VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: **Assessing Benefits of Near Infrared Autofluorescence (NIRAF) Detection for Identifying Parathyroid Glands during Total Thyroidectomy.**
Version Date: 01/18/2020
PI: [redacted]

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:
You are being asked to take part in this research study because you have thyroid disease and will be undergoing thyroid surgery. Located closely to the thyroid gland are the parathyroid glands, which are important organs that regulate calcium levels in your body. Thus, it is essential for a surgeon to correctly identify this structure when performing a thyroid surgery. A device called 'PTeye' was recently cleared for marketing by the Food and Drug Administration agency for helping the surgeon to identify and preserve healthy parathyroid glands during surgery. By assisting the surgeon in correctly identifying parathyroid glands, this device may improve the quality of the operation performed on the patient. This study will determine if the 'PTeye' truly benefits a patient undergoing surgery for thyroid disease or not. The device consists of a sterile disposable stainless-steel fiber-optic probe, which will be used to touch the tissue in your neck and the surgeon will be immediately alerted by the device if the tissue is parathyroid or not. Approximately 80 participants will be enrolled for this study from Vanderbilt University Medical Center.

There are no plans to share this with people who take part in this study. Please ask the research staff if you have any questions

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
If PTeye were to be used during your operation, the only known risk is that of an extra 5 minutes of anesthesia may be required, although not always. The study should not increase the risk of infection, as the probe that touches your tissue will be sterile and disposed after use.

Risks that are not known:
The 'PTeye' device has been FDA-cleared for marketing for label-free intraoperative parathyroid gland identification (identification through standard techniques) during thyroid surgeries. However, there may still be associated risks that we do not know about the device at this time.

Good effects that might result from this study:

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a) The benefits to science and humankind that might result from this study are:

The study doctors hope that the results of this study will help them determine if a device such as PTeye can improve the quality of operations performed for thyroid disease and can benefit patients – decrease the time taken for surgery, reduce the number of biopsies performed during surgeries, prevent complications after a thyroid operation and thus reduce overall healthcare costs.

b) The benefits you might get from being in this study are:

There are no direct benefits to you in this study.

Procedures to be followed:
In prior studies, we have found that you can tell the difference between different types of tissue based on how it responds to light, and this analysis will not bother or hurt the tissue. We have also found that parathyroid tissue responds to light in a unique way compared to other tissues in the neck. This property of parathyroid gland forms the basis of how the 'PTeye' device works and can possibly help surgeons in accurately identifying parathyroid glands during neck operations. In order to determine if PTeye improves the quality of the surgery or not, you will be assigned to either of 2 groups by a method called 'randomization'. Randomization means that the group you are in is assigned by chance, like the flip of a coin. Depending upon which group you have been assigned to, the 'PTeye' may or may not be used during the operation. If PTeye is to be used during your operation, a sterile fiber-optic probe will be used to touch the tissue in your neck and shine light on it. Based on the light signal collected back from the tissue, PTeye will indicate to the surgeon if the tissue is parathyroid or not. The light sources in the device are of very low power and cause no known side effects to you. The time needed for testing tissues with the PTeye device will be less than 2 seconds. The whole study should add less than 5 minutes to your surgery. If PTeye will not to be used during your operation, the surgeon will perform the procedure as she/he usually would.
The research staff on this study will have access to (i) information such as your age, race, gender, body mass index (without your name or personal information), (ii) reports on blood and/or biopsy tests taken before and after this surgery, (iii) medications taken before and after this surgery and (iv) details of hospital admissions after this surgery. The surgeon will assess calcium and/or parathyroid hormone (PTH) levels in your blood in the post-operative period (within 24 hours after surgery) as per routine care. If the calcium and PTH levels are not normal after surgery, the surgeon will follow up these blood investigations during your routine follow-up at clinic (5 – 14 days after surgery). As part of your routine medical care, if your calcium and PTH levels are still abnormal when followed up at the clinic, the surgeon may then again reassess your blood calcium and PTH levels up to as long as 6 months after the surgical procedure, to determine if they have eventually returned to normal levels or not.

Payments for your time spent taking part in this study or expenses:
You will not be paid for your time spent taking part in this study.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

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If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact [redacted] at **(615) 343-2735**. If you cannot reach the research staff, please page the study doctor at **(615) 835-7254**.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
The study doctor will withdraw you from the study if you have any problems during the surgery that the doctor did not expect or if your health changes while you are in the study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

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Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information may be shared with institutional and/or governmental authorities, such as the Vanderbilt University Institutional Review Board, and the National Institutes of Health, if you or someone else is in danger or if we are required to do so by law.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, [redacted] and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Confidentiality will be assured by limiting access to patient identifying data and using a coding system which will remove patient identifying information from the data. Data collected in this study will be stored on a password protected computer and data analyses will be performed without using patients' information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.
Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
The study results will be shared with the participant. If interested, you can contact [redacted].
(615) 343-2735

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Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____

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