

Supporting Statement A For:

Financial Sustainability of Human Tissue Biobanking (NCI)

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Table of Contents

A.	JUSTIFICATION.....	3
A.1	CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....	3
A.2	PURPOSE AND USE OF THE INFORMATION.....	5
A.3	USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....	7
A.4	EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....	8
A.5	IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....	8
A.6	CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....	8
A.7	SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....	9
A.8	COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE THE AGENCY.....	9
A.9	EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS.....	9
A.10	ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....	9
A.11	JUSTIFICATION FOR SENSITIVE QUESTIONS.....	10
A.12	ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS.....	10
A.13	ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS AND RECORD KEEPERS.....	11
A.14	ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....	11
A.15	EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....	12
A.16	PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....	12
A.17	REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....	14
A.18	Exceptions to Certification for Paperwork Reduction Act Submissions.....	14

LIST OF ATTACHMENTS

Attachment 1 – Questionnaire Screen Shots

Attachment 2 – Invitation Letter

Attachment 3 – List of all Survey questions

Attachment 4 – Office of Human Subjects Protection Exemption

Attachment 5 – Privacy Act Memo

The purpose of this web-based survey is to collect information regarding the challenges that human tissue biobanks encounter in achieving financially sustainable operations. The survey will collect a combination of structured, quantitative, and free-text descriptive data that characterize the type and maturity of respondent biobanks, their sources of funding, and their usage of funding in conducting operations. The survey will also collect information describing the difficulties in maintaining funding sources and establishing new ones. Finally, the survey will elicit descriptions of techniques used to overcome the difficulties. A combination of domestic and international biobanks will be asked to participate in the survey.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Public Health Service Act, Section 410 (42 USC § 285), Section 411 (42 USC § 285a), and Section 412 (42 USC § 285a-1) authorizes the National Cancer Institute (NCI) to collect financial and operational information to be used by NCI to help formulate strategies for program planning efforts to support national and international biobanks.

The National Cancer Institute's (NCI) Biorepositories and Biospecimen Research Branch (BBRB), within the Division of Cancer Treatment and Diagnosis, is pursuing its mission to facilitate cancer and biomedical research by improving the quality and consistency of human biospecimens. BBRB achieves this mission through development and deployment of standards that represent the state of the science for biospecimen collections. This mission is carried out through five core focus areas;

- Support and development of *scientific research* to bolster the evidence base for biospecimen collection, handling and processing practices
- Leading the development and continuous improvement of *policies and processes* for collection and management of biospecimen resources
- Providing *educational* materials and forums for *communication* around biospecimen related issues
- *Partnering* nationally and internationally to *harmonize* biospecimen and biobanking standards

- Providing a resource for direct *support* of NCI and NIH programs and *service* to the research community

To achieve these objectives, BBRB is involved in on-going studies of the economics of biobanking, which include cost-recovery modeling and the qualification and quantification of the economic impact of standardization of practice and centralization of resources. One of the primary goals of BBRB is to develop public products that will help biobanks implement standards of practice in a cost effective manner.

The lack of standardized, high-quality biospecimens is widely recognized as a significant roadblock to cancer research. Insufficient public and private funding presents a significant challenge to human specimen biobanking in support of translational research. Sufficient funding is essential for implementation of good laboratory practice and quality management programs that optimize specimen and data quality along the biobanking supply chain. Adequate funding is also required to ensure the long-term sustainability of the resource, which in turn promotes sharing of materials and data among the researchers studying the same or similar diseases. In economically challenging times, biobanks must increasingly rely on cost efficiency and cost effectiveness measures to stay operationally relevant with respect to improvements in biomedical technology. The consequences of insufficient funding are a reduction in the quality and or quantity of collected specimens, a premature loss of valuable specimens over time, and a diversion of resources away from the biobanking core mission to attend to tactical funding activities. It is easy to see how these phenomena in turn slow the pace of scientific progress and dilute the value that can be achieved from research investments.

The web-based Financial Sustainability of Human Tissue Biobanking survey supports that goal by addressing the financial challenges facing biobanks today. It will produce a clearer understanding of the specific challenges being faced from the point of view of those directly impacted. Insights from this survey will inform published guidance that will be publicly available to the research community and the larger medical community. The survey is a convenient, self-administered, low-cost method of collecting financial and operational data from hundreds of biobanks that vary in their size, maturity, funding, and geographic location (**Attachment 1**). The test version of the survey can be viewed on-line at <HTTP://biobank-survey.healthcit.com>. This site is currently secured but can be accessed by OMB reviewers by requesting a UserID and secure password. To request these credentials, please send an email to <XXXX@healthcit.com>. This is a request for OMB to approve the new submission titled, “Financial Sustainability of Human Tissue Biobanking” for 1 year.

Through invitation emails, interested respondents will be directed to the website (**Attachment 2**). The website will include information on how to create an account and the goals and objectives of the survey. Interested participants will provide their contact information through a secure on-line registration form. HealthCare IT, Inc., the contractor for this survey, will monitor and track registrations and the status of responses. Once participants have completed all of the survey sections, they will be directed to submit their data.

A.2 Purpose and Use of the Information

The information gathered in this survey will be used by NCI to help formulate strategies for program planning efforts.

The intent of the survey is to answer the following research question: “What is the financial burden (to the host institution) of the startup, maintenance and long-term sustainability of a human biospecimen resource used for biomedical research, given the host institution’s geographic and socioeconomic environment and organizational structure?” Specifically, the survey will seek to collect data on the full range of costs (direct and indirect) that are incurred along the biospecimen collection, processing, storage, and distribution continuum. Areas that the survey addresses include:

1. Demographic and background information about the respondents’ biobanks, for example:
 - Biobank organizational structure
 - Volume of samples in inventory
 - Average number of requests for samples per year
 - Characteristics of requesting entities (internal, external independent researcher, external academic medical center)
2. Major direct costs associated with running their biobanks (either proportional or actual, variable and fixed), for example:
 - Laboratory materials and supplies, computer and data management equipment
 - Direct labor (technologists, surgical and pathology staff, consenting nurse, research associates)
 - Inventory management costs
3. Major indirect costs (variable and fixed) associated with running their biobanks; for example:

- Indirect labor such as biobank management staff, unit director, grants and contracts management staff, information technology staff, administrative support staff
 - Packaging, shipping, storage cost; facility costs; utilities
4. Technical/operational challenges that impact their biobank’s financial well-being;
 5. Techniques used by respondents to overcome these challenges;
 6. Types of economic information or tools that would be most useful to respondents in their operation or for increasing their chances of obtaining funding or institutional buy-in;
 7. The format in which this information or tools would be most useful.

For a complete list of questions please see **Attachment 3**.

A.3 Use of Improved Information Technology and Burden Reduction

The Financial Sustainability of Human Tissue Biobanking Survey was designed and is intended to be launched using NCI’s recently acquired open source platform - caCURE. caCURE provides a very flexible and economical means of gathering data with distinct advantages over conventional survey tools. Survey questions were designed with structured responses rather than free-form text, aiding in statistical analyses and generating findings. This approach also helps improve the usability of the survey – caCURE can use structured responses to trigger skip patterns. Skip patterns allow a form to react to a user’s responses by presenting additional relevant questions based on prior responses.

Using a web-based survey complies with the Certification for Paperwork Reduction Act Submissions--[5 CFR 1320.9\(j\)](#)—which states, “The submission makes appropriate use of

information technology.” A Privacy Impact Assessment (PIA) has been determined not be needed by the NCI Privacy Act coordinator because no PII is being maintained.

A.4 Efforts to Identify Duplication and Use of Similar Information

While there have been several studies conducted on the characterization and general sustainability of biobanks, to our knowledge, the Financial Sustainability of Human Tissue Biobanking survey is the first to specifically address financial sustainability. This survey will be the first to evaluate the types of financial challenges that biobanks are experiencing, strengths and weaknesses of various funding mechanisms, and the greatest economic concerns facing biobank managers. During the preliminary research and design of the survey, several articles were used to provide background and to inform the survey design^{1,2}.

A.5 Impact on Small Businesses or Other Small Entities

No small entities will be involved in this survey. All respondents will be individuals who participate voluntarily.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time collection.

¹ Vaught J, Rogers J, Myers K, et al. An NCI Perspective on Creating Sustainable Biospecimen Resources. J Natl Cancer Inst Monogr 2011;42: 1-7

² Riegman P, Morente M, Betsou F, et al. Biobanking for better healthcare. Molecular Oncology 2 (2008) 213-222.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The Financial Sustainability of Human Tissue Biobanking survey project fully complies with the guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on May 7, 2013, Vol. 78, p. 26639. There were no public comments received.

The Financial Sustainability of Human Tissue Biobanking survey was developed through NCI's collaboration with HealthCare IT, Inc. During the development of the survey, an external focus group met to discuss the needs and interests of potential users and provide advice to the project. This is discussed in Supporting Statement B, Section B.4.

A.9 Explanation of Any Payment or Gift to Respondents

Respondents will not receive any type of payment for their participation.

A.10 Assurance of Confidentiality Provided to Respondents

The Financial Sustainability of Human Tissue Biobanking survey will be hosted at the contractor's data center facility. HealthCare IT, Inc. operates a hosting center in Rockville, MD with a backup location in Philadelphia, PA. The data center has been designed to meet the demanding security and reliability requirements for handling healthcare data (including Protected Health Information as defined by HIPAA). The data center environment includes the operation

of firewalls, switches, physical infrastructure (power, cooling, UPS, fire suppression, alarms, video surveillance, access control), backup, disaster recovery, network and server intrusion prevention detection, virus/worm/Trojan scanning, server monitoring and automated alerts, data encryption, and data destruction.

The survey has been designed with appropriate security to ensure that the respondent's data is not visible to unauthorized users. This information collection is considered exempt for IRB review by the NIH Office of Human Subjects Protection Exemption (**Attachment 4**).

A.11 Justification for Sensitive Questions

Participants will be responding on behalf of their company, not themselves. No personally identifiable information (PII) or sensitive questions will be asked in the Financial Sustainability of Human Tissue Biobanking survey. This data collection was determined to (be/not be) subject to the Privacy Act (**Attachment 5**). Participants will be asked to indicate only broad, general characteristics of their biobanks.

A.12 Estimates of Annualized Burden Hours and Costs

The participants are domestic and international biobanks. Data collection activities for all participants involve completion of 7 modules; each module consisting of 5-10 questions. The number of questions may vary between participants based on how previous questions are answered. The survey is structured with skip patterns, which are designed to reduce the burden by displaying only those questions that are relevant to that participant. The time per response is estimated to range from 1 to 1½ hours because of the skip pattern and the time needed to gather

the information requested to respond to the questions. The annual burden is 822 hours and information collection is only anticipated to last two to three months.

A.12 - 1 Estimates of Annualized Burden Hours				
Category of Respondents	Number of Respondents	Frequency of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Private Sector*	548	1	90/60	822
Totals	548			822

*Private sector will include primarily not-for-profit institutions, as well as some businesses and for-profits. Additionally, up to five (5) Federal employees will be asked to participate in the survey as part of their official job duties during work hours and thus, as directed by the Paperwork Reduction Act, are not to be considered in the burden calculations.

The total annualized cost to the respondents is estimated to be \$34,260, calculated at \$45.68 per hour (U.S., Department of Labor, Bureau of Labor Statistics, 2011, NAICS code 621500 – Medical and Diagnostic Laboratories). This total assumes that international wages are similar to domestic for this particular respondent type. The costs are summarized in Table A.12-2.

A.12 - 2 Annualized Cost to Respondents					
Category of Respondent	Number of Respondents	Frequency of Responses per Respondent	Average Burden per Response	Hourly Wage Rate	Total Respondent Cost
Private Sector	548	1	1.5	\$45.68	\$37,548
Total					37,548

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate in the study.

A.14 Annualized Cost to the Federal Government

The annual and total cost to the Federal government is estimated to be \$306,231.

Table 14-1 Annual Cost to the Federal Government		
	TOTAL	ANNUAL AVERAGE
Contractor Costs	\$286,231	\$286,231
NCI Personnel Subtotal	\$20,000	\$20,000
Grand Total	\$306,231	\$306,231

A.15 Explanation for Program Changes or Adjustments

This is a new information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

A.16.1 Data Analysis Plans

The overall cost distribution and available funding sources of biobanks will vary by the type, size, age, and factors related to the location of the biobank. For example, it is expected that newer biobanks to spend a disproportionately large part of their funding on specimen collections. Likewise, it is also expected that biobanks that have been in operation for a longer period of time to be less dependent on primary funding and to spend more staff resource cultivating new sources of funding.

Differences will be characterized in statistically reliable subsets. It is expected that the top self-identified, financial burdens to be correlated to common patterns of cost distribution and accessible revenues. For example biobanks that have cultivated a broader set of funding sources will have a longer-term sustainability outlook and will have a larger set of sustainability

strategies. It is not expected that the diversity of funding strategies to be strictly correlated to the age of the biobank. That is, it is expected that some young banks with a larger number of funding sources and a proportionately smaller allocation of core funding from their host institution as well as some older banks with a smaller number of overall funding sources and proportionately larger allocation of core funding. Further, it is expected that each of these types of banks to report fewer current financial challenges.

Strategies will be categorized based on the above-described analyses allowing banks to identify strategies that are most germane to their current or near-term future state.

The types of Planned Reports include:

- **Top 5 Challenges:** All types of biobanks, by Type and Size of Biobank, and by years in operation
Ranked Challenges: by Type and Size of Biobank, and by years in operation.
- **Direct and Indirect Cost Distribution:** All types of biobanks, by Type and Size of Biobank, and by years in operation.
- **Value Chain Labor Distribution:** All types of biobanks, by Type and Size of Biobank, and by years in operation.
- **Funding Source Frequencies:** All types of biobanks, by Type and Size of Biobank, and by years in operation.
- **Top New Funding Sources:** All types of biobanks, by Type and Size of Biobank, and by years in operation.
- **Sustainability Strategy Frequencies:** All types of biobanks, by Type and Size of Biobank, and by years in operation.
- **Direct and Indirect Staffing:** All types of biobanks, by Type and Size of Biobank, and by years in operation.
- **Stewardship Responsibility:** All types of biobanks, by Type and Size of Biobank, and by years in operation.

A.16-2 Project Schedule

The Financial Sustainability of Human Tissue Biobanking survey will begin within 3 weeks of obtaining OMB approval. The contract period will include fielding, analyzing, and

disseminating findings from this survey. The contractor will be responsible for preparing the analytic databases resulting from the survey. The timetable for the data collection is shown below, in Table A.16-2.

A.16 - 2 Project Time Schedule	
Activity	Time Schedule
Email invitations are sent to respondents	2 – 3 weeks after OMB approval
Interim report – determine response rates	4 - 5 weeks after OMB approval
Survey is closed	2 months after OMB approval
Preliminary Report	2 – 3 months after OMB approval
Final Report	3 – 4 months after OMB approval
Publication	6 – 7 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The Financial Sustainability of Human Tissue Biobanking survey will not require exemption from displaying the expiration date of OMB approval. Any reproduction of the data collection instrument will prominently display the OMB approval number and expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The Financial Sustainability of Human Tissue Biobanking survey does not require any exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).