Appendix B. Ethical considerations

1. Respect for persons-
    a. Participants were treated with respect as autonomous individuals on equal terms with the investigator. All participants took part in the study voluntarily and interactions occurred in a non-threatening environment. Those unable to freely read or write in English were assisted to complete the questionnaire and interaction with them took place in the language of their choice. All questionnaires were in plain and easy-to-understand English language, and were administered in a culturally appropriate manner.
    b. Participants were adequately informed of the aims, methods, sources of funding, institutional affiliations of investigators and anticipated benefits and risks of the study. Informed consent was given freely and in writing by all study participants before taking part in the study. For those unable to read and/or write, a provision was made for them to give it orally and to use a thumb print in place of a signature in the presence of a literate witness. The witness then certified in writing that informed verbal consent was given by the participant. Participants were informed of their right to abstain from the study or to withdraw consent to participate without reprisal. They were also informed of the size and nature of the two groups taking part in the study, and circumstances that could lead to termination of their participation.
    c. All identifiable private information obtained from participants was kept private and confidential. Participants were identified by codes that were matched against securely kept files to ensure anonymity.
2. Beneficence-participants were not subjected to any harmful interventions. All interactions with them were in the form of verbal interviews and assistance with completion of questionnaires in some cases.
3. Justice-participants were selected solely on their eligibility to take part in the study. No person was inappropriately excluded based on their race, age, disability, education, religion, marital status, ethnic or social origin, belief or language.

Appendix C. Participant information

Title of the research project: Erectile function in circumcised men: Lusaka, Zambia

University of Zambia Biomedical Research Ethics Committee Reference Number: 005-11-12

Stellenbosch University Health Research Ethics Committee Reference Number: N10/11/387

Principal Investigator: Dr Evans Chinkoyo

Address: Plot 222, Meanwood-Ibex Hill, Lusaka, Zambia

Contact number: +260977230473

You are 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. It will take you approximately 30 minutes to complete the questionnaire. 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 study has been approved by the **Health Research Ethics Committee (HREC) at Stellenbosch University** and the **University of Zambia Biomedical Research Ethics Committee,** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki.

What is this research study all about?

- ✓ This study will be conducted in Lusaka at Chilenje , Matero, George and Kanyama Health Centres. Approximately, 115 participants will be recruited at your site leading to a total of 460 participants recruited from all sites for this study.
- ✓ The project aims to establish whether male circumcision has any effect on the ability of men to achieve satisfactory erections for normal sexual function. The study is being conducted in view of the increasing number of circumcisions that are being offered to Zambian men in the context of reducing HIV transmission from infected female sexual partners to their uninfected male counterparts.

Why have you been invited to participate?

- ✓ You are selected to participate because you have met the following requirements needed to take part in the study as a participant:
  - You are a man aged 18 years and older;
  - You are sexually active;
  - You do not have any serious mental or physical problems that would make it difficult for you to participate in the survey;
  - You have agreed to participate in the survey
- ✓ Based on your circumcision status, you will be put in either the circumcised or the uncircumcised group. A questionnaire will then be administered to you with a list of questions that will help you to understand your erectile function. If you are able to read and write, you will be allowed to complete the questionnaire on your own but an assistant will be available to assist you should you require help. If you are unable to read and/or write, an assistant will also be at hand to read the questionnaire to you in a local language of your choice and to help you answer the whole questionnaire.

What will your responsibilities be?

Your responsibilities in this study will include providing proof of your age and identification, and completing the questionnaire.

Will you benefit from taking part in this research?

There are no direct benefits from the study for you if you are already circumcised as the findings will mainly help to provide information for uncircumcised persons planning to undergo male circumcision in future. Should you be found with a sexual condition requiring treatment, you will be referred to doctors with the expertise to manage it. Results of the study will be reviewed by the Department of Family Medicine at Stellenbosch University in South Africa and may be made available for public use.

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

There are no risks involved in taking part in this study.

Who will have access to your medical records?

All information collected from you will be treated as confidential and protected. Only senior members of the research team will have access to your personal information and your identity will remain anonymous in all publications that will follow this study.

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

No, you will not be paid to take part in the study and there will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

- ✓ You can contact **Dr Evans Chinkoyo** on mobile number **+260977230473** if you have any further queries or encounter any problems.
- ✓ You can contact the Biomedical **Research Ethics Committee** at the **University of Zambia at the School of Medicine, Dean's Office, P.O. Box 50110, Nationalist Road, Ridgeway Campus, Lusaka, Zambia** if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- ✓ You will receive a copy of this information and consent form for your own records.

Appendix D. Consent

Declaration by participant

By signing below, I ……..…… agree to take part in a research study entitled ***"Erectile function in circumcised men: Lusaka, Zambia"***

I declare that:

- I have read or had read to me this information and consent form and it is written or explained to me 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 may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2013.

....

Signature of participant (or thumb print) **Signature of witness (or thumb print)**