

Donating Tissue for Cancer Research: Biospecimens and Biorepositories

Key Points

- Biospecimens are materials taken from the human body, such as tissue, blood, urine, or saliva, that can be used in directing patient care or processed and stored for future medical research (see Question 1).
- Biorepositories (also known as biobanks) are “libraries” of stored biospecimens that are made available to scientists for research purposes. Personal and medical information about the people who donated the biospecimens is often provided with the tissue or fluid samples. Protecting the privacy and integrity of this personal and medical information is one of a biorepository’s highest priorities (see Question 2).
- The availability of an ample supply of high-quality biospecimens is essential to ongoing cancer research. Biospecimens contain a tremendous amount of cellular, molecular, and chemical information. This biological information and the associated personal and medical information about the people who donated the biospecimens can be used by scientists to find new ways of preventing, diagnosing, and treating disease (see Question 3).
- The National Cancer Institute is leading a major effort to develop a national repository of biospecimens that can be used for medical research (see Question 4).
- There are several ways in which patients, their families, and the public can help support cancer research that uses biospecimens (see Question 5).

1. What are biospecimens?

Biospecimens are materials taken from the human body, such as tissue, blood, urine, or saliva, that can be used to help diagnose diseases or conditions, determine a patient’s prognosis, select appropriate treatments, or measure responses to therapy. Biospecimens can also be processed and stored for later research aimed at finding new ways to prevent, diagnose, or treat diseases, including cancer.

When a cancer patient has a biopsy, surgery, or other procedure, doctors may remove biospecimens and store all or parts of them for later research. Each specimen may contain DNA, RNA, proteins, or other molecules that will help researchers better understand why and how the cancer developed and, perhaps, provide insight toward the development of new therapies.

2. What are biorepositories?

Biorepositories (also known as biobanks) are “libraries” of stored biospecimens that are made available to scientists for research purposes. Relevant personal and medical information about the people who donated the specimens is often provided with the tissue or fluid samples. One of a biorepository’s highest priorities is to protect the privacy and integrity of this personal and medical information.

There are thousands of biorepositories in the United States that vary widely based on purpose, size, and/or types of biospecimens they include.

3. Why are biospecimens important in cancer research?

Biospecimens contain a tremendous amount of cellular, molecular, and chemical information. Each specimen also contains associated personal and medical information—known as “annotation”—that is collected from patients through interviews at the time the biospecimens are



donated, from medical records that patients agree to provide, and from data generated in clinical trials that patients have volunteered to join. Annotations include information about the patient's age, sex, and ethnicity. They may also include information about the environmental exposures (diet, tobacco smoke, sunlight, toxic chemicals, infectious agents, etc.) that the patient has experienced during his or her lifetime. The quality of a biospecimen's annotation is as important as the quality of the biospecimen itself.

The availability of an ample supply of high-quality biospecimens is essential to ongoing cancer research. These resources allow researchers to frame questions that can be answered only by examining hundreds or thousands of patient specimens. For example, researchers may analyze biospecimens to identify the molecular characteristics of a particular type of cancer at various stages in its development and then determine whether these characteristics can be aligned with stages in the clinical course of the disease. Such an analysis would provide greater insight into how the cancer progresses and uncover potential new targets for interventions to disrupt the malignant process.

High-quality biospecimens are also essential for research aimed at the development of personalized medicine, in which treatments and other interventions will be tailored to patients based on their individual genetic characteristics and the unique molecular features of their disease. Such a personalized approach should reduce many of the risks associated with current one-size-fits-all approaches to cancer therapy. Unfortunately, the research that will lead to personalized cancer medicine is hampered at present by an inadequate supply of biospecimens that have been harvested and stored according to standard protocols.

An ample supply of high-quality biospecimens should make the following types of advances possible:

- The identification of specific proteins or other biomarkers associated with various stages or subtypes of individual cancers, which could lead to the development of new screening or diagnostic tests.
- The grouping of patients, based on biomarkers of their disease and their personal genetic characteristics, to receive the most appropriate, most effective, and least toxic treatments.
- The identification (and validation) of new ways to deliver drugs or other agents to cancer cells and to measure responses to treatment.

4. What is the National Cancer Institute (NCI) doing to increase the availability of high-quality biospecimens?

To address the current inadequate supply of high-quality biospecimens for cancer research that have been collected using standardized procedures, NCI's Office of Biorepositories and Biospecimen Research (OBBR) has developed a set of best practices to be used by NCI-supported biorepositories. The OBBR's Web site is available at <http://biospecimens.cancer.gov/default.asp> on the Internet. These best practices, the NCI Best Practices for Biospecimen Resources, address operational, technical, ethical, legal, and policy issues.

The best practices related to operational and technical issues provide guidance on:

- Biospecimen collection, processing, storage, retrieval, and distribution.
- Clinical data collection and management.
- Quality assurance and control.
- Biosafety (i.e., minimizing the risks to employees from exposures to infectious agents, chemicals, etc., associated with processing biospecimens).
- Bioinformatics systems needed to support all aspects of biorepository operations, including data sharing.

The best practices related to ethical, legal, and policy issues provide guidance on:

- Responsible custodianship to ensure the long-term physical integrity of biospecimens, while maintaining the privacy and confidentiality of biospecimen donors.
- Informed consent from human subjects for the collection and storage of biospecimens and for the use of these specimens in future research.
- Privacy protections for individuals who donate biospecimens, as well as maintenance of the confidentiality of associated personal information and clinical data.
- Researcher access to biospecimens and their associated data.
- Intellectual property and resource-sharing issues.

More information about the best practices can be found at <http://biospecimens.cancer.gov/bestpractices/intro> on the Internet.

OBBR has also established the Biospecimen Research Network to sponsor, conduct, and collaborate in research studies aimed at bridging the gap between current clinical practice regarding biospecimens and practices needed to take full advantage of emerging technologies for the development of personalized diagnostic and therapeutic interventions; defining the most important variables for the prospective collection of tissues, blood, and other bodily fluids; and developing evidence-based biospecimen quality indicators for specific analytic technologies. The Biospecimen Research Network Web site is available at <http://biospecimens.cancer.gov/researchnetwork/default.asp> on the Internet.

In addition, OBBR is leading the Cancer Human Biobank (caHUB) initiative. The goal of this initiative, which was launched in early 2009, is to create a national repository of biospecimens that can be used for medical research. caHUB will modernize the field of biobanking by:

- Acquiring and making available to the research community biospecimens that have been collected according to the highest technical and ethical standards.
- Providing biospecimen reference samples that will serve as benchmarks for specimen type and integrity.
- Conducting research that supports evidence-based best practices for biospecimen collection, processing, and storage.
- Creating opportunities for collaboration and the exchange of information across the medical research enterprise.

More information about the caHUB initiative is available at <http://biospecimens.cancer.gov/cahub/default.asp> on the Internet.

5. How can patients and others help?

The necessary supply of biospecimens will be available for medical research only if patients agree to donate tissue and/or bodily fluids when they undergo biopsy, surgery, or other medical procedures. Patients, their families, and the general public can help support research using biospecimens in the following ways:

- **Stay informed:** There is increasing interest in biospecimens and how they can help medical research. NCI's Web site and the Web sites of other professional and policy organizations, such as the International Society for Biological and Environmental Repositories, provide information about trends, issues, and events that affect biorepository operations. The Society's Web site can be found at <http://www.isber.org/> on the Internet. Patients can also ask their doctor or hospital for information about local biorepositories.
- **Consider donating a biospecimen:** Patients scheduled for a biopsy or surgical procedure may be asked in advance if they would consider donating a biospecimen for research. If not, they can ask their doctor whether biospecimen donation is possible and appropriate. Donating biospecimens is entirely voluntary. Patients will receive a brochure describing how the process works, as well as a consent (permission) form to review. Specimens cannot be taken until written consent is given, and this consent can be withdrawn at any time. The decision of whether or not to donate will have no effect on a patient's biopsy or surgical procedure. *Providing Your Tissue for Research: What You Need To Know* is an NCI patient education booklet that discusses these issues in greater detail. This resource is available at <http://www.cancer.gov/clinicaltrials/resources/providingtissue> on the Internet.
- **Spread the word:** Let other people know about the importance of biospecimen donation and encourage them to donate when it is medically appropriate to do so.
- **Contact NCI:** To share comments or learn more about biospecimens, biorepositories, or related NCI activities, please send an e-mail to biospecimens@mail.nih.gov.

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Related NCI materials and Web pages:

- Cancer Diagnosis Program Human Specimens for Research Web Page (<http://www.cancerdiagnosis.nci.nih.gov/humanSpecimens/default.htm>)
- Early Detection Research Network Specimen Reference Sets Web Page (<http://edrn.nci.nih.gov/resources/sample-reference-sets>)
- National Biospecimen Network (NBN) Blueprint (<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>)
- NCI Community Cancer Centers Program Biospecimens Web Page (<http://ncccp.cancer.gov/Resources/Biospecimens.htm>)
- NCI Research Resources Web Page (<http://resresources.nci.nih.gov/categorydisplay.cfm?catid=631>)
- Office of Biorepositories and Biospecimen Research Web Site (<http://biospecimens.cancer.gov/about/default.asp>)
- The Breast Cancer Intergroup of North America (TBCI) Web Page (<http://ctep.cancer.gov/investigatorResources/tbci/default.htm>)

How can we help?

We offer comprehensive research-based information for patients and their families, health professionals, cancer researchers, advocates, and the public.

- **Call** NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- **Visit** us at <http://www.cancer.gov> or <http://www.cancer.gov/espanol>
- **Chat** using LiveHelp, NCI's instant messaging service, at <http://www.cancer.gov/livehelp>
- **E-mail** us at cancergovstaff@mail.nih.gov
- **Order** publications at <http://www.cancer.gov/publications> or by calling 1-800-4-CANCER
- **Get help** with quitting smoking at 1-877-44U-QUIT (1-877-448-7848)

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