CTSA Clinical & Translational Science Awards   Translating Discoveries to Medical Practice
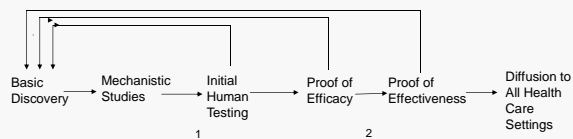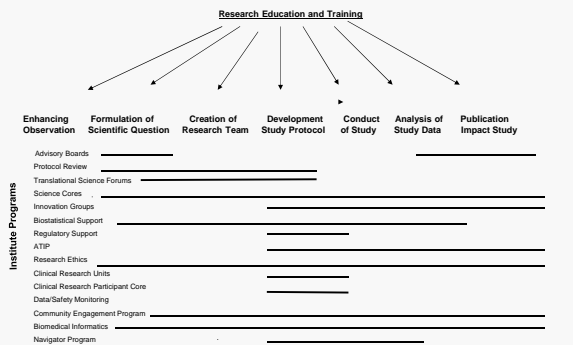
Johns Hopkins Institute for Clinical and Translational Research A CTSA Program

Daniel E. Ford, M.D., M.P.H.
Director, Institute for Clinical and Translational Research
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

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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 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

Johns Hopkins ICTR
Participating Schools

- School of Arts and Sciences
- School of Business
- School of Engineering
- School of Medicine
- School of Nursing
- School of Public Health

Research Education, Training, and Career Development

Leaders: Pete Miller, Franklin Adkinson, Mary Catherine Beach, Liz Selvin

- 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

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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
- SCAMP Program for research coordinators

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

Biomedical Informatics

Leaders: Harold Lehmann and Diana Gumas

- Have programs responsible for knowledge management, clinical research informatics, biospecimen informatics, and bioinformatics
- Piloting use of caTISSUE/OpenBiospecimen for managing biospecimens
- SciVal/Collexis for searching researchers at Johns Hopkins
- Center for Computational Genomics – Sarah Wheelan
- Developing a secure research data desktop application

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 (Epic, 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: Cheryl Dennison-Himmelfarb, Adrian Dobs, Crystal Evans

- 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

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 pre-clinical toxicology
- Provides Good Manufacturing Practices (GMP) and near-GMP for synthesis of biological reagents for pre-clinical 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

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- Link to national CTSA website:
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