Brief Title: Low-Cost, Portable Flexible Nasophryngoscope in Head & Neck Cancers in Low Resource Settings – Optimization Phase

Official Title: Partnership to Establish a Practice3 Based Network to Assess for Head and Neck Cancers Using a Low-Cost Portable flexible Nasopharyngoscope – Optimization Phase

NCT#: 04905134

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Duke University Health System

Consent to Participate in a Research Study
ADULT
Partnership to Establish a Practice-Based Network to Assess for Head and Neck Cancers Using a Low-Cost Portable Flexible Nasopharyngoscope

CONCISE SUMMARY

The purpose of this study is to evaluate the use of a new portable, flexible nasopharyngeal scope that is used to examine the upper aerodigestive track by Ear, Nose, and Throat (ENT) doctors. The new portable study scope is used in the same way as a standard flexible nasopharyngeal scope exam that is used during a routine care. During a nasopharyngeal scope exam, a flexible scope is inserted through the nasal passage into the pharynx, allowing view of the nose and throat using a small camera.

The new portable flexible nasopharyngeal scope is an investigational device. The word "investigational" means that the device is not yet approved by the U.S. Food and Drug Administration (FDA). Information collected from this study will be used to make technical improvements to the study scope camera, lighting, and video images. The risks are the same as an examination with a regular nasopharyngeal scope, and may include sore throat, loss of voice, stiff neck, difficulty breathing, and damage to the lining of the airway. The ultimate goal of this study is to develop a portable, low-cost, flexible nasopharyngeal scope that can be used in low income countries to help aid in early detection and diagnosis of head and neck cancer.

Participation in this study involves the completion of a one-time nasopharyngeal scope exam using the investigational device. You will be asked to have the study scope exam after the standard scope exam by your ENT doctor. You will also be asked to complete a short survey about your experience with use of the investigational scope device compared to the standard scope exam.

If you are interested in learning more, please read the entire consent form and discuss it with a member of the study team.

You are being asked to take part in this research study because you are scheduled to have a nasopharyngeal scope exam during a routine appointment with an ENT doctor. 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.

Please tell the study doctor or study staff if you are taking part in another research study.

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Dr. Walter Lee is conducting this study at Duke. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Lee and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Walter Lee 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 evaluate the use of a new portable nasopharyngeal scope that is used to examine the upper aerodigestive track by Ear, Nose, and Throat (ENT) doctors. The new portable study scope is used in the same way as a standard nasopharyngeal scope exam that is routinely done during a clinic visit with an ENT doctor. During a nasopharyngeal scope exam, a flexible scope is inserted through the nasal passage into the pharynx, allowing view of the nose and throat using a small camera.

The new portable flexible nasopharyngeal scope is an investigational device. The word "investigational" means that the device is not yet approved by the U.S. Food and Drug Administration (FDA).

Information collected from this study will be used to make technical improvements to the camera, lighting, and video images of the new investigational device.

The ultimate goal of this study is to develop a portable, low-cost, flexible nasopharyngeal scope that can be used in low income countries to help aid in early detection and diagnosis of head and neck cancer.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 65 people will take part in this study at Duke.

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. You may be asked to read and sign this form electronically. If so, you have provided your email address so that the link to the online document could be sent to you, and so that a copy of it can be emailed to you.

Participation in this study involves completion of a one-time nasopharyngeal scope exam using the investigational device. You will be asked to have the study scope exam by your ENT doctor after the routine scope exam is done as part of your standard of care. You will also be asked to complete a short survey about your experience with the investigational scope device compared to the routine scope exam.

We will also ask your ENT doctor to complete a survey about the use of the study scope compared to your routine scope exam.

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Information collected from use of the study scope device will not be recorded in your medical record and will not be used to change your regular care.

HOW LONG WILL I BE IN THIS STUDY?
Your study participation involves the one-time study procedure using the nasopharyngeal scope device during your routine clinic visit as described above, and completion of a short survey. Overall, your study participation is expected to last approximately five minutes.

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?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Although rare, use of the study scope device may cause some, all or none of the side-effects listed below:

- Sore throat
- Loss of voice
- Stiff neck
- Difficulty breathing
- Damage to the lining of the airway

There may be risks, discomforts, drug interactions or side effects that are not yet known.

In addition, by providing your email address for use in the consent process, you are at risk for a loss of confidentiality because email is not a secure means of communication.

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 information learned from this study will be helpful to others in the future.

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

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necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of the National Institutes of Health (NIH), the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These results will be recorded in your medical record and will be reported to representatives and affiliates of the NIH. Results of tests and studies done solely for this research study and not as part of your regular care will **not** be included in your medical record.

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.

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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 may 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.

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 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 name or other personal information 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.

A representative from the device company may be present during the study visit/exam.

WHAT ARE THE COSTS TO YOU?
There are no additional costs to you for participating in this study. However, you or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Lee. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?
No compensation will be provided for your participation in this study.

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WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians 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. Walter Lee during regular business hours at 919-681-8449 and through the Duke University paging operator at 919-684-8111 after hours and on weekends and holidays and ask that Dr. Lee be paged.

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.

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. Lee in writing and let him know that you are withdrawing from the study. His mailing address is DUMC Box 3805, Durham, NC 27710.

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

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include lack of funding or lack of data.

If this occurs, you will be notified and your study doctor will discuss other options with you.

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 data, we will no longer be able to identify and destroy them.

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

A description of this clinical trial will be available on https://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. Walter Lee at 919-681-8449 during regular business hours and through the Duke University paging operator at 919 684-8111 after hours and on weekends and holidays and ask that Dr. Lee be paged.

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