

**National Cancer Advisory Board (NCAB)  
Biomedical Technology Subcommittee Meeting**

Hyatt Regency Bethesda  
Bethesda, MD

December 8, 2008  
6:30 to 9:15 p.m.

**SUMMARY**

Participants:

Dr. Bruce Chabner, NCAB  
Dr. Donald Coffey, NCAB  
Ms. Kathryn Giusti, NCAB  
Dr. Waun Ki Hong, NCAB  
Dr. Judith Kaur, NCAB  
Ms. Mary Lester, NCAB  
Dr. Jennifer Pietenpol, NCAB  
Dr. H. Kim Lyerly, NCAB

Other Attendees:

Dr. Peter Kirchner, DOE, Ex Officio  
Dr. Carolyn Compton, Executive Secretary, NCI  
Dr. Mark Lim, NCI  
Dr. Kimberly Myers, NCI  
Dr. Jim Vaught, NCI  
Joanne Brodsky (Writer, The Scientific Consulting Group, Inc.)

Dr. Coffey opened the meeting and asked the attendees to identify themselves. He then introduced Dr. Compton, Director, NCI's Office of Biorepositories and Biospecimen Research (OBBR), who presented an abbreviated version of the presentation, "The Cancer Human Biobank (caHUB): Advancing the Vision of Personalized Medicine," that she was to give during the working lunch at the December 9 NCAB meeting.

Dr. Compton presented the basic outline, vision, and scope of the caHUB project and stated that the NCAB is being asked to approve the concept and funding for the first year's planning effort. The caHUB is intended to address the striking unmet need for high-quality human biospecimens required by efforts such as the Specialized Programs of Research Excellence (SPORes), Early Detection Research Network (EDRN), and The Cancer Genome Atlas (TCGA). This centralized public resource would use resources already developed by the NCI, including the Biospecimen Research Network (BRN) and the NCI Best Practices for Biospecimen Resources. Funding the initial planning stage would enable the OBBR to engage in a detailed planning process to include the formation of working groups to address the requirements for implementing the caHUB.

As the presentation proceeded, Subcommittee members raised questions and concerns about the broad scope of the project as outlined, its feasibility, and budget.

### **NCI's Best Practices for Biospecimens**

The adoption of the NCI's Best Practices for Biospecimens is voluntary, not policy. To encourage widespread adoption, one option is to make the adoption of the best practices a term and condition of award. This could not be done, however, without the consent of a broad array of stakeholders. Regional cancer centers, for instance, would have to agree with it. Additional challenges would be posed if pathology departments and cancer centers disagree regarding how to operate equipment. Because local conditions change continuously and innovations occur frequently in local operations, a top-down system would be difficult to maintain.

### **Market Survey**

A market survey was disseminated to institutions and investigators with a connection to the NCI, with a 15 percent response, most of whom were NCI-funded Principle Investigators. Approximately 75 percent of the respondents were positive toward the biobank. In addition, the idea of a national biospecimen bank as a standardized resource has grown in momentum, including in Congress, where the idea has been mentioned in a number of bills and reports. Clearance from the Office of Management and Budget (OMB) is being acquired to conduct a broader survey.

The Subcommittee agreed that a more extensive marketing survey is needed to determine the need for the project. Approximately 85 percent of those surveyed did not respond, which is within expected response rates from surveys of this type according to the NCI's Office of Market Research and Evaluation. More worrisome is the overall low number of laboratory scientists who responded; it is important to determine what they think about biorepositories and their current approach to biospecimens. It also is unclear how the NCI's approach to biospecimens relates to other programs, such as the SPOREs.

Other groups, such as the Multiple Myeloma Research Foundation, have attempted a similar activity and found that the tissue was not used by academics but rather in genomics and proteomics research. Tissue banking is a variable and complex process, so the NCI should be very clear about the target audience.

### **Personalized Medicine**

The Subcommittee voiced concerns about the ambitious nature of caHUB as well as how it would facilitate personalized medicine. Personalized medicine must be connected to clinical data; this is challenging at the local level, and it is unclear how this could be accomplished at the national level. The Subcommittee also asked about the gap(s) in programs such as the Cancer and Leukemia Group B (CALGB) that would be filled by caHUB and wondered if academic researchers would voluntarily switch to caHUB rather than continuing to operate as accustomed.

Regarding collecting clinical data, U.S. military cancer centers and community-based hospitals are among the sources for specimens and data. The Subcommittee noted challenges related to working with the military, access to patient information, and possible lower standards. Personalized medicine requires more specific information than simple positive/negative responses archived in databases; starting with the National Cancer Data Base of the Commission on Cancer for therapeutic data may not be the most optimal route.

### Scope of Project

Subcommittee members agreed that the project's scope is large and complicated, even overwhelming. The focus should be narrowed to a manageable level; perhaps focus on a single tumor site as a pilot feasibility effort. Once this proves successful, the project could be expanded to other areas. The project might benefit from NCI's experiences and lessons learned from the efforts of other projects, such as TCGA and SPORE.

### Other Issues

The Subcommittee discussed the participation of the pharmaceutical industry in the project and the role of the NCI Board of Scientific Advisors (BSA) in approving the caHUB concept.

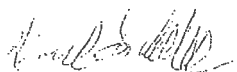
### Conclusion

Although Subcommittee members expressed support for the overall concept of the caHUB and appreciation for the OBBR's efforts to date, a consensus was reached to revise the presentation to be made at the December 9 NCAB meeting to emphasize the rationale for the project based on the urgent problems with specimen collection identified in connection with TCGA and to use the initial phase of the project to accomplish further planning and concept development in preparation for presenting the caHUB idea to the BSA.

The meeting was adjourned at 9:15 p.m.

12 - 9 - 2008

Date



Donald S. Coffey, Ph.D., Chair

12 / 9 / 2007

Date



Carolyn Compton, Ph.D., Executive Secretary