

What is a Biobank?

A biobank is a collection of human biological material or biosamples stored for use in research. The biosample of each individual is linked to ongoing health information.

Examples of biosamples include blood, organ tissue from biopsies, and cheek cells. Biobanks are used to identify differences in DNA that may be linked to various diseases, conditions, and traits and are an important resource for genomics and personalized medicine.

Is Biobanking something new?

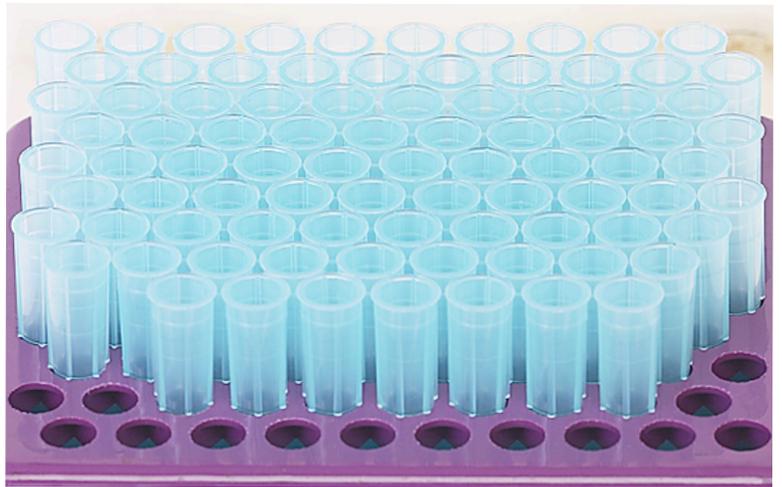
No, since the study of genetics began, physicians and researchers have collected biological samples and linked them to individuals' characteristics to study inheritance and its role in traits and diseases. A researcher or institution studying a condition like breast cancer or autism creates a biobank by collecting biological samples and health information from patients and unaffected family members. Researchers have long-term relationships with participants, and families are motivated to participate in hopes research will help them or their family members.

What about Biobanking has changed?

Since the late 1990's researchers have realized that although many diseases have a genetic component, only a few are caused by one defective gene. Meanwhile, technical advances have allowed detailed and less costly study of individuals' entire DNA sequence, which differs at millions of places between any two people. Very large numbers of samples are needed to pick out which of the million variants are more common in the people with the disease. In order to collect larger numbers of samples, researchers began combining their biosamples into biobanks. Several nations established population-wide biobanks, for example the UK Biobank and Icelandic Biobank. Now it is less common for the researchers or biobank managers to have ever met the people who donated samples.

How is next-generation Biobanking different for participants?

A large biobank can be used to study any trait or condition. For example, a researcher can use biobank samples to study heart disease. Other researchers can then use the same samples to study Parkinson's disease, schizophrenia, colon cancer, heredity, and on and on. A biobank linked to clinical health records can be used for research far into the future. Participants are unlikely to be personally invested in every type of research. Also, it is difficult for researchers to stay in contact with so many participants for many years.



What are the ethical issues in Biobanking?

Ethical issues raised by next-generation biobanks include:

- Protecting participants' privacy and identity
- Informed consent for future unspecified research
- Participants' ability to choose what research they will participate in
- Ability of participants to withdraw their samples
- Managing personal health information
- Communicating results back to participants
- Ownership of samples and findings
- Ongoing stewardship of samples and data

New best practices for governance and informed consent must be developed to address the ethical issues raised by research using large-scale biobanks.

Some examples:

Havasupai Indian Tribe

Members of the Havasupai Indian Tribe of the Grand Canyon provided blood samples to an Arizona State University diabetes researcher to investigate genetic associations with diabetes. Later, the tribe learned that another researcher from the university had used their samples to study mental health and the geographical origins of the tribe. Although using previously collected and deidentified samples for new research is legal, participating tribal members were not consulted about the new research projects and, if they had been, would not have agreed to have their samples used for these studies. The tribe claimed participants had not given consent for the research and won a lawsuit against Arizona State. The blood samples were returned to the participants and the university was required to pay a substantial settlement to the tribe.

Texas Bloodspots

Every state collects a drop of blood from each newborn baby to screen for genetic and metabolic conditions. Some states save the bloodspot samples as a public health biorepository; samples can be deidentified and used for epidemiological research. Without asking participants' permission, Texas gave the US military access to their state newborn bloodspot biorepository. Parents were surprised and alarmed when they found out the military had their babies' DNA. Some parents sued the state and won. As a result, 5 million bloodspots that could have been a valuable resource for responsible science were destroyed.

Women's Health Initiative

The Women's Health Initiative was established in 1991 as a long-term national health study focused on strategies to prevent heart disease, osteoporosis, and breast and colorectal cancer in postmenopausal women. Sponsored by the National Institutes of Health National Heart, Lung, and Blood Institute, WHI recruited 161,808 women aged 50-79 for the WHI Clinical Trial and WHI Observational Study to learn about hormone therapy, dietary patterns and calcium/vitamin D supplements and

their effects on the prevention of heart disease, cancer, and osteoporosis. A Community Prevention Study examined strategies to enhance adoption of healthful behaviors in order to develop community-based public health interventions. The WHI has an extensive participant website that provides WHI research results to participants and the public. The WHI also publishes WHI Matters, an annual newsletter for participants.



Food for Thought

1. What would motivate you to participate in a biobank?
2. As a biobank participant, what do you want to know about the research that is going on with your data or specimens? How would you want to hear about it?
3. Who should own your specimen? Should you, the biobank, or, if the biobank is public, the government?
4. Revisit the Havasupai or Texas bloodspot case. What might have been done differently?

Where to learn more

Fullerton, S. M., et al. (2010). 'Meeting the Governance Challenges of Next-Generation Biorepository Research'. *Science Translational Medicine* 2: 15cm3.

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