

### **Instructions for administration of consent**

This consent will be administered face-to-face by a trained member of the research study team. The consent process is verified by audio recording, please ensure that you seek permission from the participant to record the process. If you are unable to complete the informed consent process, this form can be saved and completed later.

### **Who are we?**

My name is Ms Irene Muchada and I am a genetic counsellor and the recruitment officer for this study. I am working under the supervision of Dr Tsaone Tamuhla and Professor Nicki Tiffin at the South African National Bioinformatics Institute (SANBI) at the University of the Western Cape (UWC). For this study we are working with doctors, who care for patients at various health care facilities in the Western Cape Province.

### **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 different diseases in South Africans.

### **Who is eligible to take part?**

In our study, we want to learn more about health and different kinds of illnesses in South African adults so we are approaching any adult (18 years or older) who is visiting a health facility because they are the type of people who we want in our study.

### **How many people will take part in the study?**

There will be at least 700 participants including yourself if you agree to participate in the study. In the future we hope that this number will grow even more.

### **How long will the study last?**

If you agree to be in this study, we will only need to see you and collect a swab from your cheek this one time, and we will not need to see you again. We will ask you if we can continue to update your health data from the Department of Health. In this way, we can understand changes in your health in the future. Although we will only need to see you this time, we hope that this will be a long study that can give us many insights about health over people's lifetime.

At any time, if you do not wish us to continue following your health journey, you can let us know using the contact details provided at the end of this form.

**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, 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 from health facilities.

**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.

**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 different kinds of illnesses in the future.

We hope in the future that information from your genes might help your doctors in your care. If this becomes possible we would like your permission to share this information with your doctors at the Western Cape Department of Health. We do not yet know if this will be possible, but we hope in the future we will be able to do this.

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 different health facilities.

**What will we ask for?**

We will ask you a few simple questions about your life, what languages your family speak, and where you grew up. This kind of information helps us to understand a little bit better the general characteristics of the participants in our study. In order to better understand your health, we will ask you for permission to look at your health records that the Western Cape Government Department of Health 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 health and illnesses?**

Yes ☐ No ☐

**If yes paste VCAMM study ID:**

**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 ☐

**If yes paste medical record / folder number:**

**What will happen when the study is over?**

Your sample will be destroyed when the study ends. It will only be used to analyse your genes in the way we have described here.

**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 individual study 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 participants. However, if we find out any new information that is useful for your health, we would like to share that with your health service providers at the Western Cape Department of Health so they can make the best choices for your health care.

**Sometimes, what we find from our research might include new information about your health. Would you like us to contact your health care providers at the Western Cape Department of Health if we believe we have new information that may directly affect your health?**

Yes ☐ No ☐

**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 (at least 700 individuals in this study)?**

Yes ☐ No ☐

**What will we do with your data and samples?**

Your sample will be stored at the Central Analytical Facility (CAF) at Stellenbosch University until the study is over. The information from your sample will be very securely stored at the University of the Western Cape. The University of the Western Cape 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 illnesses.

In the future, commercial products might be developed by companies using the information that comes out of this study and is freely available. If this happens, you will not be able to share in any profits.

**Do you agree for us to use your genetic samples together with your health information to study the effect of genes on health and different illnesses?**

Yes ☐ No ☐

**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 may be international studies that combine results from studies like ours that are taking place around the world. If we were to join an international study, we would be involved at all times to make sure that your information is properly protected and only used in the ways we have described here.

We will ask you if you would like your genetic and health information to be included in international studies in the future - you do not have to agree to join international studies, it is your choice.

**Do you agree for us to share your genetic and health information for international studies being done to better understand health and illness?**

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 genetic information 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 use your genetic information for 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 the Biomedical Research Ethics Committee (BMREC) at the University of the Western Cape by telephone at **021 959 0111** or by email at **research-ethics@uwc.ac.za**. 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 Professor Nicki Tiffin at **021 959 3645** with your questions. At any time you may request to have your genetic and health information removed from this study if you no longer wish to be part of it.

### **Participant details**

Date of consent (ddmmyyy):

Participant full name as on ID: \_\_\_\_\_

Participant date of birth (ddmmyyy):

Participant height (cm): \_\_\_\_\_

Participant weight (kg): \_\_\_\_\_

**What language(s) does your family speak at home?** You can tick more than one box

- |                                  |                                    |
|----------------------------------|------------------------------------|
| <input type="checkbox"/> Xhosa   | <input type="checkbox"/> Sotho     |
| <input type="checkbox"/> Zulu    | <input type="checkbox"/> Tsonga    |
| <input type="checkbox"/> Ndebele | <input type="checkbox"/> Venda     |
| <input type="checkbox"/> Swati   | <input type="checkbox"/> Afrikaans |
| <input type="checkbox"/> Tswana  | <input type="checkbox"/> English   |
| <input type="checkbox"/> Pedi    | <input type="checkbox"/> Other     |

**Did you grow up in a town or rural area?** You can select more than one box

Rural area ☐      Town (urban area) ☐

#### **Health care facility**

- ☐ Groote Schuur Hospital  
☐ Tygerberg Hospital

#### **Clinic**

- ☐ Diabetes  
☐ Nephrology  
☐ Hypertension  
☐ Under 10 – low EGFR  
☐ Oral Health Centre

**Participant signature:**

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**Staff member administering consent**

**Staff member name:** \_\_\_\_\_

**Staff member signature:**

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