
BIOBANKING BACKGROUND INFORMATION FOR TRAINERS

DEFINITIONS

Biospecimens: Tissue (including skin, hair) and fluids (including urine, blood) taken from an individual are biospecimens. These can be collected through blood draws, cheek swabs, urine collection, biopsy or surgery. Biospecimens from biopsy or surgery are often from extra tissue collected during a treatment or diagnosis. However, healthy individuals can also choose to donate biospecimens without surgery or biopsy. All of these specimens can be stored and used for research to better understand cancer and other diseases.

Biobanks (or biorepositories): Categorized collections of all the biospecimens that have been collected and can be used for research. Important information about the individual who donated each biospecimen is typically included in the biobank – this includes items such as age, gender, ethnicity, previous health record, and environmental exposures. All of this information is carefully protected by privacy laws and are labelled by a unique identifier, not an individual’s name.

THE IMPORTANCE OF BIOBANKS

Research: Biobanks, and the biospecimens within them, are **critical** for helping scientists understand how diseases such as cancer work, and in finding a treatment for such diseases. The components within the biospecimens, things like DNA, RNA, and proteins allow these researchers to develop more useful medicine and treatments.

Biospecimens can **answer questions** such as:

- Why does cancer develop?
- How does cancer grow?
- Who is at greater risk of developing it?

Biobanks are especially important when they include biospecimens from **all different kinds of people**. With the combination of molecular information and information about where each biospecimen comes from, scientists are able to identify patterns and unique parts of diseases that may only affect certain people or populations.

Specific ways **biospecimens aid in research** include:

- To identify ways to deliver drugs to specific cells
- To identify how diseases progress and differ
- To group patients as more or less likely to respond to specific drugs
- To group patients around the most appropriate treatment
- To develop screening tests to detect certain stages or types of a disease



There are numerous **examples** of how biobanks have helped cancer research. One such example is the discovery and development of Herceptin for the treatment of breast cancer. Scientists used well - preserved tissue samples from biobanks to develop this highly effective therapy for a specific type of breast cancer.

Personalized Medicine: Biobanks are crucial to the development and equitable access to personalized medicine, a new frontier. The goal of personalized medicine is to identify genetic differences between people and develop genetic tests that predict an individual’s response to a drug. Doctors can then provide tailored medical treatments for each individual – this increases effectiveness and minimizes side effects of treatment. Without fully resourced biobanks, scientists are not able to make personalized medicine work for all different types of people.

THE HISTORY OF BIOBANKING

Biobanks have existed in different forms for many years but have significantly expanded in scope in the past 30 years. Initially, **small biobanks** existed primarily at universities and were available for use by a small number of scientists. As technology has evolved, the biobanks have shifted from physical locations to include **virtual online-accessible repositories**. This transition has greatly **expanded the accessibility** of biobanks. Additionally, the data available within the biobanks has expanded to include more information about the individual.

Many countries, including the US, have created **population-wide biobanks** in an attempt to collect, analyze and store biospecimens that represent the population makeup of the US. A representative US biobank would be made up of biospecimens from all different races, ethnicities, geographic areas, ages, and many other attributes. It has therefore become very important to inform the public about the importance of biobanks and ensure that everyone has the ability to donate if they would like.

A large-scale initiative, **All of Us**, is a research program designed to ensure biobanks reflect the diversity of the US. The initiative seeks to support the advancement of precision medicine and is partnering with many large health systems to support education and ethical practices for biospecimen collection and biobanks. The goal is to create a biobank made up of biospecimens from more than 1 million people that are representative of the US population. Learn more about the initiative at www.allofus.nih.gov.

THE CHALLENGE

While biobanks can provide invaluable information to advance medical research, there are **serious concerns about the historical lack of** diversity within biobanks. Biobanks often include certain groups, particularly **white, middle-class, and or highly educated groups** and leave out other members of the population, including racial/ethnic minorities and low-income individuals. There have been serious barriers to donating biospecimens including mistrust of medical research, a lack of awareness of the importance of biobanks, challenges accessing donation sites, and insufficient culturally or linguistically appropriate materials for the consent process.

Historical mistrust is an important barrier to participation in biobanking for many groups in the United States. African-Americans, Native Americans, people of lower socioeconomic status, religious minorities, and many others have been subjected to unethical research activities in the past. Examples such as the



Tuskegee syphilis study, the use of Henrietta Lacks's cells, and the use of DNA samples from the Havasupai Indians come to mind quickly in underserved communities. Engaging in conversations as a community and discussing concerns about deception, discrimination, exploitation, and other concerns is critical to addressing the context of mistrust and laying a foundation for informed decision-making with regards to research, as well as accessing services.

Why does it matter if only certain groups are included in biobanks? Because the medical advances and research findings that rely on biobanks are only applicable for the groups that are represented in the biobanks. If diverse groups are not represented in the biobanks then researchers and clinicians cannot know if the important new diagnoses, drugs, and treatments work with these groups. This increases the inequity that already exists between advantaged and historically disadvantaged populations.

THE OPPORTUNITY

How can we address this challenge in biobanking? By increasing the diversity of biobanks. This means we must increase the accessibility of donating biospecimens through outreach, education, and thoughtful partnership. It is crucially important for trust to be built between communities and institutions that collect biospecimens. Local community-based organizations play an important role as community connectors and can support community members to access and understand the information they need to make informed decisions.

Increasing the awareness and accessibility of biobanking is a way to empower communities to be active participants in improving health outcomes for everyone. Providing historically disadvantaged communities with the tools to understand the process, risks and benefits of biobanking is paramount in the context of historical mistrust.

DONATING BIOSPECIMENS

Who: Anyone can be considered for donating biospecimens.

What: A person can donate any or all of the before mentioned biospecimens including skin, urine, and blood.

When: Before a surgery or procedure, a person can agree to donate a sample of a biospecimen that will already be collected from the surgery or procedure. Alternatively, someone may choose to donate samples on a voluntary basis through non-invasive procedures such as blood draws, urine samples or saliva swabs.

How: Donating a biospecimen is voluntary, even if the person is already having blood drawn, etc. Each person must provide *informed consent* before donating a biospecimen. The decision to donate or not donate biospecimens will not impact the procedure. Additional details regarding how to donate are available through the All of Us initiative (www.joinallofus.org).

Why: Community members can support cancer research and help scientists understand how disease work among all types of people. This allows them to be part of the prevention and treatment of diseases such as diabetes, heart disease, and cancer.



PRIVACY AND RISKS

Informed Consent: This is a very important part of biobanking and each individual who donates a biospecimen should go through the informed consent process. This process should:

- Provide adequate information about the donating process – how collection will work, expected uses of the biospecimen after collected, and potential findings from the resulting research.
- Ensure the individual fully understands the information
- Include voluntary consent from the donating individual

If someone is considering donating biospecimens, the informed consent process ensures that the person can ask all needed questions and receive as much information as needed to be comfortable making a decision. No one should ever feel coerced into donating biospecimens. Informed consent is a way to ensure the donor feels empowered, with information and decision-making power when choosing whether to donate.

What are the risks? Donating biospecimens is a low-risk process, however minor risks include physical pain, bruising or swelling if the donor is having a procedure, and non-physical risks such as potential loss of privacy or breach of confidentiality. Importantly, there are many safeguards (such as informed consent and privacy laws) in place to minimize these non-physical risks.

RESOURCES

National Cancer Institute – How You Can Help Medical Research Handbook: Provides brief, accessible information about donating biospecimens. This resource is geared towards potential donors and includes discussion of privacy, risks, informed consent, and a list of questions to consider when thinking about donating. (<https://biospecimens.cancer.gov/global/pdfs/MedicalResearchPatientBrochure-508.pdf>)

Biobanking Past, Present and Future: Responsibilities and Benefits: This research article provides an in-depth history of biobanks up to 2014 including how the use of biobanks has expanded and evolved. (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894636/>)

All of Us Research Program: A National Institute of Health program designed to gather data from more than 1 million people across the US. The initiative is specifically focused on increasing the diversity of biobanks so that research and medical breakthroughs, especially within precision medicine, apply to all individuals within the US. (<https://allofus.nih.gov/>)

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