

Mini Supporting Statement A For
Generic “Questionnaire Cognitive Interviewing and Pretesting (NCI)”
OMB No. 0925-0589, Expiration Date 4/30/2014

Title of Sub-Study: Requirement Gathering for a Biobank Economic Modeling Tool (BEMT)

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Section A.

A1. Circumstances Making the Collection of Information Necessary

Section 410 of the Public Health Service Act (42 USC § 285) authorizes the collection of the information. The PHS Act authorizes National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention and treatment. The Biorepository and Biospecimen Research Branch (BBRB) located within the Division of Cancer Treatment and Diagnosis (DCTD) is a world leader in the field of biobanking and biospecimen science. One of BBRB’s key objectives includes harmonizing sustainable development while increasing accessibility and availability of well annotated, high-quality biospecimen resources. The availability of high-quality biospecimen resources is directly linked to a biobank’s ability to understand true costs of biobanking, what methodology to use to adequately perform cost recovery and the capability to perform financial planning. BBRB’s efforts include ongoing studies and projects related to the economic issues related to biobanking.

This ARRA-funded formative project involves pre-testing related activities to refine the features of a web-based software application, the Biobank Economic Modeling Tool (BEMT). The BEMT is designed to assist biobanks around the world with searchable information about infrastructure costs, funding requirements, and specimen and service costs and price. Feedback from potential users is needed to assist in refining the software, to be obtained via the proposed survey.

Survey responses will provide data to guide the placement of questions, as well as the range of responses. In addition to querying respondents about the design, questions will be asked to refine the calculations needed to run this tool. Specific questions that support the interactive calculations include demographic information, geographic region, operating model and facility/organizational footprint, and cost recovery adherence. Post survey, a debriefing will be performed with a small sampling of respondents to clarify their responses and conduct a brief cognitive interview. Specifically, this interview will allow us to obtain feedback related to the length and content of the questions and responses, to evaluate the degree of difficulty, relevance of the information asked and perceived value of the survey.

This study fits within scope of the full generic as “other questionnaire testing and development” (Supporting Statement A written January, 2011, p. 11) in which program staff will “perform testing of other questionnaires that require development over a short time-frame.”

A2. Purpose and Use of the Information Collection

The primary purpose of the tool is to provide biobanks with the capability to perform essential cost recovery and financial planning functions. The information collected for this formative project will be de-identified and used to refine the application. The Biobank Economic Modeling Tool (BEMT) is designed to assist biobanks all around the world with searchable information about infrastructure costs, funding requirements, and specimen and service costs and price.

After pre-testing related activities are completed, it is anticipated that the BEMT will be publicly available and hosted on the National Cancer Institute's web site. BEMT will operate as a resource and will not collect or store the demographic and economic information that biobanks will provide.

A3. Use of Information Technology and Burden Reduction

The majority of study contact (invitation letter, survey, and reminders) will occur online. Brief phone calls will be made as needed, to clarify responses.

A4. Efforts to Identify Duplication and Use of Similar Information

To date, no other tool has been developed that provides biobanks and biospecimen resources the ability to assess their financial viability with access to peer cost and pricing market data.

A5. Impact on Small Businesses or Other Small Entities

Small businesses may be involved in this study; however efforts have been taken to minimize their burden. Additionally, they may find the tool useful in the future and as such, may want to provide their feedback about the tool in the development phase.

A6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This study will be implemented in a manner that fully complies with the Guidelines of 5 CFR 1320.5.

A8. Comments in Response to Federal Register Notice and Efforts to Consult Outside Agency

DCTD has collaborated with Gordon Willis from DCCPS in the development of the methodology and instrument. No efforts have been taken to consult outside the agency.

A9. Explanation of Any Payment or Gift to Respondents

No incentives will be provided to the respondents.

A10. Assurance of Confidentiality Provided to Respondents

The majority of identifying information on potential respondents has been collected from publicly available sources (i.e. Institutional websites, Linked in profiles, etc.), however there are a minority of respondents who did not have publicly available information.

This contact information is being referenced from the private business databases housed at the contractor; therefore this small set of data would be considered personally identifiable information (PII). All identifying information will be anonymized and kept separate from the survey. PII will not be retained once the project is completed.

A11. Justification for Sensitive Questions

PII that is being collected includes respondent’s name, job title, affiliated institution name, and biobank name. There are no sensitive questions being asked.

A12. Estimates of Hour Burden Including Annualized Hourly Costs

Table A12-1. Estimates of Hour Burden

Category of Respondent	Instrument**	No. of Respondents	Participation Time (in hours)	Total Burden Hours
Private sector*	Survey	429	90/60	644
State governments	Survey	3	90/60	5
Federal government	Survey	18	90/60	27
Private sector	Follow-up	143	30/60	72
State and local governments	Follow-up	1	30/60	1
Federal government	Follow-up	6	30/60	3
Totals		450		752

*Private sector respondents include business and other for-profits, and not-for profit institutions.

**It is estimated that some respondents will require follow-up questions to their responses and thus this is included as extra burden.

The average hourly mean wage rates are based on the May 2012 National Occupational Employment and Wage Estimates for the Unites States (http://www.bls.gov/oes/current/oes_nat.htm#00-0000).

Table A12-2. Cost to Respondents

Type of Respondent	Number of Respondents	Total Burden Hours	Wage Rate	Respondent Cost
Private sector, State and Federal governments	429	644	\$22.01	\$14,174.44
	3	5	\$22.01	\$110.05
	18	27	\$22.01	\$594.27
	143	72	\$22.01	\$1,584.72
	1	1	\$22.01	\$22.01
	6	3	\$22.01	\$66.03
Totals				\$16,551.52

A13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital costs, operating costs, or maintenance costs to report.

A14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal government is \$42,300.

A15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A16. Plans for Tabulation and Publication and Project Time Schedule

HOW will you analyze results?

We will perform qualitative review of the survey responses evaluating completeness of the data and consistency of the responses provided. Upon passing the quality review, we will integrate the data set into the BEMT application. If data sets do not pass quality review, the survey respondent would be a candidate for follow-up to clarify responses.

Will there be any publications (aside from website with the tool) from this?

At present a scientific abstract and potential paper about the Biobank Economic Modeling Tool (BEMT) are anticipated, however no analysis of survey data will be performed and/or included in the publication. .

The study time schedule is outlined in Table A.16-1.

Table A16-1. Study Time Schedule

Activity	Months after OMB Approval
Recruit participants (collect information)	Months 0 – 2
Complete Study (final participants)	Month 3
Clean data and run analyses	Month 3
Summarize results	Month 3

A17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB Clearance Number, Expiration Date, and Burden Disclosure Statements will be displayed.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Certification for Paperwork Reduction Act Submissions.

Attachments:

1. Survey Invitation Letter
2. Survey Screenshots
3. Survey Reminder Email
4. Follow-up Questions and Debriefing Guide