

INFORMED CONSENT FORMS

Evaluation of the Acceptability and Safety of the ShangRing Device for Male Circumcision in Shinyanga, Tanzania

July 2018

CONSENT FORM FOR MALE CIRCUMCISION USING SHANGRING

What you should know about this program:

- This consent form explains the requirements for circumcision by the ShangRing device.
- Please read it carefully and take as much time as you need. Someone is available to read the material to you, if you are not able to read by yourself.
- A device called ShangRing is now available as an alternative method of circumcising males 13 years and above who are HIV-negative. The ShangRing device has been used to perform large numbers of circumcisions in China and other countries and has been researched in Kenya, Uganda, and Zambia. You are being offered the opportunity to choose between being circumcised by the ShangRing device or through the conventional surgical method.

Purpose of the implementation pilot

You are being offered the opportunity to take part in a program being done by the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and its partners to offer 575 circumcisions using the ShangRing device in selected health facilities. Although ShangRing has been successfully used in other countries, the purpose of this program is to learn more about using this method of circumcision for large numbers of males in Tanzania to decide whether to begin offering it all over the country.

ShangRing circumcision differs from surgical circumcision because it is done without stitching, which makes the procedure much faster, but the device must stay on the penis for 7 days before removal. However, most men and boys who have been circumcised using the device are not bothered while wearing the device.

Why you are being asked to participate

You are being asked if you want to take part in this implementation pilot evaluation because you have come to the clinic for circumcision, you are 13 years or more, and have indicated that you are willing to take an HIV-test. If you choose to take part in this activity, you will be assessed to determine if you are eligible for circumcision using the ShangRing device. This will include HIV testing.

Procedures

If you are eligible and agree to ShangRing circumcision, the health care team will give you anesthetic by [injection/topical cream] in your penis to prevent pain during the procedure. The ShangRing will be placed on your foreskin, compressing it to prevent bleeding. The rest of your

penis is protected and will not be compressed. Then your foreskin will be removed and the ShangRing will be left in place to protect the wound while it heals.

You will be asked to return to the clinic on the seventh day to have the device removed. It is important not to try to remove the device yourself, as this can cause bleeding and infection, and to contact the clinic immediate if the device comes off or moves.

You will also be asked to return 6 weeks (42 days) after the device is removed in order to review healing. If you are not healed 6 weeks after the device is removed, you will be asked to return to the clinic once a week until you are completely healed.

You will be asked to answer some questions by telephone three days after the device has been removed. During this call you will be asked questions to assess how well you are recovering from the procedure. You will also be asked if you are willing to participate in an interview three weeks (21 days) after the device is removed. If you agree and are selected to participate in an in-person interview, you will be reimbursed for your time and transportation to the interview site and provided a snack during the interview.

To receive ShangRing circumcision, you must also provide your contact information and alternative information for contacting you, including a physical address, and you must consent to being contacted by text, phone and visits if needed, to make sure you get the ShangRing removed in case you are unable to return to the clinic. Alternative contact information may include workplace, school or cell number belonging to a friend or relative through whom you can be reached. If you do not return to the clinic to have it removed in time, we will need to use your contact information to reach or visit you. If we send you a text message, it will include your name and specify the name and phone number of our clinic. But the purpose of appointment visit will not be included in the text message reminder.

You may come to the clinic at any time if you have concerns or a problem related to circumcision. You will be given instructions for how to care for your wound. For any care needed after normal clinic hours, or any concerns at any time, please call the 24-hour clinic phone number provided:

Primary # _____ (Site specific or assigned to the clinician on call)

Secondary # _____ (Site specific)

In the unlikely event of a complication, the medical team would also like to request your permission to take photographs of your penis. This will help us to learn about possible complications so that we can better prevent them. It is up to you to decide whether or not to allow photographs, and you can still participate and receive ShangRing surveillance activity whether or not you agree to have photographs taken. If you agree, your permission will still be asked before any photograph is taken. There are no risks to you related to the pictures taken because your name will not be attached to the photograph but only your program identification number. Your face or other body parts will not be photographed. Any photographs of your penis

that may be taken, as well as all information collected from you in the surveillance, will be kept in your file in a locked cabinet at the clinic to be accessed only by clinic staff responsible for your care.

Risks/discomforts

There are some risks and discomforts with ShangRing circumcision.

- You may have some pain during the week you are wearing the ShangRing device because of the pressure on the penis. You may also have some pain when you have erections before the ring is removed.
- As with any circumcision, there are risks of infection, delayed healing, and other complications. Rarely, these can be serious, requiring more surgery or hospitalization to treat. Very rarely, there can be death or deformity due to the procedure. In order to minimize these risks, your providers follow careful quality standards, and you will be educated about correct wound care.

Benefits

The benefits of being circumcised include lowered risk of HIV infection for men who are currently HIV-negative, lowered risk of some sexually transmitted infections, and improved hygiene. The benefit of circumcision from the ShangRing device compared to surgical circumcision may include less time and less pain from the procedure, the ability to return to work or your regular activities sooner, and a better appearance of the penis after the circumcision has healed because no stitches are used. By participating in this surveillance activity, you will provide additional information about ShangRing that the MOH will use to guide further and more widespread use of this device for circumcision. You will also be compensated for your time, including reimbursement for time and travel to all ShangRing related follow-up visits to the clinics, and for the qualitative interview, if applicable. The value of compensation will be determined based upon the cost of transportation and is expected to be between 16,000-22,000 Tanzanian Shillings. You will be reimbursed at the clinic, upon the conclusion of your visit, for each visit after the initial placement visit (device removal, healing assessment, and interview, if applicable).

Alternatives: You can choose not to be circumcised, or you can choose to be circumcised using the surgical method.

Do you have any questions?

We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principal Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

Dr. Lija Gissenge

Head of the Prevention Unit/National AIDS Control Program

Ministry of Health & Social Welfare, Community Development, Elderly and Children

Building No. 11
P.O.Box 743
40478 - Dodoma, Tanzania
Phone: + 255 784 284148| Email: j.lija@hotmail.com

2. Dr. Lucy Mphuru (Co-Investigator of this study) and the Project Director at IntraHealth International in Tanzania through the following contact address:

Dr. Lucy Mphuru
IntraHealth International
Plot #446, Golf Street, Kawe Area –
P.O.Box 12007
Dar Es Salaam, Tanzania
Phone: +255 282 501155/Mobile | Imphuru@intrahealth.org

If at any time you have any questions regarding your rights as a participant in this research study; you may directly contact the ethics review committee through the following contact details:

Secretariat,
Physical Address:
National Institute for Medical Research
3 Barack Obama Drive, 11101 Dar es Salaam, Tanzania.

Postal Address:
National Institute for Medical Research
P.O. Box 9653,
Dar es salaam, Tanzania.
Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this program's purpose, procedures, and possible benefits and risks of the procedure.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this program and to return for device removal.
- You agree to be contacted by phone, through friends, at your workplace, home or any other place for device removal or any other necessary follow ups.
- You have been informed that you will not be charged for the treatment received.

- You have been informed that you will not be given monetary compensation for participating, except for reimbursement for time and travel.

Client Consent:

I understand and accept the benefits and risk for taking part in this program as stated above.

I have decided on my own free will to take part (or allow my child to take part) in this program.

Name of client: _____

Name of guardian if applicable: _____

Signature of client: _____

Day Month Year

If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:

I was present throughout the entire informed consent process with the volunteer. All questions from the volunteer were answered and the volunteer freely decided whether to accept the benefits and risk for taking part in this program.

Signature of Witness

Date

Printed Name of Witness

I certify that I have explained to the client (and volunteer if applicable) the nature and purpose, the potential benefits, and possible risks associated with participating in this program.

Signature of Clinic Staff Person Who Obtained Consent

Date

Printed Name of Clinic Staff Person Who Obtained Consent

ADDITIONAL INFORMED CONSENT FORM FOR PHOTOGRAPHY

Purpose of the Photography

The purpose of the photographs is to document healing over time, to better understand the healing timeframe. When an AE is reported, the photos will be reviewed and verified by project investigators as part of a medical investigation. Information derived from these photos will complement other study related data to inform the use of the ShangRing device in the Tanzania voluntary medical male circumcision program.

Procedures

Photographs of your penis and genital area will be taken by a clinic staff member, after the ShangRing device is placed, after the ShangRing device is removed, at the day 49 healing assessment visit, and at subsequent healing visits for those clients not healed at day 49. Additional photographs may be taken at the request of the attending clinician as necessary in case of unscheduled medical visits, such as occurrence of AEs.

Each time a photograph is taken (placement, removal, healing assessments, or possible AEs), the photographer will take four photographs, presenting a 360° view around the glans and showing the frenulum. The photographer will take photographs while a special photo frame is placed around the penis including the subject evaluation number, date of photo, and evaluation day. The photos will not include your face. You will be asked for oral consent prior to any photograph, and you reserve the right to refuse photographs at any point. You will not be removed from the study if you choose not to be photographed.

Do you have any questions?

We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principal Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

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Head of the Prevention Unit/National AIDS Control Program
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Dar es salaam, Tanzania.
Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

Volunteer Agreement for Photography

This Additional Informed Consent Form for Photography during the program has been read and explained to me. I have had a chance to ask questions about the program. I have agreed to take part as a volunteer. I have freely decided to allow clinic staff to take pictures of my penis during this program. I also understand that if I agree, the clinic staff will still ask my permission before pictures are taken at any contact.

YES, **I also agree** to have clinic staff take photographs of my penis during this program.
 NO, **I do not agree** to have program staff take photographs of my penis during this program.

Signature or Thumb Print of Volunteer

Date

Printed Name of Volunteer

If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:

I was present throughout the entire informed consent process with the volunteer. All questions from the volunteer were answered and the volunteer freely decided whether to permit photography of his penis during this review. If he agrees, the volunteer also understands that he will be asked for his permission before photographs are taken at each visit/before each occurrence.

Signature of Witness

Date

Printed Name of Witness

ADDITIONAL INFORMED CONSENT FORM FOR QUALITATIVE INTERVIEW

Purpose of the Qualitative Interview

You are being asked to participate in an interview meant to evaluate your experience with the ShangRing device. The purpose of this interview is to gauge the attitudes of men who have received a ShangRing device-based circumcision, in order to evaluate its acceptability to clients. Information derived from these interviews will be used to inform the use of the ShangRing device in the Tanzania voluntary medical male circumcision program.

Why you are being asked to participate

You are being asked if you want to take part in this qualitative interview because you received a ShangRing circumcision as part of the program being done by the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and its partners to offer 575 circumcisions using the ShangRing device in selected health facilities.

Procedures

If you are one of the 50 clients selected to take part in this activity, you will be asked a series of questions by an interviewer that are designed to assess your feelings and attitudes about your ShangRing circumcision. All of your answers are confidential, and you will not be quoted by name in any report that is produced as a result of this program. The interview will last for approximately one hour (60 minutes). The interview will be recorded in order to better accurately capture your opinions, but in order to preserve your anonymity, your name will not be used during the interview, and your name will not be attached to the recording in any way.

You will be reimbursed the amount not exceeding Tanzanian Shillings 50,000/- for your time and for transportation costs to and from the interview site and provided a snack during the interview. You may choose not to participate in this interview, not to answer certain questions, or to end the interview whenever you wish and this will not affect your participation in the study.

Do you have any questions?

We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principle Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:
Head of the Prevention Unit/National AIDS Control Program
Ministry of Health & Social Welfare, Community Development, Elderly and Children
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Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

Volunteer Agreement for Qualitative Interview

This Additional Informed Consent Form for Qualitative Interview has been read and explained to me. I have had a chance to ask questions about the interview. I have agreed to take part as a volunteer, and I understand that the interview will be recorded. I have freely decided to participate in this interview.

YES, I agree to participate in a qualitative interview, and allow for it to be recorded.

NO, I do not agree to participate in a qualitative interview.

Signature or Thumb Print of Volunteer

Date

Printed Name of Volunteer

If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:

I was present throughout the entire informed consent process with the volunteer. All questions from the volunteer were answered and the volunteer freely decided whether to participate in this interview.

Signature of Witness
Printed Name of Witness

Date

ASSENT FORM FOR MALE CIRCUMCISION BY SHANGRING (FOR AGES 13-17)

What you should know about this program:

- This form explains what will happen if you get circumcised using the ShangRing device.
- Please read it carefully and take as much time as you need. Someone can read the material to you, if you are not able to read by yourself.
- A device called ShangRing is now available as a new method of circumcising males who are 13 years old or older and who do not have HIV. The ShangRing device has been in China and other countries and has been studied in Kenya, Uganda, and Zambia. You have the chance to choose whether to be circumcised by the ShangRing device or through the normal surgical method.

Purpose of the implementation pilot

You have the chance to take part in a program being done by the Ministry of Health, Community Development, Gender, Elderly and Children (/MoHCDGEC) and its partners to offer 575 circumcisions using the ShangRing device.

The purpose of this program is to learn more about using the ShangRing in Tanzania to decide if it should be offered all over the country.

ShangRing circumcision is different from surgical circumcision because the client does not need stitches after the procedure. It is faster, but the device must stay on the penis for 7 days before it is taken off. But, most men and boys who have been circumcised using the device are not bothered while wearing the device.

Why you are being asked to participate

You are being asked if you want to take part in this program because you have come to the clinic for circumcision, you are 13 years old or older more, and have agreed to take an HIV-test.

If you choose to take part in this activity, you will be checked to see if you are eligible for circumcision using the ShangRing device. This will include taking an HIV test.

Procedures

If you are eligible and agree to ShangRing circumcision, the health care team will apply a cream to your penis to prevent pain during the procedure.

The ShangRing will be placed on your foreskin, squeezing it tightly to prevent bleeding. The rest of your penis is protected and will not be squeezed. Then your foreskin will be removed and the ShangRing will be left in place to protect the wound while it heals.

Do not try to remove the device yourself, because it can cause bleeding and infection. Contact the clinic immediate if the device comes off or moves.

You will be asked to come back to the clinic on the seventh day to have the ring taken off. You will also be asked to return 6 weeks (42 days) after the device is removed in order to look at healing. If you are not healed 6 weeks after the device is removed, you will be asked to return to the clinic once a week, until you are completely healed.

You will be asked to answer some questions by telephone three days after the ShangRing is taken off. You will be asked questions about how well you are recovering from your circumcision.

To receive ShangRing circumcision, your parents must also provide:

- A telephone number and backup number
- Your physical address
- Your parents must agree to being contacted by text, phone and in-person visits. This information is needed to make sure you get the ShangRing removed in case you are unable to return to the clinic
- Your parents must also agree to come back to the clinic with you when you have the device taken off, and when you come back for your healing visit

The backup number may be a number at your workplace or school, or a cell number belonging to a friend or relative where we can reach them. If you do not return to the clinic to have the ShangRing removed in time, we will need to use this contact information to reach or visit you. If we send your parents a text message, it will include your name and the name and phone number of our clinic. But the reason of the visit will not be included.

You may come to the clinic at any time if you have concerns or a problem related to circumcision. You will be given instructions for how to care for your wound. For any care you need when the clinic is closed, or any concerns at any time, please call the 24-hour clinic phone number provided:

Primary #+ _____ (Site specific or assigned to the clinician on call)

Secondary # _____ (Site specific)

It is unlikely, but if you have a problem because of the circumcision, the medical team will ask for your permission to take photographs of your penis. This will help us to learn about possible problems so that we can better stop them from happening. It is your choice whether or not to allow photographs. You can still participate even if you do not want to have photographs taken.

If you agree, your permission will still be asked before any photograph is taken. There are no risks to you related to the pictures taken because your name will not be attached to the photograph. Your face or other body parts will not be photographed. Any photographs of your penis that may

be taken, as well as all information collected from you, will be kept in your file in a locked cabinet at the clinic, and only clinic staff taking care of you will be able to open it.

You and your family will not be charged for your circumcision as part of this program, this also includes treatment if you need to return to the clinic for any reason after your surgery. You and your family will also not be paid to participate in this program, but your family will be given money to cover the cost of travel to and from the clinic.

Are there risks or discomforts?

There are some risks and discomforts with ShangRing circumcision.

- You may have some pain during the week you are wearing the ShangRing device because of the pressure on the penis. You may also have some pain when you have erections before the ring is removed.
- As with any circumcision, there are risks of infection, delayed healing, and other complications. Rarely, these can be serious, and you may need more surgery or hospitalization to treat. Very rarely, there can be death or permanent damage to the penis due to the procedure. In order to reduce these risks, your health care team follows careful quality standards and you will be taught correct wound care.

What are the benefits?

The benefits of being circumcised include:

- Less risk of HIV infection for males who are HIV-negative right now
- Less risk of some sexually transmitted infections
- Improved hygiene.

The benefits of circumcision from the ShangRing device compared to surgical circumcision may include:

- Less time and less pain from the procedure
- The ability to return to work or your regular activities sooner
- And the penis may look better after it has healed because no stitches are used.

By participating in this program, you will provide additional information about ShangRing that the MoHCDGEC will use to guide further and more widespread use of this device for circumcision. Your family will also be paid back for its time and travel costs, including for time and travel to all ShangRing related follow-up visits to the clinics (16,000-22,000 Tanzanian Shillings per visit, depending upon cost of travel).

What are my other choices?

You can choose not to be circumcised, or you can choose to be circumcised using the surgical method.

Do you have any question?

We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principle Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

Dr. Lija Gissenge
Head of the Prevention Unit/National AIDS Control Program
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Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

Your parent/guardian will also give a parental consent because you are below the age of consent according to the law. However, the decision to be circumcised or not is yours and you have the

final decision. If you sign below, it means that you agree to be circumcised using the ShangRing method.

Client Assent signature: _____

What does parent/guardian's signature on this form mean?

Your parent/guardian will give a parental consent because you are below the age of consent according to the law. However, the decision to be circumcised or not is yours and you have the final decision.

Your guardian's signature on this form means:

- They know about this program's purpose, procedures, and possible benefits and risks of the procedure.
- They have been given the chance to ask questions before you sign.
- They have voluntarily agreed to be in this program and to return for device removal.
- They agree to be contacted by phone, through friends, at your workplace, home or any other place for device removal or any other necessary follow ups.
- They have been informed that you will not be charged for the treatment received.
- They have been informed that you will not be paid for participating, except for reimbursement for transportation costs to the clinic to have the device removed.

Parent/Guardian Consent:

I understand and accept the benefits and risk for taking part in this program as stated above.

I have decided on my own free will to allow my child to take part in this program.

Name of parent/guardian: _____

Signature of parent/guardian: _____

Day Month Year

If Parent/Guardian Cannot Read the Form Himself, A Witness Must Sign Here:

I was present throughout the entire informed consent process with the volunteer and their guardian. All questions from the volunteer were answered and the volunteer and parent/guardian freely decided whether to accept the benefits and the risk of participating in this program.

Signature of Witness

Date

Printed Name of Witness

I certify that I have explained to the volunteer and their parent/guardian the nature and purpose, the potential benefits, and possible risks associated with participation in this program.

Signature of Clinic Staff Person Who Obtained Consent

Date

Printed Name of Clinic Staff Person Who Obtained Consent

CLIENT ASSENT FORM FOR PHOTOGRAPHY (FOR AGES 13-17)

Purpose of the Photography

The purpose of the photographs is to document healing over time, in order to better understand the healing timeframe. When an AE is reported, the photos will be reviewed and verified by project investigators as part of a medical investigation. Information derived from these photos will complement other study related data to inform the use of the ShangRing device in the Tanzania voluntary medical male circumcision program.

Procedures

Photographs of your penis and genital area will be taken by a clinic staff member, after the ShangRing device is placed, after the ShangRing device is removed, at the day 49 healing assessment visit, and at subsequent healing visits for those clients not healed at day 49. Additional photographs may be taken at the request of the attending clinician as necessary in case of unscheduled medical visits, such as occurrence of AEs. The photographer will take four photographs, presenting a 360° view around the glans and showing the frenulum. The photographer will take photographs while a special photo frame is placed around the penis including the subject evaluation number, date of photo, and evaluation day. The photos will not include your face. You will be asked for oral consent prior to any photograph, and you reserve the right to refuse photographs at any point. You will not be removed from the study if you choose not to be photographed.

Do you have any questions?

We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principle Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

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Your parent/guardian will also give a parental consent because you are below the age of consent according to the law. However, the decision to agree to be photographed is yours and you have the final decision. If you sign below, it means that you agree to allow clinic staff to take pictures of your penis as part of this program.

Client Assent signature: _____

Parent/Guardian Agreement for Photography

This Additional Informed Consent Form for Photography during the program has been read and explained to me. I have had a chance to ask questions about the program. I have agreed that my child may participate as a volunteer. I have freely decided to allow clinic staff to take pictures of my child's penis during this program. I also understand that if I agree, the clinic staff will still ask both my child's and my permission before pictures are taken at any contact.

YES, I also agree to have clinic staff take photographs of my child's penis during this program.

NO, I do not agree to have program staff take photographs of my child's penis during this program.

Signature or Thumb Print of Parent/Guardian

Date

Printed Name of Parent/Guardian

Client Assent:

Your parent/guardian has given parental consent because you are below the age of consent according to the law. However, the decision to be agree to be photographed is yours and you have the final decision. If you sign below, it means that you agree to allow clinic staff to take pictures of your penis as part of this program.

Client Assent signature: _____

If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:

I was present throughout the entire informed consent process with the volunteer and their parent/guardian. All questions from the volunteer and their parent/guardian were answered and the volunteer and their parent/guardian freely decided whether to permit photography of his penis during this review. If he agrees, the volunteer and their parent/guardian also understands that they will be asked for permission before photographs are taken at each visit/before each occurrence.

Signature of Witness

Date

Printed Name of Witness