UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
MASENO UNIVERSITY SCHOOL OF MEDICINE

NCT# 04191967

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Cervical cancer screening among HIV-infected women in Western Kenya: Evaluation of the safety, acceptability, and efficacy of an alternative ablation method for treatment of precancerous lesions

Name	Organization	Role on Project
Chemtai Mungo, MD, MPH	University of California, San Francisco	Principal Investigator
Megan Huchko, MD, MPH	Duke University, Department of Obstetrics and Gynecology	Co-Investigator
Jackton Omoto, MB ChB, MMed	Maseno University School of Medicine	Co-Investigator
Cirillus Ogollah, CO	Kenya Medical Research Institute, Kisumu, Kenya	Site – Principal Investigator
Elizabeth Bukusi MB.ChB, M.Med, Ph.D., MPH	Kenya Medical Research Institute, University of Nairobi	Co-Investigator
Craig Cohen, MD, MPH	University of California, San Francisco	Co-Investigator

Principal Investigator's contact information:

Study Principal Investigator - Chemtai Mungo, MD, MPH, Postdoctoral fellow. UCSF. [redacted]

Site Principal Investigator - Cirilus Ogollah, CO [redacted]

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Dr. Chemtai Mungo at the University of California, San Francisco (UCSF) and Kenyan collaborators including Dr. Jackton Omoto of Maseno University and Cirillus Ogollah of FACES.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

Purpose of the study:

The purpose of this study is to investigate a newer method for treatment for women with abnormalities (pre-cancer) after screening for cervical cancer. We also want to understand women's perspective with a cervical cancer screening method which involves taking a picture of cervix. This is part of an effort to create new screening tests based on pictures of the cervix.

Study Procedures: If you choose to be in this study, at the time of your pelvic exam, if you are between the age of 25 years and 49 years, a vaginal sample will be taken with a swab, and an image of your cervix will be taken using a study phone without showing any pictures of you. All participants will then undergo treatment for HPV with a method known as Thermocoagulation. Following the treatment, you will be asked questions about your experience with the treatment. Human papillomavirus test (HPV) is one of the tests used to screen for cervical cancer.

You will be in this study about 12 months and visit the research site approximately two to three times.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- *Risk of slight discomfort while collecting your specimen for testing*
- *Risk of slight discomfort during the colposcopy and biopsy procedure and treatment*
- *Small risk of light bleeding after the biopsy procedure*
- *Risk of potential loss of privacy when offered study participation*

There are also rare but serious risks of participation, like:

- *Significant bleeding leading to a blood transfusion*

We'll tell you about the other risks later in this consent form.

Possible Benefits:

In participating in this study, you may benefit from the extra testing (biopsy) done as part of the study which may identify early signs of cancer, resulting in early diagnosis, for which you will be offered treatment. You will be able to see an image of your cervix, which may help you understand your body better, and the treatment being done. If your HPV test is positive, you will be offered treatment here at FACES Lumumba rather than being referred, which will save you time and transport. The extra time you spend with study clinicians discussing your screening and diagnosis may benefit you by increasing your understanding of cervical cancer screening and prevention among women living with HIV.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your condition without being in a study.
- Taking part in another study.
- Getting no treatment.
- Being referred to a different facility to get a different treatment procedure (cryotherapy – this is the treatment currently used to treat precancer. It involves using cold gas to freeze off the abnormal cells on the cervix)

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are between the age of 25 and 65 years old eligible for cervical cancer screening at your clinic.

Why is this study being done?

The purpose of this study is to investigate a newer method of treatment (known as Thermocoagulation) for women with abnormal results (pre-cancer) after screening for cervical cancer. Thermocoagulation is a treatment method for cervical precancer that uses heat to destroy the abnormal cells on the cervix.

We are also investigating women's perspective on a cervical cancer screening method which involves taking a picture of the cervix. The images will be used in an effort to create a new screening test that is based on pictures of the cervix. This test will be used for women age 25 – 49 years.

This study is being paid for by a grant from the National Institute of Health (NIH) and the American Society of Clinical Oncology (ASCO). The NIH is a research agency, and a part of the United States Department of Health.

How many people will take part in this study?

About 400 women will participate in the study.

What will happen if I take part in this research study?

The following things will happen if you agree to be part of the study:

Medical chart review: Your medical chart will be reviewed by the study clinicians to see if you are eligible for the study.

Interview: You will be asked a brief series of questions about your health and habits, including detailed questions about your sexual activity and medical history.

Summary of study activities:

In this study, you will undergo a screening test offered to all women at FACES to screen for cervical cancer. This may be a test you collect yourself or one that is done by the clinician. In addition, you will undergo a second test called a colposcopy to confirm whether you have any cervical disease. If you are between 25 yrs and 49 years of age, a picture of your cervix will be taken with a study-only phone. This picture will not have your name or show any other part of your body. The picture will be used to in trying to develop a better screening test for cervical cancer. If your doctors think you have cervical precancer, they will take a sample of cells from your cervix for confirmation by a Pathologist. This is called a biopsy. If your HPV screening test is positive and if you are a candidate, you will be offered treatment called Thermocoagulation, which is being investigated for use among HIV-positive women with pre-cancer. As part of the study, you will be contacted a few weeks after your treatment to ask you about how you are recovering. Twelve months after treatment, you will return to the clinic to have repeat screening to confirm that you have been cured using the same tests we did at your first visit.

Description of study procedures:

- **Human Papillomavirus (HPV) testing:** You will be provided a test and given instructions to collect a sample for screening for HPV, which is the virus that causes cervical cancer. If this test comes back positive, you will then have a pelvic exam for additional testing and treatment by a clinician.

- **Vaginal sample collection for HPV typing: Your clinician will collect a vaginal sample that will be tested to determine the specific type of HPV infection you may have.**

- **Visual Inspection with Acetic Acid (VIA) testing:** During your pelvic examination, study clinicians will apply acetic acid to your cervix to look for any abnormalities which will determine which type of treatment you need.

- **Cervicography: Your clinician will take pictures of your cervix (only), which will be used to develop a test to help screen for cervical cancer. No other parts of your body will be photographed and your name or any other identifying information will not be included with the photo.**

- **Colposcopy and Biopsy:** If your HPV test is positive, during your pelvic exam, you will undergo another exam called colposcopy. This examination will be done after the VIA test described above. The colposcope provides bright light and magnifying lenses to help the clinician examine your cervix more closely. During this test, your clinician will use an instrument to take a small sample – the size of a grain of rice from your cervix to help make a diagnosis. This is called a biopsy. This could cause a small amount of discomfort and bleeding.

- **Treatment with Thermocoagulation:** If your screening test is positive, the study clinician may recommend same day treatment with a procedure known as thermocoagulation. This is a procedure in which abnormal cells from the cervix are destroyed using a heated device. The device is applied to your cervix for about 20 seconds at a time, and only the part that is in contact with your cervix is heated. This procedure may cause minimal discomfort. If at any time the treatment is too uncomfortable, you can ask the clinician to stop. Following your treatment, you will be asked a few questions and given instruction to care for yourself, including signs to look out for and when to call us or come back to the clinic.

- **Post-treatment visit:** About 4-6 weeks after your treatment, you will be contacted by phone and asked a few questions about your recovery. You may be asked to come to the clinic if the clinician feels you may need to be seen.

- **12-month Follow-up:** At twelve months after your treatment, you will have a follow-up visit at which time you will have repeat screening to confirm that you no longer have HPV virus, or any cervical abnormality. If you test positive for HPV at this time, the same tests described above will be performed – the VIA and colposcopy and biopsy.

- **Study Location:** All visits and procedures related to the study will take place at the FACES clinic where you routinely get your care.

How long will I be in the study?

You will be in this study about 12 months and you will visit the research site approximately two to three times during this time.

Can I stop being in the study?

Your participation in the study is entirely voluntary. You may drop out at any time without changing or affecting the care you receive at FACES. Tell the study clinician if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely. The study clinicians may stop you from taking part in this study at any time if she/he believes it is in your best interest, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away a few weeks after treatment.

You should talk to your study doctor about any side-effects you experience while taking part in the study.

Risks and side effects related to the treatment procedure include those which are:

Likely

- *Slight discomfort while collecting your specimen for testing*
- *Slight discomfort during the colposcopy and biopsy procedure and treatment*
- *Small risk of light bleeding after the biopsy procedure*

Less Likely

- *Significant bleeding leading to a blood transfusion*

Are there benefits to taking part in the study?

Taking part in this study may have minimal direct benefits for your health. However, this study will help doctors learn more about thermocoagulation treatment for precancer, and it is hoped that this information will help in the treatment of future patients with precancer of the cervix.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care as usual, including screening for cervical cancer
- Taking part in another study
- Getting no treatment
- Getting referred to a different facility for a different type of treatment (cryotherapy)

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will my specimens and information be used?

Researchers will use your specimens (cervical biopsies) and information to conduct this study. The pictures taken of your cervix, which will have no personally-identifying information or image of another part of your body, as well as the results of the biopsy test taken, will be shared with researchers at the National Cancer Institute who are working on building a screening test using images of the cervix. All the information shared will not have your name or other information that can be used to identify you. The results of the biopsy specimen will be placed in your clinic chart once available and provided to the clinicians who care for you regularly. Your clinician will discuss the results with you at your next clinic visit. If there are signs of early cancer in the biopsy, you will be contacted by phone and referred for appropriate treatment.

Shipment of Specimens

A certain number of specimens (cervical biopsies) will be shipped to the University of California San Francisco for evaluation by Pathologists there. The specimens will be stored only for the time needed to have them evaluated, after which time they will be destroyed. The specimens will only include study ID numbers and will not include your name.

The vaginal samples may be shipped to the United States for more testing, if we are unable to perform the test within the Country. The sample will only have a study ID and will not have your name or other information that may identify you.

Do you agree to have your specimens (cervical biopsies) shipped to the laboratory in the United States for testing? If you decline this shipment, you may still participate in other parts of the study.

☐ Yes _____ Participants initials or thumbprint and date

☐ No _____ Participants initials or thumbprint and date

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Some information from your medical record will be collected and used for this study. Study tests that are performed as part of the research, and the information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representations of the University of California
- Representatives of Maseno University Ethics Review Board (MUERC)
- Representatives of the National Institutes of Health

Your information about you will be handled as confidentially as possible. A separate research file will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record, which will be kept in a separate place from your clinic records. Hospital regulations require that all health care providers treat information in medical records confidentially.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study. You will not be charged for any of the study activities.

Will I get paid for taking part in this study?

You will not be paid for your participation in the study. You will receive reimbursement for travel costs to the clinic (up to Kshs 300) if your attendance was only for study purposes.

What if I get injured because I took part in this study?

It is important that you tell your study clinician Cirilus Ogollah if you feel that you have been injured because of taking part in this study. You can tell your clinician in person or call him at [redacted].

You can also contact Maseno University Ethics Review Board (MUERC) for any concerns of injury associated with being in the study, at this address. The Secretary, Maseno University Ethics Review Committee, Private Bag, Maseno; [redacted]; Email address: [redacted]

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study clinician about any questions, or complaints you have about this study. Contact your study clinicians Cirilus Ogollah [redacted] or Dr. Chemtai Mungo [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you have about the study, please contact Maseno University Ethics Review Board (MUERC). [redacted],

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.

Based on your participation in this study, you may be eligible to participate in other future studies at FACES. Do we have your permission to contact you in the future to ask for your participation in other studies?

[ ] Yes [ ] No

CONSENT

You have been given a copy of this consent form.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date Participant's Signature for Consent or Thumbprint

Date Person Obtaining Consent or Thumbprint

Date Person Witnessing Consent