DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
A see and treat paradigm for cervical pre-cancer

Concise summary: This is a research study to find out if our device can be used in place of a standard colposcopy. You will undergo a standard of care colposcopy or LEEP .The physician will insert the trans-vaginal colposcope and take an image of the cervix. Standard of care treatment will still take place regardless of study participation.

The risks of this study are no greater than those of colposcopy or LEEP procedures on their own. There is, however, the potential risk of loss of confidentiality.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you are undergoing colposcopy or loop electrosurgical excision procedure (LEEP). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

A grant from the Duke University Global Health Institute and the National Institutes of Health will sponsor this study. Portions of Drs. Ramanujam's and Schmitt's and their research team's salaries will be paid by this grant. The Principal Investigator, Dr. Ramanujam, is the inventor of the devices being studied licensed to Calla Health, Inc. She is also a founder of Calla Health and its Chief Science Advisor. If the devices become commercially available, Dr. Ramanujam, study staff and Duke University may benefit financially.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Schmitt will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to see if the transvaginal colposcope we are testing produces similar results to colposcopy for the screening of cervical cancer. In this study we are using an investigational device called the transvaginal colposcope. The word investigational means that the device is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA).

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 500 people will take part in this study at five different hospitals and medical facilities. Approximately 50 people will take part in this study at Duke.

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WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. Then you will undergo standard of care colposcopy or LEEP. After this is completed, the images will be collected with the transvaginal colposcope. Use of the transvaginal colposcope is a research procedure, and the images collected with the transvaginal colposcope will not be used to determine your care. Then biopsies, if necessary, will be taken as part of your standard of care. If you are undergoing LEEP, then your tissue will be removed after imaging. After your procedures, the images from the colposcope and transvaginal colposcope will be compared. Participation in this study is voluntary. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study for about 5 to 10 minutes while the research procedures are preformed. Imaging time will take about 1 minute. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
The risks of this study are no greater than those of colposcopy or LEEP procedures on their own. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed. You may experience mild discomfort during the use of the probe and there may be risks not known at this time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there is no direct medical benefit to you. We hope that in the future the information learned from this study will benefit other people with your condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, Calla Health and representatives of the Duke University Health System Institutional Review Board. If your research record is reviewed by any of these groups, they may also need to review your entire medical record. The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS?
There will be no costs to you for participating in this study.

WHAT ABOUT COMPENSATION?
There is no compensation as a result of participating in this study.

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WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at DUMC in the event that you are injured as a result of your participation in this research study. However, there is no commitment by DUMC or your physician to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Schmitt at (919) 684-1165 during regular business hours, after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

If you agree to allow your [tissue/blood/cells] to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Schmitt in writing and let him know that you are withdrawing from the study. His mailing address is 329 Baker House, DUMC 3084, Durham, NC 27710.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. 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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Schmitt at (919) 684-1165 during regular business hours, after hours and on weekends and holidays.

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For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time