



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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Subject: Online Focus Groups to Inform the Development of a National Biorepository  
(OMB No. 0925-0046-15; Expiration Date 1/31/10)

The National Cancer Institute (NCI) proposes conducting two online focus groups (using a methodology called “Advance Strategy Labs”, described below) with high-level representatives from biotech and pharmaceutical industries to help inform the development of a national biorepository. The goal of this research is to triangulate the information with data previously obtained from an earlier, approved sub-study entitled, “Survey of Human Biospecimen Needs and Challenges for the Biomedical Research Enterprise” (OMB #: 0925-0046-13). This current research design will be focusing on key informants and will utilize a method similar to a moderated, online focus group, rather than the survey method, as previously approved. It is hoped that OMB will approve this request so that the focus groups can be conducted in July, 2009.

Background

The quality of biomedical research is rooted in the quality of the biospecimens scientists use, and progress in the fight against cancer appears to be threatened by inadequate access to quality biospecimens. In response to challenges researchers have said they face in obtaining the high quality biospecimens needed for cancer research, the National Cancer Institute’s (NCI) Office of Biorepositories and Biospecimen Research (OBBR) is considering the potential advantages and drawbacks of creating a national, standardized biorepository resource. As it is envisioned, this resource would supply the research community and industry with cancerous and healthy biospecimens. The concept is called caHUB (cancer HUmAn Biobank).

OBBR has asked the NCI Office of Communications and Education’s (OCE) Office of Market Research and Evaluation (OMRE) to explore specific needs of the biotech and pharmaceutical industries around obtaining and using biospecimens today and potential ways to improve it. The information gathered through these online focus groups with high-level representatives from such industries will help OBBR better understand the potential market for a repository of high quality

biospecimens for cancer research before they make a significant commitment to the project. The results will also help OBBR determine the factors that would make a national biorepository useful and sustainable.

### Participants

A list of potential participants will be provided by OBBR. These individuals were identified from NCI Best Practices Road Show rosters and advertising strategies as well as other NCI Office of Biorepositories and Biospecimen Research (OBBR)-sponsored meetings, and are now part of an NCI OBBR contacts database. This list will include potential participants who work in the pharmaceutical and biotechnology industry. The industry is expected to be a key user of this national resource and has the potential to support or inhibit the successful adoption of this resource. Therefore, it is important to hear from key stakeholders from these industries to accurately understand and overcome challenges in the resource's development.

### Research Instrument

The moderator's guide (attached) has been developed based upon internal discussions with NCI-affiliates in the target audiences, including NCI researchers, industry representatives, government representatives, and cancer advocates. The guide for these two online focus groups will address the following topic areas:

- Information and prioritization of biospecimen needs
- Benefits (and prioritization) of a national, standardized human biospecimens resource
- Perceived challenges (and prioritization) in the development of this resource
- Motivations/barriers (and prioritization) to contribute to this resource
- Quality assurance expectations (and prioritization) for this resource
- Operating procedures/intellectual property expectations (and prioritization) for this resource

### Methodology

For this sub-study, a methodology called "Advanced Strategy Lab" (ASL) would be utilized. The Advanced Strategy Lab (ASL) is a qualitative research process that uses an online interactive discussion. Approximately 20 participants typically participate in each ASL session. Each participant needs two lines of communication for the session: a computer with internet connection, and a telephone to call into a toll-free conference line that will be provided. Sessions are designed in accordance with project objectives and moderated by one or more research professionals with extensive experience in both the software technology and opinion research techniques. The sessions will be facilitated by Stratacomm, an NCI contractor that specializes in communications and research of this nature.

In ASL sessions, participants are connected to each other in a 90-minute online session. They receive instructions and are asked questions from the moderator over the phone on the conference call. Participants then type their answers into their designated dialogue box (which hides their identity from the other participants, such that each participant can see all the responses, but will not know who wrote what). Following this process, the facilitator guides the group through online brainstorming, discussion, and assessment exercises. As stated, all responses are anonymous to others in the session to ensure confidentiality and free thinking within a guided format.

The ASL methodology is designed to provide a range of electronic activities among the participants, including:

- Brainstorming
- Idea Categorization
- Idea Prioritization
- Voting
- Survey Questions
- Topic Commentary
- Evaluating Alternative Implementation Steps

The ASL's software automatically formats and tabulates data as the session proceeds. This means immediate turnaround: summaries of survey results are available seconds after respondents complete a question, and full verbatim reports are available within hours after a session.

### Respondent Burden and Costs

Participants will be invited to participate via email or phone. We expect 20 persons per group, for a total of 40 participants. Each group will last 90 minutes. The total respondent burden for this effort is estimated to be 60 hours. This effort will account for 3.0 percent of the total annual burden hours (2010) granted in our approval package.

Estimates of Hour Burden and Respondent Cost						
Types of Respondents	Number of Respondents	Frequency of Response	Average Time Per Response (Hours)	Annual Hour Burden	Hourly Wage Rate	Annual Respondent Cost
Stakeholders	40	1	1.50	60	\$17	\$1,020

Please feel free to contact me at 301-435-7789 if you have any questions.