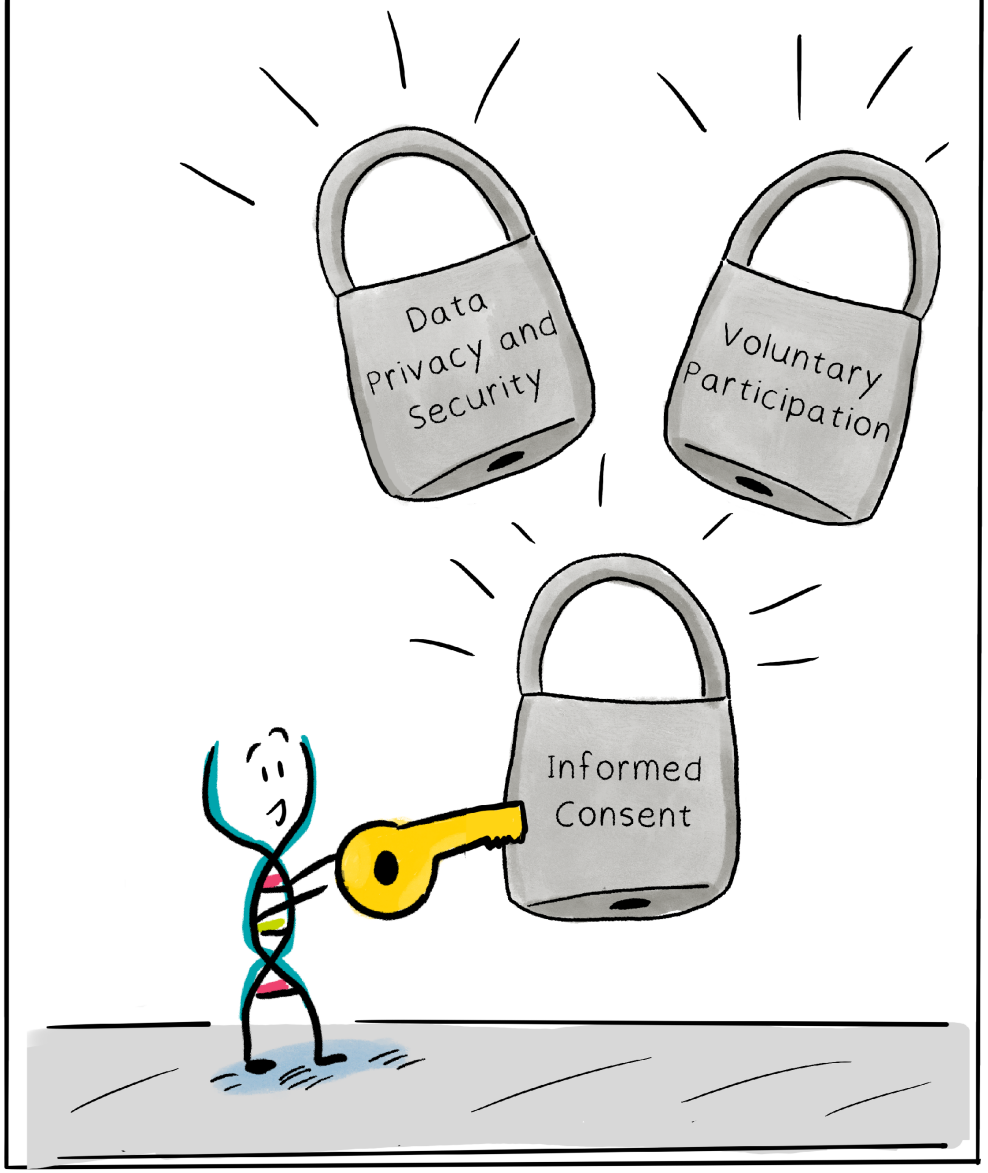
Privacy and Protections in Genetic and Genomic Research



Age-Based Genomic Screening

Website: go.unc.edu/abgs

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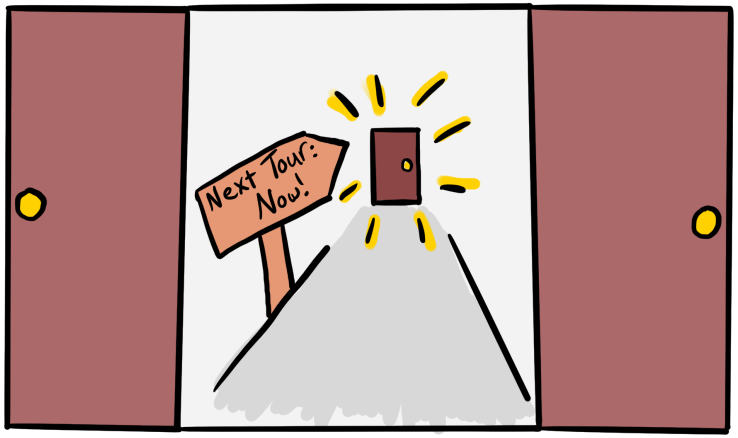
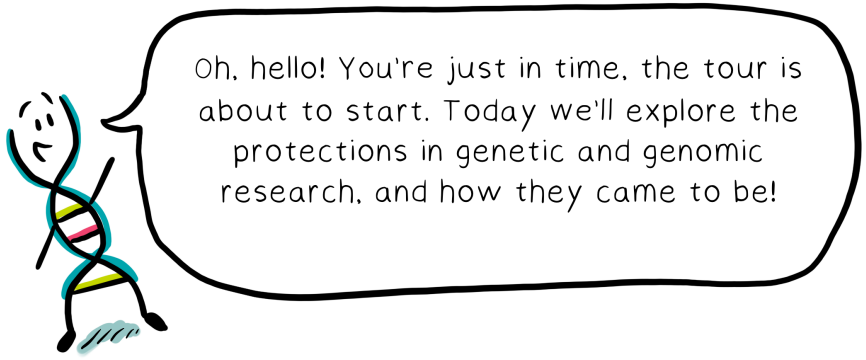
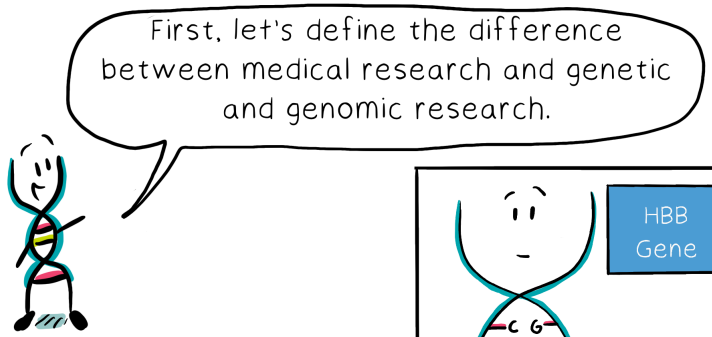
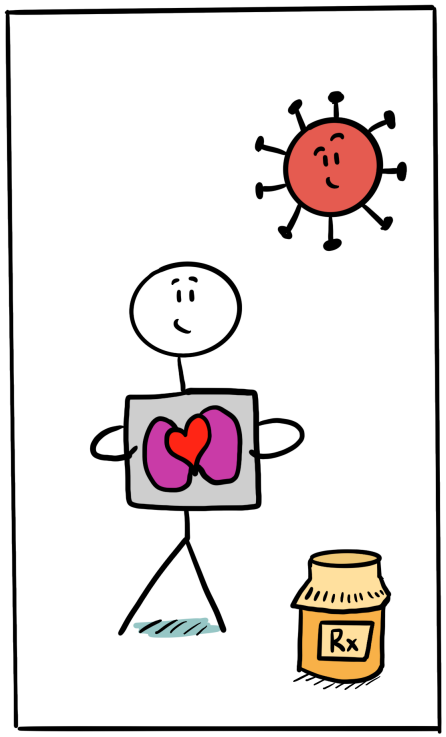
Genetic and Genomic Research: A Tour

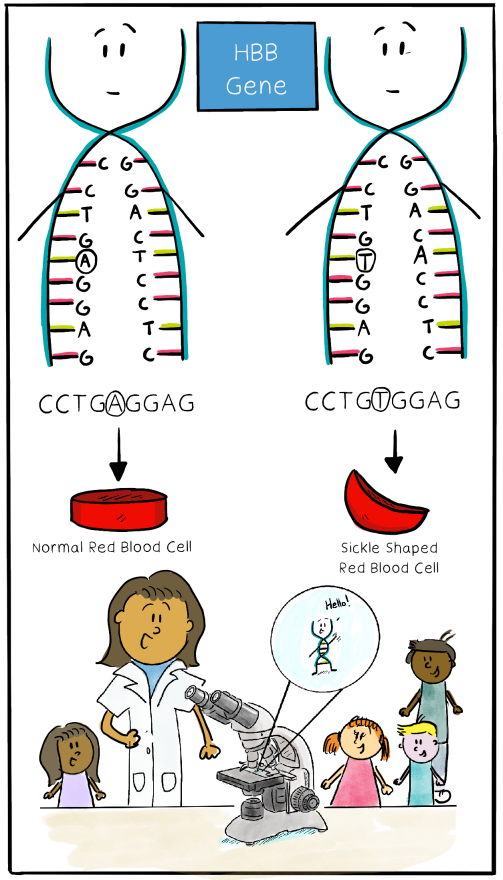




*Underlined words are defined in the Glossary at the end of this comic.



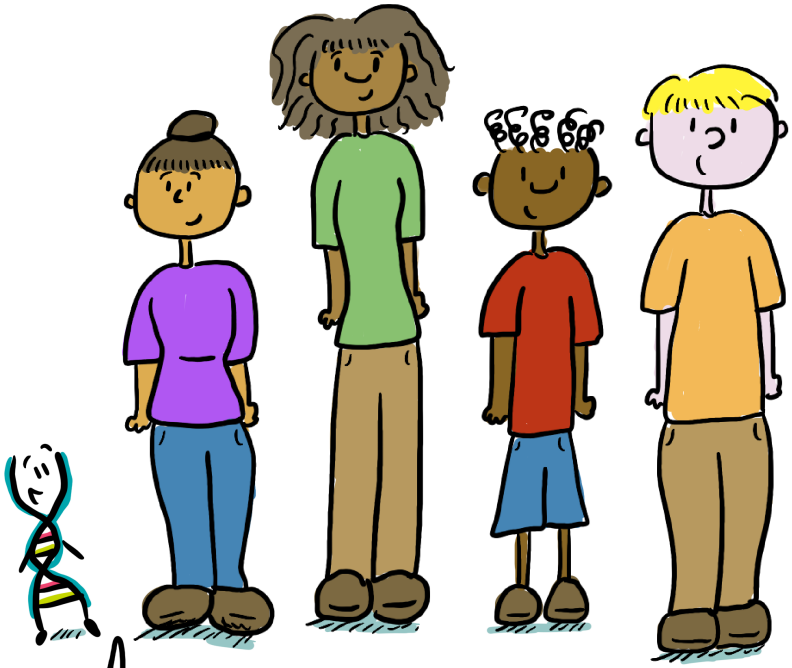




Medical research studies how the human body works and how diseases and treatments affect our health.

Genetic and genomic research studies how genes can cause diseases in different people and how to treat them. For the rest of the tour, we'll just call it genetic research.

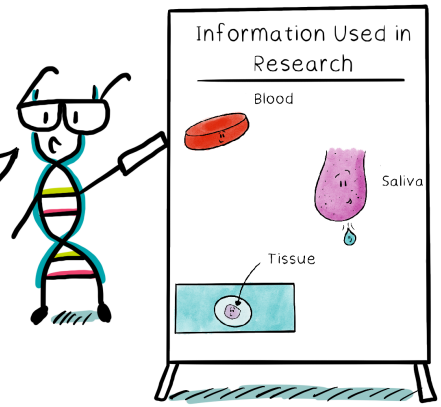
Many kinds of genetic research need people to take part. That's how researchers learn how discoveries affect real lives.

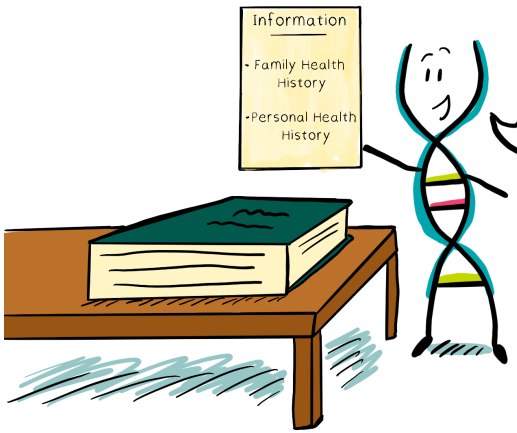


It's important for people from all backgrounds, across races, ethnicities, and genders, to participate. That way, research can improve health for *everyone*.

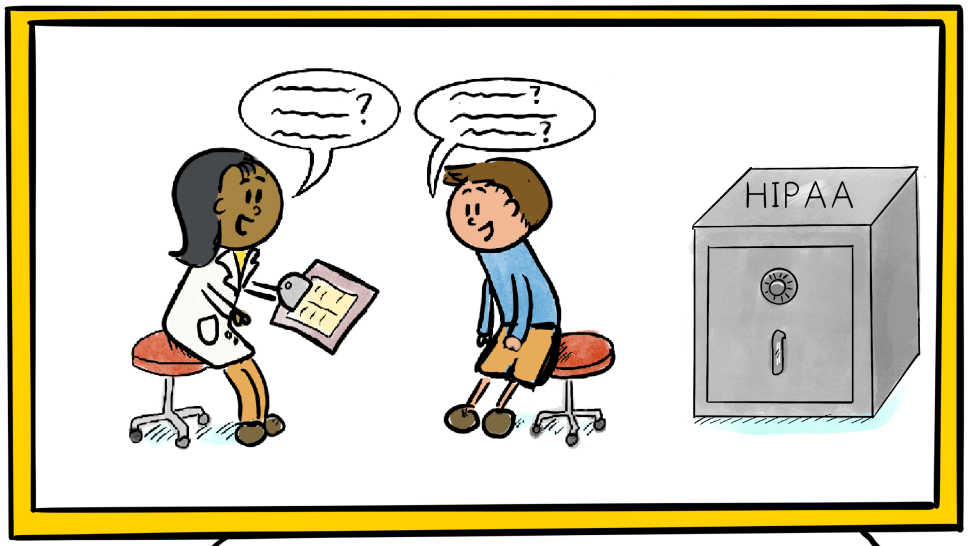
In genetic research, scientists study how genes affect health, including a person's risk for certain diseases, and how to prevent or treat them.

Study participants provide information such as a sample from a person's body such as blood, saliva, or tissue.



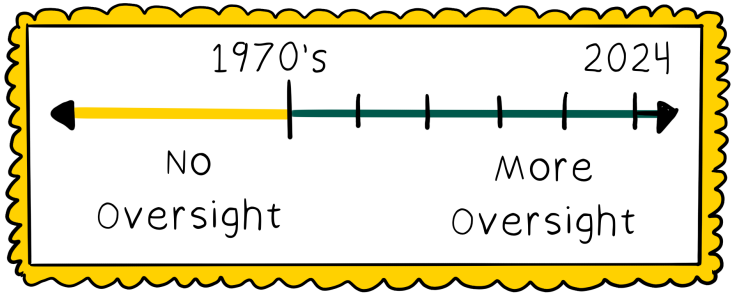


Or it could be information like a person's health history, family health history, or even opinions.



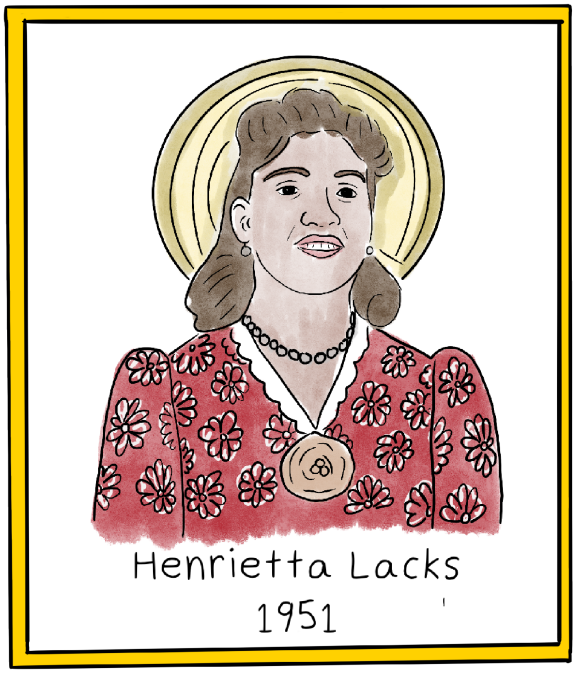
In all genetic research, keeping people safe is a priority. That means making sure they know how the study could affect them, so they can choose what's best for them. It also means the research team keeps their personal information protected.

Exhibit:
Protections Today vs. the Past



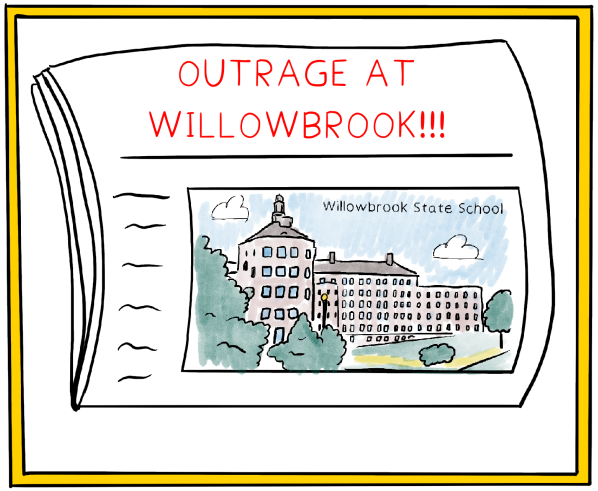
Today, research has strong protections to keep participants safe. But before the 1970s, those protections didn't exist. People weren't told the risks, and some were harmed. Often, those harmed had less power in society, like minorities, people with disabilities, and people in prison.

In 1951, Henrietta Lacks, a Black woman being treated for cancer, had her cells taken for research without her permission. At the time, researchers often took cells without asking permission. Her special cells were widely used in science and even sold by companies, but her family was not told.



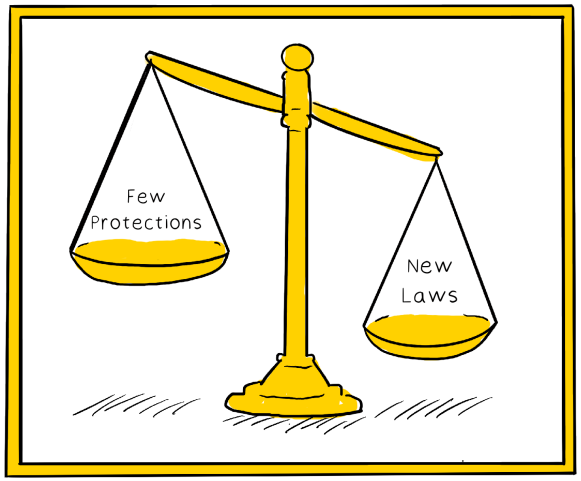
Ms. Lacks' case helped strengthen consent and transparency in research.
Today, people must be informed and agree before taking part.

From 1956 to 1971, disabled children living at Willowbrook State School were intentionally infected with hepatitis for research. Parents were not fully informed about the study.



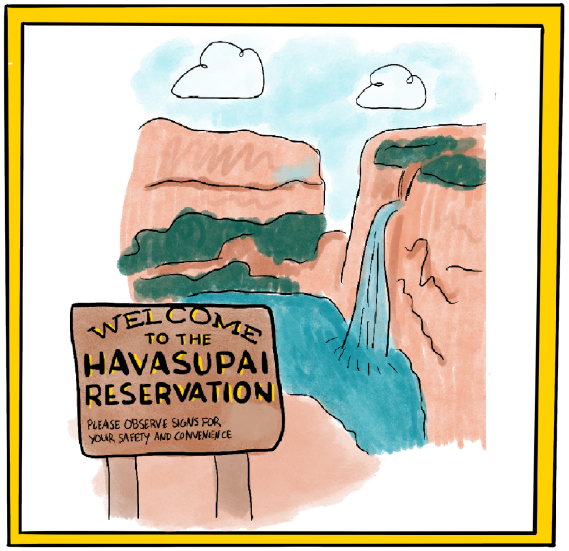
This case led to stronger protections for children and other vulnerable groups in research. It increased oversight to protect participants.

From 1932 to 1972, the U.S. Public Health Service conducted the Tuskegee Study of Untreated Syphilis. Hundreds of Black men were enrolled. Some had syphilis and were not told or treated, even after penicillin was available.



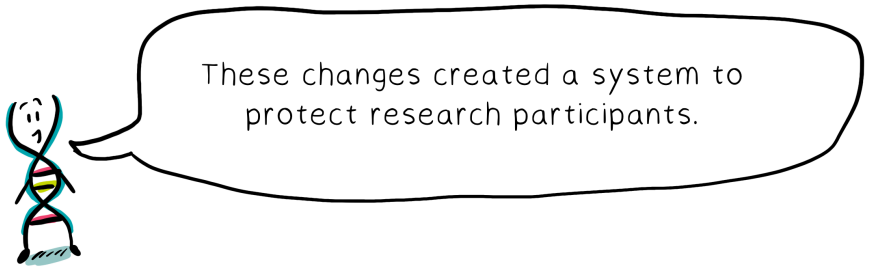
When the study was exposed, survivors and families sued with support from the NAACP. Public outrage led to new federal research laws and Institutional Review Boards to protect research participants.

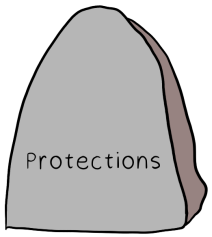
In the 1990s, members of the Havasupai Tribe gave blood samples for diabetes research. The samples were later used for other studies without their permission.



The tribe later sued and had their samples returned. It led to clearer consent about how research samples can be used and greater respect for tribal rights.

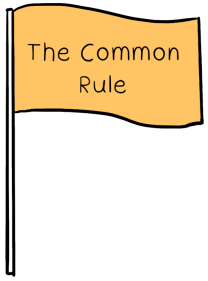
Today's protections exist because of harms in the past.





1974 - National Research Act

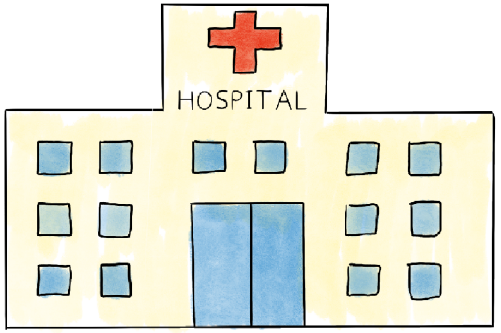
1978 - The Belmont Report

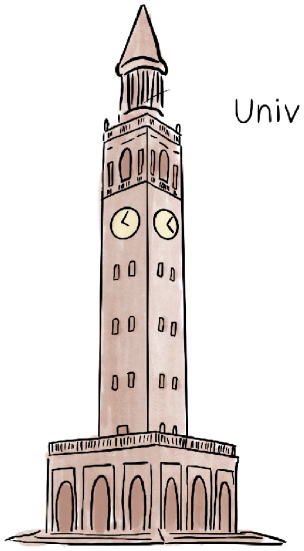


1991 - The Common Rule

The National Research Act created the basic protections that still shape research today.	The Belmont Report laid out key ethical principles: informed consent, voluntary participation, and respect.	The Common Rule made these protections the law for all federally funded research.
These changes turned painful lessons into safeguards that still protect research participants today.		

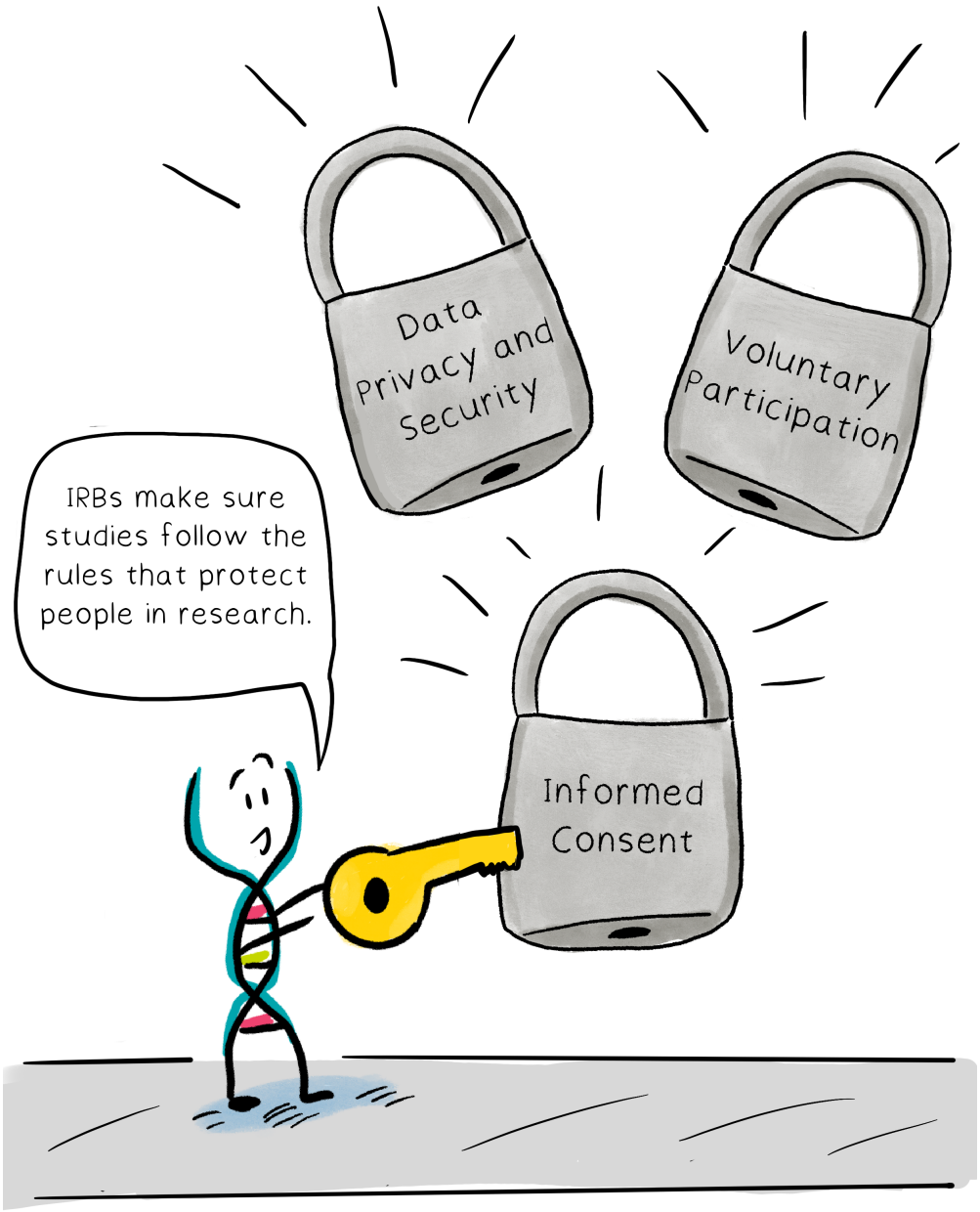
Community members





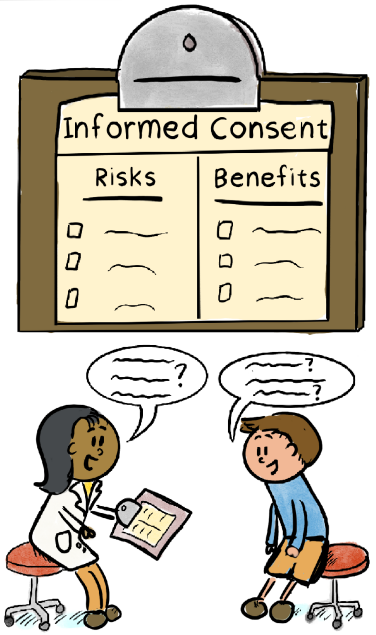
University

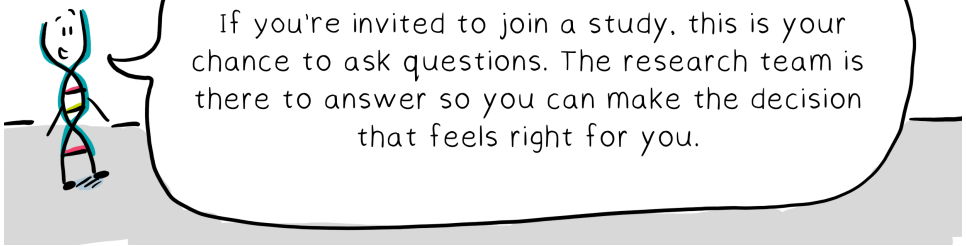
Every organization that does research with people — like universities and hospitals — has an IRB. And no study can begin without IRB review and approval.
Every study with human participants must have IRB approval.



Informed Consent

Informed consent means people are clearly told what a study is about, the possible benefits and risks, and how their information will be used.
It is a conversation between researchers and participants before they decide whether to join.

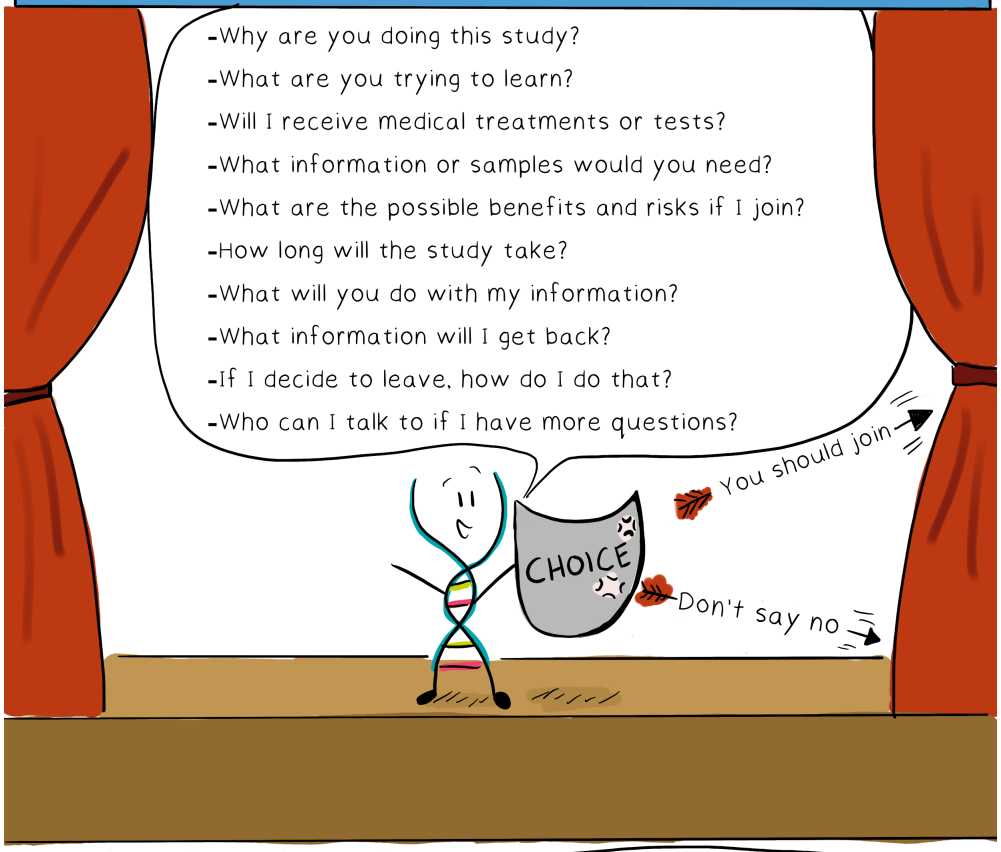


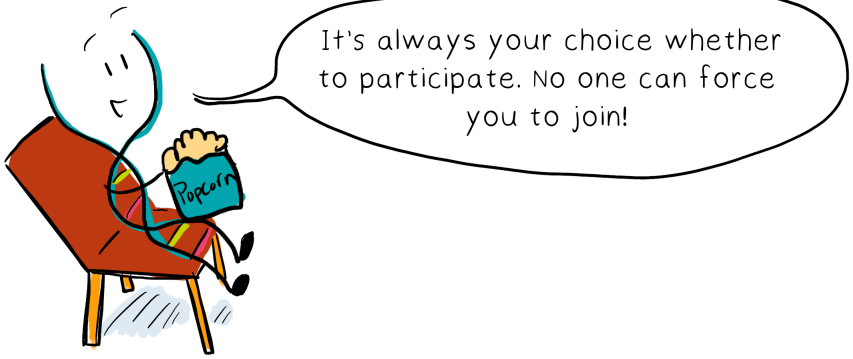


NOW SHOWING:

What should you know before participating in a research study?

-Why are you doing this study?
-What are you trying to learn?
-Will I receive medical treatments or tests?
-What information or samples would you need?
-What are the possible benefits and risks if I join?
-How long will the study take?
-What will you do with my information?
-What information will I get back?
-If I decide to leave, how do I do that?
-Who can I talk to if I have more questions?

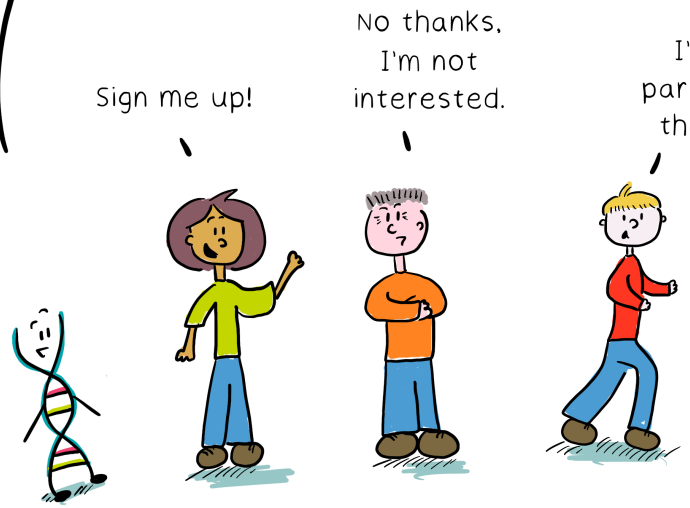




Voluntary Participation

Voluntary Participation means no one can be forced or pressured to take part. You — and only you — decide whether to join a study.

After the **informed consent** conversation, if you're not comfortable, you can say no. You can even say no in the middle of the discussion!

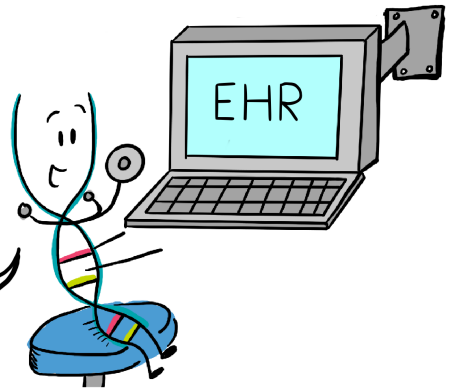


If you do join, you can stop at any time, for any reason, or no reason at all. You never have to explain why you're leaving.

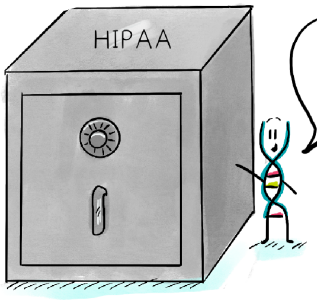
Data Privacy and Security

Researchers take data privacy and security very seriously. Your data is kept in a secure **research database** that only the study team can access. For extra protection, personal details are removed so the information can't be linked back to you.

Sometimes, research results can also help with a participant's health care. If the participant agrees, that information can be shared with their doctor and added to their **Electronic Health Record (EHR)**.

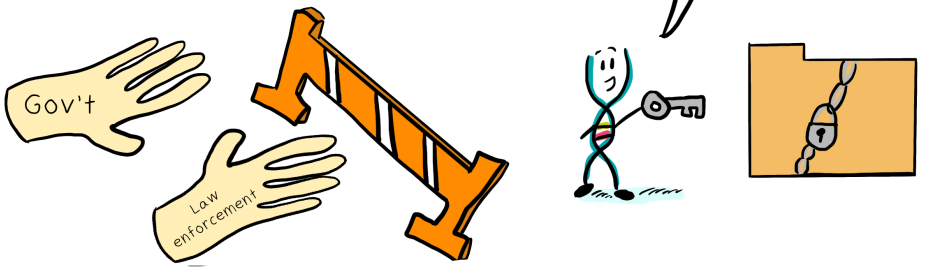


No matter where your information is stored, laws and security safeguards help protect it. Together, they reduce risk and safeguard your health and genetic information.

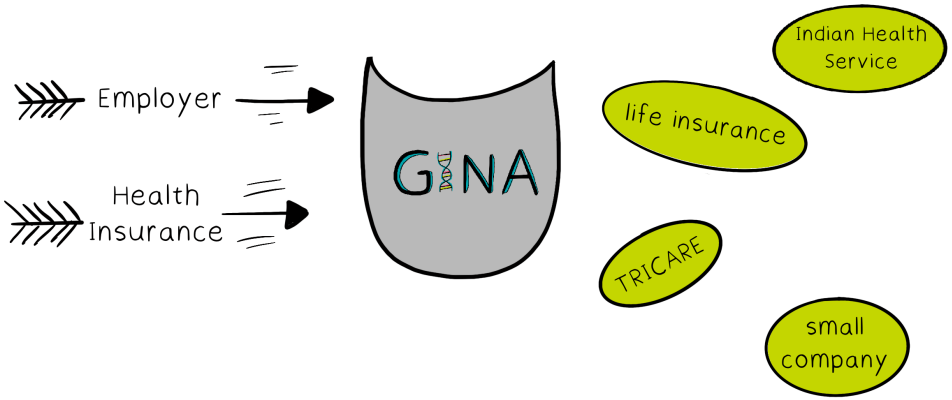


First, **HIPAA** (the Health Insurance Portability and Accountability Act) protects your personal health information in medical records.

Next, an **NIH Certificate of Confidentiality** gives extra protection for research. It keeps your personal and genetic information from being shared with the government or law enforcement - unless you agree or the law requires it (like in cases of child abuse). This applies to all genetic research across the U.S.



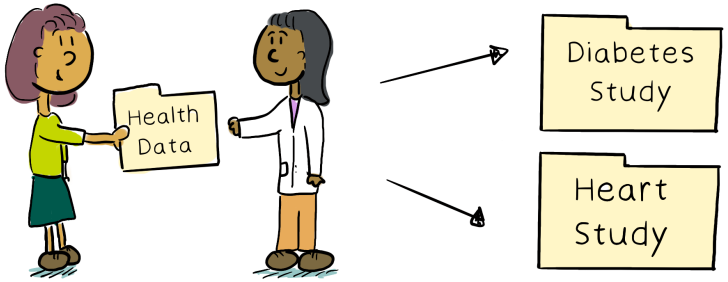
Finally, GINA — the **Genetic Information Nondiscrimination Act** — protects you from unfair treatment by most health insurers and employers because of your genetic data.



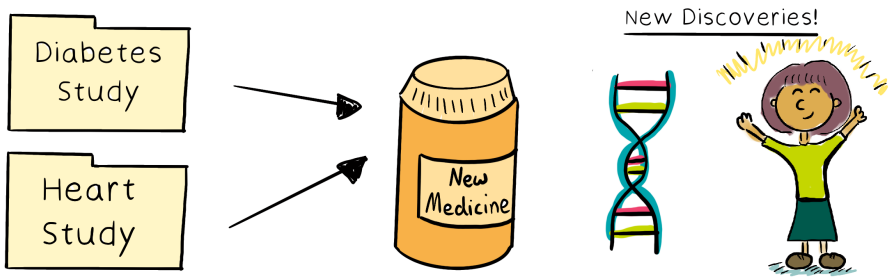
But, GINA doesn't cover everything — like life insurance, long-term care insurance, very small companies, TRICARE, or the Indian Health Service.

Data Sharing

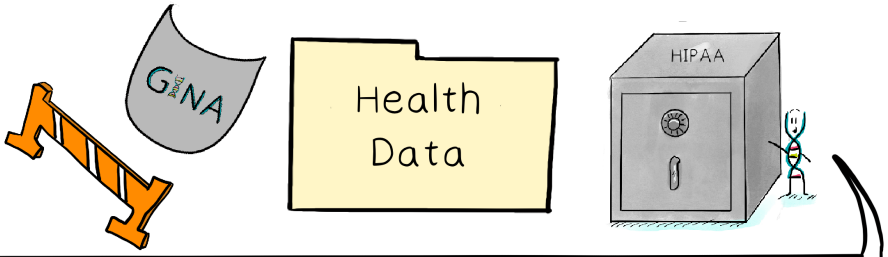
Sometimes researchers want to use your data for other projects, like combining it with other studies or saving it for future research.



Sharing data can lead to new treatments and new ways to keep people healthy.



If researchers plan to share your data, it has to be explained during informed consent, and you get to decide whether to allow it.



No matter what you choose, your data is still covered by the same strong legal protections

Thanks for coming along on the tour!
Here are some things to remember about protections in genetic research.

Important things to remember

- Past harms led to today's protections, so participants are treated with fairness and respect.
- IRBs review every study to be sure it is ethical and that any risks are reasonable and clearly explained.
- Informed consent means you are told what the study is about before you decide, and participation is always your choice.
- Your information is protected by privacy and anti-discrimination laws, and you can ask how they apply to you.
- Research needs people from all backgrounds so discoveries improve health for everyone.

Glossary

- **Electronic health record (EHR):** A digital file that holds health information like lab results or info gathered from a genetic test.
- **Genetic and genomic research:** Research that looks at DNA and other types of data to help us learn more about how to detect and treat diseases in people.
- **Genetic Information Non-discrimination Act (GINA):** A US law that provides protections against genetic discrimination in health insurance and employment.
- **HIPAA:** The Health Insurance and Portability and Accountability Act protects your personal health information in medical records.
- **Informed consent:** A conversation between a researcher and person interested in being part of a research study. The researcher will explain the risks and benefits of being a part of the study and answer any questions before a person can join the study.
- **Institutional Review Board (IRB):** A group of people at places like hospitals or universities whose job is to oversee human subjects research happening there. Their goal is to closely look at how researchers do their work and keep the data of those taking part in research safe.
- **Medical research:** Studies how the human body works and how diseases and treatments affect our health.
- **NIH Certificate of Confidentiality:** Keeps your personal and genetic information from being shared with the government or law enforcement unless you agree or the law requires it (like in cases of child abuse).
- **Research database:** The place where a research team holds data gathered during a study. Any identifying information is removed from this data.
- **Voluntary participation:** Means no one can be forced or pressured to take part in research. You and only you decide whether to join a study.