

The Challenges of Research Collaborations

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Agenda

- Data and biospecimen sharing among research collaborators
 - Why does it matter?
 - What's in the way?
 - How will the HITECH Act affect research collaborations?
- Collaboration in the CTSA world
- IRB review of multi-institutional research

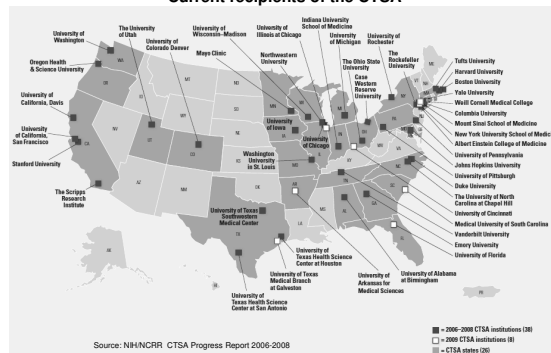
Collaboration in the CTSA World

Collaboration in the CTSA world

Clinical & Translational Science Award (CTSA) Overview

- Clinical and Translational Research Programs are critical to advancing the quality of patient care in the United States yet institutions that manage them often face tremendous challenges.
- The Clinical and Translational Science Awards (CTSA) managed by select institutions seek to facilitate research innovation across the continuum of bench to bedside and improve the practice of medicine.
- The CTSA presents a unique opportunity to invest in an infrastructure to better support and improve clinical research collaborations and speed innovations from bench to bedside.

Current recipients of the CTSA



Source: NIH/NICRR CTSA Progress Report 2008-2008

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CTSA Goals and Objectives

- The goal of the CTSA is to transform how clinical and translational research is conducted and managed, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients.
- CTSA's now comprise 46 academic health centers in 26 states. The consortium **ultimately will link about 60 institutions together** to energize the discipline of clinical and translational science.
- In order to achieve the objective, the NCRR provides funding that ranges from \$10M to \$100M+ to establish clinical and translational infrastructure. In addition, the recipient institutions have committed matching funds in the \$10's of millions.
- These funds are support clinical and translational infrastructure and the training of cadre of clinical and translational research and support staff.

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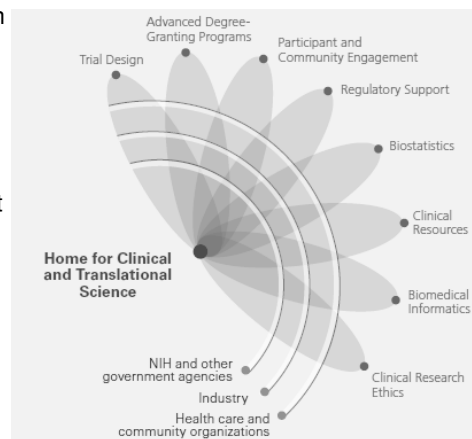
Source: NIH/NCRR CTSA Progress Report 2006-2008

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CTSA Implications

- The CTSA requires a new approach for facilitating efficient clinical trials, where tools are necessary for managing clinical trials at an enterprise-wide level.
- Many organizations are looking to establish central support in an effort to better manage the intricacies of the CTSA across the entire institution.
- Although the CTSA's have existed for less than 5 years the infrastructure created has become the platform for regional programs in clinical & translational research.



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Source: NIH/NCRR CTSA Progress Report 2006-2008

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CTSA Collaborations – A Case Study

Two large CTSA recipients combine their knowledge of clinical research management to co-develop a Clinical Trial Management System (CTMS).

- Both worked with a common IT vendor to design the software.
- **CTMS Definition:** an information system that interfaces with all facets of a clinical trial, providing a **single point of reference, standardization of business practices**, and **stores the clinical trial data** in a central electronic repository for the users within medical center including the University, School of Medicine, Physician Practice Plan and Affiliated Hospital(s).
- **CTMS Functionality:**
 - Central Registration for all clinical trials and all clinical trial participants
 - Develops a detailed Medicare Coverage Analysis (MCA) & Sponsor Budget
 - Develops patient calendars & visit checklist based on protocol requirements
 - Supports research participant recruitment efforts
 - Electronic Case Report Forms, Data Warehouse, Document Management
 - Sponsor billing, cash receipt tracking, study financial reporting
 - Tracks regulatory approvals in real time.

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CTSA Collaborations – A Case Study

Benefits of the Collaboration

- Able to share the substantial cost of development between the two institutions.
- Each entity focuses their efforts on areas of relative strength such as regulatory approvals, budget development or clinical trial billing compliance and then they would vet what was developed with the other institution.
- Established a valuable platform for future research collaborations:
 - Institutional leaders had already worked very closely together.
 - They shared the same IT “platform” for clinical research which enabled improved ability to participate in data sharing between the two institutions.
- Software can currently be licensed from the IT vendor is currently being implemented in a third CTSA recipient and being considered by a number of others.

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CTSA Collaborations – A Case Study

Collaboration – Lesson Learned

- The cost of this type of development is not insignificant – even when shared!
- Both entities managed their own part of the IT development and met periodically to review progress . . . but in future large collaborations like this I would highly suggest that someone independent provide project management across the organizations. This would have saved time and \$.

IRB Review of Multi- Institutional Research

IRB Review of Multi-Institutional Research

A Proposed Approach

Current State:

- Anxious investigators, impatient sponsors, frustrated IRB staff
- 1 or more local IRBs
- Requirement for compliance with a single set of federal regulations
- Even within one institution, multiple IRBs are often perceived to operate under different sets of operating procedures for IRB review and IRB oversight
- Expectations of busy clinicians for efficient and responsive IRB operations
- Institution may not have a formal Human Research Protection Program that is accredited by AAHRPP®
- No system-wide information technology to manage IRB workflow
- It is a challenge for your operation to generate a timely report of processing times and bottlenecks for research protocols

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IRB Review of Multi-Institutional Research

A Proposed Approach

Potential Solution:

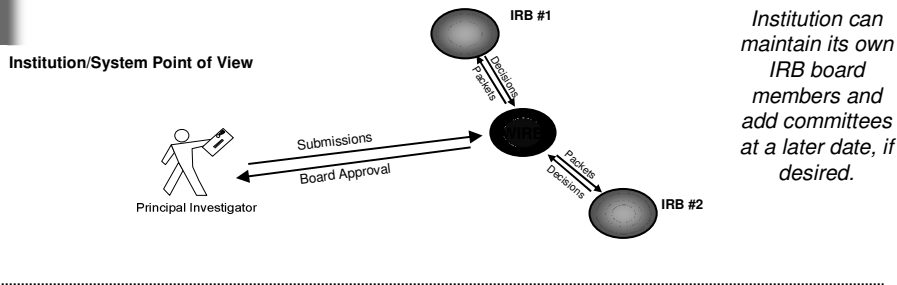
- ◆ A new model for IRB management – BOOST-IRB™
- ◆ Concept: Institution retains its IRBs, but the back-office infrastructure is centralized to provide robust, state-of-the-art electronic workflow
- ◆ Utilizes information technology and first-class industry know-how at all sites
- ◆ No need to invest millions of dollars in improved infrastructure
- ◆ Taps into the back-office of Western IRB (WIRB®)
- ◆ Customized reports available in real time
- ◆ Investigator can track their protocol's progress
- ◆ Provides the service on an affordable per-use basis
- ◆ WIRB, which is accredited by AAHRPP®, will share its Standard Operating Procedures to be used by each facility
- ◆ Substantial acceleration of the process of achieving AAHRPP® accreditation, when desired.

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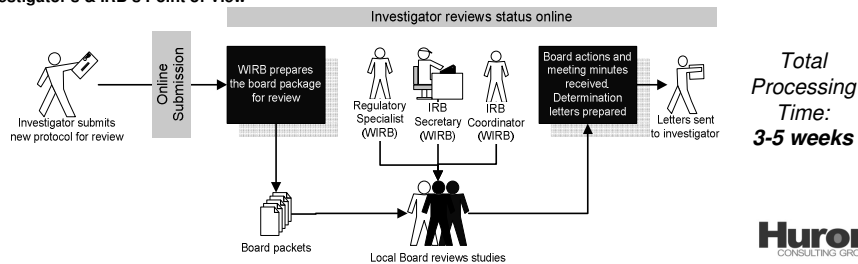
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IRB Review of Multi-Institutional Research

A Proposed Approach



Investigator's & IRB's Point of View



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IRB Review of Multi-Institutional Research

Value Proposition

Compliance

- Compliant policies and procedures provided
- AHHRP® accredited administrative processes
- Regulatory and administrative support provided at Board meetings
 - Helps ensure compliance with FDA and OHRP documentation requirements and decision-making guidelines
- Regulatory guidance available
- Up-to-date training for IRB Board members and investigators

Financial

- ◆ Lower total cost structure¹
 - Excluding initial transition costs
- ◆ Volume dictates cost more closely
 - Hiring, training and oversight are significantly reduced

Service

- ◆ Processing time:
 - ~1 week to prepare documents for board meeting
 - ~5 days for turnaround of decision memos
- ◆ A team of trained IRB professionals is available for questions and guidance
 - National experience and expertise
- ◆ eIRB: Online submission, tracking and review systems
- ◆ WIRB management of multi-center Adverse Event Reports
- ◆ Records are maintained by WIRB electronically or paper

Strategic

- ◆ The institution maintains local perspectives in the protocol review process
 - Input and buy-in by your medical staff
- ◆ Robust support improves IRB member satisfaction
- ◆ Major improvement in Investigator satisfaction
- ◆ Accelerated path to accreditation

1 – Based on cost structures of low-volume IRBs. Source: Wagner, T, et.al. "The Cost of Operating Institutional Review Boards (IRBs)" Academic Medicine. Vol. 78, No. 6, June 2003.

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Questions?

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