

**Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: Carmen C Solórzano, MD, FACS

Revision Date: December 8, 2020

Study Title: Evaluating Impact of Near Infrared Autofluorescence (NIRAF) Detection for Identifying Parathyroid Glands during Parathyroidectomy
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to Adults

(Example: adults, child 12-17 years, parent, legal guardian, healthy volunteer, etc.)

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.

You do not have to be in this research study. 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.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have parathyroid disease and will be undergoing parathyroid surgery. Parathyroid gland is an important organ in your neck that regulates calcium levels in your body. Thus, it is essential for a surgeon to correctly identify this organ when performing parathyroid surgeries. A device called 'PTeye' was recently cleared for marketing by the Food and Drug Administration agency, to help the surgeon in locating a diseased parathyroid gland 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 parathyroid 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 160 participants will be enrolled for this study at 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.

2. What will happen and how long will you be in the study?

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 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. At the surgeon's discretion, she/he will assess calcium and parathyroid hormone (PTH) levels in your blood as per routine care at your first routine follow-up at clinic after surgery. If the calcium and PTH levels are not normal after surgery, the surgeon will follow up these blood investigations. As part of your routine medical care, if

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Date of Expiration: 01/04/2022

1 of 4

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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.

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study. There will be no additional required testing or clinic visits.

4. 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.

5. Risks that are not known:

The 'PTeye' device has been cleared for marketing by the FDA for label-free intraoperative parathyroid gland identification during surgeries. However, there may still be associated risks that we do not know about the device at this time.

6. 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.

7. Good effects that might result from this study:

- 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 parathyroid disease and can benefit patients – decrease the time taken for surgery, reduce the number of biopsies performed during surgeries, prevent complications after a parathyroid 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.

8. Other treatments you could get if you decide not to be in this study:

If you do not wish to take part in this research study, you will still have surgery for your parathyroid gland as planned with your doctor. Your doctor will discuss all treatment options with you. You can decide not to take part in this study and it will not affect the care your doctor gives you.

9. Payments for your time spent taking part in this study or expenses:

Date of IRB Approval: 01/05/2021
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2 of 4

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You will not be paid for your time spent taking part in this study.

10. 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.

11. 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.

12. 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 **Dr. Carmen C. Solórzano** 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.

13. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

14. 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, Dr. Solórzano 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.

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3 of 4

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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.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (“authorization”) to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study – laboratory reports, pathology reports, ultrasound, CT and/or Sestamibi scans – as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, National Institute of Health, and the Food and Drug Administration Agency. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Carmen C. Solórzano in writing and let her know that you withdraw your consent. Her mailing address is Division of Surgical Oncology and Endocrine Surgery, Vanderbilt University Medical Center, 597 Preston Research Building, 2220 Pierce Avenue, Nashville, TN 37232. At that time, we will stop getting any more data about you. But the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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.

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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