**PARTICIPANT INFORMATION AND INFORMED CONSENT FORM FOR RESEARCH INVOLVING GENETIC STUDIES**

**TITLE OF RESEARCH PROJECT:**

**Collection of Genotypic and Ethnographic Information from Individuals of South African Ethnic Groups**

**REFERENCE NUMBER: 1220180**

**PRINCIPAL INVESTIGATOR: Dr. Brenna Henn1**

**CO-INVESTIGATORS:**

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**+1-916-703-9151 (USA) UC Davis IRB contact or hs-irbeducation@ucdavis.edu**

We would like to invite you to participate in a research study that involves genetic analysis and long-term storage of saliva. Please ask the witness or researcher any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand this research. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part initially. It will take about an hour of your time if you choose to help. If at any time you are unhappy about helping with this research, please tell \_\_\_\_\_\_\_\_\_\_\_ (name of translator). We will then stop. If you do not want to answer a particular question, please say so and we will go on to the next question. We will also give you a paper with information about how to reach us at our University, and who to contact if you are concerned about our research. We are happy to answer any questions you have about our work.

This research study has been approved by the ethics **Committee for Human Research at Stellenbosch University** and the Institutional Review Board at University of California, Davis. It will be conducted according to international and locally accepted ethical guidelines for research, namely the Declaration of Helsinki, and the SA Department of Health’s 2004 Guidelines: *Ethics in Health Research: Principles, Structures and Processes.* Please see the Contact Info sheet if you would like to contact us later.

# What is Genetic research?

Genetic material, also called DNA or RNA, is usually obtained from a small sample. Occasionally genetic material is obtained from other sources such as saliva or blood. Genes are found in every cell in the human body. Our genes determine what we look like and sometimes what kind of diseases we may be susceptible to. Worldwide, genetic researchers are continually discovering new information that may be of great scientific benefit to future generations and also that may benefit people today, who suffer from particular diseases.

**What does this particular research study involve?**

We are here because we want to learn more about the history of South Africa and of the Nama and N|u (Bushmen) people. For our research we ask people a few questions about their family, collect DNA from saliva/blood and measure particular things about them: height and skin color. We study how genetic (DNA*, explained above and in supplemental sheets*) data may affect physical characteristics like eyes or skin color, and to learn more about your group’s history and the history of African people. We have already learned that many people in the Northern and Western Cape have KhoeSan ancestors. The KhoeSan may be the most genetically diverse group in the world. We would like to study more KhoeSan people to better understand their special genetic diversity. To get useful results we will need approximately 1,000 people to take part in this research.

You are completely free to choose whether or not you decide to take part in this study. Should you have any questions you are free to contact Prof Eileen Hoal (021-9389 412).

**Why have you been invited to participate?**

If you identify as “Nama”, “Bushman”, “N|u” or “Khomani”, or “Coloured” you may have KhoeSan ancestry and we invite you to participate in our study.

**What procedures will be involved in this research?**

If you agree, we will ask you a few questions. We will ask to collect your saliva/blood in a tube (*show tube*) for DNA analysis. We will then measure several things about you. We may ask you to stand against a wall to measure your height, to let us use a tool to measure your skin color, take a photo of your eye color, and to ask questions about your family history. We may have to perform some of these tests multiple times. If we draw your blood (3 teaspoons in total), you might experience a small amount of pain at the site, and there is a small risk of bruising, infection, or fainting. It will take about an hour of your time if you choose to help.

**Are there any risks involved in genetic research?**

No one will get sick from this research. Collection of these measurements does not involve risk. We will not link your name with the results of the tests. None of the measurements that we obtain will be sold. Your anonymous DNA data may be put in a free public database accessible through the Internet by other researchers (e.g. dbGaP), or made freely available to researchers after project approval from the San Council (if you self-identify as “San”). Because your name and photograph will NOT be associated with data, there should be no risk for you. There might be minor local discomfort if we draw your blood.

**Are there any benefits to your taking part in this study and will you get told your results?**

We do not expect that our work will help you directly. Instead you will be helping to generate new knowledge about the history of South Africa and of the KhoeSan and Coloured people. Your personal results will NOT be returned to you. We will return general results of the study from the entire community.

**How long will your DNA be stored and where will it be stored?**

DNA will be stored at UC Davis, USA, and Stellenbosch University, South Africa. DNA from saliva or blood will be stored for at least 1 year and up to 10 years.

**If your blood is to be stored is there a chance that it will be used for other research?**

Your DNA will only be used for genetic research that is directly related to  
KhoeSan ancestry, population history and human evolution. Also if the researchers wish to use your stored DNA for **additional research in this field** they will be required to apply for permission to do so from the Human Research Ethics Committee at Stellenbosch University and, if the subject is Khomani San, from the South African San Council.

If you do not wish your DNA specimen to be stored after this research study is completed, please tell us and we will check this request box below.

**How will your confidentiality be protected?**

Confidentiality will be protected by the Health Professionals Council of South Africa’s guidelines. The results of the study will be published in medical or science journals, but without mentioning the name of any person on whom saliva or blood was taken. Research Ethics Committee members may need to inspect research records. This committee can be contacted at 021 938 9207.

We ask your name and some other questions about you, but that is the only time that we will write down your name. We will not link your name with the results of the tests. Only one person will see your name and the assigned sample number (Dr. Brenna Henn). She may try to contact you again, but only to let you and your family know the general results of the study or to re-consent you for new research participation. Other researchers will *only* see a study ID number and your measurements. Your DNA will be sent to UC Davis (USA), Stellenbosch University (South Africa) or other collaborators where we will use new technology to look at all the unique mutations in your DNA. They may look at your DNA data to understand genetic ancestry of the KhoeSan or the genes underlying height / skin / eye pigmentation. Your DNA data will be combined with other individuals and the dataset may be put in a public database for scientists to use. Your name will NOT be in the database.

**Will you or the researchers benefit financially from this research?**

You will not be paid to take part in this study, but we would like to give you a small gift such as a t-shirt, food or cell phone minutes. If the interview takes more than an hour, we may compensate you for your time with a small financial reimbursement. We do not expect you to receive any other financial benefit.

**Important information: In the unlikely event that this research leads to the development of a commercial application or patent, you or your family will not receive any profits or royalties. Profits will be reinvested for future research which in future may have advantages for your familty of community.**

### Declaration by participant

By signing below, I …………………………………..…………. agree to take part in a genetic research study entitled: Collection of Genotypic and Ethnographic Information from Individuals of South African Ethnic Groups

I declare that:

* I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
* I have had a chance to ask questions and all my questions have been adequately answered.
* I understand that taking part in this study is voluntary and I have not been pressurised to take part.
* I have received a signed duplicate copy of this consent form for my records.

**Tick the option you choose:**

I agree that my saliva or blood sample can be stored **stored for 10 years** after the project is completed but that it is anonymized with all possible links to my identity removed, and that the researchers may then use it for additional research in this or a related field. Once my sample is anonymised, my rights to that sample are waived. My sample may be shipped to another laboratory in SA or abroad to be used in other research projects. For any research beyond the scope of this consent form, the investigators may contact me to re-consent use of my sample for additional research questions.

**OR**

Please destroy my saliva or blood sample as soon as the current research project has been completed.

Signed at (*place*) on (*date*)

Signature of participant Signature of witness

### Declaration by investigator

I *(name)* ………………………………………………… declare that:

* I explained the information in this document to …………………..……………...
* I encouraged him/her to ask questions and took adequate time to answer them.
* I am satisfied that he/she adequately understands all aspects of the research as discussed above.
* I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.)*

Signed at (*place*) ......................…........…………….. on (*date*) …………....……….. 2018.

Signature of investigator Signature of witness

## Declaration By Interpreter

I *(name)* ………………………………………………… declare that:

* I assisted the investigator (*name*) …………………………. to explain the information in this document to (*name of participant*) …………………………….. using the language medium of Afrikaans/Nama.
* We encouraged him/her to ask questions and took adequate time to answer them.
* I conveyed a factually correct version of what was related to me. I attest that the requirements for informed consent for the research described in this form have been satisfied – that the participant has been provided with the Experimental Subject’s Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in the informed consent form, including any risks.
* I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) ......................…........…………….. on (*date*) …………....……….. 2018.

**Signature of interpreter**