PARTICIPANT INFORMATION AND INFORMED CONSENT FORM FOR RESEARCH INVOLVING GENETIC STUDIES

TITLE OF RESEARCH PROJECT:

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR:

ADDRESS:

CONTACT NUMBER:

We would like to invite you to participate in a research study that involves genetic analysis and possible long-term storage of blood or tissue specimens. Please take some time to read the information presented here which will explain the details of this project. Please ask the study staff or doctor 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 what this research entails and how you could be involved. 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.

This research study has been approved by the ethics **Health Research Ethics Committee at Stellenbosch University** and 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.*

What is Genetic research?

Genetic material, also called DNA or RNA, is usually obtained from a small blood sample. Occasionally genetic material is obtained from other sources such as saliva or biopsy specimens. (A biopsy is a tiny piece of tissue that is cut out e.g. from the skin or from a lump, to help your doctor make a diagnosis.) 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, researchers in the field of genetics are continuously discovering new information that may be of great benefit to future generations and also that may benefit people today, who suffer from particular diseases or conditions.

What does this particular research study involve?

- *Give a brief summary in **simple language** about your particular research project and what you hope to discover? Be sure to explain terms like "genetic mutation" or "polymorphism" and also be sure to use these terms appropriately.*

Why have you been invited to participate?

- *Explain briefly.*

What procedures will be involved in this research?

- *Explain any procedures e.g. Volume of blood samples etc. Saliva samples etc.*

Are there any risks involved in genetic research?

- *All potential risks, depending on the specific research protocol, should be discussed transparently. These risks could include detection of unsuspected medical conditions, anxiety, group or individual stigmatisation, employment discrimination, adoption of exclusionary policies, including discriminatory insurance policies, , potential implications of the possible outcomes of the research on other family members even discovery of mis-attributed paternity*
- *The possible need for genetic counselling should also be discussed, if relevant, including who will cover the costs of this service.*
- *Please include any/all of these risks if they may be relevant to your particular research study.*

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

Please explain here whether or not any results will be made known to the participants. If not explain why not e.g. that blood will be stored and only tested at a later date, or that the techniques to be used are experimental and thus possibly unreliable etc. Also indicate that the research may benefit people with a similar condition in the future.
Optional wording:
*Your personal results will be made known to you **only if they indicate** that you may:*

- *Have a definite risk for developing a particular disorder.*
- *Have a condition or predisposition to developing a condition that is treatable or avoidable e.g. by a lifestyle modification.*
- *Need genetic counselling.*

How long will your blood be stored and where will it be stored?

- *Answer this question according to the specifics of your research study. Be transparent and include sufficient detail. If you are likely to ship stored specimens to another country either now or at a later date, this needs to be clarified up front.*

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

Your blood will only be used for genetic research that is directly related to

…… (*the disease or condition or reason for your original research)*. Also if the researchers wish to use your stored blood for **additional research in this field** they will be required to apply for permission to do so from the Health Research Ethics Committee at Stellenbosch University.

If you do not wish your blood specimen to be stored after this research study is completed you will have an opportunity to request that it be discarded when you sign the consent form.

How will your confidentiality be protected?

- *Please explain this in detail. This is particularly important with collaborative research when the specimens will be shipped to a laboratory abroad. Will the specimens be anonymised, or linked only to demographic/clinical information or will it remain possible to link the specimens to identifying information. Is there a remote possibility that information that comes to light in the future may be beneficial to the participant or possibly have unpleasant implications? If so will an attempt be made to contact participants?*

Will you or the researchers benefit financially from this research?

You will not be paid to take part in this study *although your out-of-pocket expenses may be reimbursed (include if applicable)*.

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

Declaration by participant

By signing below, I …….…… agree to take part in a genetic research study entitled *(insert title of study)*.

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 blood or tissue sample can be stored **indefinitely/ stored for, ……years,** but I can choose to request at any time that my stored sample be destroyed. My sample will be identified with a special study code that will remain linked to my name and contact details. I have the right to receive confirmation that my request has been carried out. *(NB This option can be excluded completely if the genetic research has no clinical relevance to the patient and you plan to completely and permanently anonymise all samples)*

OR

☐ I agree that my blood or tissue sample can be stored **indefinitely/ stored for, ……years** after the project is completed but that it is anonymised 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 waivered. My sample may be shipped to another laboratory in SA or abroad to be used in other research projects in this or a related field

OR

☐ Please destroy my 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 a interpreter. (*If a interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) .....…..…….. on (*date*) ……...…….. 2005.

....

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/Xhosa.
- 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 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*) ……...…….. 2005.

....

Signature of interpreter **Signature of witness**