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

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Impetus for the CTSA Program

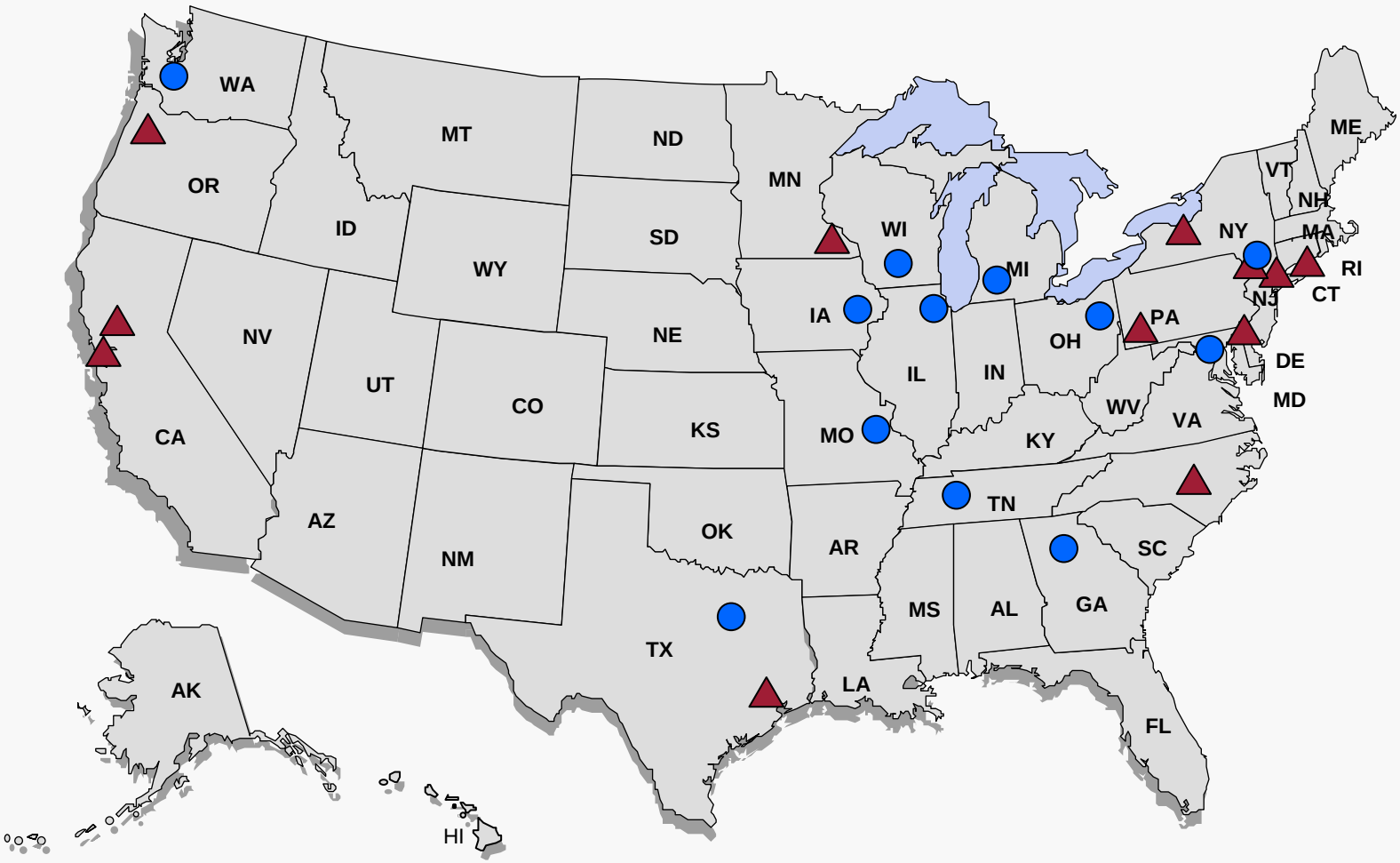
- Implementing biomedical discoveries made in the last 10 years demands an evolution of clinical science.
- New prevention strategies and treatments must be developed, tested, and brought into medical practice more rapidly.
- CTSA awards will lower barriers between disciplines, and encourage creative, innovative approaches to solve complex medical problems.
- These clinical and translational science awards will catalyze change -- breaking silos, breaking barriers, and breaking conventions.

CTSA Clinical & Translational Science Awards

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

CTSA Clinical & Translational Science Awards

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 Science 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)

CTSA Clinical & Translational Science Awards

CTSA Committees & Activities

Oversight Committees

- CTSA Consortium Oversight
- Pediatrics Oversight Committee

Clinical Integration Committee Workgroups:

- Administration
- Alternative IRB Model Pilots
- Biostatistics / Epidemiology / Research Design
- Clinical Research Ethics
- Communications
- Participant and Clinical Interactions
- Regulatory Knowledge

Steering Committees

- Community Engagement
- Education / Career Development
- Evaluation
- Informatics
- Public Private Partnerships
- Translational

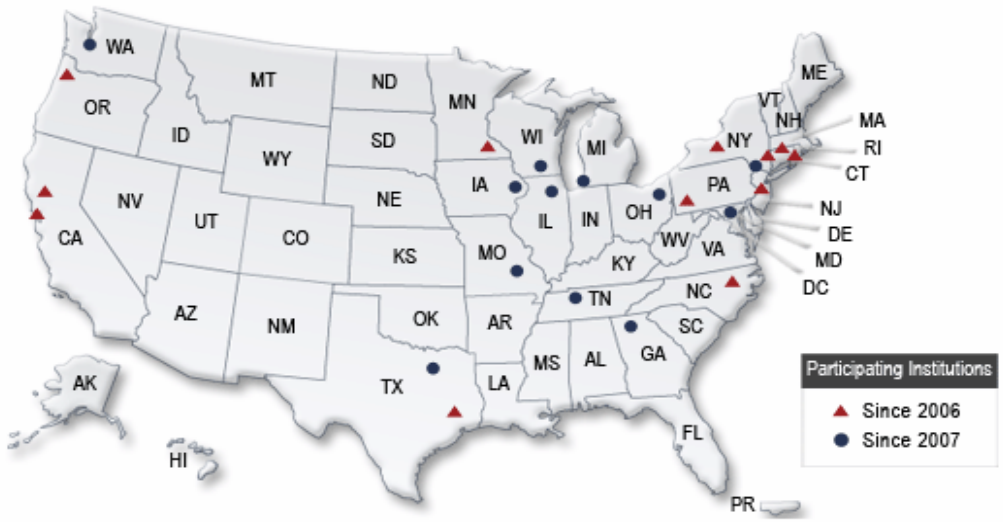
Clinical and Translational Science Awards

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 - Go



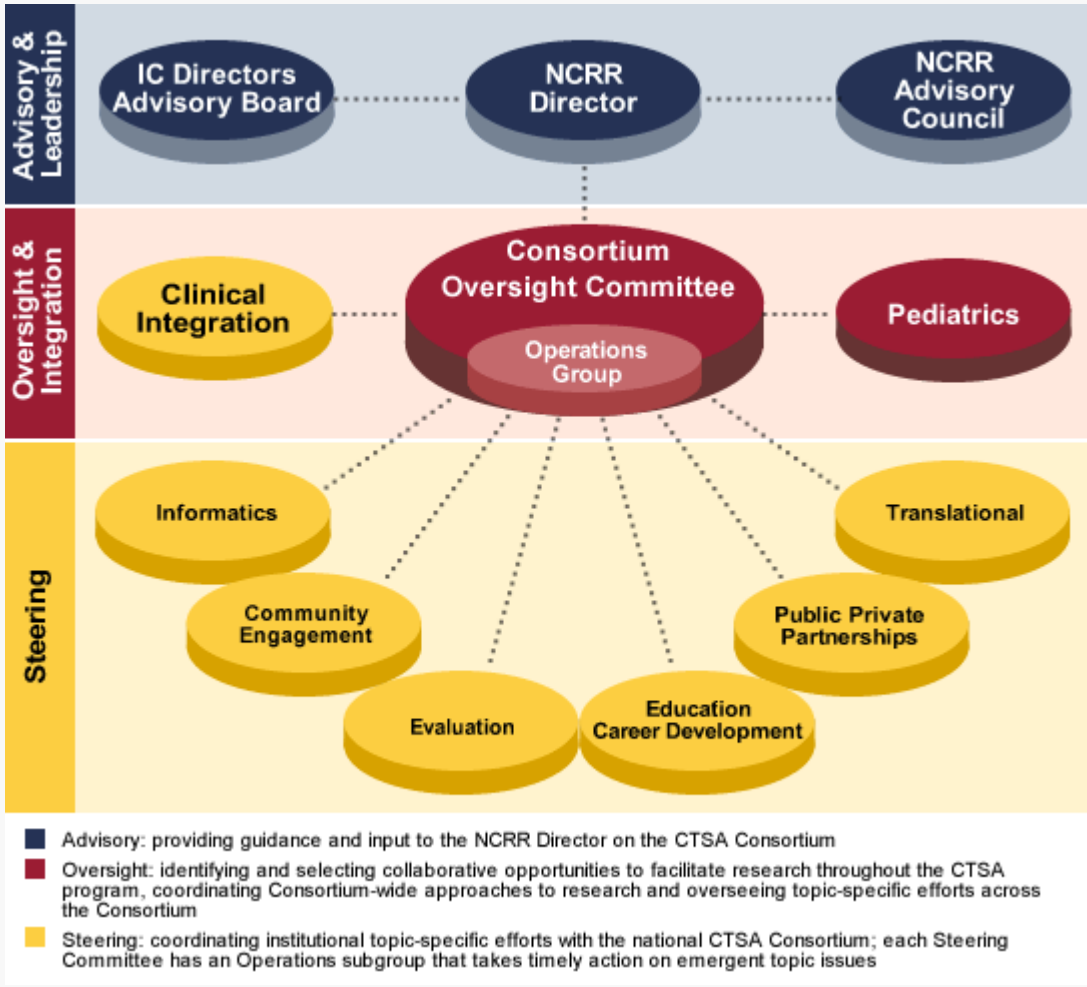
Quick Links

- Calendar
- CTSA Committee Representatives
- Communication Tool Kit
- Resource Access
- Governance Manual
- Institution Search

NIH CTSA Information

- NIH Expands Consortium
- NCRR CTSA Information
- Current RFA
- CTSA Funding Guidelines
- Fact Sheet
- Join CTSA Listserv

Consortium Governance & Organization



Governance Manual available at
http://ctsaweb.org/Docs/CTSA_Governance_Manual.pdf

CTSA Clinical & Translational Science Awards

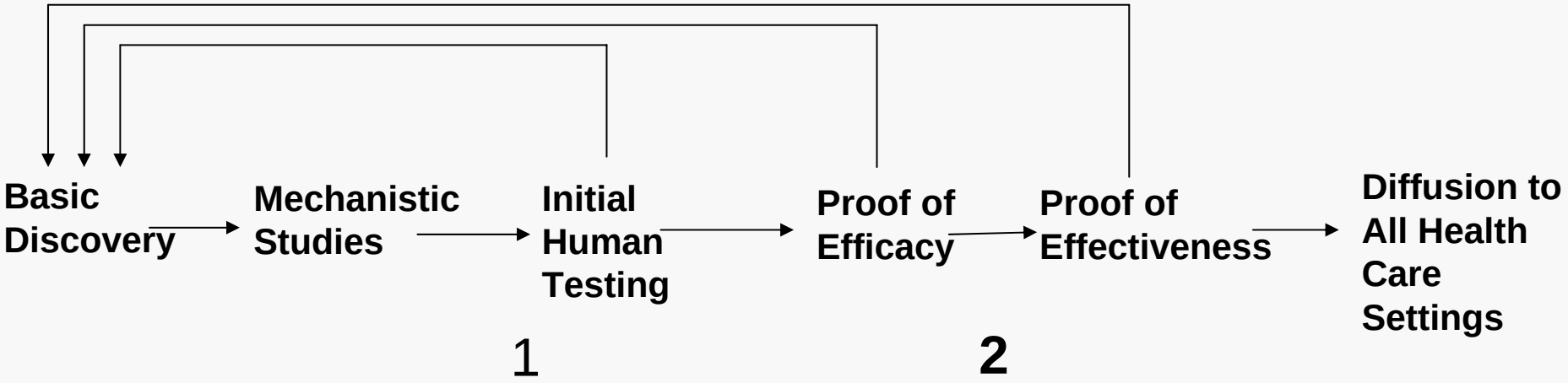
CTSA Working Groups

- 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



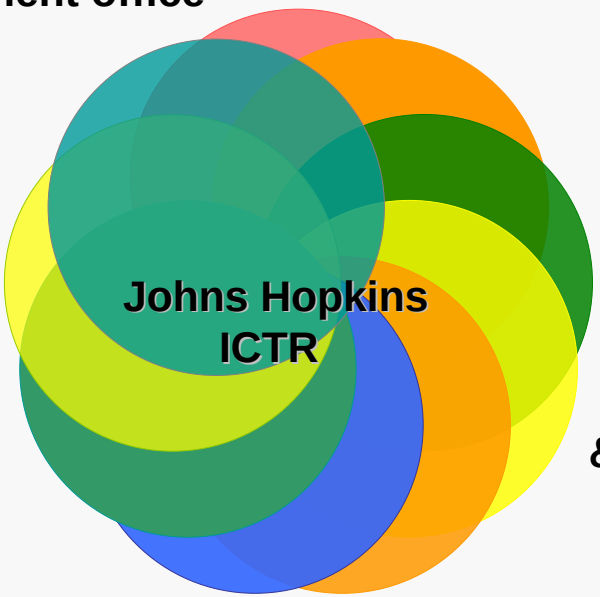
Johns Hopkins Institute for Clinical and Translational Research

- 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 Institute for Clinical and Translational Research



Research participant
Recruitment office

Trial Design

Biomedical
Informatics

Advanced
Degree-Granting
Programs

Clinical
Resources

Participant
& Community
Involvement

Biostatistics

Regulatory
Support

NIH & other
government
agencies

Industry

Healthcare
organizations

CTSA Clinical & Translational Science Awards

Johns Hopkins ICTR Progams

- 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

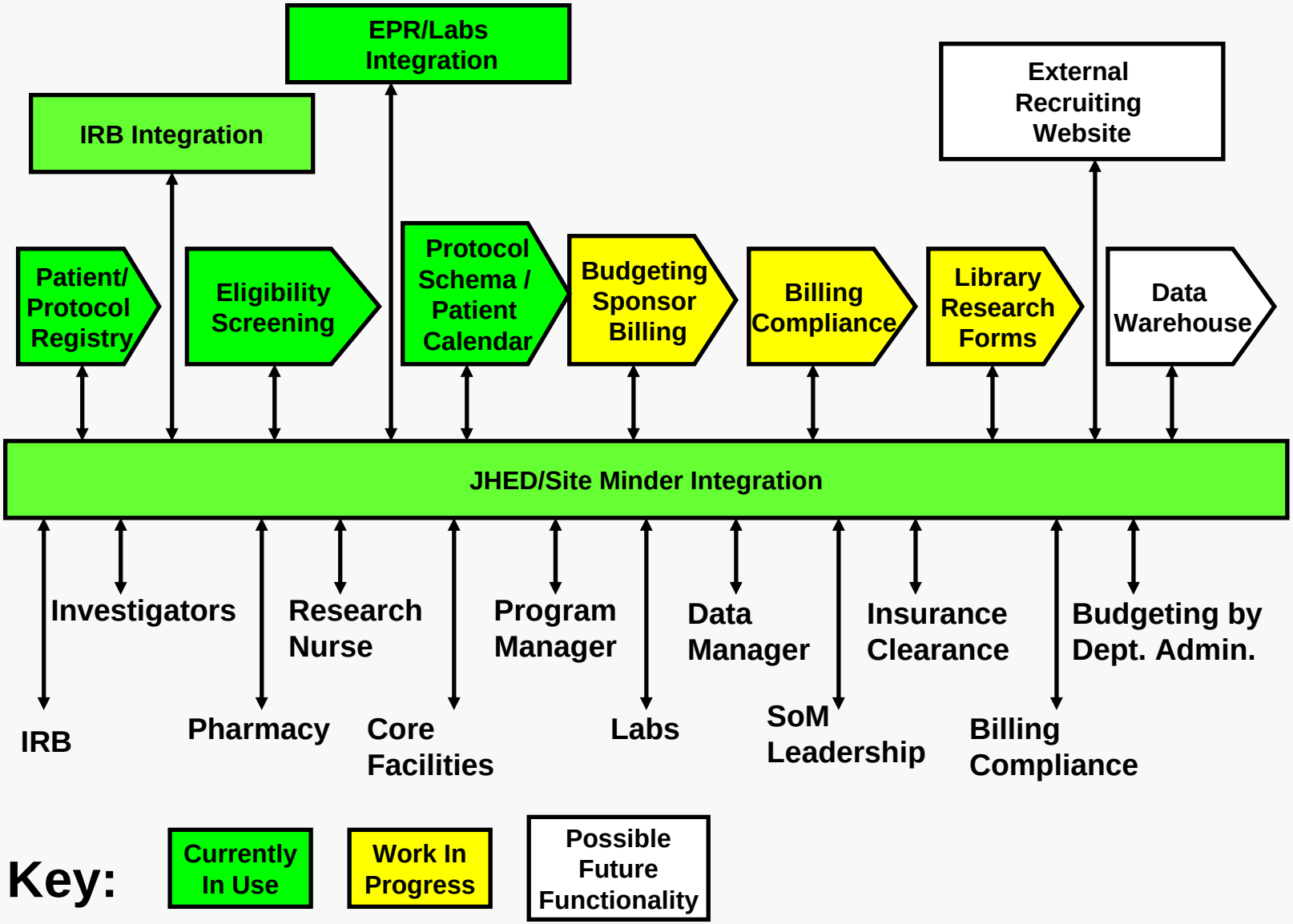
Johns Hopkins ICTR Progams

- Biostatistical Consultation
- Innovative Methodology Workgroups
- Clinical Research Ethics Consultations
- Data and Safety Monitoring Services
- Translational Research Navigators (project managers)
- Clinical Research Management Database

Johns Hopkins ICTR Progams

- Biomedical informatics
  - Knowledge Management
  - Clinical Research Management System
  - Biospecimen Tracking
  - Bioinformatics

Clinical Research Management System



Johns Hopkins ICTR Progams

- 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)