PARTICIPANT CODE_____

PARTICIPANT INFORMATION SHEET FORM AND INFORMED CONSENT FORM FOR RCT

Expanding and Scaling Two-way Texting to Reduce Unnecessary Follow-up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision Clients in Republic of South Africa

Principal Investigators:
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Funding Source and/or Sponsor: NIH

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Study sites: Bojanala District, North West and Ekurhuleni District, Gauteng

Good day, my name is …….. (INSERT NAME), I am a ……. (INSERT DESIGNATION) at The Aurum Institute. I would like to invite you to consider participating in a research study, entitled Expanding and Scaling Two-way Texting to Reduce Unnecessary Follow-up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision Clients in Republic of South Africa

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.
- The main goal of research studies is to gain knowledge that may help people in the future.
- We cannot promise that this research will benefit you.
- Your participation is voluntary. You have the right to refuse to take part or agree to take part now and change your mind later.
- You should only volunteer for the study if you are willing to use your own cell phone to communicate daily with the study team about your healing after your circumcision
- You should only volunteer for the study if you are willing to come in to the clinic on Day 14 for in-person follow-up
- You should only volunteer for the study if you are 18 years or older
- The study will compare two different ways to provide follow-up care and information to men who received circumcision. Half of those who enrol in the study

will undergo routine, in-person care while the other half have text-based follow-up. You will be randomized to the texting follow-up or not.

- Please review this consent form carefully. Ask any questions before you make a decision.

- If you need urgent medical assistance related to the circumcision there is a staffed, 24-hour number to provide assistance. This number is: 078 149 0446.

Study Contact telephone numbers:

Name	Position	Phone number
24 Hour Urgent Assistance		
Felex Ndebele	Project Manager	078 149 0446

PURPOSE

We are studying whether SMS'ing clients after their circumcision improves early awareness of any problems in the healing process after their procedure. We want to know if SMS-based follow-up after circumcision as safe as in-person follow-up is to ensure proper wound healing.

The study will enrol men from Sekhukhune and Ekurhuleni Districts. 1104 men in the study will be randomized: half of those will be in the text-based follow-up after surgical male circumcision (MC), and half will have routine follow-up. We will also help determine how long follow-up reviews take in the clinic.

Men will text with the study nurse daily for 14 days. Men come in only if they are concerned about their healing. Most men heal without any complications. What we learn from this study will help the National Department of Health (NDOH) decide if men, themselves, can determine if they need to be seen by a clinician after circumcision.

PROCEDURES AND DURATION

Screening Procedures:

If you are eligible to participate in this study and you agree to participate, you will be randomized (like flipping a coin) to one of two arms. If you agree, we will record your name and ask for your consent to use your routine MC records, including demographic and clinical information as used in routine care. We will ask you a few additional questions about your wages and transportation costs. We will also check your phone to make sure

it will work for the study purposes. You will need to ensure you have enough call credit to respond to daily texts. You will receive R100 in cell phone credit on Day 14.

A number in an envelope will place you in one of the study groups. Neither you nor your nurse can choose the group you will be in. You will have an equal chance of being placed in either group. Group 1 is the texting group. Group 2 is the routine care group. This number and assignment cannot change.

You will consent to surgical MC separately from this study consent.

Study Procedures: Routine care group

If you are placed in the routine care group, you will undergo VMMC and follow-up as per routine care including in-person follow up on Day 2 and Day 7. As part of the study, you will be required to return to the clinic for an extra visit on Day 14 for clinical review. You may be observed during a follow-up visit to determine your time spent in the clinic as part of the study. On Day 14, you will receive R100 in cell phone credit. You will then be done with the study, but will be told to return for any unexpected problem with your circumcision and cared for by the clinic team as per routine care. You will also have access to the emergency services as with all MC clients

Study Procedures: Texting group

If you are placed in the study intervention group for text-based follow-up, you will be asked to give your phone numbers and agree to be texted, and reply by text, every day for 13 days. You will be followed-up by phone call if you miss your daily text. You are reminded that you may seek in-person follow-up if you want at any time, just as with routine care. You will also have access to the emergency services as with all MC clients.

Before the actual circumcision procedure, we will review home-based wound care, just as we would for routine care. We will show you photos of what normal healing looks like and how to identify any concerns with your healing. We will answer any questions you have.

We will review the daily texting process, show you what the texts will look like, and review your possible responses. We will also explain how you can text to a study nurse at any time if you have concerns. We will also explain how you can have a nurse call you if you have any concerns.

As part of this study, there would be no mandatory post-MC visits. But as with routine follow-up, men may come for in-person review at any time if you have any concerns at all. You will have a surgical MC as with routine care.

- Before your MC, we will send you an example text and make sure you can receive and respond on your phone.
- If you do not receive this confirmation text before you are ready to leave the clinic, you will be withdrawn from the study and receive routine follow-up as per NDOH guidelines.
- Each day after MC, we will send you a message that you need to respond to. On Day 2, we will send you a reminder text to remove the bandage as well as instructions about bandage removal. Then, we will text you about your bandage removal experience.
- We will text you every day until day 14. A response is required.
- On Day 14, you will come for an in-person clinical review. You will receive your R100 phone credit then.
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  - 100 men in the full study will be asked to answer some written questions about your experiences on Day 14 as well. In a chosen week, some of you will be observed moving through the clinic during a review visit to see how long your visit lasts.
  - You will also receive a brief text-based survey on Day 21 which will be completed by text to follow-up on your healing progress and satisfaction. You will then be done with the study, but will be told to return for any unexpected problem with your circumcision. If complications or delayed healing require longer follow-up, you will be followed by study staff if necessary or until study close-out. If clinical care is required after study close-out, care will be provided at the study site as part of regular clinical service. If necessary, you may be referred to a hospital near the study site for additional care.

RISKS AND DISCOMFORTS

This study poses no additional risk beyond the known risks that you can expect from the routine circumcision.

For men in the text-based follow-up group: Although there are no routine follow-up in-person visits at 2 and 7 days, you will receive daily texts to check on your healing. You are reminded to seek in-person follow-up if you suspect any problem with your healing or if you desire in-person follow-up for any reason. You will receive referral cards for after hours and emergency care, and you are encouraged to use them if you need after hours or emergency care. The availability of staff in-person or phone is same as for the routine care arm. Overall, the type of the follow-up is changing but not frequency or access to care.

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Management of healing problems will be undertaken according to NDOH guidelines for all MC clients, where applicable. Also, your recent MC may be known to others outside the study as a result of the texting intervention if others view your cell phone. You may also feel uncomfortable answering questions about your wages, employment, transport costs, service quality and your opinions about the intervention; however, we hope we will reduce these risks as much as possible. You can leave the study at any time with no impact to yourself or the care you will receive by the DoH.

ALTERNATIVE TO TAKING PART IN THIS STUDY

If you are not interested in participating in this study, you may have routine follow-up after surgical male circumcision as per standard care at this same site.

BENEFITS

This study is not designed for your benefit. However, future clients could save time and money by only attending the reviews that were desired and forgoing compulsory reviews. This would ensure their safety and peace of mind while avoiding unnecessary follow-up.

COMPENSATION

You will be given R100 airtime credit at the Day 14 visit in appreciation for participating in the study.

SOURCE OF FUNDING: National Institutes of Health, USA.

CONFIDENTIALITY

The information you give us will be kept private (in secret). No one outside of the study will know you participated. Any information that could be used to identify you will not be used in any reports or publications from this study. The investigator will keep information connecting your name to your results according to the retention period required by the Aurum Institute and University of Washington in accordance with the applicable law. This list will be kept locked in a separate file cabinet that only the study manager can access.

Wits Human Research Ethics Committee (HREC), the Aurum Institute, funders, and/or University of Washington staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. By signing the written informed consent form, you or your representative authorise such access to your records.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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We have a Certificate of Confidentiality from the United States from the National Institutes of Health. These protections only apply to data held in the United States. This helps us protect your privacy. The certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We cannot use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the United States government who needs it in order to audit or evaluate the research.
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly.
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form.
- to relevant authorities as required by other Federal, State, or local laws.

The Certificate expires when the NIH funding for this study ends. Currently this is 31 March 2025. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

ETHICAL APPROVAL:

• This clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee.

• The study has been structured in accordance with the Declaration of Helsinki (last updated: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

FUTURE USE

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information may then be used for future research studies or given to

another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

RESEARCH-RELATED INJURY

If you experience any problems related to the study, you should call the research manager at **0781490446** or return to this clinic or any local clinic. If you experience any complication or injury as a result of the study, care will be provided at no cost to you.

VOLUNTARY PARTICIPATION

It is up to you whether you want to be part of this study. If you decide to be in it, you may stop at any time. These decisions will not affect your future medical care from the NDOH or partners. If you decide to leave the study, we will ask you for information about why you are choosing to leave. It is up to you whether to answer these questions.

What if you have questions about this study?

You have the right to ask and receive answers to questions about this research. If you have questions, complaints, or concerns, contact the local researchers listed below:

Prof Geoffrey Setswe at 072 025 9875 or Jacqui Pienaar at 082 965 5098

SIGNATURE PAGE

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Version 3.0 dated 27 July 2020

OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any part of the study that is not clear to you. You may take as much time as you need to think about it.

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AUTHORISATION

I am making a decision about whether or not to participate in this study. My signature indicates that I have read and understood the information provided above, have had all my questions answered, and I have decided to participate.

_____ _____
Name of Research Participant (please print) Date

_____ Time in 24:00 format _____
Signature of Participant

_____ _____
Names of Study Staff Signature of Staff Obtaining Consent

_____ _____ _____
Name of Witness Signature of witness date/time

YOU WILL BE OFFERED 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 participant 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 Prof. Clement Penny, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants at (011) 717 2301.