

Study Consent

Study description

Instructions for administration of consent

PAGE ONE

Who are we?

Name, job title, and institutional affiliation of the main researcher.

Include information about the principal investigator (If they are not the main researcher) and the rest of the research team (if they are directly in contact with the participants e.g. study clinicians). Include information about collaborators (If there are any).

Why are we doing this study?

We want to study something called "genes". These "genes" are present in all of us and are the same in all parts of our bodies. "Genes" are sometimes also called DNA, which is the name of the material they are made from. Genes are responsible for why people in families are often more like each other, and different from other families. For example, some families are generally taller or shorter than others. This kind of information is passed from both the father and the mother to their children and on to their grandchildren, from one generation to the next. Some of these genes may prevent some people from getting certain illnesses. Other genes may be one of the reasons why some people get sick or have side effects from some medicines when others do not. We are still learning how genes might contribute to different diseases, and how they work together with our lifestyle and other factors - such as our environment or what we eat - to affect our health. We want to explore whether genes may affect (specific health phenotype under study) in (specific target population if relevant).

What do we do to decide if you are eligible to be take part?

In our study, we want to learn more about [specific disease phenotype] in [target study population] so we are approaching any person who fits this description because they are the type of people who we want in our study.

How many people will take part in the study?

There will [insert number] of participants including yourself if you agree to participate in the study.

How long will the study last?

We expect the study to last for [insert time frame], but we will notify you immediately if there are any changes that impact you directly.

What will happen if you decide to take part in the study?

We will go through the participant information with you to ensure that you understand what the study is about, what is expected of you as the participant, and also, what is expected of us as the researchers. While going through this information we will be asking you some questions and at the end, you will be asked to give signed permission to participate in our study.

Participation in our study is voluntary and you have the option not to participate. Even after you have agreed to join our study, you can still change your mind and we will destroy your sample and remove you from the study. If you choose not to participate in our study or drop out later, it will NOT affect the care you are receiving at [insert health care facility].

What are the risks?

We will make sure that your health information and sample are protected and safely stored, because there is always some small risk that the special pattern of genes from your sample could be used to work out who you are and see your health information if other people were to get hold of this information. We will be very careful in making sure all this personal information is very secure so that this could not happen.

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What happens if I get hurt taking part in this study?

This study poses minimal risk of physical harm to you as a participant. However, if you get hurt as a direct result of participating in the study, you should inform the principal investigator [full names and contact number] immediately and they will assist with the next steps.

Are there any benefits to you for being in the study?

You may not get any benefit directly from this study, but we hope that the information we get about your genes and your health may benefit others who have [specific health phenotype] and many different kinds of illnesses, in the future. You do not have to take part in this study, it is your choice if you want to take part, or not. If you do not want to take part, it will NOT affect the health care you receive at [specific health facility].

Will you receive any reward (money or food vouchers) for taking part in this study?

Participation in research is voluntary and research participants do not get paid for it. However, if you use your own money to travel from home for the specific purpose of taking part in our research we can reimburse you for that. We can also provide food or food vouchers if participating in our research requires a special diet or if you miss meals while participating in our research.

What will we ask for?

We will ask you a few simple questions about your life and where you grew up. In order to better understand your health, we will ask you for permission to look at your health records that [name of organisation/department] collects when you visit government health facilities like clinics or hospitals - such as any medical tests that have been done and any medication that you have been given at any government facility. We will also ask you to provide a swab or rinse of the inside of your mouth and we will use this to prepare a sample of your genes.

Do you agree for us to collect these body fluid samples and your health information for this study we have described about how genes might affect [specific health phenotype]?

☐ Yes ☐ No

We would like to know more about your general health.

Do you agree for us to use your health information that is collected by health care workers (nurses, doctors, pharmacists) during your visits to health care facilities?

☐ Yes ☐ No

Medical record number:

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What will happen when the study is over?

Your sample will be destroyed unless you have agreed for us to use it in future studies.

Who will see the information which is collected about you during the study?

To make sure that your privacy is protected in this study, we will make sure that your information is used for this research without your name, or your date of birth, or any other identifying information attached to it. This way, no one working on this study will know who the information or the genetic sample comes from.

How will we protect your information?

All your genes together make a special pattern in all of your body that only you have, and this is why no two people are exactly alike. Because each person has their own special pattern of genes, researchers are very careful to protect the genetic samples that are collected and the information from these samples, and these samples and information will only be used in the way you have agreed to.

To make sure that your privacy is protected in this study, we will make sure that your information is used for this research without your name, or your date of birth, or any other identifying information attached to it. We will be very careful in making sure all this personal information is very secure and we will lock away any document with your name on it so that no-one can identify you from it. We will make sure all computers used for the study are kept securely and are protected by passwords.

Will your test results be shared with you?

We will not give you any individual results from the study of the samples you give us. This is because it will probably take a long time for this project to result in specific health information that is useful to patients.

If you agree for your information to be used in other studies in the future, it is possible that some new health information might be discovered in those studies. We will ask you if you would like to know any new information that might become available about your health.

Sometimes, what we find from our research might include new information about your health.

Would you like us to contact you again if we believe we have new information that may directly affect your health?

☐ Yes ☐ No

Would you like us to contact you again if there is some kind of action or treatment that might be able to help you with the health issue?

☐ Yes ☐ No

Would you like us to contact you again if there is NO kind of action or treatment that might be able to help you with the health issue?

☐ Yes ☐ No

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Will the results of the research be shared with you?

At the end of the study, we will put our general findings from the study in some pamphlets and posters at the clinics where people have joined this study. There, you will be able to read how this study is contributing to our understanding of health and disease. When we describe the results of this study in this way, we will only show summary results or overall study results from the whole study, and there will be no information about the individual people who took part in the study.

Sometimes researchers combine the genetic information from everyone in the study and provide a summary of genetic data for the whole group.

Do you agree for us to use your information when providing combined information about the whole research group (x total individuals in this study)?

☐ Yes ☐ No

What will we do with your data and samples?

Your sample will be stored at [name of storage facility] until the study is over. The information from your sample will be very securely stored at [name of storage facility]. The [name of storage facility] will lock away any document with your name on it so that no-one can identify you from it. We will make sure all computers used for the study are kept securely and are protected by passwords.

Your samples will never be sold, and we will not make any money from this research. The scientific results that we find from this study will be free and openly available to all scientists to help understand how we can better treat [specific disease]. In the future, commercial products might be developed by companies using the information that comes out of this study. If this happens, you will not be able to share in any profits.

Will any of your blood, tissue or other samples be stored and used for research in the future?

Your samples will only be stored and used for future studies if you give us permission to use them this way. If you do not give permission for your samples to be used for future studies, they will be destroyed at the end of this study. It is your choice to give permission for future use and that choice will not affect your participation in the current study and will not affect the health care you are receiving at [insert name of health care facility].

Do you agree for us to use your genetic samples together with your health information for other studies in the future that want to study the effect of genes on [specific health phenotype]?

☐ Yes ☐ No

Do you agree for us to use your genetic samples together with your health information for other studies in the future to study the effect of genes on other health conditions or related biological processes?

☐ Yes ☐ No

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Sometimes what we find from a study like this might lead to new studies being done in the future. Can other researchers contact you in the future to invite you to take part in other research studies?

☐ Yes ☐ No

If yes, how would you like to be contacted?

- ☐ Telephone
☐ Letter
☐ Visit
☐ Email

Can my samples and information be used in research outside the country?

There is an international study that is combining the results from [specify disease] studies like ours that are taking place around the world. The information from samples donated from everyone around the world will be made available to researchers in a large data storage resource in Europe called the European Genome Archive (EGA) and will be provided to other researchers who want to do more studies using the combined genetic and health information.

We will ask you if you would like your sample and health details to be included in this international study - you do not have to agree to join the international study, it is your choice.

Do you agree for us to share your DNA sample for genetic analysis together with your health information for International studies being done to better understand [specific disease]? Your genetic data and health data may be shared with other international researchers for other studies in the future

☐ Yes ☐ No

Can my samples be used in studies about population origins and ancestry?

There are researchers who are interested in studying genes to find out more about the origins and ancestry of different populations. Our genes contain information that can be used to work out where our family and our ancestors come from - our origins.

Sometimes the information from genetic studies about our ancestry may be different to what we already believe about where our family came from, or who our ancestors were, but this information can also help us understand more about human history and how people migrated around the world in the past.

We will ask you if you would like your DNA sample to be included in studies about population origins and ancestry - you do not have to agree for your sample to be used in this kind of study, it is your choice.

Do you agree for us to share your DNA sample for genetic analysis in other research studies about population origins and ancestry?

☐ Yes ☐ No

What to do if you have questions or change your mind about being in the study?

If you have any questions, you can contact [name of institutional review board (IRB)] and speak to [full names and contact number of the relevant person at the IRB]. If you change your mind and you no longer want your information or sample to be included in this study, or you have other questions you can also contact [full names and contact number of study principal investigator] with your questions, or to have your information removed from this study and to have your sample destroyed.

PARTICIPANT AGREEMENT

Date of consent:

(DD-MM-YYYY)

Study ID Number:

Participant full name:

(Full name as on Identification Document)

Participant confirmation:

☐ I understand that signing this form electronically is the equivalent of signing a physical document

Participant signature:

STAFF MEMBER ADMINISTERING CONSENT

Staff member name:

(Fullname)

Staff member signature:

CONSENT AUDIO CONFIRMATION

Checklist for consent audio validation

- ☐ Date of consent administration
- ☐ Researcher verbally confirms identity
- ☐ Research study named
- ☐ Participant verbally confirms identity and participation in study
- ☐ Quality of audio file checked before upload

Audio verification

Study Consent - Core Instrument Version 2.0 Released September 2022
H3ABioNet & H3Africa Phenotype Standards