

# ADMINISTRATIVE WORKING GROUP SUMMARY

*Cancer Human  
Biobank, Office of  
Biorepositories and  
Biospecimen  
Research, National  
Cancer Institute*

## Overview Statement

Since its inception in 2005, the National Institutes of Health (NIH) National Cancer Institute (NCI) Office of Biorepositories and Biospecimen Research (OBBR) has been assessing the need for standardization in biobanking and biospecimen quality standards for postgenomic medical research and technology development. To further this end, OBBR launched the Cancer Human Biobank (caHUB) in 2009. Through the development of publicly available tools and resources, such as standard operating procedures (SOPs), quality measures, and ethical and regulatory guidelines, the caHUB will provide a national infrastructure to support the advancement of molecular medicine. In 2009, OBBR commissioned a large-scale survey and several focus-group research projects through the NCI's Office of Communication and Education in order to gain insight into the types and quantities of biospecimens and data most needed by the research community as well as to better anticipate the challenges and opportunities OBBR would face in launching caHUB. Also in 2009 OBBR established expert working groups (the Administrative Working Group and eight subgroups) through a Federally Funded Research and Development Center (SAIC-Frederick, Inc.) to provide input in several critical areas, including strategic planning; ethical, legal, and social issues (ELSI); partnerships development; informatics; cost modeling and cost recovery; and biospecimen collection and processing SOPs. The market research, the working group deliverables, and other reports and white papers developed by OBBR staff and expert consultants through early 2011 represent the due diligence performed by OBBR in planning for the establishment of caHUB. In January of 2011, the caHUB budget was significantly reduced, and the scope modified to preclude prospective collection of biospecimens (referred to as the "benchmark collection"). The focus of the pilot phase of caHUB was altered to accommodate the new scope and resource limitations. During the pilot phase, caHUB is focusing on the conduct of biospecimen research to create biospecimen-quality standards and evidence-based protocols. It will continue to provide an array of biospecimen-collection and -processing services in support of strategic, funded NCI and NIH projects. caHUB also continues to develop strategic partnerships with stakeholder groups with the aim of leveraging resources and expertise in the area of biospecimen research and standards development. While the objectives of caHUB have changed since the Working Groups were charged with their mission, the recommendations provided by this team of experts are relevant to any group attempting to improve the reach and impact of its biospecimen sample collection, and continue to inform and guide the implementation of caHUB's biospecimen-research focused mission.

## Pilot Phase Products

The caHUB Administrative Working Group (AWG) included a wide range of experts and opinion leaders across relevant disciplines to produce key recommendations on the components necessary to establish caHUB. This was accomplished by formation of a series of strategic and operational subgroups that met over a period of approximately 9 months to develop recommendations, SOPs, best practices, research findings, and issues for consideration. These focused subgroups (SG) were organized as follows: Strategic Planning/Organizational Structure (SPOS), Cancer Biospecimens (CB), Acquisition of Normal Tissues (ANT), ELSI, Communications, Facilities, Informatics, and Partnerships. In addition to these subgroups, the OBBR engaged the consulting firm Booz Allen Hamilton to perform a thorough analysis of the economic considerations involved in establishing caHUB and to develop cost-recovery models for long-term sustainability.

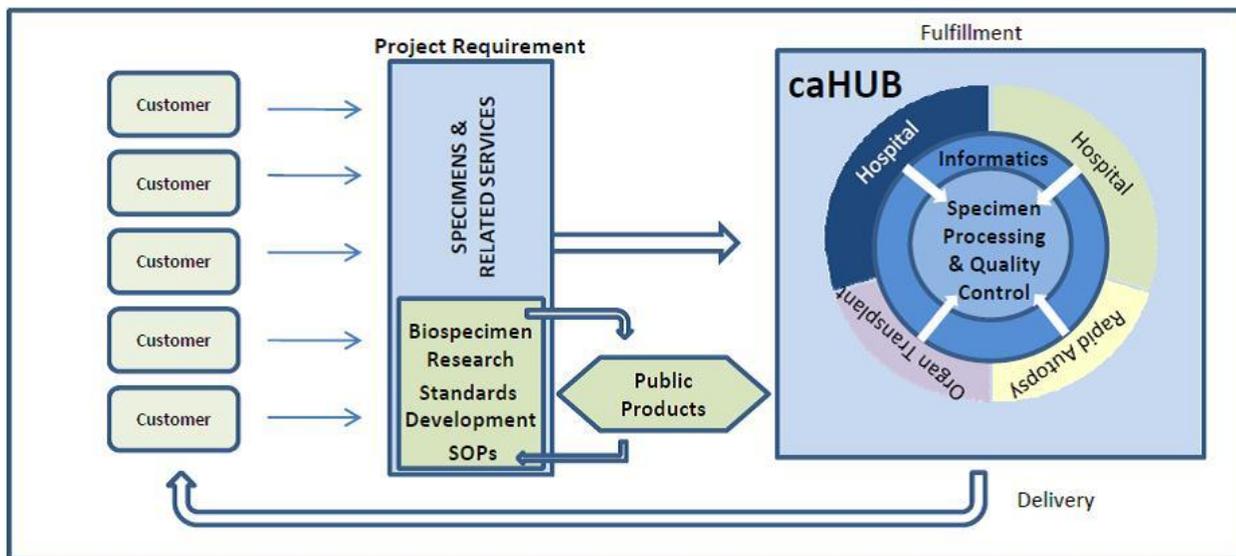
Among the many recommendations from this group was the recommendation that caHUB evolve into a public-private partnership (PPP) as soon as practicable. One reason behind this recommendation is that a PPP is required to enable the alternative cost-recovery options needed for sustainability and as a reality of limited capacity for Federal financial support. Secondly, forming partnerships with patient advocacy groups, industry, and academia likely would enable caHUB to respond quickly to changing scientific needs and engender greater public trust.

The AWG also provided many other products to the caHUB team that might prove useful to individuals interested in developing biorepositories. These include:

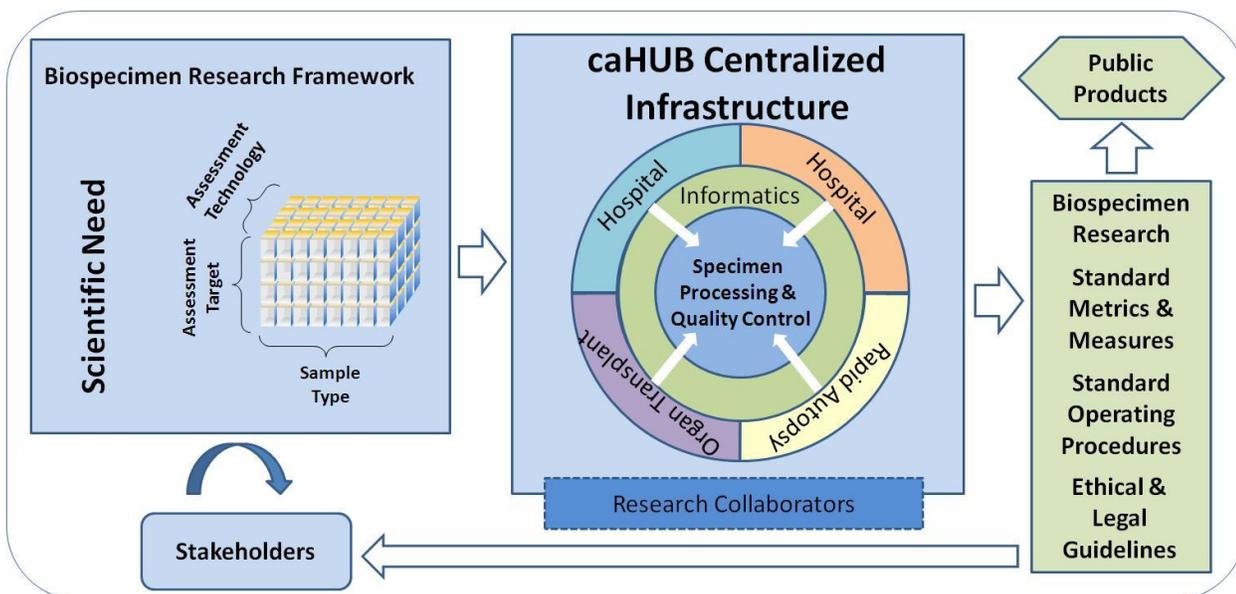
- Strategic mission and vision recommendations outlining worthy goals and an appropriate array of services of use to the research community
- Cancer-specific acquisition SOPs (based on input from nationally recognized pathologists and surgeons, incorporating evidence-based practices when available)
- Best practices for postmortem recovery of normal human tissue for research
- An informed consent template document (including minimum criteria and key elements such as clear description of physical donation, potential use of contributed specimens, protection of privacy, ability to withdraw, and expectations for future interaction or benefit from donation)
- General guidance principles surrounding the breadth of ethical, legal and social issues relevant to collection of human biospecimens (e.g. governance, intellectual property rights, return of research results, conflict of interest policy, pediatric participation, and issues related to rapid-autopsy donations)



## Original Concept: caHUB as a National Biospecimen Resource

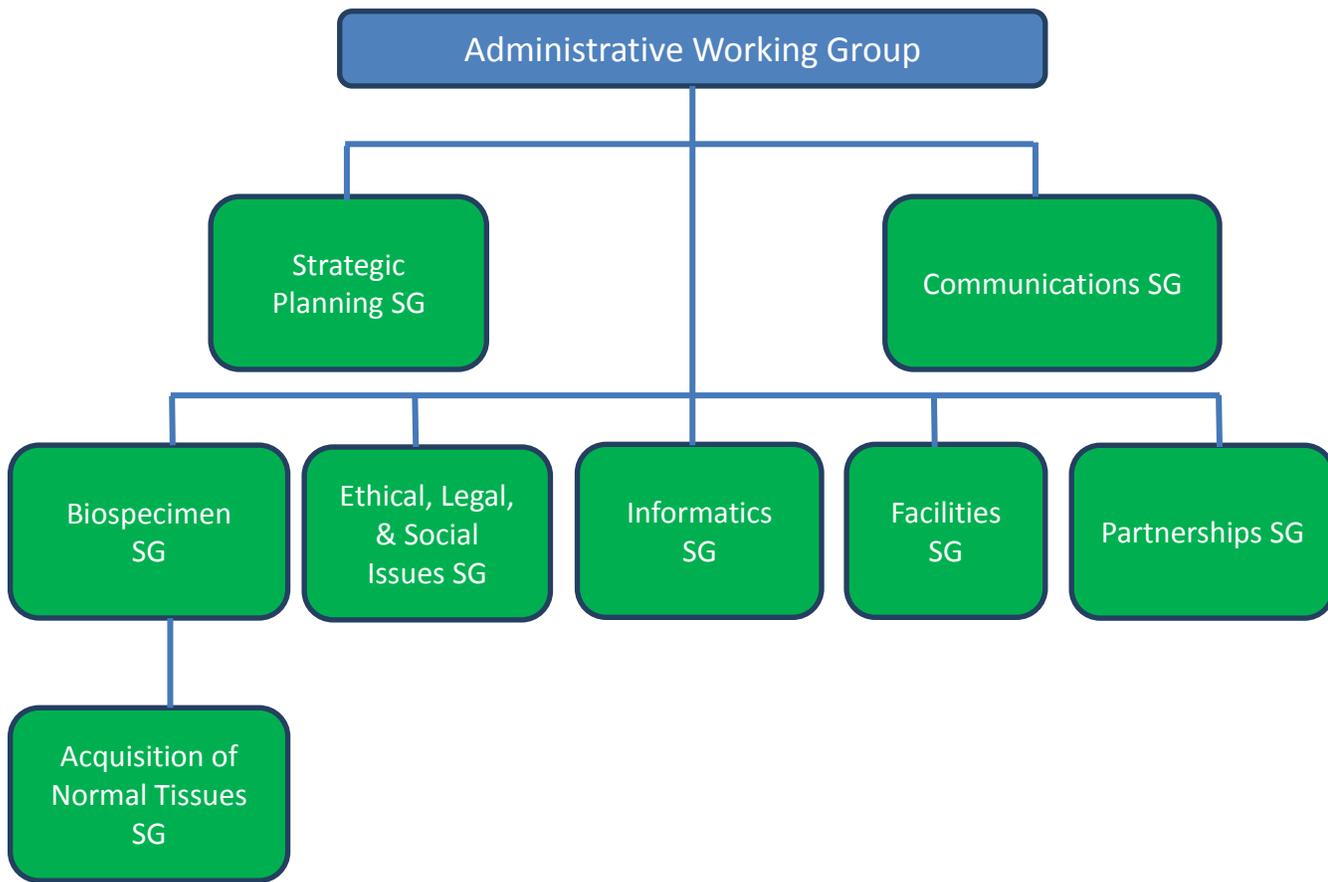


## New Concept: caHUB as a Center for Biospecimen Science and Standards



## Administrative Working Groups

Below is an organization chart of the caHUB Working Groups. Each box provides a link to list of participants for each group.



Goal	Deliverable	Appointed SG	Key Recommendations/ Products
Define WG(s) Mission and Operating Framework	Define working group (WG) reporting structure – what, frequency, mechanism for issue resolution	AWG	
	Document that describes the mission and goals of the AWG, communications plan, the frequency of meetings, and desired products and timeline.	AWG	
	Description of what other small groups or SGGs will be needed and their purpose, reporting structure to AWG, and timeline for specifics and deliverables	AWG	
	Agendas and action items from each SG teleconference and face-to-face	AWG	
	SG status reports	AWG	
Define caHUB Mission, Objectives, Scope of Operations	Develop the mission statement for caHUB: Vision, Mission, & Value Proposition	SPOS	Strategic Plan Document
	Develop list of key objectives, distinguishing between short term and longer term	SPOS	
	Define caHUB scope for Phase 1 and 2 (Profile of clients; gap analysis for client's needs; biospecimen accrual plan (sample types, volumes, sourcing objectives) based on clients' needs; budget/personnel/facilities requirements; ARRA reporting requirements)	SPOS	
	Develop the strategic plan document	SPOS	
Define caHUB Organizational Structure	Propose and define research and consulting services	SPOS	
	Develop overall organizational plan: Org Structure Management Structure Governance and oversight committee recommendations Reporting structures Proposal on need, organization, and charter for advisory committee(s) Charters for expert groups	SPOS	

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Define caHUB Business and Operating Plans	Develop tissue collection standard operating procedures	Biospecimen	Biospecimen Subgroup Key Recommendations
	Develop biospecimen qualification criteria: snap frozen & formalin-fixed, paraffin embedded	Biospecimen	
	Tissue collection prioritization strategy	Biospecimen	
	Develop quality assurance/quality control process metrics	Biospecimen	
	Bridge requirements/ needs of processes with repository facility attributes. (Review and refine facility plans and metrics/measurements. Building of facility will occur in Phase 2)	Facilities	Key Recommendation Document
	Establish architectural framework that comprehensively illustrates interoperable components of caHUB	Facilities	
	Establish use cases that illustrate the informatics vision for caHUB (high level)	Informatics	Notional Informatics Architecture (NIA) Document
	Provide operational informatics input into activities of other caHUB subgroups	Informatics	
	Address and compile subject matter vocabularies	Informatics	

Goal	Deliverable	Appointed SG	Key Recommendations/ Products
Define Ethical, Legal, and Social Issues (ELSI)	Preliminary considerations document: Analysis of the ethical, legal, and policy issues surrounding informed consent, privacy, ownership, intellectual property, etc.	ELSI	Preliminary Considerations Document
	Draft informed consent documents (cancer and normal tissues)	ELSI	
Define Partnering Objectives and Potential Targets. - Biobanks - CAP - FDA - Pharma	Report on caHUB partnering Objectives customers, needs, cost-recovery potential and ideas, proposed timeline	Partnerships	Key Recommendation Document
	List/profiles of potential partners, list of key assumptions, risks, opportunities for each: Assess relationship between industry and caHUB	Partnerships	
Define Communications Strategies	Develop a communications strategy for all stakeholders including description of key stakeholders (intramural, extramural, other government agencies, patients and patient advocacy, private foundations, Congress) and their role in design and implementation of the caHUB	Communications	Preliminary Communications Plan

Goal	Deliverable	Appointed SG	Key Recommendations/ Products
Define "Rapid Autopsy" Parameters and the Range of Normal ("Non-diseased") Sample and Data Requirements to Meet Genotype-Tissue Expression Project and Other Identified Market needs	Best Practices Document for Rapid Autopsy/Post Mortem Recovery of Normal Tissues (Includes: 1. operational and technical overview of common types of recovery programs, 2. unique ethical and legal considerations, 3. donor family and community considerations, 4. common normal tissue sampling schema, 5. example next of kin informed consent, 6. example materials transfer agreement, 7. common data elements for post mortem recovery)	ANT	Key Recommendations for Rapid Autopsy/Post Mortem Recovery of Normal Tissues
	Manuscript Featuring Recommendations for Rapid Autopsy/Post Mortem Recovery of Normal Tissues	ANT	Manuscript Featuring Recommendations for Rapid Autopsy/Post Mortem Recovery of Normal Tissues ( <i>pending publication</i> )