UNIVERSITY OF NAIROBI (UoN)
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH-UoN ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: ttps://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC ttps://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL (KNH)
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

STUDIES INVOLVING CHILDREN

PARTICIPANT INFORMATION AND CONSENT FORM

SAMPLE PARENTAL CONSENT

NB: This is intended to help you create a consent document. The text is a suggestion on how to introduce the essential elements of an informed consent. Kindly customize it to your needs.

(To be administered in English or any other appropriate language e.g Kiswahili translation

Title of Study: _____

Principal Investigator \ and institutional affiliation:

Co-Investigators and institutional affiliation:

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not your child should participate in the study. Feel free to ask any questions about the purpose of the research, what happens if your child participates in the study, the possible risks and benefits, the rights of your child as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide if you want your child to be in the study or not. This process is called 'informed consent'. Once you understand and agree for your child to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your child decision to participate is entirely voluntary ii) You child may withdraw from the study at any time without necessarily giving a reason for his/her withdrawal iii) Refusal to participate in the research will not affect the services your child is entitled to in this health facility or other facilities.

May I continue? YES / NO

For children below 18 years of age we give information about the study to parents or guardians. We will go over this information with you and you need to give permission in order for your child to participate in this study. We will give you a copy of this form for your records.

Add comment on ascent (e.g If the child is at an age that he/she can appreciate what is being done the he/she will also be required to agree to participate in the study after being fully informed).

WHAT IS THE PURPOSE OF THE STUDY?

The researchers listed above are interviewing individuals who_____. The purpose of the interview is to find out_____. Participants in this research study will be asked questions about_____ Participants will also have the choice to undergo test such as _____.

There will be approximately _____ participants in this study randomly chosen. We are asking for your consent to consider your child to participate in this study.

WHAT WILL HAPPEN IF YOU DECIDE YOU WANT YOUR CHILD TO BE IN THIS RESEARCH STUDY?

If you agree for your child to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately _____minutes. The interview will cover topics such as_____.

After the interview has finished, (*explain in details any procedures that are necessary eg blood draws, counselling etc.)*

A specimen e.g a few drops of your child's blood will also be preserved _____ and stored for up to five years. This blood will be analyzed to _____

You will be informed about the results.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: _____

ARE THERE ANY RISKS, HARMS, DISCOMFORTS ASSOCIATED WITH THIS STUDY

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify your child in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting confidentiality can be absolutely secure so it is still possible that someone could find out your child was in this study and could find out information about your child.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

It may be embarrassing for you to have _____ We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, _____ may be stressful.

Your child may feel some discomfort when _____ and may have a small bruise or swelling in_____. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat your child for minor conditions or refer the child for treatment for conditions that require more extensive care.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

Your child may benefit by receiving free _____testing, you may be counseled on _____, health information etc. We will refer your child to a hospital for care and support if necessary. Also the information you provide will help us better understand _____. This information is a major contribution to science and _____

WILL BEING IN THIS STUDY COST YOU ANYTHING?

(Explain) _____

IS THERE REIMBURSEMENT FOR PARTICIPATING IN THIS STUDY?

(Explain) _____

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about your child participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your child's rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to have your child participate in this research is voluntary. You are free to decline or withdraw participation of your child in the study at any time without injustice or loss of benefits.
Just inform the study staff and the participation of your child in the study will be stopped. You do not have to give reasons for withdrawing your child if you do not wish to do so. Withdrawal of your child from the study will not affect the services your child is otherwise entitled to in this health facility or other health facilities.
For more information contact _____ at _____ from

_____ to _____

CONSENT FORM (STATEMENT OF CONSENT)

The person being considered for this study is unable to consent for him/herself because he or she is a minor (a person less than 18 years of age). You are being asked to give your permission to include your child in this study.

Parent/guardian statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered by him or her in a language that I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation and that of my child in this study is voluntary and that I may choose to withdraw it any time.

I understand that all efforts will be made to keep information regarding me and my child's personal identity confidential.

By signing this consent form, I have not given up my child's legal rights as a participant in this research study.

I voluntarily agree to my child's participation in this research study:

	Yes	**No**
I agree to have my child undergo _____ testing:	Yes	No
I agree to have (**define specimen**) preserved for later study:	Yes	No
I agree to provide contact information for follow-up:	Yes	No

Parent/Guardian signature /Thumb stamp: _____ Date _____

Parent/Guardian printed name: _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his/her consent.

Printed Name: _____ **Date**: _____

Signature: _____

Role in the study: _____ *[i.e. study staff who explained informed consent form.]*

Witness Printed Name (*If witness is necessary*) _____

Signature: _____ Date; _____