Date: August 20, 2024
Principal Investigator: Kaitlyn Frazier, MD
Application No.: IRB00224302

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Early feasibility study on intraoperative parathyroid gland (PTG) identification using a hand-held imager (HHI)

Application No.: IRB00224302

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

In thyroid surgeries, it is often challenging to tell apart the parathyroid glands from the surrounding area such as lymph nodes, fat and thyroid tissue. If the surgeons are not able to tell where the parathyroid glands are, they might accidentally be removed or damaged. This can lead to complications such as hypocalcemia (low calcium level) requiring treatment and sometimes lead to longer hospital stay. This study is designed to test a new method (a non-invasive hand-held imaging device) to assist surgeons in identifying the parathyroid glands. If you join this study, we will use the Hand-Held Imager (HHI) for approximately 1 minute during your surgery to test if it improves our ability to identify the parathyroid glands. Additionally, in a few cases where the surgeon deems necessary an additional test will be done using a contrast agent to check whether the blood supply to the parathyroid glands was compromised or not.

2. Why is this research being done?

This research is being done to determine the capability of our Hand-Held Imager (HHI) to distinguish parathyroid glands from surrounding tissues during thyroid surgeries in order to preserve them from being accidentally damaged or removed. This study is mostly an observational study, designed to measure autofluorescence signals of the parathyroid glands and distinguish them from the surrounding anatomical structures such as thyroid, lymphatics, muscles or connective fat tissues intraoperatively. We hope to use this study to gain further insight to develop a solution that will improve clinical outcomes and increase clinician confidence in making surgical decisions during thyroid surgeries.

Who can join this study?

Adult participants (ages 18-60 years) undergoing thyroid or parathyroid surgery, where intraoperative frozen section is deemed necessary under the surgeon's estimation, may join.

How many people will be in this study?

There will be a total of 200 participants in this study and 10 participants will get the contrast agent.

3. What will happen if you join this study?

This is not a treatment study. If you agree to be in this study, we will take the following steps:

We will prepare the Hand-Held Imager (HHI) prior to surgery. The HHI is a passive camera system and does not affect any of the surgical sites, including the surgical instruments and does not emit radiation. During your routine surgery, the study staff will collect tissue data using the HHI for about 1 minute after surgeons expose the thyroid tissue area or pathological thyroid/parathyroid tissues, and accordingly note the classification afterwards. In some cases, if the surgeon thought that the parathyroid gland blood supply was compromised, he will conduct an additional test by injecting a contrast agent named Indocyanine green (ICG). This contrast agent will give them the ability to visualize the vascular structure, then decide if it's intact or not.

Following surgery, study staff will upload data to the computer to analyze the autofluorescence characteristics of parathyroid glands. No further observation or follow-up is needed in relation to this research, regardless of the study findings.

Your participation in this study will not affect your standard clinical care.

Photographs/Video recordings:

As part of this research, we are requesting your permission to create and use images of only the surgical field during your thyroid surgery to help answer the research question. Any images will not be used for advertising or non-study related purposes.

You should know that:

- You may request that the images of the surgical site be stopped at any time.
- If you agree to allow the images of the surgical site and then change your mind, you may ask us to destroy that imaging. If the imaging has had all identifiers removed, we may not be able to do this.
- We will only use these images of the surgical site for purposes of this research.

Will the research test results be shared with you?

This study involves research tests that we do not expect will be useful for your clinical care. We will not share these results with you.

How long will you be in the study?
You will be in this study only for the duration of your thyroid surgery.

4. What happens to data that is collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data we collect about you is important to this effort.

If you join this study, you should understand that you will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

How will your data be shared now and in the future?
Sharing data is part of research and may increase what we can learn from each study.

Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

However, no photos will be shared with a third party.

Data sharing could change over time and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) no further review and approval by an Institutional Review Board (IRB) is needed. If data are shared with identifiers, further IRB review and approval may be needed. The IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

5. What are the risks or discomforts of the study?

Because the time for data collection is anticipated to be 1 minute, the total operation time or procedure will potentially be increased by 1-2 minutes accordingly. If ICG dye was used there is a risk of allergic reaction.

There is the risk that information about you may become known to people outside this study.

6. Are there benefits to being in the study?

The potential benefit of correctly identifying all parathyroid glands is to prevent postoperative hypocalcemia and to prevent their accidental removal, Several studies suggest that using these new techniques may reduce the risk of complications (specifically hypoparathyroidism).

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

No.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of 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 Johns Hopkins Medicine 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 Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. 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.

How will your information be protected?
To minimize the potential risk of breach of confidentiality to subjects, medical records will be kept confidential by using a double-locked storage of notes and data. All electronic material will be kept in password-protected terminals. Patient identifiers will be minimally used and also kept in double locked storage.

12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

13. What is a Certificate of Confidentiality?

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.

14. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study?
Call the principal investigator, Dr. Kaitlyn Frazier at 706-825-4265. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

15. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/ADVANCED PRACTICE PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Advanced Practice Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).