

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR USE BY PARENT(S)/LEGAL GUARDIAN(S)

TITLE OF THE RESEARCH PROJECT:

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR/RESEARCHER:

ADDRESS:

CONTACT NUMBER:

Your child (*or ward, if applicable*) is being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the researcher/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 your child could be involved. Also, your child's participation is **entirely voluntary**, and you are free to decline to participate. If your child is seven years of age or older, your child will be asked for assent. If you think that your child younger than seven years of age can participate in the decision-making process please inform the researcher to allow your child to provide assent.

If you say 'NO', this will not affect you or your child negatively in any way whatsoever. You are also free to withdraw him/her from the study at any point, even if you do initially agree to let him/her take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- *Explain what research aims to achieve or study in participant friendly language what your project aims to do and why you are doing it? Should be pitched at Grade 6 to 8 level of language.*
- *Explain all procedures.*
- *Explain any randomization process that may occur and why this is done.*
- *Explain the use of any medication or study procedures, if applicable.*

Why has your child been invited to participate?

- *Answer this question clearly.*

What will your responsibilities be?

- *Answer this question clearly.*
- *Where appropriate, please include a study schedule or any other procedures the parent and child will be expected to undertake or be part to show the commitment and length of time the commitment will entail.*

Will your child benefit from taking part in this research?

- *Explain all benefits objectively. If there are no personal benefits then indicate who is likely to benefit from this research, e.g., future patients or whether it is about improving understanding about treatment etc.*

Are there any risks involved in your child taking part in this research?

- *Identify any risks objectively and concisely so that parents/caregivers are able to make an informed decision.*

If you do not agree to allow your child to take part, what alternatives does your child have?

- *Clearly indicate in broad terms what alternative treatment is available and where it can be accessed, if applicable.*

Who will have access to your child's medical records?

- *Explain that the information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participant will remain anonymous. Clearly indicate who will have access to the information.*

What will happen in the unlikely event of your child getting injured in any way, as a direct result of taking part in this research study?

- *Clarify issues related to insurance cover if applicable. If any pharmaceutical agents are involved will compensation be according to ABPI guidelines (Association of British Pharmaceutical Industry compensation guidelines for research related injury which are regarded as the international gold standard)? If yes, please include the details here. If no, then explain what compensation will be available and under what conditions.*

Will you or your child be paid to take part in this study and are there any costs involved?

You or your child will not be paid to take part in the study, but out-of-pocket expenses will be covered for each study visit. There will be no costs involved for you if your child does take part. *(Edit as applicable)*

Is there anything else that you should know or do?

- You should inform your family practitioner or usual doctor that your child is taking part in a research study. *(Include if applicable)*
- You should also inform your medical insurance company that your child is participating in a research study *(Include if applicable)*
- You can contact Dr..... at telephone..... if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your child's study doctor.
- According to South African law, the researcher(s) will need to report any suspicion of child abuse or other illegal circumstances.
- You will receive a copy of this information and consent form for your own records.
- **Your child will be asked to give their assent to participate in the research if he/she is considered able to do so from the age of 7. Please confirm that you consider this to be appropriate.** *(Please adapt the separate assent template to your project and use it in conjunction with this template. The assent template is available at www.sun.ac.za/rds/)*
- The researcher(s) may wish to share my child's data and or samples with other researchers either in South Africa or overseas. This could be to compare findings from similar research or for further tests that the researchers are not able to perform. When data/samples are shared with others, the researcher will ensure that the information cannot identify my child.
- The researcher(s) may wish to store my child's data and or samples for further research in the future. In such cases, the studies would be in a similar area (e.g. *TB or diabetes research*) and the research would need to be approved by the Stellenbosch University Health Research Ethics Committee.

Declaration by parent/legal guardian

By signing below, I *(name of parent/legal guardian)*
agree to allow my child (name of child) who is
years old, to take part in a research study entitled *(insert title of study)*.

I declare that:

- I have read or had read to me this information and consent form and that it is written in a language with which I am fluent and comfortable.
- If my child is 7 years or older, he/she must agree to take part in the study and his/her ASSENT must be recorded on this form.

- I agree/confirm that, as parent/guardian, I consider my child mature enough to understand what it means to participate in the research and to give assent.
- 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 let my child take part.
- I may choose to withdraw my child from the study at any time and my child will not be penalised or prejudiced in any way.
- My child may be asked to leave the study before it has finished if the study doctor or researcher feels it is in my child's best interests, or if my child do not follow the study plan as agreed to.

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

.....
Signature of parent/legal guardian

.....
Signature of witness

Permission to have all anonymous data shared with journals:

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether you can be in the research study, or your routine health care.

When this study is finished, we would like to publish results of the study in journals. Most journals require us to share your anonymous data with them before they publish the results. Therefore, we would like to obtain your permission to have your child's anonymous data shared with journals. In accordance with the POPI Act, the researchers will take care to ensure that your child is not identifiable (personal information is not linked to the data shared).

Permission for sharing samples and/or information with other investigators:

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether you can be in the research study, or your child's routine health care.

In order to do the *research* as we have discussed, we must collect and store [*describe the samples that are going to be collected e.g. blood/tissue/urine etc. and volume of blood/tissue/urine etc.*] and health information from your child with [*disease X*]. We will do some of the tests right away. Other tests may be done in the future as technology improves. Other investigators from all over the world can ask to use these samples in future research [*please indicate if the samples will be shipped from South Africa, where the samples will be stored and who will have access to these samples*]. To protect your child's privacy, we will replace his/her name with a unique study number. We will only use this code for your child's sample and information about you. We will do our best to keep the code private. It is however always possible that someone could find out about your child's name, but this is very unlikely to happen given the precautions taken to protect this very important information. Therefore, we would like to ask for your permission to share your child's sample(s) and information with other investigators.

Permission to store samples and/or information for future studies:

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether your child can be in the research study, or your child's routine health care.

As you are aware technology is constantly changing and so tests that may not be available at the time of this research may be possible in the future. As researchers learn more about illnesses or diseases, new research can be done using existing samples instead of returning to participants to ask for additional samples.

In order to do such further *research* in the future, we would like to ask your permission to store [*describe the samples that are going to be collected from your child e.g., blood/tissue/urine etc. and volume of blood/tissue/urine etc.*] and health information from people like you with [*disease X*]. Any future studies or reuse of samples or data will need to be approved by the Stellenbosch University Health Research Ethics Committee.

Tick the Option you choose for anonymous data sharing with journals:

I agree to have my child's anonymous data shared with journals during publication of results of this study.

☐

Signature_____

OR

I do not agree to have my anonymous data shared with journals during publication of results of this study.

☐

Signature_____

Tick the Option you choose for sharing samples and/or information with other investigators:

I do not want my child's sample and/or information to be shared with other investigators.

☐

Signature_____

OR

My child's sample and/or information may be shared with other investigators who are able to conduct further analysis in ... [*describe the field of your study, e.g., diabetes research*].

☐

Signature_____

Tick the Option you choose for storage and reuse of samples/data for studies in the future:

I do not want my child's sample(s) and/or information (data) to be stored for reuse for future studies.

☐

Signature_____

OR

I hereby agree that my child's sample(s) and/or information (data) may be stored for future research in a field related to ... [*describe the field of your study, e.g., diabetes research*]

☐

Signature_____

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 understand 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

Declaration by interpreter (Only complete if applicable – please delete if not applicable to your study)

I (*name*) declare that:

- I assisted the investigator (*name*) to explain the information in this document to (*name of parent/legal guardian*) 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 parent/legal guardian fully understands the content of this informed consent document and has had all his/her questions satisfactorily answered.

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

.....
Signature of interpreter

.....
Signature of witness