1) **Protocol Title: Increasing early infant male circumcision uptake in Zambia: Like Father Like Son**
2) **Clinical Trials Number: NCT04119414**
3) **Version #: 1.2 (8/14/2022)**

Permission to Take Part in a Human Research Study

TITLE OF RESEARCH STUDY: Increasing Early Infant Male Circumcision Uptake in Lusaka Province, Zambia: Like Father Like Son

INVESTIGATORS: Prof. Robert Zulu (Zambia)
Prof. Kasonde Bowa (Zambia)
Prof. Stephen M Weiss (USA)

PURPOSE: This purpose of this study is to look at the best way to offer the Like Father Like Son + Spear & Shield program. We want to one day make a big study.

PROCEDURE: We will ask about 300 pregnant couples (600 men and women) from 4 Community Health Centers in Lusaka Province, Zambia; 75 couples from each clinic to be in the study. To be in this study, your partner must also say yes to be in the study with you. You will take part from when you enroll until 6 months after delivery.

STUDY VISIT: If you say yes to be in the study, you will be asked to do the following at the clinic site where you enrolled**:**

1) Questionnaires:
    a. You will answer the questionnaires when you enroll in the study and answer a questionnaire 6 months after your baby is born. The questionnaires are about male circumcision for adults and baby boys. When you do the first questionnaire, you will use headphones and a computer laptop in a private office. The first questionnaire will take about 1 hour. The second questionnaire will be over the telephone. We expect it will take about 3-5 minutes.
2) Group sessions (4 men's or women's groups):
    a. Group sessions will be about adult and child voluntary medical male circumcision, how you feel about medical male circumcision, and how you feel men and babies being able have medical male circumcision at your clinic. The groups will meet once every week for about two hours for the first month you are in the study. The sessions will also talk about the good and bad points of male circumcision and how to protect you and your partner from sexually transmitted infections, including HIV. We expect the group session will take about 2 hours each time.
3) Couple sessions (2):
    a. The couple sessions, just you and your partner, will be just before you give birth and one week following the birth of your baby. These sessions will be about infant male circumcision, and circumcision for fathers and sons. During each couples session your will also fill up a short paper and pencil questionnaire on how you feel about circumcision. The session will be about the good and bad points of male circumcision for babies. We expect the sessions will take about 2 hours each time.

What should I think about before I enroll in this research?
You may want to be in this study if you would like to learn more about circumcision for men, boys and baby boys. You may not want to be in this study if you are worried about talking with your partner about the or your baby being circumcised. You should ask the study staff and get their answers before you decide. This study will be registered and may report results on www.ClinicalTrials.gov, a publicly available online registry of clinical trials.

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RISKS: The questionnaires and groups will have questions and talk about how you feel about adult, child, and infant male circumcision. You might feel nervous, embarrassed and tired when you answer these questions.

Study staff leading the group will remind group members about the importance of keeping information shared during the group private. All group members will be asked to pledge to keep the group information private. The researchers cannot guarantee that group members will share the information outside the group. Breaking this agreement could cause you to be terminated from the study.

BENEFITS: No direct benefit can be promised to you. But, you may learn a lot and have good experiences that may be helpful. You may also learn from talking about your own experiences.

With your participation, you can help us find the best ways to offer early male infant circumcision in Zambia as a way to possibly prevent HIV.

COMPENSATION: You will be paid Zambia Kwacha K100 each for each visit (9 visits) for your time and effort.

CONFIDENTIALITY: Our study staff have been trained in ethics, protection of privacy, and other issues for your protection. All information you will provide will be kept private. The questionnaires will be held in a private office area inside your clinic. All information about you being in the study will be coded with a number linked to your name. All information with your name and contact will be separated in a locked cabinet in the PI's offices in Lusaka. Audio recordings will be kept private as permitted by law. Information that you give will be destroyed in three years, when the study is over. Your records will not be linked to you in any report published in any scientific journal.

The US Department of Health and Human Services (DHHS) can request to review the study records. Your records may also be reviewed for audit purposes by authorized University employees or other agents who will be bound by the same provisions of confidentiality.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health in the US. Researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any government, federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. Your information may not be used as evidence if there is a court subpoena, unless you consent to this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except as described below, and

- If you consent to the disclosure;
- If it is used for other scientific research as allowed by federal regulations protection research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure of information as required by government, federal, state, or local law. Should you tell a study staff member that you are having suicidal thoughts, you will be immediately referred to a physician, psychologist or qualified mental health professional for evaluation, and actions may be taken to protect you. If you indicate that you have plans to in any way physically or sexually harm another person, we are required to take steps to intervene. If you indicate that you believe that you are at risk of being physically or sexually harmed, steps will be taken to protect you.

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WITHDRAWAL FROM THE STUDY: Being in this study is voluntary, and your choice. If you choose not to be in the study, you will not have any benefit taken away that you would normally have. You are free to leave the study at any time. Nothing bad will happen to you. If you decide to leave the study, contact the investigator or the study contact so that you will have no further contact.

The researchers also have the right to take you out of the study without your agreement if they feel that it is in the best interest for you. Information that was collected while you were in the study before you dropped out will still belong to the researchers.

QUESTIONS: The staff of the research program will be ready to talk with you and answer any questions you may have about the study. You will be provided with a copy of your signed consent form. If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the Like Father Like Son study team or contact the Zambia study investigators at the contact below:

Professor Robert Zulu
Professor Kasonde Bowa
University Teaching Hospital
Dept. of Pediatrics
Nationalist Road
Lusaka, Zambia
phone: 260 9 781 57961

You can also contact the US investigators:
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Phones: +1 305-243-2601

This research has been reviewed and approved by the University of Zambia Research Ethics Committee (REC) and the Institutional Review Board ("IRB") at the University of Miami.

If you have any questions about your rights as a research participant, you may contact the REC Representative at the University of Zambia Biomedical Research Ethics Committee Representative or the University of Miami Human Subjects Research Office if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

University of Zambia Biomedical Research Ethics Committee Representative
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Signature Block for Capable Adult

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Signature of Participant	Date
_____	
OR Thumbprint of Participant	
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Printed Name of Participant	
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Signature of person obtaining consent	Date
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Printed name of person obtaining consent	
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Signature of person witnessing consent	Date
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Printed name of person witnessing consent	