Pepper Center and Clinical & Translational Science Awards (CTSA) Collaboration

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Impetus for the CTSA Program

- Implementing biomedical discoveries made in the last 10 years demands an evolution of clinical science.

- New prevention strategies and treatments must be developed, tested, and brought into medical practice more rapidly.

- CTSA awards will lower barriers between disciplines, and encourage creative, innovative approaches to solve complex medical problems.

- These clinical and translational science awards will catalyze change -- breaking silos, breaking barriers, and breaking conventions.
Urgency to Change at Johns Hopkins

- NIH funding is flat
- Faculty want more training and resources in translational research
- Regulatory environment more complex
- Not enough well trained research staff (coordinators)
- Basic scientists cannot easily find clinical research collaborators
- Competition from both community hospitals/physician and international sites
- Need to preserve academic reputation of Johns Hopkins by continuing to have active clinical research program
- Insufficient support for research informatics and biospecimen tracking
Building a National CTSA Consortium

Participating Institutions

- Since 2006
- Since 2007
Building a National CTSA Consortium

**FY06 Grantees**

- Center for Clinical and Translational Science
  The Rockefeller University
- Center for Clinical and Translational Sciences
  University of Texas Health Sciences Center at Houston
- Clinical and Translational Science Center
  University of California, Davis
- Clinical and Translational Science Institute
  University of Pittsburgh
- Clinical and Translational Sciences Institute
  University of California, San Francisco
- Clinical and Translational Sciences Institute
  University of Rochester School of Medicine and Dentistry
- Duke Clinical and Translational Science Institute
  Duke University
- Institute for Translational Medicine and Therapeutics
  University of Pennsylvania
- Irving Institute for Clinical and Translational Research
  Columbia University
- Mayo Center for Translational Science Activities
  Mayo Clinic
- Oregon Clinical and Translational Research Institute
  Oregon Health and Science University (partnering with Kaiser Permanente)
- Yale Center for Clinical Investigation
  Yale University

**FY07 Grantees**

- Atlanta Clinical and Translational Science Institute
  Emory University (partnering with Morehouse College)
- CTSA at Case Western University
  Case Western University
- CTSA at Washington University
  Washington University
- CTSA at Weill Cornell Medical College
  Weill Cornell Medical College (partnering with Hunter College)
- Institute for Clinical and Translational Research
  University Of Wisconsin Madison
- Institute for Clinical and Translational Research
  Johns Hopkins
- Institute of Translational Health Sciences
  University Of Washington
- Michigan Institute of Clinical and Health Research
  University Of Michigan At Ann Arbor
- North & Central Texas Clinical and Translational Science Initiative
  University of Texas Southwestern Medical Center - Dallas
- University Of Chicago CTSA
  University Of Chicago
- Univ of Iowa's Inst for Clinical and Translational Science
  University Of Iowa
- Vanderbilt Institute for Clinical and Translational Research
  Vanderbilt University (partnering with Meharry Medical College)
Clinical and Translational Science Awards

The Clinical and Translational Science Awards (CTSAs) is a consortium that is transforming how clinical and translational research is conducted, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients. The consortium is designed to:

- Encourage the development of new methods and approaches to clinical and translational research
- Improve training and mentoring to ensure that new investigators can navigate the increasingly complex research system
- Design new and improved clinical research informatics tools
- Assemble interdisciplinary teams that cover the complete spectrum of medical research
- Forge new partnerships with private and public health care organization

NIH Expands National Consortium to Transform Clinical and Translational Research

- Select State -
Consortium Governance & Organization

CTSA Working Groups

- PIs/Operations Group
- Pediatrics Oversight
- Participant and Clinical Interactions (CRUs/old GCRCs)
- Biostatistics and Research Design
- Bioinformatics
- Translational Cores
- Education and Research Training
- Communications
- Regulatory Knowledge
- Public Private Partnerships
- Community Engagement
- Clinical Research Ethics
- Evaluation
Sample National CTSA Projects

- Developing research certification programs for community physicians
- National set of competencies for trainees
- RFP for data sharing (bioinformatics)
- CDC grants for community engagement
- Workshop to create and post metrics on IRB/contracting performance
Translational Pathway

1. Basic Discovery → Mechanistic Studies → Initial Human Testing → Proof of Efficacy
2. Proof of Effectiveness → Diffusion to All Health Care Settings
Johns Hopkins Institute for Clinical and Translational Research

• Goals
  – Academic Home for Clinical and Translational Researchers
  – Expand the Working Relationships of Clinical Investigators with Basic Scientists and Population-oriented Scientists
  – Coordinate Translational Research Activities to Increase Innovation and Speed of Translation
Johns Hopkins Institute for Clinical and Translational Research

• **Goals**
  – Support Training of Clinical and Translational Research Faculty and Staff
  – Provide Centralized Support for Research Where Efficient
  – Measure and Track Efficiency of Human Subjects Research to Address Barriers
Johns Hopkins ICTR Programs

- Translational research training
  - K junior faculty/fellow level
  - Medical Student level
  - Research staff and community physicians

- Clinical Research Units (old GCRCs)
  - Pay for imaging (Kennedy Krieger)
  - Some centers closing inpatient GCRCs
  - Moving resources outside confines of center
Johns Hopkins ICTR Programs

- Biostatistical Consultation
- Innovative Methodology Workgroups
- Clinical Research Ethics Consultations
- Data and Safety Monitoring Services
- Translational Research Navigators (project managers)
- Clinical Research Management Database
Biomedical informatics
  – Knowledge Management
  – Clinical Research Management System
  – Biospecimen Tracking
  – Bioinformatics
Johns Hopkins ICTR Programs

- Basic Discovery Translational Forum
- Clinical Sciences Translational Forum
- Accelerated Translational Incubator Program (ATIP) support pilots
- Research Participant Recruitment and Retention Program
- Community Research Networks Office
- Secondary Translation or Knowledge Transfer Office
Drug/Device/Vaccine Development

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
Genetics Translational Technology Core

• 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
Proteomics/Biomarker Core

- 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
CTSA Pepper Center Collaborations

• KL clinical translational research scholars
• Pilot projects
• Informatics/IT applications to facilitate translational research
• Utilize old “GCRC” resources in new ways
• Patient recruitment/retention specialists
• Innovative methodology projects
• Regulatory Support (CMS Research Partners)