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National Cancer Institute
Survey of Human Biospecimen Needs and Challenges for the Biomedical Research Enterprise

Thank you for assisting us with this survey.

The NCI's Office of Biorepositories and Biospecimen Research (OBBR) has as its mission to ensure that human specimens available for cancer research are of the highest quality in terms of physical integrity and associated clinical data. NCI has formulated a long-range plan to address the challenges raised by current biorepository practices and procedures. This plan stems from recommendations made in the 2003 National Biospecimen Network Blueprint (available at: http://biospecimens.cancer.gov/resources/reports/nbn.asp).

As one element of this plan, NCI is investigating the feasibility of developing a national human biorepository. As part of its planning process, NCI wants to hear from external stakeholders who have direct contact with cancer biospecimens and their research results, or who are involved with public policies that govern biospecimen usage. Therefore, NCI's Office of Market Research and Evaluation (OMRE) will be conducting an online survey to better understand current biospecimen-related practices and gauge stakeholder support of a national biospecimen infrastructure.

Given your involvement in the cancer biospecimen field, we appreciate your interest and look forward to receiving your input on this important survey. If you have any questions about the survey, please do not hesitate to contact the NCI OBBR at biospecimens@mail.nih.gov.

Thank you in advance. The survey will take about 15 minutes of your time.

Note: Are you wondering whether you are the right person to answer this or not? Click here to see a sampling of the questions. If not, click here to forward this survey to another person.

To continue and begin the survey, click the 'next' button below.

[in footer] If you experience any technical difficulties, please contact the survey administrator at User-Centered Design at survey@user-centereddesign.com.

Privacy Statement

Your participation in this survey is completely voluntary. Please be assured that your responses will be kept confidential and will not be disclosed to anyone outside NCI or its contractor, User-Centered Design, Inc. All data will be reported in aggregate only and neither your name nor your organization's name will be included in any reports. You may skip any questions that you prefer not to answer or withdraw at any point during the survey. If you choose to withdraw and want to delete your data, simply click the "Delete Survey" link at the top of the page.

In order to better understand your responses, we would like to know a little more about you and your field of work.

Information about You and Your Work

1. Which of the following best describes the primary role you undertake on a day-to-day basis? (Please select one.)

   □ Clinical researcher
   □ Surgeon
   □ Oncologist/Other MD clinician
   □ Nursing personnel/Clinical research coordinator
   □ Other clinical or healthcare staff
   □ Pathologist
   □ Laboratory scientist/researcher
   □ Laboratory personnel/technician
   □ Non-laboratory scientist/researcher
   □ Bioinformatics specialist
   □ Information technology specialist
   □ Executive/Administrator
   □ Program manager
   □ Policy analyst
   □ Health educator
   □ Patient/Patient advocate
   □ Biorepository manager
   □ Other: _____

2. How many years have you been involved in the biomedical field?

   □ < 1
   □ 1 – 5
   □ 6 – 10
   □ 11 – 15
   □ 16 – 20
   □ More than 20

3. In what type of organization are you currently working or involved? (Please select one.)

□ Academic/Research institution
□ Hospital, clinic, or other care setting
□ NCI
□ NCI-designated cancer center
□ NIH institute other than NCI
□ Federal government agency (other than NIH)
□ State/local government agency
□ Non-profit organization (e.g., foundations)
□ Advocacy organization
□ Pharmaceutical/Biotechnology company
□ Other biomedical company
□ Biospecimen “broker” or commercial biobank
□ Other (specify): _____

4. Do you work in a biospecimen bank?

□ Yes
□ No

Experience with biological specimens

5. In what capacity do you deal with biological specimens in your work? (Select all that apply from the following lists.)

Collect
+ Administer informed consent
+ Collect/gather samples for my own use
+ Collect/gather samples for use by others
+ Collect/gather samples specifically for medical care purposes (e.g., surgical removal of tumors, tissue for biopsies or screening tests)
+ Obtain/purchase samples (e.g., from a biobank) for my own use
+ Obtain/purchase samples (e.g., from a biobank) for use by others

Process
+ Process Intellectual Property (IP) and Material Transfer Agreements (MTA)
+ Prepare/review IRB proposals

Store
+ Oversee or work with the storage of specimens (e.g., responsible for storage conditions, inventory)

Distribute/Supply/Share

+ Share/supply specimens to others in my organization
+ Supply specimens to others external to my organization

Use in Research
+ Use specimens for biomedical research
+ Surgical treatment
+ Medical care delivery

+ Other_____
+I do not deal directly with biological specimens in my work

Access to Biospecimens

Before we ask your opinions about a national biospecimen resource, we would like your input on accessing biospecimens today.

6. What percentage of the biospecimens you work with or obtain come from each of these sources?

_____ % - My patients/study participants/volunteers
_____ % - Other patients/volunteers in my organization
_____ % - Other medical care facilities (e.g., community hospitals)
_____ % - Other research institutions (e.g., SPORES)
_____ % - Non-profit biobank
_____ % - Commercial biobank in the U.S.
_____ % - Commercial biobank outside the U.S.
_____ % - Cooperative Human Tissue Network (CHTN)
_____ % - Other: _____
_____ Question does not apply to me

6a. What proportion of your biospecimens come from individuals or organizations who are your research collaborators (excluding biospecimen samples you collect yourself or receive from your patients or biobanks)?

None
Some
Most
All
Does not apply

7. What types of biospecimen samples do you most want or need for the research you conduct? (Select all that apply.)

Patient demographics:

- □ Fetal
- □ Neonatal
- □ Pediatric
- □ Young adult
- □ Aged
- □ Racial/Ethnic Minorities

Biospecimen characteristics

- □ Normal blood
- □ Normal serum / plasma
- □ Blood (disease states)

- □ Serum / plasma (disease states)
- □ Cell lines from human tissue
- □ Normal healthy tissue
- □ Cancer
- □ Pre-malignant (dysplastic, adenomatous, intraepithelial, neoplasia, etc)
- □ Inflammatory / Autoimmune states
- □ Infectious
- □ Degenerative
- □ Brain / central nervous system
- □ Urine
- □ Saliva
- □ Duct secretions

Other: _____

8. What information do you typically know about the biospecimens available to you in your work? (Select all that apply.)

_____ Biospecimen type (e.g. cell, fluid, tissue)
_____ Anatomical location
_____ Collection procedures
_____ Storage procedures
_____ Transfer procedures
_____ Patient demographics
_____ Patient complaint/history of current illness
_____ Patient past medical history
_____ Patient family history
_____ Clinical diagnosis
_____ Pathological diagnosis
_____ Patient treatment information
_____ Patient treatment outcomes
_____ Patient consent/authorization status
_____ Quality control data on the specimen itself (e.g., use of standard operating procedures for collection, storage, and management)
_____ Does not apply
Other: _____

9. Thinking about the information you typically know about the biospecimens you work with, which statement best describes your situation?

___I usually have enough information about the biospecimens, and don't need more
___I usually have enough information about the biospecimens, but I would like to have more
___I usually do not have enough information about the biospecimens
___I am not sure whether or not I have the information I need or should have
___Does not apply to me

10. How easy or difficult is it for you to obtain the <u>quantity</u> of biospecimens you need for your work?

□ Very easy
□ Easy
□ Somewhat easy
□ Somewhat difficult
□ Difficult
□ Very difficult

□ Does not apply to me

Perceptions of the Quality of Biospecimens

11. If all barriers were removed, what information or characteristics about biospecimens would you consider ideal to know in order for you to label them “high quality”?

_____ Biospecimen type (e.g. cell, fluid, tissue)
_____ Anatomical location
_____ Collection procedures
_____ Storage procedures
_____ Transfer procedures
_____ Patient demographics
_____ Patient complaint/history of current illness
_____ Patient past medical history
_____ Patient family history
_____ Clinical diagnosis
_____ Pathological diagnosis
_____ Patient treatment information
_____ Patient treatment outcomes
_____ Patient consent/authorization status
_____ Quality control data on the specimen itself (e.g., use of standard operating procedures for collection, storage, and management)
_____ Does not apply
Other: _____

[INSERT OPEN-ENDED TEXT BOX TO ELABORATE ON ANSWERS]

Elaborate on how you would define a “high quality” biospecimen by completing the following sentence:

A specimen is most valuable to my work objectives when _____.

For the remaining questions about "high quality" biospecimens, please think of the characteristics of biospecimens that you defined as ideal to the work you do and for producing quality outcomes.

12. What percentage of the time in your work is biospecimens of "high quality" necessary?

- □ Never (0%)
- □ Rarely (1-25%)
- □ Sometimes (26-50%)
- □ Often (51-75%)
- □ Usually (76-99%)
- □ Always (100%)
- □ Don't know
- □ Not applicable

In what situations with your work is it necessary or desirable to use these "high quality" biospecimens?

_____

13. In general, how easy/difficult do you think it is to obtain "high quality" biospecimens when they are needed?

- □ Very Easy
- □ Easy
- □ Somewhat easy
- □ Somewhat difficult
- □ Difficult
- □ Very difficult
- □ Don't know

14. Below is a list of possible challenges to accessing “high quality” biospecimens. For each one, please indicate how much of a problem it is overall for you in your work.

[Likert: Not a problem → very big problem]

- □ Lack of evidence-based best practices for collection of biospecimens
- □ Lack of evidence-based best practices for processing biospecimens
- □ Lack of evidence-based best practices for storing biospecimens
- □ Lack of adherence to existing best practices
- □ Time needed to obtain specimens
- □ Restrictive nature of HIPAA and human subjects guidelines
- □ Lack of standardized IRB review
- □ Lack of funding or reimbursement to collect or process specimens
- □ High cost of specimens
- □ Lack of willingness of researchers to share specimens
- □ Lack of standardized patient recruitment and consent procedures
- □ Lack of patient willingness to provide or donate biospecimens

[INSERT OPEN-ENDED TEXT BOX TO ELABORATE ON ANSWERS]

What other problems or barriers would you say impede access to biospecimens and what could be done to improve access?

_____

15. How often, if ever, have you questioned findings/outcomes from your work because you had concerns about the quality of the samples you had available to use?

- □ Never (0%)
- □ Rarely (1-25%)
- □ Sometimes (26-50%)
- □ Often (51-75%)
- □ Usually (76-99%)
- □ Always (100%)
- □ Don’t know
- □ Not applicable

16. How often, if ever, have you limited the scope of your work/objectives because of difficulty obtaining biospecimen samples that met your needs?

- □ Never (0%)
- □ Rarely (1-25%)
- □ Sometimes (26-50%)
- □ Often (51-75%)
- □ Usually (76-99%)
- □ Always (100%)
- □ Don’t know
- □ Not applicable

17. What percentage of the specimens you typically acquire for your work/ objectives are you unable to use because of poor quality or other problems with the sample itself?

- □ None (0%)
- □ Rarely (1-25%)
- □ Sometimes (26-50%)
- □ Often (51-75%)
- □ Usually (76-99%)
- □ Always (100%)
- □ Don’t know
- □ Not applicable

___Does not apply to me

18. To what degree do the following existing sources meet your needs for "high quality" biospecimens?

[Likert: Never → Always DK/NA

- My patients/study participants/volunteers
___- Other patients/volunteers in my organization
___- Other medical care facilities (e.g., community hospitals)
___- Other research institutions (e.g., SPORES)
___- Non-profit biobank
___- Commercial biobank in the U.S.
___- Commercial biobank outside the U.S.
- Cooperative Human Tissue Network (CHTN)

19. Imagine all challenges were removed and you had unlimited access to "high quality" specimens. How would this change the work you conduct? That is, what possibilities would it create for furthering biomedical research and product development?

_____

□ Perceptions of a Standardized Repository for Biospecimens

National Biobank and Standards Development Initiative

The NCI's mission is to ensure that human specimens available for cancer research are of the highest quality. The reliability of data derived from biospecimens is directly related to the quality and consistency of the biospecimens themselves. The NCI has formulated a long-range plan to address the challenges raised by current biorepository practices and procedures. This plan stems from recommendations made in the 2003 National Biospecimen Network Blueprint (available at: http://biospecimens.cancer.gov/resources/reports/nbn.asp).

As part of this plan, the NCI is investigating the feasibility of a national cancer biorepository for human specimens. If undertaken, the NCI envisions this national cancer biorepository as a nonprofit, public service project to collect and store biospecimens of the highest quality required for research in an open, transparent manner and in compliance with human subjects regulations. The stored biospecimens will be made available to the entire cancer research community. Normal human tissue would also be collected under the same rigorous protocols to serve as a point of comparison and control.

This initiative is intended to serve a number of stakeholders, including cancer researchers, pathologists, biorepository managers, National Institutes of Health-funded researchers, other Federal agencies such as the Food and Drug Administration and the Centers for Disease Control and Prevention, pharmaceutical and biotechnology companies, patient advocates, and ultimately the patients who will benefit from the products and therapies that result from the research. The reach of this initiative could extend beyond cancer to other diseases.

20. After reading this description, what is your initial reaction to the idea of creating a standardized, national repository for "high quality" biospecimens?

- □ Mostly positive
- □ Positive
- □ Somewhat positive
- □ Somewhat negative
- □ Negative
- □ Mostly negative

20a Please elaborate Tell us why you think this way. What potential benefits or downsides do you foresee?

_____

21. If a biospecimen resource like the one described in this survey was created, how likely do you think you would be to obtain specimens from it for your work?

- □ Definitely would
- □ Very likely
- □ Somewhat likely
- □ Somewhat unlikely
- □ Very unlikely
- □ Definitely would not

22. How willing would you be to contribute samples to a biospecimen resource like the one described in this survey?

- □ Completely willing
- □ Very willing
- □ Somewhat willing
- □ Somewhat unwilling
- □ Very unwilling
- □ Not at all willing

23. A repository of "high quality" biospecimens would need to be multifunctional and useful for a diverse group of individuals. Which of the following aspects do you think are the **most important** for a national resource to provide? (Mark up to 5 aspects that are most important to you.)

- □ Provide highly-annotated specimens
- □ Provide enough samples for statistical analyses
- □ Provide a central resource for investigators to access available specimens
- □ Provide quality criteria met by each specimen to allow researchers to choose specimens that fit the needs of their research
- □ Provide a searchable database to quickly find out information about biospecimens and locate available biospecimens
- □ Provide an equitable access process
- □ Provide a biospecimen resource to include in proposals that will be trusted and expedite grant support
- □ Serve as a standard for other groups that are establishing repositories
- □ Serve as a leader for standardized human subjects and HIPAA protocols to other groups collecting biospecimens
- □ Enable addition of follow-up data over time
- □ Establish standardized quality control and assurance mechanisms
- □ Provide standardized "reference samples" to serve as controls during validation of discovery research and technology development

□ Enable comparison of findings across research studies
□ Enable interdisciplinary and multidisciplinary research
□ Other (specify): _____

24. Based on the description of the proposed repository, how concerned are you about each of the following issues? [Likert: Not at all concerned → very concerned]

- Potential for the repository to shift funds from other current biomedical projects
- Expense of such a repository
- Potential lack of long-term funding or commitment
- Establishment of equitable procedures for access
- Quality of the biospecimens
- Quality of associated clinical data
- Availability of biospecimens relevant to your work
- Potential for under usage because researchers will continue to use their current sources for biospecimens
- Adequate infrastructure to manage such a large enterprise
- Challenges posed by our current medical enterprise system

25. What other issues, if any, would you have about a standardized repository?

_____

Recommendations for Alternative Measures to Improve Access to "High Quality" Biospecimens

26. Of the following actions that NCI could take as an alternative to developing a national-scale biorepository for "high quality" specimens, which of these alternatives would be worth pursuing. Please mark up to 3 choices.

- □ Developing a virtual biospecimen repository that links researchers to biospecimens at various host institutions
- □ Supporting the infrastructure and science of biobanking with grants
- □ Managing a consortium of cancer centers to share repository practices and samples
- □ Continuing or expanding research on best practices for collecting, processing, storing and distributing high quality specimens
- □ Creating a smaller scale biorepository focused on specific, rare diseases
- □ Creating a smaller scale biorepository focused on reducing health disparities (e.g., collecting/providing specimens from underserved populations)
- □ Creating a smaller scale biorepository focused on providing specimens to particular researchers (e.g., investigators just beginning their careers)
- □ Developing a public partnership or campaign to increase interest in donating specimens among the public
- □ Developing a public partnership or campaign to increase interest in collecting specimens among specific health care providers
- □ Developing an outreach effort designed to foster greater collaboration and sharing among investigators

Please share any other approaches to fulfilling this mission of "making high quality biospecimens available" that come to mind.

_____

Final Thoughts

27. Are there any other details about biospecimens or biorepositories that have not yet been mentioned that you would like to comment on? Please elaborate below.

_____