

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY  
INVOLVING HUMAN SUBJECTS

FAX:  
To: Rabiner, Chana  
NCI  
RKW1 BG RM 766

Exempt #: 11633

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The National Cancer Institute's (NCI) Biorepositories and Biospecimen Research Branch (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. The first step in accomplishing this goal is to gain a clearer understanding of the specific challenges being faced, from the point of view of those directly impacted, through techniques such as this

Original Request Received in OHSR on: 10/10/2012

Responsible NIH Research Investigator(s): Chana Rabiner, PhD NCI

OHSR review of your request dated Mon, Oct 8, 2012 has determined that:

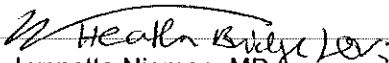
- Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.
- The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.
- NOT EXEMPT.** OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.
- Confidentiality Agreement
- Reliance
- Amendment 4-24-13 hb
- Other

Office Person HB

Admin Assist. CB

Note:

4/26/2013 AMEND: To conduct another survey regarding Financial Sustainability of Human Tissue Biobanking. hb

  
Lynnette Nieman, MD

Director, OHSRP

10/22/2012

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1  2  3  4  5  6

## **Bridge, Heather (NIH/OD) [E]**

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**From:** OHSR (NIH/DDIR)  
**To:** Horovitch-Kelley, Vivian (NIH/NCI) [E]; Rabiner, Chana (NIH/NCI) [E]  
**Cc:** Grant, Nicole (NIH/NCI) [E]  
**Subject:** AM Determination OHSRP #11633

Good Afternoon Chana and Vivian,  
Attached is the Amendment Determination of Exempt from IRB Review under 45 CFR 46.102 for the new survey regarding Financial Sustainability of Human Tissue Biobanking for your project: International Focus Group to Inform Economic Barriers and Challenges to Biobankers

Please retain this revised documentation as you would other research records. Please refer to [OHSRP #11633](#) for future amendments to this activity. To request other future amendments, please use the attached email template modified to meet the specific changes needed for your project.

Best,  
Heather Bridge  
Office of Human Subjects Research Protections  
Office of Intramural Research  
National Institutes of Health  
10 Center Drive,  
Bldg. 10, Room 2C146  
Bethesda, MD 20892  
Direct line: 301-402-4504  
BB: 240-281-9015  
Office Main: 301-402-3444  
Fax: 301-402-3443  
E-mail: [bridgeh@od.nih.gov](mailto:bridgeh@od.nih.gov)  
OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

---

**From:** Horovitch-Kelley, Vivian (NIH/NCI) [E]  
**Sent:** Wednesday, April 24, 2013 5:01 PM  
**To:** Bridge, Heather (NIH/OD) [E]  
**Cc:** Rabiner, Chana (NIH/NCI) [E]  
**Subject:** RE: OHSR new forms for survey- Introductions

Hi Heather – quick question – does this program staff need to submit another OHSRP review to conduct a survey, when the focus group was approved. It is on the same topic and in the same branch.

I have attached the OHSRP review approval that was done in 2012 for the focus groups – now this group is going to be conducting a survey (see detail in the memo and the attached screenshots) and we are wondering whether Chana should submit another OHSRP review – or whether the current review for the focus groups can be used?

Thanks.

Vivian Horovitch-Kelley  
(Office Number) 301-480-0541  
(Fax) TBD  
[vivian.horovitch-kelley@nih.gov](mailto:vivian.horovitch-kelley@nih.gov)

Office of Management Policy and Compliance (OMPC)  
PRA/OMB Liaison/Program Analyst  
PRA-OMB Clearance Program  
National Cancer Institute (NCI)/National Institutes of Health (NIH)  
Office of Management Policy and Compliance  
11400 Rockville Pike, Room 707, MSC 9162  
Rockville, MD 20852

**For more information about PRA/OMB clearance:**  
<http://ompc.cancer.gov/about/omb-clearance>

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Date: April 24, 2013

TO: Office of Management and Budget (OMB)

Through: Keith Tucker, Reports Clearance Officer, HHS  
Seleda Perryman, Program Clearance Officer, NIH  
Vivian Horovitch-Kelley, PRA OMB Clearance Liaison, NCI

FROM: Chana Rabiner, PhD  
Biorepositories and Biospecimen Research Branch  
Cancer Diagnosis Program  
Division of Cancer Treatment and Diagnosis  
National Cancer Institute (NCI)/NIH

SUBJECT: Financial Sustainability of Human Tissue Biobanking

This is a request for OMB to approve the new submission titled, "Financial Sustainability of Human Tissue Biobanking" for 1 year. The supporting statements and various attachments accompany this memorandum.

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 information will be used to assist the National Cancer Institute (NCI) in strategizing program plans to provide increased and tailored support for national and international biobanks.

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.

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?"

A combination of domestic and international biobanks will be asked to participate in the survey, totaling approximately 548 respondents. The annualized burden for the survey by all participants is estimated to be 822 hours.

# Screen Shots for Financial Sustainability of Human Tissue Biobanking Survey Site

## Main Landing Page

**BBRB** Biorepositories and Biospecimen  
Research Branch

[NEWS](#) [FAQS](#) [ABOUT BBRB](#)

### Login

Username & Password are case sensitive

Username \*

Password \*

[Register account](#)

[Request new password](#)

**LOG IN**

Welcome to the *Biobank Economic Survey*  
Site

placeholder text

[login](#) [contact us](#) [refer a friend](#)

Copyright 2011 © HealthCare Inc. All Rights Reserved.

## Self-registration Screen

### ACCESS ACCOUNT

[Login](#)

[Register Here](#)

[CREATE NEW ACCOUNT](#) [LOG IN](#) [REQUEST NEW PASSWORD](#)



## Create Account

\*Required

**Username \***

Spaces are allowed; punctuation is not allowed except for periods, hyphens, apostrophes, and underscores.

**E-mail address \***

A valid e-mail address. All e-mails from the system will be sent to this address. The e-mail address is not made public and will only be used if you wish to receive a new password or wish to receive certain news or notifications by e-mail.

**Password \***

Password strength:

**Confirm password \***

Provide a password for the new account in both fields.

**Biobank info**

**Name of your biobank \***

Please indicate if your biobank resides in the U.S. or is international

## Burden Statement and List of Available Survey Sections



National Cancer Institute

U.S. National Institutes of Health | [www.cancer.gov](http://www.cancer.gov)

**BBRB** Biorepositories and Biospecimen  
Research Branch

Welcome US | [logout](#)

[HOME](#) [NEWS](#) [FAQS](#) [ABOUT BBRB](#)

OMB No.: 0925-0642  
Expiration Date: 9/30/2014

Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0642). Do not return the completed form to this address.

Thank you for signing up to participate in this survey. Listed below are the sections included in the survey. To access a section, please click on the name or on the **Add info** link.

### Economic Biobank Survey

<a href="#">General Demographics</a>	<a href="#">Add info</a>
<a href="#">US Demographics</a>	<a href="#">Add info</a>
<a href="#">Operations - Common</a>	<a href="#">Add info</a>
<a href="#">Funding Sources</a>	<a href="#">Add info</a>
<a href="#">Cost Information</a>	<a href="#">Add info</a>
<a href="#">Challenges - Common</a>	<a href="#">Add info</a>
<a href="#">Summary - Common</a>	<a href="#">Add info</a>

General Demographics

US Demographics

Operations - Common

US Funding Sources

Cost Information

Challenges - Common

Summary - Common

## General Demographics

### GENERAL

How long has your biobank been in operation?

- Less than 1 year
- 1-3 years
- 3-5 years
- 5-10 years
- Greater than 10 years

Please indicate the phase that your biobank is currently in:

- Startup - Staff is putting the bank in operation. No collection or distribution
- Build up - Bank is operational. Collection started. No distribution yet.
- Expand - Distribution started. Collection expanding. Pursuing new users.
- Operate - Stable collection and distribution.
- Shut-down - (For some banks), collection is stopped. Distribution continues until collections depleted

What the start of your biobank's fiscal year?

Please Select... ▾

What the end of your biobank's fiscal year?

Please Select... ▾

### ACCREDITATION AND CERTIFICATIONS

Is your biobank:

- Accredited
- Not accredited

Does your biobank plan to participate in the Biorespository Accreditation Program offered by the College of American Pathologists (CAP)?

- Yes
- No
- I was not aware that CAP is offering a certification program specifically for biorepositories

General Demographics

US Demographics

Operations - Common

US Funding Sources

Cost Information

Challenges - Common

Summary - Common

## US Demographics

Please verify that your biobank operates in the US?

My biobank operates in the US or a US Territory

Please indicate the state in which your biobank resides:

MD ▾

Save and Go Back

Save For Later

Save and Continue



General Demographics

US Demographics

Operations - Common

US Funding Sources

Cost Information

Challenges - Common

Summary - Common

## Operations - Common

Please describe your specimen collection network:

We have local collection sites

We have remote collection sites

Please describe your specimen storage network:

We have a single central storage facility

We have remote storage facilities

Please indicate the number of samples by type in your collection at this time. [Need help?](#)

Sample Type	Room Temperature	Refrigerated	Frozen	Cryogenic Storage
Please Select..	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

How many samples by type have you collected in the past 12 months?

Sample Type	Room Temperature	Refrigerated	Frozen	Cryogenic Storage
Please Select..	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

How many samples by type were requested in the last 12 months? [Need help?](#)

Sample Type	Number Requested
-------------	------------------

General Demographics

US Demographics

Operations - Common

Funding Sources

Cost Information

Challenges - Common

Summary - Common

## Funding Sources

What is your biobank's total annual budget?

Is your biobank funded as part of publicly provided healthcare services or publicly funded clinical research?

- Yes. Our annual budget is fully funded
- Yes. Our annual budget is partially funded
- No. Our annual budget is not funded through public healthcare support or publicly funded clinical research.

Please categorize the process for appropriating public funds:

- We annually request earmarked funds and get approval based on performance and related criteria
- Our funds are not earmarked. We must compete with other usages of public funds in securing our annual budget.
- Other

How does your biobank respond to fluctuations in publicly provided funds?

- We adjust staffing levels to available funding
- We make up the difference with alternative sources of funding
- Other

How is your biobank planning to sustain funding as budgets are tightening?

- Reduce staff
- Reduce scale of operations
- Defer acquisitions of new capital equipment

To what degree do you feel that the original sponsors of your biobank bare a long-term responsibility for the stewardship of your specimen collections.

- High - Our original sponsors continue to work to secure long-term funding.
- Medium - Our biobank was founded to be in operation for only a finite period of time, after which specimens will be disposed.
- Low - Our original sponsors expect that the long-term support of our biobank will be assumed by others. (biobank management, other sponsors, etc)

Please provide any additional details related to your answer above that you feel would be helpful.

## Cost Information

General Demographics

US Demographics

Operations - Common

US Funding Sources

Cost Information

Challenges - Common

Summary - Common

In the following questions when we ask for current, past, and next year, we are referring to your biobank's fiscal year.

What were your total cost of operations last year?

What is your total cost of operations this year?

What do you project your cost of operations to be next year?

### DIRECT COSTS FOR THE CURRENT YEAR

What are your total direct labor costs? (salary and fringe benefits for biobank staff)

Please indicate the distribution of your costs in percentages for the following parts of the biobank value chain framework. (\*Please do not include shipping costs in your ODC's) [Need help?](#)

	Collection	Processing	Storage	Retrieval and Distribution
Budgeted Labor	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Associated Labor	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Materials	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other Direct Costs (*ODC)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

### INDIRECT, ADMINISTRATIVE, AND INFRASTRUCTURE COSTS FOR THE CURRENT YEAR

What are your total indirect labor costs? (salary and fringe benefits for management and administrative staff)

What are your total information technology (IT) costs?

## Challenges - Common

[General Demographics](#)

[US Demographics](#)

[Operations - Common](#)

[US Funding Sources](#)

[Cost Information](#)

**[Challenges - Common](#)**

[Summary - Common](#)

Please indicate the criticality for the challenges that your biobank is currently facing or anticipates facing in the next 12 months.

	Rating	Describe your MAJOR issue/challenge	Describe your solution, if applicable
Sustaining current growth	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Acquiring new specimens	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Replacing declining funding sources	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Keeping pace with quality standards	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Managing regulatory demands	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Labor attrition	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Managing changing consent	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Data security	<input type="text" value="Please Select..."/>	<input type="text"/>	<input type="text"/>
Integrating			

## Summary - Common

- General Demographics
- US Demographics
- Operations - Common
- US Funding Sources
- Cost Information
- Challenges - Common
- Summary - Common

Please tell us how useful the following information and tools would be to your biobank.

	Rating	Timeframe	Preferred Format	Comments/Desirable Features
Annual Strategic Planning Guide	<input type="text" value="Please Select.."/>	<input type="text" value="Please Select.."/>	<input type="text"/>	<input type="text"/>
Financial Benchmark	<input type="text" value="Please Select.."/>	<input type="text" value="Please Select.."/>	<input type="text"/>	<input type="text"/>
Operational Benchmark	<input type="text" value="Please Select.."/>	<input type="text" value="Please Select.."/>	<input type="text"/>	<input type="text"/>
Biobanking Business Case Development Guide	<input type="text" value="Please Select.."/>	<input type="text" value="Please Select.."/>	<input type="text"/>	<input type="text"/>
Inventory Management Tool	<input type="text" value="Please Select.."/>	<input type="text" value="Please Select.."/>	<input type="text"/>	<input type="text"/>
Cost and Revenue Tracking	<input type="text" value="Please Select.."/>	<input type="text" value="Please Select.."/>	<input type="text"/>	<input type="text"/>
Biobanking Technology Comparison Guide	<input type="text" value="Please Select.."/>	<input type="text" value="Please Select.."/>	<input type="text"/>	<input type="text"/>

Please use this table to suggest new tools and information that you would find useful.

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## International Demographics

- General Demographics
- International Demographics
- Operations - Common
- International Funding Sources
- Cost Information
- Challenges - Common
- Summary - Common

On what continent is your biobank located

In what North American country is your biobank located?

We'll be asking for cost and other financial information in your local currency. Please indicate the currency in which you are reporting financial information.

- Save and Go Back
- Save For Later
- Save and Continue

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY  
INVOLVING HUMAN SUBJECTS

FAX:  
To: Rabiner, Chana  
NCI  
RKW1 BG RM 766

Exempt #: 11633

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The National Cancer Institute's (NCI) Biorepositories and Biospecimen Research Branch (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. The first step in accomplishing this goal is to gain a clearer understanding of the specific challenges being faced from the point of view of those directly impacted through techniques such as this

Original Request Received in OHSR on: 10/10/2012

Responsible NIH Research Investigator(s): Chana Rabiner, PhD NCI

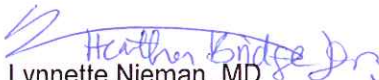
OHSR review of your request dated Mon, Oct 8, 2012 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.
- The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.
- NOT EXEMPT.** OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.
- Confidentiality Agreement
- Reliance
- Amendment
- Other

Office Person HB

Admin Assist. CB

Note:

  
Lynnette Nieman, MD  
Signature

Director, OHSRP  
Title

10/22/2012  
Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1  2  3  4  5  6

## **Bridge, Heather (NIH/OD) [E]**

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**From:** OHSR (NIH/DDIR)  
**To:** Rabiner, Chana (NIH/NCI) [E]  
**Cc:** Grant, Nicole (NIH/NCI) [E]  
**Subject:** Determination for OHSRP #11633

Good Morning Dr. Rabiner,  
Attached is the OHSRP determination of Exempt from IRB Review under 45 CFR 45.101(b)(2) for the survey and interview procedures for your project: International Focus Group to Inform Economic Barriers and Challenges to Biobankers

Please retain these records as you would other research records. Please refer to OHSRP #11626 for future amendment requests for this activity.

Best of luck with your research,

Heather Bridge  
Office of Human Subjects Research Protections  
Office of Intramural Research  
National Institutes of Health  
10 Center Drive,  
Bldg. 10, Room 2C146  
Bethesda, MD 20892  
**During renovation, please use BB to reach me directly: 240-281-9015**  
Office Main: 301-402-3444  
Use Direct line for voicemail only: 301-402-4504  
Fax: 301-402-3443  
E-mail: [bridgeh@od.nih.gov](mailto:bridgeh@od.nih.gov)

---

**From:** OHSR (NIH/DDIR)  
**Sent:** Tuesday, October 16, 2012 12:11 PM  
**To:** Rabiner, Chana (NIH/NCI) [E]  
**Subject:** Req for Determination Rec'd\_OHSRP 11633

Good afternoon Dr. Rabiner,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as **OHSRP #11633**. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

**Protocol Title:** International Focus Group to Inform Economic Barriers and Challenges to Biobankers

Thank you.

Sincerely,  
OHSRP - National Institutes of Health  
Bldg 10, Suite 2C146  
Bethesda, MD 20892  
Office Telephone: 301-402-3444  
Office Fax: 301-402-3443

**REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES, PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH**

Date of Request: October 8, 2012

Requestor's name: Chana Rabiner e-mail: chana.rabiner@nih.gov


Role:  Administrative support  Investigator  Other, explain: \_\_\_\_\_

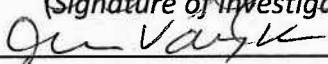
Name of NIH Senior Investigator: Chana Rabiner  
(The investigator must be an NIH employee)

IC  NCI  Laboratory/Branch  DCTD/CDP/BBRB \_\_\_\_\_

Building & Room No. Rockwall  Tel. No. 301-827-4319 FAX No. \_\_\_\_\_

Is the NIH Senior Investigator an NIH employee (FTE)?  Yes  No

Senior Investigator Signature:   
(Signature of Investigator who will conduct research)

Supervisor Signature:   
(Signature of official for IC, e.g., Lab/Branch Chief)

Name of NIH investigator conducting research if not the NIH Senior Investigator: (i.e., junior investigator, contractor investigator, fellow, student)  
\_\_\_\_\_

Please provide the name and e-mail of any others who should receive a copy of the OHSRP determination: \_\_\_\_\_

1. What role will the NIH investigator(s) have in this research project? (check all that apply)

- Conduct research activity
- Analyze samples/data only
- Consultant/advisor to collaborator(s)
- Author on publication(s)/manuscript(s) pertaining to this research
- Other, please describe: project manager

2. Title: International Focus Group to Inform Economic Barriers and Challenges to Biobankers  
(Provide a short title to distinguish this activity from other projects that you may have)

3. Describe in lay terms the research activity that will be performed:



**REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES,  
PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH**

\_\_\_\_ The National Cancer Institute's (NCI) Biorepositories and Biospecimen Research Branch (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. The first step in accomplishing this goal is to gain a clearer understanding of the specific challenges being faced, from the point of view of those directly impacted, through techniques such as this focus group. The focus group will provide impressions and comments regarding a survey to occur in the future (a separate request will be submitted to OHSRP when the survey is finalized)

**4. Proposed start date** \_11\_/\_7\_/\_2012\_      **Proposed completion date**  
\_11\_/\_9\_/\_2012\_

**5. Specify the nature of the data: (select all that apply)**

Interview procedure

Survey

Educational Testing

Educational Research

Research on public benefit or service programs

Other, describe: \_\_\_\_\_

**6. What kind of human data (e.g., private information, responses to questionnaires, test results, recordings) will be collected in your research?**

responses to proposed survey  
questions \_\_\_\_\_

**7. Will human data be? (select all that apply)**

Collected    Yes  No

Received      Yes  No

Sent            Yes  No

**8. If receiving or sending, list the collaborating investigator(s):**

Name	Institution/IC	Address/e-mail	FWA number*
------	----------------	----------------	-------------

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**9. Where are the subjects of this research activity located? (Provide a general description or complete the institutional information below)**

**They will be attending the European, Middle, and African Society for Biobanking and Biopreservation in Granada, Spain November 7-10**

Institution: \_\_\_\_\_ Contact Name: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

**REQUEST FORM: OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES,  
PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH**

**10. Will NIH investigator(s) have direct contact or intervention with the subjects of the study? (For example, by interviewing, surveying or recording the subjects?)**

Yes\_\_ NoX

If yes, what is the age range of subjects involved in the research?

\_\_ Children aged < 18 years

\_\_ Adults aged ≥ 18 years

**11. Who will collect the data or information?**

(a) \_\_ NIH Investigator

(b) \_\_ non-NIH Collaborator

(c) X NIH Contractor

(d) \_\_ Other, specify \_\_\_\_\_

If b or c, will an Honest Broker or data use agreement be used? Yes\_\_ NoX

*If yes, complete and attach the Honest Broker Assurance or data-use agreement to this submission; e-mail [ohsr\\_nih\\_ddir@od.nih.gov](mailto:ohsr_nih_ddir@od.nih.gov) to request a form.*

**12. Select the best description that applies to the human data or information:**

X Data or information will not contain any identifiable information, nor can it be linked to individual subjects by you or your collaborators.

\_\_ Data or information will be recorded in such a manner that subjects can be identified directly or through identifiers linked to the subjects

**13. Per NIH guidance, are all conflicts of interest by NIH employees (sender or receiver), if any, resolved? X Yes \_\_\_\_ No\*\***

*\*A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/ Office of Human Research Protections (OHRP) to institutions which receive Federal funds/support to conduct human subjects research. To search for the FWA# for domestic or international institutions go to <http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>*

*\*\*If the answer is "No", note that OHSRP will be unable to make a determination and research may not proceed until all conflicts are resolved. For more information, see the October 2011, A Guide to Preventing Financial and Non-Financial Conflict of Interest in Human Subjects Research at NIH. For assistance review the list of Ethics Coordinators and find the contact for your IC: <http://ethics.od.nih.gov/coord.pdf>*



**HEALTHCARE IT, INC.**  
TARGETED INNOVATIONS FOR RESEARCH

# Questions for BBRB Study

ESBB Conference

# Sections

1

- Organizational structure (network / stand-alone)
- Current funding sources
- Scale of operations
- Coverage of current and projected growth
- Feedback on new potential funding sources
- Current challenges

# Organizational structure and governance (network / stand-alone)

2

- Is your biobank part of a:
  - Healthcare provider
  - Clinical research organization
  - Drug or device developer
  - Commercial biobank
  - Other: \_\_\_\_\_
- What internal governance model oversees your biobank?
  - Permanent steering committee
  - Ad-hoc steering committee
  - Scientific/pathologist oversight team
  - Other: \_\_\_\_\_
- Is your biobank part of a network?
  - If yes, does the network have a steering committee
  - Do you exchange samples within your network?
  - Does your institution receive funding from the network?



# Feedback on new potential funding sources

3

- How likely are you to initiate/increase each of the following new/current sources:

New/Current; Highly likely, maybe, we will not pursue

- ▣ Charitable donations: \_\_\_\_\_
- ▣ Support from our host enterprise: \_\_\_\_\_
- ▣ Support from our network: \_\_\_\_\_
- ▣ Grants: \_\_\_\_\_
- ▣ Specimen sales: \_\_\_\_\_
- ▣ Other: \_\_\_\_\_

# Current funding sources

4

- What is your biobanks total annual budget?
- What percentage of your budget comes from:
  - ▣ Charitable donations: \_\_\_\_\_
  - ▣ Support from our host enterprise: \_\_\_\_\_
  - ▣ Support from our network: \_\_\_\_\_
  - ▣ Grants: \_\_\_\_\_
  - ▣ Specimen sales: \_\_\_\_\_
  - ▣ Other: \_\_\_\_\_
- What percentage is used for:
  - ▣ Labor/staffing: \_\_\_\_\_
  - ▣ Capital equipment: \_\_\_\_\_
  - ▣ Other operational expenses: \_\_\_\_\_

# Scale of operations

5

- How many full time staff? \_\_\_\_\_
- How many FTE's in part-time staff? \_\_\_\_\_
- How many researchers do your support?
- How many grants do you support?
- What portion of grant funding goes to your bank?
- How many samples in your bank?
- How many samples do you add monthly?
- What is the annual sample turn-over rate?



# Coverage of current and projected growth

6

- At what rate are your total costs increasing per year? \_\_\_\_\_ What is the breakdown:
  - ▣ Labor: \_\_\_\_\_
  - ▣ Capital: \_\_\_\_\_
  - ▣ Other operational expenses: \_\_\_\_\_
  - ▣ (need clarifying instructions for these percentages)
- At what rate are your funding sources changing (+/- percentage)
  - ▣ Charitable donations: \_\_\_\_\_
  - ▣ Support from our host enterprise: \_\_\_\_\_
  - ▣ Support from our network: \_\_\_\_\_
  - ▣ Grants: \_\_\_\_\_
  - ▣ Specimen sales: \_\_\_\_\_
  - ▣ Other: \_\_\_\_\_

□



# Coverage of current and projected growth

7

- At what rate are your total costs increasing per year? \_\_\_\_\_ What is the breakdown:
  - ▣ Labor: \_\_\_\_\_
  - ▣ Capital: \_\_\_\_\_
  - ▣ Other operational expenses: \_\_\_\_\_
  - ▣ (need clarifying instructions for these percentages)
- At what rate are your funding sources changing (+/- percentage)
  - ▣ Charitable donations: \_\_\_\_\_
  - ▣ Support from our host enterprise: \_\_\_\_\_
  - ▣ Support from our network: \_\_\_\_\_
  - ▣ Grants: \_\_\_\_\_
  - ▣ Specimen sales: \_\_\_\_\_
  - ▣ Other: \_\_\_\_\_

# Current challenges

8

- Please list the top three challenges that you are currently facing and/or anticipate in the next 12 months:
    - Sustaining current growth
    - Acquiring new specimens
    - Replacing declining funding sources
    - Keeping pace with quality standards
    - Labor attrition
    - Managing changing consent
    - Data security
    - Keeping pace with new informatics
    - Integrating our information systems
    - Centralizing biobank operations in my enterprise
    - Establishing a competitive pricing strategy/policy
1. \_\_\_\_\_
  2. \_\_\_\_\_
  3. \_\_\_\_\_

# **Attachment # 2**

## **Financial Sustainability Study Focus Group Moderator Guide**

**Assessing Biobank Feedback regarding:  
Financial Survey Instrument**

**October/November 2012**

# Focus Group Moderator Guide

## BBRB Assessing Biobank Feedback Regarding: Financial Survey Instrument

OMB No.: 0925-0642  
Expiration Date: 9/30/2014

### NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0642). Do not return the completed form to this address.

### 1. WELCOME (1 minute)

- a. Good morning/afternoon, my name is [Moderator Name]. I am the BBRB Biobank Financial Sustainability Study Advisor and will be the moderator for today. Welcome and thank you for participating in the Biobank Financial Sustainability Survey Focus Group Discussion.
- b. Many of you may have participated in a focus group previously. A focus group is a small group discussion that focuses on a particular topic in depth. The purpose of this focus group is to discuss the Financial Sustainability Study Survey, specifically to understand your impressions, comments and suggestions regarding the survey. I will be asking your opinions informed by your experiences in biobanking. The information obtained will be used to refine and improve the Survey before we deploy in the coming months.

### 2. GROUND RULES (4 minutes)

Before we begin, I would like to review a few things about how the discussion will work.

- a. In a focus group, there is no right or wrong answers, only opinions, and I'd like to hear from all of you about your perspectives equally. It's important that I hear what each of you thinks. Please talk one at a time and in a clear voice. Because we are taking notes and taping the discussions, I may occasionally interrupt you if two or more people are talking at once to be sure everyone gets a chance to talk and that responses are recorded clearly.
- b. Everyone needs to talk but each person doesn't have to answer each question. If I haven't heard from you I may call on you occasionally. You don't need to address all answers to me; I encourage you to exchange points of view with each other. Also, please feel free to speak up even if you disagree with someone else here. It's OK to disagree, because it's helpful to hear different points of view. I'm also interested in any questions you may have as we go along.
- c. This focus group will last approximately 1½ hours. To ensure that we stay within the allotted time, I may jump ahead to the next topic from time to time to move us along, but please stop me if you want to add anything.

- d. This focus group will be audio-taped so that we can capture all of the relevant quotes and comments. Everything you say is important to us, and we want to make sure we don't miss any comments. Later, we'll go through all of your comments and use them to prepare a report of our discussion. I want to assure you, however, that all of your comments are secure to the extent provided by law, and will be used only for research purposes. Nothing you say will be connected with your name. As well, we would like focus group participants to respect the confidentiality of all responses provided as well. Also, if there are any questions you would prefer not to answer, please feel free not to respond to them.

Does anyone have any questions before we begin?

### **3. INTRODUCTIONS (10 minutes)**

- a. I'm going to ask each of you to introduce yourself to the group. I'd like to ask that you tell us: current position, years in your current position, years of experience in biobanking, the name of the biobank that you represent, and the number of years it has been in operation.

### **4. PERCEPTIONS AND FEEDBACK ON THE SURVEY**

#### **Relevance (20 minutes)**

This survey captures the most important aspects of financial sustainability, funding, and related issues. As you respond, please state whether you agree with this statement and for each of the first five sections of the survey and please rate each section including:

- a. Organizational structure (network / stand-alone)
  - i. Highly relevant to understand biobanking financial sustainability
  - ii. Somewhat related to understand biobanking financial sustainability
  - iii. Not needed to understand biobanking financial sustainability
- b. Current funding sources
  - i. Highly relevant to understand biobanking financial sustainability
  - ii. Somewhat related to understand biobanking financial sustainability
  - iii. Not needed to understand biobanking financial sustainability
- c. Scale of operations
  - i. Highly relevant to understand biobanking financial sustainability
  - ii. Somewhat related to understand biobanking financial sustainability
  - iii. Not needed to understand biobanking financial sustainability
- d. Coverage of current and projected growth
  - i. Highly relevant to understand biobanking financial sustainability
  - ii. Somewhat related to understand biobanking financial sustainability
  - iii. Not needed to understand biobanking financial sustainability
- e. Feedback on new potential funding sources
  - i. Highly relevant to understand biobanking financial sustainability
  - ii. Somewhat related to understand biobanking financial sustainability
  - iii. Not needed to understand biobanking financial sustainability

### **Complexity (20 minutes)**

The Survey was easy to understand and to use. As you respond, please state whether you agree with this statement and for each of the first five sections of the survey and please discuss and rate each section including:

- a. Organizational structure (network / stand-alone)
  - i. Very easy to understand
  - ii. Some questions were unclear (please let us know which ones need clarification)
  - iii. Most questions were unclear and need better explanation (be specific)
- b. Current funding sources
  - i. Very easy to understand
  - ii. Some questions were unclear (please let us know which ones need clarification)
  - iii. Most questions were unclear and need better explanation (be specific)
- c. Scale of operations
  - i. Very easy to understand
  - ii. Some questions were unclear (please let us know which ones need clarification)
  - iii. Most questions were unclear and need better explanation (be specific)
- d. Coverage of current and projected growth
  - i. Very easy to understand
  - ii. Some questions were unclear (please let us know which ones need clarification)
  - iii. Most questions were unclear and need better explanation (be specific)
- e. Feedback on new potential funding sources
  - i. Very easy to understand
  - ii. Some questions were unclear (please let us know which ones need clarification)
  - iii. Most questions were unclear and need better explanation (be specific)

### **Confidentiality (20 minutes)**

The Survey asks for information that may be too confidential for your organization to disclose under certain circumstances. As you respond, please state whether you agree with this statement and for each of the first five sections of the survey and please discuss and rate each section including:

- a. Organizational structure (network / stand-alone)
  - i. We would share this information publicly with attribution to our enterprise
  - ii. We would share this information provided our data were not attributed to our enterprise
  - iii. We would not share this information under any circumstance
- b. Current funding sources
  - i. We would share this information publicly with attribution to our enterprise
  - ii. We would share this information provided our data were not attributed to our enterprise
  - iii. We would not share this information under any circumstance
- c. Scale of operations
  - i. We would share this information publicly with attribution to our enterprise
  - ii. We would share this information provided our data were not attributed to our enterprise
  - iii. We would not share this information under any circumstance
- d. Coverage of current and projected growth
  - i. We would share this information publicly with attribution to our enterprise
  - ii. We would share this information provided our data were not attributed to our enterprise
  - iii. We would not share this information under any circumstance

- e. Feedback on new potential funding sources
  - i. We would share this information publicly with attribution to our enterprise
  - ii. We would share this information provided our data were not attributed to our enterprise
  - iii. We would not share this information under any circumstance

## **5. CHALLENGES (10 minutes)**

The Survey requests your views on the challenges you now face anticipate in the near future. Please discuss and rate this section by considering the following two statements:

The challenges listed include the most critical for my organization. Agree / disagree

Some important challenges are missing including . . .

## **6. CONCLUSION (2 minutes)**

We've come to the end of our discussion. The BBRB team has worked hard to develop these questions so we can improve the Survey for Financial Sustainability.

Do you have any additional comments you would like to make on our focus group topics?

On behalf of the BBRB, I want to thank you for your participation. This has been a valuable session. I want to remind you that all of your comments are secure to the extent permitted by law, and will be used only for research purposes. Thank you again for your comments and your time.



## OHSR (NIH/DDIR)

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**From:** Rabiner, Chana (NIH/NCI) [E]  
**Sent:** Wednesday, October 10, 2012 11:52 AM  
**To:** OHSR (NIH/DDIR)  
**Subject:** Request form for international focus group  
**Attachments:** OHSRP BBRB SUBMISSION.pdf; BBRB Study Questions for Spain.pptx; #16\_Attach\_2\_BBRB\_Moderator\_Guide.docx

Please find the request for an international focus group. Thank you.

*Chana*

Chana Rabiner, PhD  
Program Director  
Biorepositories and Biospecimen Research Branch  
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11400 Rockville Pike  
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Phone: +1.301.827.4319  
[chana.rabiner@nih.gov](mailto:chana.rabiner@nih.gov)

## OHSR (NIH/DDIR)

---

**From:** OHSR (NIH/DDIR)  
**Sent:** Tuesday, October 16, 2012 12:11 PM  
**To:** Rabiner, Chana (NIH/NCI) [E]  
**Subject:** Req for Determination Rec'd\_OHSRP 11633

Good afternoon Dr. Rabiner,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as **OHSRP #11633**. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

**Protocol Title:** International Focus Group to Inform Economic Barriers and Challenges to Biobankers

Thank you.

Sincerely,  
OHSRP - National Institutes of Health  
Bldg 10, Suite 2C146  
Bethesda, MD 20892  
Office Telephone: 301-402-3444  
Office Fax: 301-402-3443

***The NIH is committed to maintaining the highest standards for the protection of human subjects.***



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