DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: December 17, 2008

To: Office of Management and Budget (OMB)

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Subject: Pretesting/Formative Research for NCI Communications Messages
OMB No. 0925-0046, Expiration Date 1/31/10
Survey of Human Biospecimen Needs and Challenges for the Biomedical Research Enterprise (Proposed OMB No. 0925-0046-13)

The National Cancer Institute (NCI) proposes conducting a web survey with researchers who use biospecimens and other stakeholders to help inform the development of a national biorepository.

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 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 topics related to how researchers obtain and use biospecimens today and what they and other stakeholders think about the current situation regarding biospecimens and potential ways to improve it. The information gathered through this survey 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.

Research Instrument

A survey instrument has been developed based upon internal discussions with NCI-affiliates in the target audiences, including NCI researchers, biorepository managers, government representatives, and cancer advocates. The survey questions first seek to determine what researchers are currently doing to meet their needs for biospecimens and the barriers and problems they and others face in getting the number and quality needed to conduct cancer research appropriately. Next, survey respondents will be presented with a possible solution; for the NCI to develop a national standardized biorepository (cancer HUman Biobank) with high quality specimens that researchers could access. The respondents will then be asked to share their reactions to this potential solution as well as other possible solutions. Results for respondents doing different types of jobs and from different organizations will be examined to discover if differences in opinions by subgroup populations exist. Both the Word version and the PDF of the screen shots of the survey instrument are attached. The screen shots are included to help visualize what the actual survey will look like. Note that the online version is still in development and made not reflect the more up-to-date Word version that is also included in this submission.

Participants

A list of potential participants will be developed by OBBR. This list will include potential participants who work in academia, NCI, NCI-designated cancer centers, pharmaceutical and biotechnology companies, nonprofit and advocacy organizations, clinical settings, and federal, state, or local governments. It is important to include all potential types of stakeholders in this survey because they have different experiences working with biospecimens (i.e., tasks related to collection, processing, storage, distribution, patient care, and program administration) as well as different research needs.

Survey Administration

The survey instrument will be converted to a computer-based survey and will be tested to ensure that the formatting is clear and that data entry errors will be minimized. For example, respondents will not be permitted to select an answer to a question while simultaneously selecting "does not apply to me." Participation will be strictly voluntary and respondents will be able to discontinue their participation at any time by clicking on an "opt out of survey" button on each page. Respondents will be assured that neither their participation/non-participation nor any responses to survey questions will have any effect on their eligibility to contribute to or obtain samples from the cancer Human Biobank if it is developed.

Potential survey respondents will receive an email in advance to announce that they will be invited to complete a survey from the NCI OBBR. Survey invitations will be distributed by email with a link to the survey. A unique identification number (ID) will be sent to each potential respondent in the survey invitation. The unique IDs will be used to manage the responses, but will be generated randomly and will not be associated with an individual's responses or stored with any survey responses. The purpose of the IDs is solely to ensure that respondents do not distribute the survey to multiple members of their organization thereby skewing the results. The IDs will be set up to allow only one person to complete the survey per ID, however, potential respondents will have the ability to forward the invitation to a different individual if they feel that a different person in their organization is better suited to answer the survey questions.

All data will be collected by the contractor, User-Centered Design, Inc., and all personal identifiers will be excluded from the data records that are delivered to NCI. The data will be analyzed in aggregate and no respondents will be individually identifiable.

Survey invitations will be sent to 5,000 potential respondents. Based on the results from two previous surveys with similar audiences: 1) the *NCI Cancer Bulletin* survey (previously approved under OMB# 0925-0046-06) and 2) the OCE External Stakeholder Survey (previously approved under OMB# 0925-0046-04) we expect a 10% response rate, or a maximum of 500 responses from non-government employees. Based on an average, pilot-tested administration time of 15 minutes and approximately 500 non-government employee respondents, the total respondent burden for this effort is 125 hours. This effort will account for 6.2 percent of the total annual burden hours (2010) granted in our approval package. Previous sub-studies approved by OMB under this umbrella submission total 1007 burden hours requested to date.

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	500	1	0.25	125	$17	$2,125

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