

You are invited to take part in a genetic research project

Please refer to the glossary to read about some words that are used in this document.

Health and medical research:

- can help answer questions about what makes people healthy and what can make people sick.
- may lead to ways for people to live healthier lives – now and in the future.
- can help people, families and ancestry communities.
- may lead to better treatments, better ways to identify health conditions early, or better ways to run health services.

Your participation is voluntary. You can choose to participate or not to participate in health and medical research.

[More information about health and medical research](#)

Genetic research

Genetic research is a type of health research. It looks at the way people's **genetic information** is important to health and the way bodies work. Some genetic information can tell you things about your health and your family's health, now and in the future. Genetic information could be very important to your family, your relatives, or other people who are from the same ancestry as you.

[More information about genetic information and genetic research](#)

What is genetic information?

Genetic information contains the instructions that bodies need to develop, grow and function. The instructions are mainly found in sections of DNA called **genes**. DNA can be found in all parts of your body, including blood and saliva. Small changes (or variants) in our genetic information can cause health conditions or increase the chance that we might develop health conditions in the future.

Every person has unique genetic information but some of that information is the same as that of their blood relatives. This includes parents and grandparents, brothers and sisters, and children. People from the same ancestry also have some similar genetic information.

Taking part in genetic research – English version

What do you do as part of the research?

If you take part in genetic research, what you are asked to do will be different for different projects. You might be able to choose which parts you take part in.

You will be asked to listen to or read information about the research project.

You can ask questions to help you decide if you will take part or not take part AND

You will be asked to answer questions in a survey AND/OR

You will be asked for some blood or tissue. This is how your DNA is collected in this project OR

You will be asked for some saliva. This is how your DNA is collected in this project.

AND/OR

You will be asked to let researchers see your health records AND/OR

You will be asked to tell researchers how to contact you or your family members.

[More information about the research project](#)

[More information about people you may meet as part of genetic research](#)

Will you get any genetic information from research?

Whether or not you are offered genetic information depends on the research project. Some genetic research projects will offer to give some information back to you. Only a small number of people who are involved in the research may get this information. Many research projects will not give any information back at all.

The researchers may:

- offer you information to help explain a health condition you may have.
- offer you information that could tell you about your chances of developing health conditions in the future.

Researchers will often only tell you this information if there are actions that you can take to improve your health or prevent health conditions.

If you do choose to get genetic information back from research, you may want to, or have to, share that information with other people. This information may be useful for you and for your blood relatives. Your family members who are blood relatives have similar genetic information.

Genetic information can also affect some types of insurance where you are asked about health information or health risks.

[More information about information you could receive from genetic research](#)

What happens to your information?

In research projects, information about you is collected, stored, and studied. Researchers follow laws and rules to keep your information safe and secure. There are also rules about who can look at the information during the research project.

Before the research project can begin, the researchers must tell you:

- who can see your information.
- how your information will be kept safe.
- how your information will be stored.
- how long your information will be stored for.

In genetic research there is a lot of information to study. Researchers often work together and share information between research projects to try to find answers. If you take part in the research, you might be asked about who you allow your information to be given to.

[More information about storing your information](#)

[More information about sharing your information](#)

Risks and benefits of taking part in genetic research

- Information and samples you give to the researchers will help them to understand more about health and health conditions, which can help to improve healthcare in the future.
- Researchers may find something in your genetic information that could affect your health or the health of your family.
- The research may help to improve healthcare in your ancestry community.
- You may want to, or have to, share genetic information you are offered by a research project.
- Even if your personal details have been removed, there is a very small chance your genetic information could be linked back to you.

[More information about benefits and risks of taking part in genetic research](#)

About the research project

What is the purpose of the research?

If you choose to take part in this research project we will gather health information and personal details about you to study. We will combine it with information from other people who join. Researchers will remove the personal details from your health information and may use it for lots of health and medical research projects in the future. By looking for patterns in the information, researchers may learn more about what affects people's health. OR

This research project is trying to find out which genes make a difference in a person's treatment. We will use the information you give us for this research. OR

This research project is trying to find out the genetic cause of a health condition you may have or a health condition a person in your family may have. We will ask you for information about your health and the health of your family to help us to find an answer in your genetic information. We may also ask other members of your family to take part in the project. We may compare your genetic information with the information from other people around the world with a similar health condition. OR

We are building a large database with the information you give us. It will be made available to all researchers to help make discoveries. The database will not have personal details like names or birth dates in it. OR

Researchers in this project will try to find all of the genetic changes (or variants) in people's DNA and genes. Researchers will study the DNA from many people who have families from different parts of the world. This project may help researchers make discoveries more quickly.

How long will the research project take?

Your information will be stored and used for research for [number] years. OR

This research project will last for at least [number] years. OR

This research project will last for many years. It does not have a date when it will close.

Who will take part in the research?

We hope that [number] people or more will join the research project. OR

We hope that [number] or more people who have families from different parts of the world will join the research project.

Where did the funding for this research come from?

Funding has been provided by: [Name/organisation/government(s)] OR

Researchers in different countries are working together on this research project. Funding for the project is coming from governments, hospitals, companies and people who donate money for research.

You can find out more about the research here: [study information]

About health and medical research

What is health and medical research?

Health and medical research studies what makes people healthy and why they might have health conditions or disabilities. It provides information to help people live healthier lives – now and in the future.

Health and medical research can look at any part of people's health such as:

- different types of injury or health conditions
- how well a treatment might work;
- how people are coping with health conditions; or
- the quality of health service delivery.

The findings from medical research can help people, families and ancestry communities because they could lead to better treatments, better ways to identify a health condition early, or better ways to deliver health services.

Researchers learn from each other by building on answers that have already been found to help answer new questions. This means that answers from health research can also be shared with other researchers. They may be shared through writing an article, or some parts of the information can be put into a database and used to help answer new questions. Sharing the results means that the answers can be used to help people wherever they live.

Who does research?

People who do research (researchers) can work at many different places. They might work at a university, a hospital, or a research centre. Researchers also come from different professions. They might be scientists, doctors, psychologists, nurses, or social researchers. Sometimes research can involve many researchers from across Australia or from different countries. Researchers may get funding to pay for projects from the government, private companies or from people who donate money to research.

How is health and medical research different from healthcare?

In healthcare: a doctor orders a test for you to answer how to help with your healthcare now. In health research: a researcher looks for answers to improve the health of people in the future, not your own health right now.

Health research may use the same tests as healthcare and involve your doctor.

Health research may not provide answers that help you, or that change anything about your healthcare.

There are different laws and guidelines for health researchers and healthcare professionals. The guidelines for health research are set by the government and all health researchers must follow them. If the research involves people, it has to be approved by a group of people called a Human Research Ethics Committee (HREC). Their job is to make sure that the research projects meet the standards and guidelines.

About genetic information and genetic research

What is genetic information?

Genetic information contains the instructions for bodies to develop, grow, and work. These are mainly found in sections of DNA called genes. DNA is found in every part of the body, including blood and saliva.

Each person has their own genetic information but some of that information is the same as their blood relatives'. This includes parents and grandparents, brothers and sisters, and children. Tiny differences in genes and DNA can help to explain differences in how people look and how their bodies work.

Genetics and genomics

Researchers can look at one piece of genetic information at a time, or study groups of genes. All of a person's genes or genetic information is called a **genome**. Studying people's genomes is called **genomics**. Depending on the research project, your genes may be studied one at a time, or studied as a group of hundreds or thousands of genes.

What is genetic research?

Genetic research is a type of health research. It looks at genetic information to understand which parts are important to people's health or the health of their families.

Some changes (or **variants**) in genetic information can cause a health condition or increase the chance of developing conditions such as cancer, diabetes, asthma or depression. A lot of conditions are caused by a combination of people's DNA changes (variants), how they live, and their environment.

Studying the genetic causes of health conditions can help researchers and doctors to identify, treat, manage or prevent different conditions.

Is genetic information different to other health information?

Some people think that genetic information is different from other kinds of health information.

Some genetic information can tell you things about you as a person and your health, now and in the future. It also holds information about your family and their health. Your genetic information could also be important to your family, your relatives, or people from the same ancestry as you.

People you may meet as part of genetic research

If you decide to take part in genetic research and choose to receive genetic information, you may meet scientists, health professionals and doctors who are trained in genetics. They might be talking to you about the research, looking at the information you give, or providing results.

Here are some of the people you might meet:

Health researchers:

People who design and do the research. They collect and study the samples or information you provide. You might meet researchers, research assistants or research students. Some researchers are also health professionals, such as doctors, genetic counsellors, nurses, midwives, or psychologists.

Health professionals:

Health professionals are people who provide healthcare to patients. Many health professionals do research to try to improve patient care.

Genetic counsellors: help people and families understand their genetic information and how it may cause a genetic health condition. They are trained in genetics and counselling and are skilled at making complex information easier to understand and helping people make decisions about genetic information that are right for them.

Clinical geneticists: doctors who are trained in the field of genetics. They can identify different genetic health conditions caused by genetic variants and care for people with these conditions.

Medical specialists: doctors that usually focus on body systems (such as the heart, brain, or kidneys etc.) who will sometimes work with a genetic research team to make sure that people and their families get the best care.

What you might be asked to do as part of genetic research

What you may be asked to do if you take part in health research depends on the reason for the research and the answers the researchers are trying to find.

In this project, you may be asked to:

- Give your opinion about your healthcare or service
- Answer questions in a survey
- Answer questions about your health and/or the health of your family members
- Have a medical examination
- Provide a sample of blood, saliva or body tissue so that your DNA can be studied
- Let researchers contact your doctors or see your health records

You can choose which sections of the project you want to be part of.

How long will the research project take?

If you take part in research, you might be asked to do something once or you might be asked to do something over a period of time. A research project can go for weeks or years. Researchers will tell you how long their project will go for before you choose whether to take part or not. You can also ask them questions about what you might be asked to do before you decide.

About some benefits and risks of taking part in this research

Taking part in research may or may not have some benefits for you. It depends on the type of research.

Research that does not benefit you but may benefit healthcare in the future

This research has no direct benefit to you or your family and genetic information will not be given back to you.

The research is at an early stage and it may take many years to answer the research questions and find something that is useful for people.

OR

- a) The research looks at the genetic information of many people at once. People's names and other personal details have been removed from the genetic information before it is studied, so there is no way to tell who the genetic information belongs to.

OR

- b) The research is being done to improve the health of people in the future. This means that the information and samples you give to the researchers will help them to understand more about health and health conditions.

OR

- c) The research is being done to find out whether genetic information can improve the health of people who have a health condition that you may also have. The research may help with diagnosis or treatment in the future.

OR

- d) The research is being done to improve the health of people in the future who may be part of your ancestry community.

OR

Research that has direct benefits for you and your family

This research may have a direct benefit for you. Researchers may contact you if they find something in your genetic information that may affect your health or the health of your family. If researchers do find something, you will be asked if you would like this information before it is given to you. This information could tell you whether you are likely to develop, or have a higher chance of developing, a health condition that could affect you and your family. This information may also be used to help you make choices for your future if you are planning on having a child or planning to have more children.

OR

Research that benefits your ancestry community

The research may help to improve healthcare in the community of people from the same ancestry as you.

If some ancestry communities have not taken part in research before, there might not be enough information about people's health and the different causes of health conditions in that ancestry community. If more people from an ancestry community take part in research, it can help researchers to understand, treat or prevent health conditions. This may mean better healthcare for that ancestry community in the future.

Taking part in genetic research – English version

**Taking part in research may or may not have risks for you.
It depends on the type of research.**

Getting genetic information back may affect your emotions and how you feel

If you find out genetic information that can affect your health and the health of your family, it might affect how you feel. Some people feel worried or upset when they first find out this information. Other people might feel relieved. Other people might not feel any different. These feelings may also change over time.

The information may tell you whether or not you have a health condition, or whether you have a higher chance of developing one. You may not have expected to receive this information or it might not give you the answers you were hoping for.

You may learn information that could be useful to others in your family. People can react in different ways if the information is unexpected. Some family members may not want to know this information.

You may have to share genetic information you get back from a research project

If you choose to get genetic information back from research, and are offered information that could affect your future health, you may have to share that information with other people, such as your family, your doctor or insurers. It is up to you whether or not you get this information.

Genetic information will not affect your health insurance in Australia. It may affect your ability to buy some other types of insurance, such as life insurance, income protection insurance, or travel insurance.

If you choose not to get genetic information back from a research project, it will not affect your insurance.

Even if your personal details have been removed, there is a very small chance your genetic information could be linked back to you

Genetic information is protected in strict ways to make sure the information is secure. There are rules and laws to protect genetic information. However, like fingerprints, it is possible to know who someone is if their genetic information and other pieces of information are put together.

Linking information back to you is unlikely. The chances of linking information back to you increase if you or your family members have already put your DNA and personal details into ancestry websites or forums.

Unexpected risks

The risks of taking part in research may change over time. As the technology improves there will be new ways to look at and understand genetic information. There may be new information that comes up in the future that we cannot guess now.

About information you could receive from genetic research

There are many types of genetic research projects.

Some research projects will give information back about a person's health that can tell them something about their health now or in the future. Some researchers will only give information to a very small number of people who take part. Many projects will not give any information back at all.

You may be offered this information. If you are, you can choose whether or not you want to get this information back. You may also be able to choose for your family members to find out about this information if you are not available.

What information could be found?

Information that is found and offered to people usually tells them about a genetic change (or variant) that could affect their health in some way.

This information might be about the health conditions being studied in the research or it might be other information revealed during the research that could have an effect on a person's health.

Researchers will often only offer this information:

- for genetic variants that are well understood.
- where there are actions that people can take to improve their health or prevent health conditions.

Depending on the research project only a small number of people who take part in the research may receive a result like this. If a genetic variant is found during a research project and offered to you, your doctor will need to do another test to check the information before it is used in your healthcare.

Information that may help explain your health

You may receive information that helps to explain your health or a condition that you have. It could help doctors to make a diagnosis for you or put a name to a health problem you may have.

[Name] takes part in a heart health genetic study. He has had high cholesterol for many years. The study found that [Name] has a variant for familial hypercholesterolemia (FH), or high cholesterol that helps to explain his current health. His GP ordered a test to check the result and [Name] now takes medication to lower his risk of a heart attack.

Taking part in genetic research – English version

Information that may tell you about the chance of developing health conditions in the future

You may receive information that says that you have an increased chance of developing a health condition in the future. This information may be unexpected. Having a genetic variant does not necessarily mean that you have a health condition or that you will develop one. People often use this information to take steps that can help them reduce their chance of developing the condition, such as to look out for early signs of a health condition or try other things to reduce their chance of developing one.

[Name] took part in research looking at the genetic information of young, healthy people. [Name] receives a call from a genetic health professional and finds out that she is one of the few people receiving a result from the study. The researchers found that she has a gene variant that increases her chances of developing breast and ovarian cancer at a young age. [Name] has regular breast screening and is receiving medical care to reduce her chances of developing cancer.

Information that may help you or family members plan for future children

You may receive information that could be important if you are planning to have a child. This information may also be helpful to other relatives who plan to have children.

[Name1] and [Name2] took part in research to understand how people might use genetic information when they have children. They were told that they each carried a genetic variant that meant that they had one in four chance of having a child with a common genetic condition. [Name1] and [Name2] could use this information to think about what life might look like if they have a child with this condition and find out about their options for screening or support.

Information that could be useful for your relatives

Information you get from genetic research could also be important for your relatives. That means your family members might want to know about the research. They may include your partner and your blood relatives, including parents, children, aunts, uncles and cousins. Some of your family may want to be tested to see if they carry the same genetic variant as you. If you take part in research and decide that you want this type of information given back to you, your doctor and the researchers can help you work out ways to share this information with others.

[Name] found out from a research project that they had a genetic variant that increased their risk of developing cancer. They were told that this information was also important for their relatives because they may have the same variant. [Name]'s GP helped them to discuss their genetic information with their mother, who agreed to be tested. As [Name]'s mother was older, she had different options to reduce her risk. [Name]'s mother was able to prevent an advanced cancer developing and she told other relatives on that side of the family who were at risk so that they could find out more and make their own decisions.

About storing your information

What happens to your information if you take part in research?

When you give a sample for research (such as saliva, blood, or other body tissue), information about you is collected, stored, and studied. The researchers will tell you how they will keep your information safe and how long they will keep your information for. There are laws and guidelines that researchers must obey and refer to about keeping different types of information safe and secure. There are also rules about who can look at the information during the research project. Before the research project can begin, the researchers must tell you who can see your information and how they will keep it safe.

How will your biological sample and information be stored?

If your sample goes to a laboratory for testing, it will be stored securely in a way that obeys national and state laws. Biological samples sent to a laboratory are not stored with personal information such as names or birthdates. All computer-based information collected for the research project will be protected and stored on secure computer systems in Australia.

How long will your biological sample and information be stored?

Samples such as blood or saliva may be stored in laboratories for a few months or for many years. This will depend on what choices you make when you joined the study. This lets the researchers study the information again if they learn something new or if there is a reason to do this. For example, new gene variants might be discovered that are linked with a health condition you might have.

Will your biological sample and information be linked to you?

Most researchers will not need to know your personal details to do their research. They will only see a code. The code may be used to re-link your genetic information with your personal details (such as your name and birthdate) if researchers find some genetic information that could be useful to you, for your health or your family's health. This means that your personal details can be held in one place and your genetic information can be held in another. In some research projects, all of your personal details are permanently removed before your genetic information is studied by researchers, kept or given to other researchers.

If the researchers write an article about their study, they will not include any personal details so it cannot be linked to you. If parts of your genetic information are put into research databases, it is not connected to your name or other personal details. Because your DNA is unique, there is always a very small chance that your personal details could be re-linked with your information.

Can you see or have a copy of your information from the research project?

The laws in Australia say that you can ask for any of your information, such as genetic information, that has been collected and stored by the researchers. This can only be done if the information is still linked with your name.

About sharing your information

Who will be able to look at and study your information?

The researchers involved in the study will be able to look at your information. Most researchers who work with or study your sample(s) or genetic information will only see the code or number that is linked with your genetic information. They will not know your name or see other personal information.

If you have agreed for the researchers to have access to information about yourself that is in your health records (at hospitals or with your doctor), the researchers will contact them and tell them some details about you, such as your name and your date of birth. This is so the health centre can find your health record and send information back to the researchers. The researchers will not give your genetic information to your hospital or your doctor unless you agree to it.

Sometimes the people who make the rules and laws about research (regulators) may look at the information collected as part of a project, known as an audit, to make sure that the researchers are doing their work well. They will only look at the type of information that has been collected and how it is being stored.

You may be able to choose how long your information is stored and who your information can be given to. If you agree to give your information to other research projects or research centres, the new researchers have to get approval from a committee. The committee makes sure that they follow the rules and keep your information safe.

How could your information be used in the future?

If you join a research project, the researchers might also ask you if your sample or information can be used in other research projects. Health research gives us information that we can use to help people live healthier lives. In genetic research there are many possible genetic variants and thousands of different health conditions to look at, so researchers often work together and share information to try to find answers.

If you say yes and let your sample and genetic information be used for other research projects:

- your personal details (name, date of birth) will not be given out, only the sample and/or genetic information. Sometimes other researchers only need parts of your genetic information to help answer their questions;
- these projects will also need to be approved by an ethics committee to make sure that the standards and guidelines are being followed;
- you will not get any information back from this research, but you may be helping other people to have better healthcare in the future;
- your information will not be given to marketers or organisations (such as insurance companies) that are not connected to research.

Taking part in genetic research – English version

If you say yes to your information being given to other researchers, your sample and genetic information may be given to:

- researchers in Australia or overseas, including at universities, hospitals, medical research institutes, and not-for-profit organisations;
- researchers who are part of for-profit biomedical, pharmaceutical or diagnostic testing companies; and
- national and international databases.

What happens to your information if you leave the research project?

You have the right to leave the research project at any time. However, researchers will have used any sample(s) or information that has been collected up until you tell them not to. The researchers may not be able to destroy or give you all of your samples or information back if your name is no longer linked to the information, or if they have already been given to other researchers. If you decide to leave the research, it will not affect your healthcare, your relationship with your doctors, or your relationship with the researchers.

Will you be contacted again in the future?

You will be asked if researchers can contact you about future research projects. If you agree, you can decide to take part in any future research when you are contacted.

What happens if you die, or are unable to make your own decisions?

The researchers may ask you for information about a friend, partner, or family member who they can contact if you die or are unable to make decisions for yourself before the research is finished. It may be important for your family members to find out about your genetic results because the information could also affect them.

Consent form

- I have read the information about this health research project or someone has read it to me in a language that I understand.
- I understand why the research is being done and any risks to me or my family.
- I agree to take part in this research project as it has been described to me.
- I know that I can withdraw at any time during the project and that this will not affect my future healthcare.
- I have asked questions that I wanted to ask and I am satisfied with the answers I have received.
- I understand that I will be given a signed copy of this form to keep.

My choices:

Having information given back to me:

If research with my DNA shows I have or could develop a/another genetic condition that could affect me or my family:

(a) I do not want to be offered this information

(b) I want to be offered this information

(c) I want my family members to be able to have the information. If I cannot get this information myself, I would like my family to have it and I would like you to contact:

.....

[name, relationship to me, phone number, email address]

I understand that I may be contacted with information from the research project that is related to my health or my family's health.

Sharing my health information with researchers:

I give permission to my doctors, other health professionals, healthcare centres, hospitals, or laboratories to give information about my health, any health conditions, or treatments to [Name of research institution] to take part in this research project.

I understand that the health information they provide will only be used for this research and that it will be treated as sensitive information and kept safe and private.

OR

I give permission for my health information to be used for this research AND given to other research projects that have been approved by ethics committees. I understand that my personal details (such as name and birthdate) will not be given out.

Taking part in genetic research – English version

Sharing my genetic information and samples:

I give permission for the use of my DNA (from my blood, saliva or tissue) to be used for this research project only.

OR

I give permission for my DNA (from my blood, saliva or tissue) to be used in other health or medical research about my health condition.

OR

I give permission for my DNA (from my blood, saliva or tissue) to be used in other health or medical research.

OR

I give permission for my DNA (from my blood, saliva or tissue) to be used for any future research projects.

OR

I give permission for my DNA (from my blood, saliva or tissue) to be used for population or ancestry research, including about a specific population.

If I want to leave the research project:

I understand that I can leave the research project by filling out a form that has been given to me.

If I leave the study, I can decide if I want to have any of my samples or information destroyed or returned to me.

I understand that this information can only be found and destroyed or returned if the information is still linked with my name and has not been given to other researchers.

I know that if I have any other questions about the research project or how my information will be used, I can contact

Glossary

Ancestry community: people who are descended from the same geographic region.

Ancestry website or forum: Companies providing genealogy services to trace your family history.

Biological sample: material from a person's body such as DNA, blood, urine or tissue.

Database: a collection of information organised and stored electronically.

DNA: can be found in every part of the body, including blood and saliva. DNA contains a person's genetic instructions, mostly in sections called **genes**.

Gene: a section of **DNA** that contains instructions for a body to develop, grow and work. Differences in genes can help to explain how people look and how their bodies work.

Genetic information: contains the instructions that are used by bodies to develop, grow and work. Differences or variants in genetic information can affect health. Some of a person's genetic information is the same as their blood relatives' genetic information, including parents and grandparents, brothers and sisters, and children.

Genetic variant: a change in a person's genetic information. Some genetic variants can affect a person's health or the way they respond to medicines or treatments.

Genome: A person's **genome** is the complete set of their genetic information, containing all of their genes.

Genomics: the field of medical science that studies the information contained in genomes.

Health information: information about a person's health, which could include test results, doctor's notes and reports, prescriptions, and information about any symptoms or diagnoses. Health information can include genetic information.

Researchers: People who do research.

Risks and benefits: this phrase is used to think about possible good or bad events that could occur as part of the research, including the chance of unexpected findings.