns Hopkins
- Provide consultations on various IRB-approved recruitment strategies
- Develop Johns Hopkins strategic initiatives focused on recruitment and retention
### Johns Hopkins Data and Safety Monitoring Board

**Leaders:** Fred Luthardt and Daniel Ford

- Help investigators who do not have access to a DSMB develop a data and safety monitoring plan
- If a DSMB is needed provide the structure and administrative support for an institutional DSMB
- Communicate DSMB decisions to appropriate IRBs
- DSMB courses

### Research Ethics Achievement Program

**Leader:** Jeremy Sugarman

- Provides ethics consultations for research groups concerning design and conduct of studies
- Conducts empirical studies to inform policies related to risks and benefits associated with different study designs and consent procedures
### Research Participant Advocate

**Leaders:** Liz Martinez and Daniel Ford

- Consultation to research teams about best ways to work with research subjects
- Work with research teams who need an intermediary for working with dissatisfied research participants
- Leads efforts to thank research participants for their work in research studies

### Community Engagement Office

**Leaders:** S. Darius Tandon, Kostas Lyketsos, Peter Pronovost

- **Johns Hopkins Clinical Research Network**
  - Focus on expanding sites and providers performing research, e.g. Anne Arundel Medical Center; community physicians
- **Community Research Advisory Council**
  - Focus on working with patient disease advocacy groups to set research agenda and enlist help with translational research projects
- **Knowledge Translation Office**
  - Focus on consultation service for research teams as they design efficacy/effectiveness studies. Consumers of research include patients, providers, payers, and hospitals
Innovative Methodology Workgroups

**Leader:** Karen Bandeen-Roches

- Identifies important and recurrent clinical research methodologic and biostatistics problems
- Directs multidisciplinary work groups to address these issues
- Creates new methodologic approaches that are available to the broad Johns Hopkins community
- Working Group 1: Genome-wide Association (GWAS) working group
- Working Group 2: Assessment and development of comparative effectiveness research approaches to translate evidence from randomized trials into individualized management of chronic diseases

Drug/Device/Vaccine Development

**Leaders:** Elizabeth Jaffee and Craig Hendrix

- Provides consultation to research teams on using institutional resources to promote drug/device/vaccine development
- Provides medicinal chemistry expertise for preclinical toxicology
- Provides Good Manufacturing Practices (GMP) and near-GMP for synthesis of biological reagents for preclinical toxicology and early Phase 1 testing
- Provide pharmacologic and biologic endpoint expertise
- Individual and group seminars and hands on experience with core technologies
Proteomics/Biomarker Core

Leader: Jennifer Van Eyk

- Integrates discovery and validation strategies and technologies for the development of robust biomarkers
- Assists in study design, cohort development, appropriate experimentation and data analysis as part of discovery process
- Develops and coordinates new technologies and optimizes/standardizes protocols specifically for biomarker development
- Individual and group seminars and hands on experience with core technologies

Genetics Translational Technology Core

Leader: Gary Cutting

- Provide consultation to clinical and translational research teams regarding the feasibility, design, power and costs of projects using molecular technologies
- Provide clinical grade services such as DNA banking, sequencing and genotyping for qualified investigators
- Can help evaluate test performance in a CLIA-certified environment
- Individual and group seminars and hands on experience with core technologies
Imaging Core

**Leader:** Katarzyna Macura

- Provides consultation for best imaging approach in translational studies
- Developing an imaging library in cooperation with Kennedy-Krieger Institute

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