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and Biospecimen Research

Role of the Administration Working Group and Subgroups in the caHUB Planning Process

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Creation of the caHUB Administration Working Group (AWG)

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- June 17, 2009: 1st Meeting, Bethesda, MD
- Mission: To understand caHUB's mission and envisioned structure, and to start the planning process



Challenge: Understanding How caHUB Will Differ From Traditional Biorepositories

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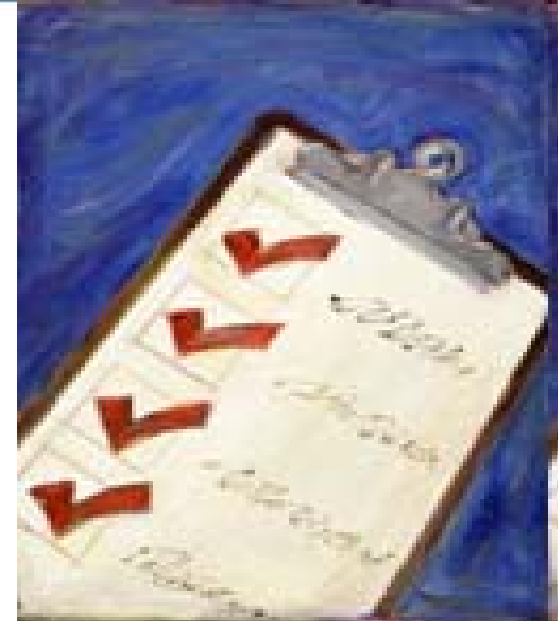
- Not just a typical biobank
- Aims to be the “NIST” of biorepositories by setting standards using the best techniques
- Provides benchmark specimens
- Educational emphasis: teaching, training
- Will provide expert services



Issues to be Considered for caHUB

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1. Consider lessons learned from previous NCI biobanking initiatives
2. Define caHUB mission and envisioned structure
3. Implement market analysis strategy and consider results
4. Assess caHUB organizational workflow considerations
5. Establish business plan framework
6. Design organizational structure
7. Develop project management plan
8. Define available resources to accomplish tasks
9. Develop an operational plan for biospecimen collection activities
10. Establish economic sustainability model
11. Create informatics framework





Charges to the AWG:

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- Generate additional questions to be addressed
- Prioritize all questions
- Identify gaps in the proposed strategic plan and WG representation
- Identify important issues/challenges and propose solutions
- Outline operational plan
- Propose/comment on timeline





Working Process

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- Monthly teleconference calls of the AWG (49 members)
- Weekly, biweekly, or monthly SG calls as needed
- Face-to-face meetings and workshops with additional invited experts





Challenges that caHUB Represents

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- Phase 1 is American Recovery and Reinvestment Act (ARRA)-funded, totally NCI-run
- Funds must be obligated by September 2011 to tissue source site (TSS), facility, operational staff
- Phased implementation necessary
- Phase 2 has to move long-term toward Public-Private Partnership (PPP) for financial sustainability
- Wide spectrum of stakeholders needed to ensure success of caHUB



Challenges (cont.)

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- NCI must maintain major funding presence for sustainability & direction
- caHUB has to be planned *as a business*, not as another NCI biorepository function
- Intellectual property (IP) offer: “Collaborate on the science; compete with the products”
- Pressing needs of potential customers constantly changing
- Science is constantly evolving

Strategic Planning/ Organizational Structure SG

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Peter Fielding, leader

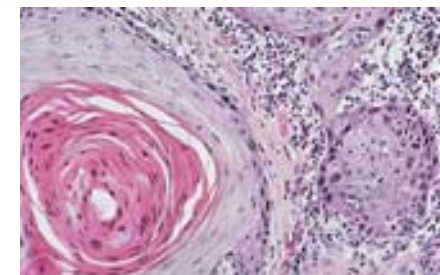
- Define Vision and Mission statements, Background & Value Proposition
- Describe caHUB operational/functional business units
- Propose different organizational structures for Phase 1 and 2
- Define milestones and success factors



Biospecimens SG

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Jim Robb, leader



5 Deliverables:

1. Action plan
2. Tissue prioritization quantitative matrix tool (standard operating procedures [SOPs] for 19 organs & 23 major cancers; looked at 60 cancers using 9 criteria including SEER data)
3. Tissue morphologic & molecular quantification SOP
4. Blood collection & processing SOP
5. Quality control monitors for caHUB Flow Process (*Foundation of Quality Management Plan*)

Acquisition of Normal Tissues SG

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Neil Mucci, leader

- Objective: Consolidate expertise from ANTSG to support Genotype-Tissue Expression Project (GTEx)
- Develop *Best Practices for Postmortem Recovery of Normal Human Tissue for Research* (Built on existing *NCI Best Practices for Biospecimen Resources*)
- Orient caHUB and research community stakeholders to best technical, operational, ethical, and legal practices
- Harmonize document with other caHUB SOPs





Facilities SG

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Mark Cosentino, leader

- Created case flow, sample quantities, and processing diagrams
- Met with biobanking industry experts for facility design input
- Provided estimates of facility space requirements and design for caHUB operations, laboratories, teaching/training, staff, storage, growth, automation
- Generated recommendations for Phase 1 & 2 design





Ethical, Legal and Social Issues SG

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Joan Scott and Karen Maschke, leaders

- Collected and reviewed current reports, policies, and academic literature
- Identified key issues: Governance, privacy, access, data sharing, ownership and IP, return of research results, informed consent
- Developing white paper and draft template for informed consent documents for caHUB



Informatics SG

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Ian Fore and Kenyon Erickson, leaders

- Identified capabilities of systems required
- Created the Notional Informatics Architecture
- Established functional benefits of interoperability
- Reviewed lessons learned from The Cancer Genome Atlas (TCGA)
- Developing use cases for comprehensive data resource, connection to caBIG™
- Addressing subject matter issues:
Defined vocabularies for pathology
-controlled and specimen processing data elements





Partnerships SG

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Ann Ashby, leader



- PPP: Government + (industry, academia, advocacy groups, foundations, interested individuals)
- Defined possible types of PPPs and pros/cons
- Looked at lessons learned from for-profit and patient advocacy biobanks
- Recommended governance structure
- Identified potential partners
- Recommended PPP be established through the Foundation for the NIH *now* to develop a case for support

Communications & Marketing

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- Plan developed by the *NCI Office of Communications and Education* is modeled on TCGA plan
- Created Web page and media kit materials
- Developed targeted audience for messages and potential contacts
- Identified key publication sites
- Starting media outreach in all forms
- Scheduling multi-audience Webinars, distributing descriptive materials, & holding interactive presentations by September 2010





Financial Modeling

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- Booz Allen Hamilton
- Developed comprehensive caHUB Total Life Cycle Cost of Ownership estimates
- Looked at current market pricing for quality biospecimens
- Examined potential cost recovery through marketed services for financial sustainability

Booz | Allen | Hamilton





Preparation of Subgroup Products for caHUB Planning Document

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- January 28, 2010 – Meeting of Subgroup Leaders (SGLs), SAIC-Frederick, Inc. and the NCI OBBR
- Presented drafts to the OBBR and other SGLs for review and initial comments
- Next: Finish drafts, undergo SAIC-Frederick, Inc. and OBBR review, finalize documents
- Presentation to entire AWG and OBBR by late March 2010
- Final document to OBBR by early April 2010

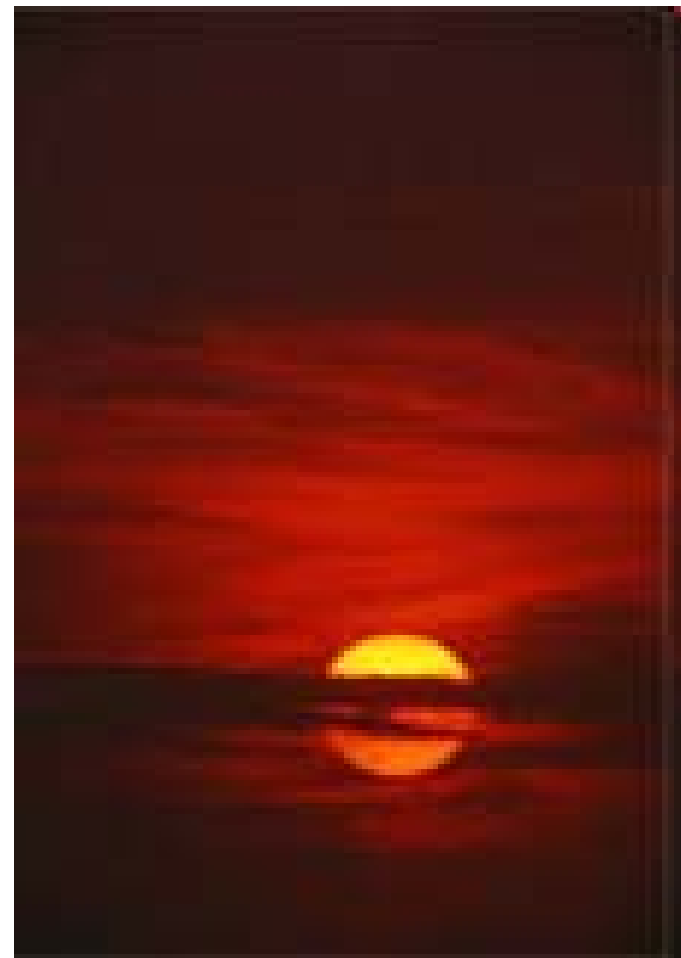




AWG and Subgroups Fate

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- AWG and all Subgroups “sundown” by March 31, 2010 with final conference call





Helping caHUB Through Phase I

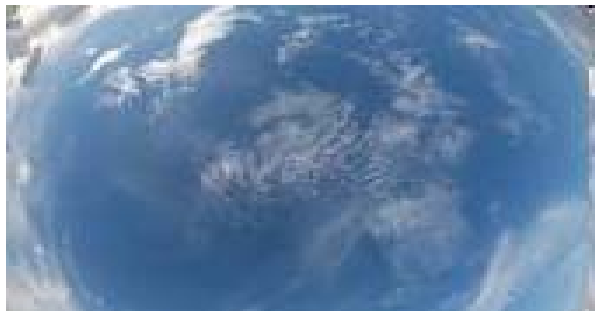
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- Summary Report to be submitted to OBBR by early April 2010
- Continued feedback through expert workshops as required



Working Toward Phase 2: Shifting Gears

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- 15-19 member Technical Discussion Group to serve as a sounding board for caHUB operational staff in Phase 1