

# **Supporting Statement B For:**

## **Financial Sustainability of Human Tissue Biobanking (NCI)**

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## **LIST OF ATTACHMENTS**

Attachment 1 – Survey 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

## B. STATISTICAL METHODS

### B.1 Respondent Universe and Sampling Methods

A total of 548 biobank representatives will be invited to participate in the Financial Sustainability of Human Tissue Biobanking survey. These potential participants have been identified through public information sources. Participants will be divided into two study groups, distributed among biobank type as shown in Table B.1. The different types of biobanks represent the spectrum of types found internationally and domestically. An accredited tissue bank has some type of internationally recognized standards, a study is for a particular use, and a networked biobank is part of a system of biobanks.

**Table B.1 Expected number of participants by type and geographic location**

	Biobank Type					TOTAL
	Accredited Tissue Bank	Biobank	Study	Network	Other	
Domestic	116	32	51	3	149	351
International	0	15	126	7	49	197
<b>TOTAL</b>	<b>116</b>	<b>47</b>	<b>177</b>	<b>10</b>	<b>198</b>	<b>548</b>

Out of the 548 biobank representatives invited to participate in the study we expect 500 (350 domestic, 150 international) to agree to participate. The overall response rate is expected to be approximately 80% (548/438).

The subcontractor will recruit participants and send out invitation emails (**Attachment 2**). Invitees who choose to participate will log onto the web-based survey at <http://biobank-survey.healthcit.com> to create an account and complete the survey. By allowing open participation and self-selection, we expect to receive data from biobanks that are aware of financial sustainability challenges and who are concerned about overcoming such challenges. This self-selection process is being used instead of a

statistical sampling method. Industry subject matter experts and our focus group participants agree that this process is best aligned with the study objectives.

## **B.2 Procedures for the Collection of Information**

All potential participants will receive an invitation by email (**Attachment 2**) giving information about the survey and inviting participation. The email will include a link directing interested members to the survey site. The survey site will include links that will explain the survey, respondent privacy and security of the website, and registration procedures. All materials will be written in plain and clear language. Once members register online, an email alert will be sent to the subcontractor. The subcontractor will monitor and track registrations. Registered participants will be asked to complete brief online questionnaires regarding topics such as demographics, operations, funding sources, cost information and challenges (**Attachment 3**).

### **B.2.1. Quality Control**

The contractor for this study will establish and maintain quality control procedures to ensure standardization, and high standards of data collection and data processing. The contractor will maintain a log of all decisions that affect sample enrollment and data collection. The contractor will monitor response rates and completeness of acquired data.

## **B.3 Methods to Maximize Response Rates and Deal with Nonresponse**

The Financial Sustainability of Human Tissue Biobanking survey expects to achieve a response rate of 80%, determined by the actual number of respondents divided by the total number expected.

We will follow up non-response to the initial contact (defined as within 10 days of mail-out) with a second emailed invitation.

**B.4 Test of Procedures or Methods to be Undertaken**

A small focus group was held in November 2012 (refer to OMB No. #0925-0642-16, Fast Track NCI) with potential respondents. The main goal of the focus group was to validate the appropriateness of the survey questions. We wanted to ensure that the respondents were able to provide the data without considerable burden and that the sample questions were understandable. The intent and purpose of the survey was also discussed with the group.

Focus group participants provided favorable feedback after reviewing the survey questions. Participant suggestions to improve clarity were incorporated into the survey design.

**B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The following individuals were critical in developing the research plan, the conceptual framework, survey questions, and sampling strategies underlying evaluation of the survey. Many of the same individuals will be involved with analysis once the data are collected.

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