CARILION CLINIC
CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

TITLE: A Novel, Low-Cost, Handheld 3D Imaging System for Improved Screening for Cervical Neoplasia in Resource-Limited Settings

IRB#: IRB-24-2185

INVESTIGATOR:

Dr. Isaiah Johnson, MD
101 Elm Ave
Roanoke, VA 24013
Phone: (540) 981-2987
Email: imjohnson@carilionclinic.org

SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study doctor. A summary of the study is provided below.

- Being in this research study is voluntary; it is your choice.
- If you join the study, you can still stop at any time.
- Do not join this study unless all your questions are answered.
- Your decision will not affect your health care or any other benefits to which you are entitled.
- You can say no even if the person inviting you to participate is part of your healthcare team.
- The purpose of this study is to evaluate the design & engineering of a new minimally invasive medical imaging device, CervImage™ (Pensievision, Inc San Diego, CA).
- We are trying to find out if CervImage™ is reliable and easy to use to obtain clinical 3D (3 Dimensional) photographs and to record 3D measurements of human cervixes.
- This is a research study to test a new investigational medical device. An investigational device is one that is not yet approved by the United States Food and Drug Administration (FDA). This study is for research purposes only and will not include any medical treatment.
- There will be 18 participants in this study. You will be assigned to one of two groups, the "Case" group or "Control" group based upon your past Pap smear results. The Research Doctor will tell you which group you are in.

IRB NUMBER: IRB-24-2185
IRB APPROVAL DATE: 10/01/2024

- If you participate and complete the study, you will receive a Vanilla Visa Gift Card for $100.
- We do not anticipate any direct benefits to you from participating. The investigator(s) expect to learn more about using the CervImage™ device to detect changes in the cervix which may benefit other women in the future.
- If you choose to participate in this research, prior to your scheduled gynecologic exam and after the speculum has been placed, Dr. Johnson or another study doctor will insert the CervImage™ camera to capture images of your cervix and record other 3D measurements.
- A 3% vinegar acid wash will be used to remove mucous from the cervix and then the CervImage™ camera will capture further images and measurements.
- The CervImage™ device will not physically contact you during this procedure.
- You will then be asked to complete a questionnaire about your experience.
- Your participation will only last for one research visit. The research procedures will take about 15 minutes all together. The exam will take 5-10 minutes and the questionnaire will take about 5 minutes.
- Your doctor will also complete a survey about their experience with the device.
- The most likely risks to participating are: (1) Minor discomfort from the 5-10 minutes extra time the speculum will be used, (2) inconvenience, (3) a small increase in the risk of a loss of confidentiality. Rare risks include infection.
- Alternatives to participating in this research include choosing not to participate and receiving your care as normal.
- Being in the study will not cost you anything.
- You or your insurance will still be billed for the standard medical care you receive after the research exam is complete; you will be responsible for any medical costs your insurance does not cover.
- Only Dr. Johnson or a clinician under his supervision will be present during your exam.
- Other information that may be important for you to consider so you can decide whether to take part in this research is that the images of your cervix will be shared with the device manufacturer; however, they will not contain any of your personal information.

The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

WHAT IS INFORMED CONSENT?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the informed consent form that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

The research is funded by the National Cancer Institutes, part of the National Institutes of Health (NIH). Investigators are collaborating with Pensievision, the maker of CervImage ™; Pensievision is not paying the investigators to conduct this research study. The person running this study locally is Dr. Isaiah Johnson. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research participant. Being in this study is voluntary.

Be aware that the role of the study doctor is different from the role of your personal doctor. Your personal doctor decides how to treat your specific problem to help you. The study doctor treats all participants under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you know more about these different roles.

Research participants are chosen based on a set of criteria including age, previous Pap smear results, and others, which it appears you have met after a review of your medical chart. You will be asked to verify these criteria if you agree to participate in this study.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this study is to evaluate the design and engineering of a new minimally invasive medical imaging device (CervImage™). We are trying to find out if CervImage™ is reliable and easy to use to obtain clinical 3D photographs and to record 3D measurements in human cervixes. We then plan to use these images to determine if CervImage™ design and engineering improvements need to be made.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

This is a research study to test a new investigational medical device, CervImage™ (Pensievision, San Diego, CA). An investigational device is one that is not yet approved

IRB NUMBER: IRB-24-2185
IRB APPROVAL DATE: 10/01/2024

by the United States Food and Drug Administration (FDA). CervImage™ is not a diagnostic tool and this study will not generate any data to be used for diagnosing or treating you.

You will be assigned to one of two groups, the "Case" group or "Control" group based upon your past Pap smear results. The study doctor will verify that you meet certain criteria for your group including age and pregnancy status, prior to the research exam.

The research exam procedure entails the following:

Immediately prior to your scheduled gynecologic exam at Carilion Clinic OB/Gyn and once the speculum is placed in your vagina, Dr. Johnson or Dr. Choi-Klier will introduce the CervImage™ camera into the speculum to capture images of your cervix. The CervImage™ camera will not come into direct physical contact with you. The device does not release any measurable energy or heat. Investigators will measure the length of time from when the CervImage™ camera is introduced into the speculum until it is removed. Capturing images of your cervix is expected to take fewer than 5 minutes. After these initial images are captured, a 3% vinegar acid wash may be used on your cervix to remove mucous; additional images will then be taken. This washing step is also used in standard-of-care cervical exams.

Once image capture is complete, the CervImage™ camera will be removed from the speculum, concluding the experimental portion of your procedure.

Only Dr. Johnson or a clinician under his supervision will be present during your exam. The images of your cervix will be shared with the device manufacturer; however, they will not contain any of your personal information."

Your physician will then proceed with your scheduled gynecologic exam. At the end of your visit, you will be asked to complete a brief, five-minute questionnaire about your experience having an examination with the CervImage™ camera; your physician will also complete a survey about his experience using CervImage™. The questionnaire may ask you questions about your comfort and satisfaction with the device, amongst other questions.

There is only one research exam to be performed; you will not need to return to Carilion Clinic for study purposes. You will not be contacted concerning this research study after the single, study exam except in the event that a suspected, unexpected, serious, adverse reaction (SUSAR) would occur with this device in this or another study using CervImage™; this is not expected to occur and very unlikely.

Because the CervImage™ device is an experimental device and not approved by the United States Food and Drug Administration (FDA), you will not be able to receive future gynecologic exams with this device until it is approved by the FDA.

Researchers may record certain information described later in this form from your medical chart to use when they analyze the study results. No identifying information or images will be published.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

- Prior to the study exam with the CervImage™ device, the study doctor will ask you about certain criteria you must meet to participate in this research study. You will be responsible for providing accurate answers to these criteria when asked, to the best of your knowledge.

- Additionally, by participating in this research you agree to follow reasonable instructions given by the study team and give them any new information about any new medical issues that may arise during the study procedure.

- Finally, you agree to seek immediate medical attention for any medical emergency that arises in relation to the study or device, including if you suspect you have an infection. CervImage™ is not intended to touch you, and has a single-use, disposable, clean, non-allergenic sleeve that will be used for additional safety; however, infection or allergic reaction cannot be completely ruled out as risks.

WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

Participation in this study may involve some added risks or discomforts. These include the following:

1. The most common risks to participating in this study are inconvenience, stress, emotional distress, or embarrassment; these are typically mild in nature.

2. A speculum will be in place in your vagina for 5-10 minutes more time than for your scheduled gynecologic exam. Mild discomfort is a common side effect of this.

3. The CervImage™ is not intended to make physical contact with you. Incidental contact with you can uncommonly cause mild discomfort.

4. There is a rare risk for infection. CervImage™ has a single use, disposable, aseptic, non-allergenic sleeve that will be used to reduce the likelihood of this risk.

5. As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see "What about confidentiality?" section below).

Because this is a research study with an experimental device, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings by mail or telephone.

WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the development of an easy-to-use, cost effective, high resolution, cervical-cancer/pre-cancer, screening device which may benefit women in the future.

ARE THERE ANY ALTERNATIVES TO BEING IN THIS RESEARCH STUDY?

Options include choosing not to participate in the research study and receiving your normal care.

WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY OR ABOUT MY STUDY RESULTS?

In general, we will not give you any individual results from the study because the clinical significance may not be known. It is possible though that we will discover information of medical importance that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you by phone or mail.

Sometimes new information comes out during a research study that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about the new information. If you decide you no longer wish to participate, they will also tell you about other options for your care. You may need to sign another form with your consent to continue in the study.

It is possible that we will discover information of medical importance that is unexpected and unrelated to the purpose of this study. We will share this information with you after the exam. Depending on the type of incidental finding, we may contact you by mail or by phone. If you want, we can give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation. An incidental finding may cause you to feel anxious. Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

We are therefore asking your permission to re-contact you in case we need to notify you of unexpected events in the future. We may also contact you to ask about follow- up information about your health or medical care.

You will be getting imaging with the CervImage™ device for research purposes only. The research does not require the images to be read for healthcare purposes. However, if the researchers are concerned about something they see on the images they will tell you and ask you if you want the scan to be reviewed for healthcare purposes (possibly by other clinicians); you may then be referred for medical treatment. You or your insurance company may have to pay for the review for healthcare purposes and for any such treatment.

WHAT ABOUT CONFIDENTIALITY?

The research records will be kept private on a password-protected computer in a locked office. All research data will be coded with a unique number. Your name and medical record number will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be stored in a locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

Questionnaires will be completed in a private, confidential room. The completed questionnaires will be kept private in a locked office and in a locked filing cabinet. The questionnaires will be coded with a unique number. Your name will be linked to the code number on the master list which will be kept separate from the questionnaires and stored in a second locked filing cabinet.

Images captured of your cervix will not contain any protected health information or personal identifying information. A unique study number will be assigned to your images. Study investigators will keep the file that links your unique study number to any of your identifying information in a secure password-protected file. Only IRB-approved study personnel will have access to the file containing the key linking unique image study numbers to patient identifying information. Following FDA marketing approval of the CervImage™ device, this file and all images will be deleted as required by federal law. Research records may be reviewed by the Carilion Clinic Institutional Review Board, FDA, Office for Human Research Protections (OHRP), key stakeholders at Pensievision, Inc., the National Institutes of Health (NIH), which has funded this study, and other regulatory bodies as required by state and federal law.

You may ask for the study doctor to stop making images with the CervImage™ device at any time and for any or no reason. Due to these images being central to the present study, the study doctor may choose to withdraw you from the study if you no longer wish for this imaging to occur.

Please check Yes or No to the statements below. You may still participate in the study if you check No to any statement.

_____**Yes**, I agree that CervImage™ images without any information that would identify me may be used in the publication of this research.

_____**No**, I do NOT agree that CervImage™ images without any information that would identify me may be used in the publication of this research.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

Your research data and personal information, collected as part of the research, will not be used or distributed for future research studies even if your identifiers are removed.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION:

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

- Personal identifiers such as name or medical record number
- Your social security number or TIN for an IRS form acknowledging the $100 Vanilla Visa Gift Card compensation
- Demographic information such as age, race, ethnicity, and gender
- Results of physical exams, laboratory tests, x-rays and other diagnostic procedures
- Tests and procedures that will be done in the study
- Information from surveys or questionnaires done for this study
- The following information specific to this study:
    - Images and 3D parameters collected by the study device
    - Time required to complete your exam
    - HPV status
    - Pregnancy status
    - Incarcerated status
    - Cognitive-impairment diagnoses
    - Primary language spoken & English language comprehension
    - Past & present gynecologic diagnoses

The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- Laboratories and other individuals and organizations that analyze your health information in connection with this research.
- The Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.

- The sponsor or funder of this research: The National Institute of Health (NIH)
- Other individuals or organizations, specifically: Pensievision, Inc.

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form. Refusing to sign will not affect the present or future care you receive at Carilion.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you end your permission.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Taking part in this research will not cost you any money. You or your insurance will still be billed for the standard medical care you receive after the research exam is complete; you will be responsible for any medical costs your insurance does not cover.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

For taking part in this research and to compensate you for the time and effort of participating, you may be compensated up to a total of $100 USD in the form of a Vanilla Visa Gift Card. Your compensation will be broken down as follows:

- Following completion of the study procedure and questionnaire, you will be given a Vanilla Visa Gift Card with the value of $100 USD.

- If you consent to participate in this research study but do not meet certain criteria necessary for participation you will be compensated $20 on the Vanilla Visa Gift Card.

- If you choose to withdraw your consent partially or fully to continue participation in the research prior to the normal conclusion of your participation, you will be paid $50 on the Vanilla Visa Gift Card.

- If you are withdrawn from the study for any reason, you will be paid $50 on the Vanilla Visa Gift Card.

In order to receive compensation for your participation, you will be asked to complete an Internal Revenue Service (IRS) W-9 form. Your social security number will be required to complete the IRS form. Compensation to study participants greater than $600 in a calendar year is considered taxable compensation and is reportable to the Internal Revenue Service (IRS). Carilion will be required to provide your name, social security number, address, and amount of payment to the IRS. You will be issued a 1099 tax form by Carilion Clinic if you meet this reporting threshold. This information and your payment amount will be kept secure and confidential in our research financial records and Carilion's financial office. This information will not be associated with the study name or the research data you provide as a participant

This research may lead to new medical knowledge, tests, treatments, or products. This research could have some financial value and result in commercial profit. There are no plans to provide financial payment to you or your relatives should this occur.

WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time for any or no reason. Your decision not to take part in the study or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion Clinic.

CAN I BE REMOVED FROM THIS RESEARCH WITHOUT MY APPROVAL?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- You do not meet certain criteria needed to be included in one of the two study groups
- It is in your best interest
- You have a side effect that requires stopping the research
- You are found to be or become pregnant, incarcerated, or cognitively impaired
- The research is canceled by the Carilion Clinic IRB, FDA, regulatory body, or the study doctor
- You are unable to undergo the necessary study procedure with CervImage™

The reason for any exclusion will be explained to you.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you will be able to get treatment. If you need emergency care, call 911 or go to your nearest hospital or emergency room right away. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation, nor payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

Call the person in charge of this study as soon as you are able. They will need to know that you are hurt or ill.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

None of the investigators or research staff will receive money or other benefits from the company that makes the investigational drug or device being tested in this study.

The maker of CervImage™, Pensievision, Inc, is lending this study's researchers the CervImage™ device(s) at no charge for the duration of this study.

This research is supported by a grant from the National Institute of Health (NIH).

WHO ARE THE CONTACT PERSONS?

If you encounter complications or have any questions about the study, you may call:

Dr. Isaiah Johnson, MD
101 Elm Ave
Roanoke, VA 24013
Phone: (540) 981-2987 [Daytime Phone]
Cell Phone: (540) 529-8825 [Nighttime / Weekend Phone]
Email: imjohnson@carilionclinic.org

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (540) 224-5878 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

IRB SURVEY:

The IRB committee is a group of people that reviews research to protect the rights of research participants. One job of the IRB is to make sure the research is done in a way that is respectful to participants. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____ Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research.

_____ No, I do not want Carilion IRB to send me such a survey.

ClinicalTrials.gov

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

CONSENT SIGNATURES:

- **Research Participant Box** must always be completed unless the participant cannot read, or is physically unable to sign the form. Separate boxes are provided for these exceptions.
- **Person Obtaining Consent Box** must always be completed.
- **Signatures must be obtained/documented on the same date, prior to enrollment.**
- **Participants** must receive a signed copy of this consent form.

ADULT RESEARCH PARTICIPANT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): The research study as described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time.

_____
Printed Name of Research Participant (**18 years or older**)

_____ _____
Participant's Signature Date

IRB NUMBER: IRB-24-2185
IRB APPROVAL DATE: 10/01/2024

RESEARCH TEAM MEMBER OBTAINING CONSENT (<u>WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES</u>): I certify I was present for the informed consent discussion. The participant had an opportunity to ask questions about and appeared to understand the information presented. The participant agreed to take part voluntarily in the research and I obtained the signature. I will give the participant a copy of the signed consent.

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Research Team Member Obtaining Consent Date

TO BE COMPLETED <u>BY WITNESS TO THE CONSENT PROCESS</u> WHEN PARTICIPANT <u>CANNOT READ</u>:
I was present during the consent process. The material in the consent form was read to the research participant. Consent was given voluntarily.

_____
Printed Name of Research Participant

_____
Printed Name of Witness to Consent Process
(This person cannot be part of the study team)

_____ _____
Signature of Witness to Consent Process Date

IRB NUMBER: IRB-24-2185
IRB APPROVAL DATE: 10/01/2024