



## Zimbabwe Study for Enhancing Testing and Improving Treatment of HIV in Children: ZENITH Project

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### PREVALENCE SURVEY

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#### What you should know about this research study:

- We give you this consent so that you may read about the purpose, risks, and benefits of this research study.
- We cannot promise that this research will benefit your child. The main goal of research studies is to gain knowledge that may help other people in the future.
- You have the right to refuse to allow your child to take part, or agree for your child to take part now and change your mind later.
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your choice to allow your child to participate is voluntary.

#### PURPOSE:

You are being asked to allow your child to participate in a research study to find out how common HIV infection is among children. Your child was selected as a possible participant for this study because he/she is aged between 8 and 17 years living in one of the households selected by chance in the 7 suburbs of Harare where the study is taking place. The study will enroll 7500 children in Harare and your household has been selected by chance. The research team is made up of scientists from the University of Zimbabwe, the Biomedical Research and Training Institute (BRTI), Harare and the London School of Hygiene and Tropical Medicine, UK. The research is funded by the Wellcome Trust, which is a medical charity.

#### PROCEDURES AND DURATION:

If you decide to allow your child to participate, we will ask some questions about your child, and whether he/she has ever been tested for HIV. If available, we will ask you for a record showing the results of a previous HIV test and when that was done. We will take a sample of fluid from the mouth to test for HIV. This will take approximately 15 minutes. The result of the test will not have your child's name and we will not trace the result of the HIV test from this study back to your child. We will also ask for a fingerprick blood sample or a urine

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sample, which will be used only to confirm the results of the test taken from the mouth. Like the test from the mouth, it will not be possible to trace your child's test result from the blood or urine test. You or your child can refuse to have the blood or urine test and still take part in the study by giving a sample from the mouth.

The research team will not know your child's HIV test result, and will not be able to tell you what it was. If you want to know your child's HIV result, we will provide a voucher for your child to have free HIV testing at your local clinic, where your child will have a separate HIV test with more counselling.

**RISKS AND DISCOMFORTS:**

The mouth or urine sample for HIV testing will not cause any discomfort. If your child undergoes a blood test, the needle for the blood test could cause discomfort or a small bruise, as with any other blood test. Having an HIV test may cause anxiety, even if you chose not to know the results.

**BENEFITS AND/OR COMPENSATION:**

Taking part in the study will cost you nothing. We cannot and do not guarantee or promise that your child will receive any benefits from this study. There are no direct benefits to your child from taking part but other children could benefit in the future from the findings of this study. Your child will be able to have an HIV test and get a result at your local clinic FREE of charge.

**CONFIDENTIALITY:**

If you indicate your willingness for your child to participate in this study by signing this document, all information obtained will be for study purposes only, and will be held securely and stored on paper and computer files. Dr Rashida Ferrand will take responsibility for keeping your child's personal information confidential. The sample for HIV testing will be marked with a special study number only, and not your child's name. We will not be able to trace any HIV result back to any one person, so that none of the research team will know your child's result. No-one will be told your child's HIV result, and no-one outside of the study team will have access to any of the information that is given to us. Under some circumstances, the Medical Research Council of Zimbabwe, Research Council of Zimbabwe and the local Institutional Review Board may need to review participant records for compliance audits.

**VOLUNTARY PARTICIPATION:**

Participation in this study is voluntary. If you decide not to allow your child to participate in this study, your decision will not affect your or your child's future relations with the Biomedical Research and Training Institute, its personnel or with collaborating institutions like London School of Hygiene and Tropical Medicine, UK. If you decide to allow your child to participate, you and your child are free to withdraw your consent and assent and discontinue participation at any time without penalty.

**Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.**

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**AUTHORIZATION**

YOU ARE MAKING A DECISION WHETHER OR NOT TO ALLOW YOUR CHILD TO PARTICIPATE IN THIS STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE, HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO ALLOW YOUR CHILD TO PARTICIPATE.

- I have read the information sheet concerning this study [or have understood the verbal explanation] and I understand what will be required of my child and what will happen to him/her if he/she takes part in it
- I understand that the sample from the mouth that my child gives will be tested for HIV infection, but that he/ she will need a separate test to know his/her HIV test result because no-one will trace the result of this test back to the child.
- I understand that at any time my child may withdraw from this study without giving a reason and without affecting his/her normal care and management.

I agree that my child may take part in this study YES/NO

**Consent from parent/ guardian/ legally authorised representative:**

Name (Print) \_\_\_\_\_ Date \_\_\_\_\_

Signature \_\_\_\_\_

Relationship to Participant \_\_\_\_\_

**Participant Assent (Children aged 13years and older only):**

My participation in this research study is voluntary. I have read [or been explained] and understood the information. All my questions have been answered and I agree to take part in this study.

Name of Participant (Print) \_\_\_\_\_ Date \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Signature of Research staff \_\_\_\_\_ Date \_\_\_\_\_

*If the participant gave verbal assent, enter the name of person who witnessed the assent here, and signature:*

Witness Name: \_\_\_\_\_ Witness Signature: \_\_\_\_\_

**YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP**

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe on telephone 791792 or 791193.