"National Virtual Biorepository"

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Agenda

- Overview of CTSA Biobank Consortium
- Executive Steering Committee
- Technical/Administrative Expectations for Members
- Automation in 5 years
- Other sites are joining by writing this effort into their renewal
- Benefits:
  - Sample sharing
  - Business plan and cost recovery model
- Issues for Discussion

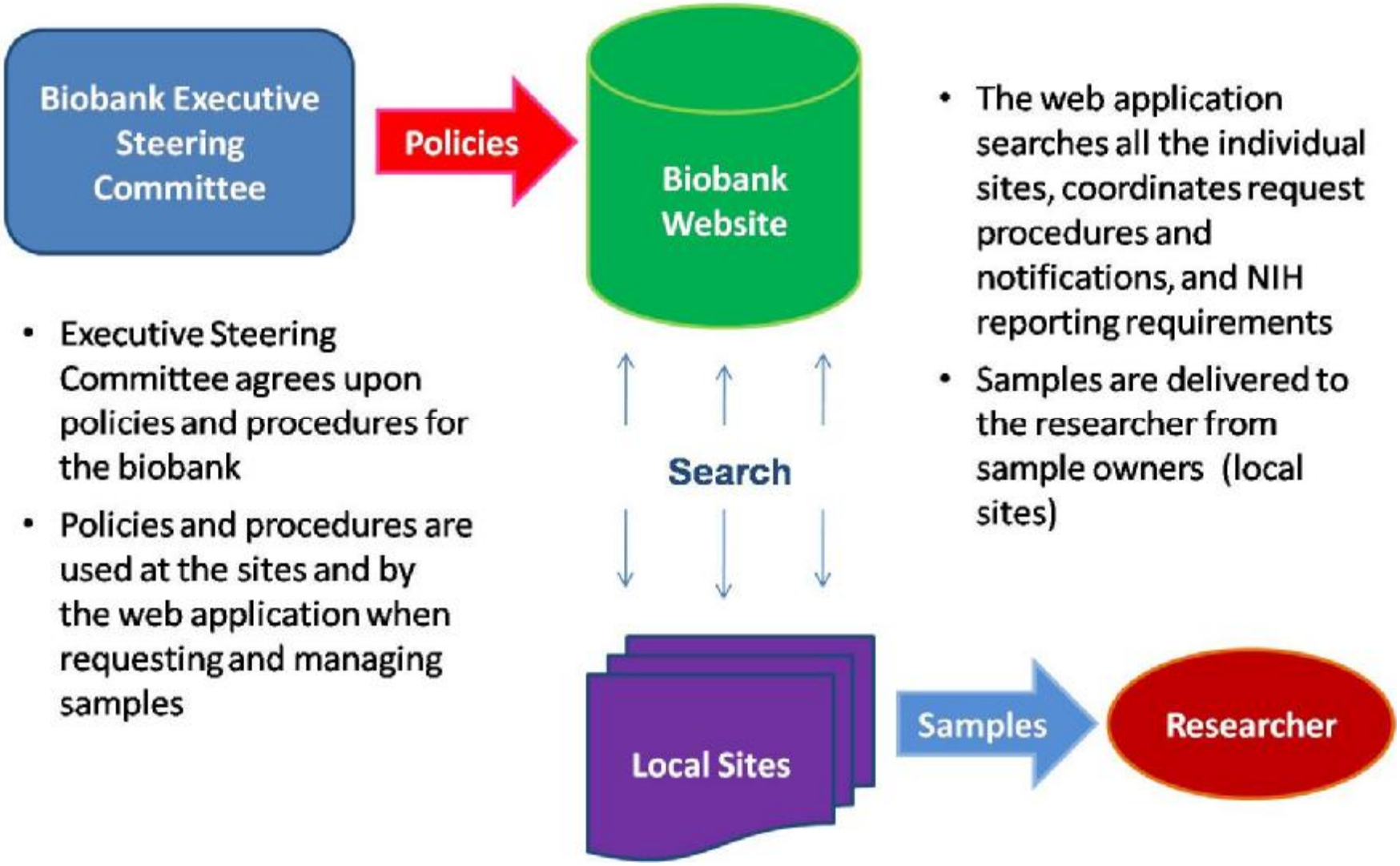
Overview
CTSA Biobank Consortium

- CTSA Admin Supplement from 2008-2009
  - Began as a manual system: 48,634 patients / 188,057 samples; 70% of the biobank collected with standardized protocols; 12,000+ samples distributed to 46 researchers since 2002
  - Our goal: to develop a prototype to automate an online sample request management system for use locally and across multiple CTSA Centers using a federated model
- Current partnerships:

UTHSC-Houston	UTHSC-San Antonio	Indiana (IUPUI)
University of Michigan	UC Davis	Baylor College of Medicine

- Accomplishments:
  - Created and tested a prototype custom biobank software application and associated technologies including i2b2
  - Piloted the use of iMed Consent (electronic capture of patient consent variables)
  - Ongoing biobank executive steering committee to review and adopt agreed upon best practices from the biobanking industry

Model of Federated Biobank Operations



- Executive Steering Committee agrees upon policies and procedures for the biobank
- Policies and procedures are used at the sites and by the web application when requesting and managing samples

- The web application searches all the individual sites, coordinates request procedures and notifications, and NIH reporting requirements
- Samples are delivered to the researcher from sample owners (local sites)

Executive Steering Committee Functions

1) Members are administrative and informatics leaders of each participating site
2) Review and come to consensus on agreed upon “best practices” in the biobanking industry
3) Share resulting adopted policies and procedures across participating CTSA centers

Examples of policy topics:

- Patient privacy and informed consent
- Handling IRB issues across multiple sites
- Minimum dataset expectations; sample and data distribution
- Standardized application request criteria
- Sample quality and disease representation
- Ethical and scientific oversight; appeals process
- Cost recovery and business plan
- Final outcomes reporting

Expectations for Participating Sites – Part 1

- Executive oversight of site biobank team personnel and contributing sample owners
- Participation on the executive steering committee by administrative and informatics leaders
- Provide funding for personnel and technical resources (write collaborative efforts into CTSA renewal)
- Oversee that:
  - Sample related data, clinical data and patient consent variables are migrated from paper to electronic format
  - Samples & data are consented for secondary use
  - Data are validated

Expectations for Participating Sites – Part 2

- Appoint a Site Technical Coordinator to populate and maintain local biobank node components
- Appoint a Site Database Coordinator to populate and maintain the local sample and consent databases; manage standard terminology
- Appoint a Site Biobank Coordinator to function as primary contact for applicant and approved researchers; oversee local approval and distribution processes, tracking, and reporting

Benefits of Membership

Improved synergy and interactions among research efforts across multiple institutions with:

–Sample sharing

–A business plan and cost recovery model

–An automated online sample request management system including an online sample and data search tool and embedded regulatory compliance

–Lower costs for entry and maintenance than closed data models inherent in commercial software solutions; harmonization with already established software applications

What are the unique cultural issues in sharing biospecimens and data?

Lessons learned to benefit sharing of biospecimens and data

What key structures are required for a framework of sharing?