MKT_2021_lung_01 / 21-008276

nCLE Guided Randomized Controlled Trial for Lung Cancer Diagnosis

NCT05556525

Document Date: 06/21/2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **June 21, 2024**
Not to be used after: **June 20, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Needle based confocal laser endomicroscopy guided For Lung Cancer Diagnosis: A Randomized Controlled Trial

IRB#: 21-008276

Principal Investigator: Sebastian Fernandez-Bussy, MD and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to evaluate the feasibility of using nCLE (Needle-based Confocal Laser Endomicroscopy), a laser light to create 'real-time' microscopic images of tissue in a smart needle that may allow for real-time cancer detection during bronchoscopy. You have been asked to take part in this research because you are going to have a biopsy of lung lesions using robotic bronchoscopy.
What's Involved	Study participation involves utilizing a microscopic probe at the time of your bronchoscopic biopsy to see if microscopically cells can be visualized to better direct more efficient biopsies.

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Key Information	**nCLE Risks-**During the procedure the following may occur: • Poses no additional risk than standard of care biopsy • Hypoxia • Respiratory failure • Bleeding at puncture site • Pneumothorax • Infection including pneumonia, bronchitis, or mediastinitis • Sore throat • Fever There is a small risk of allergic reaction, anaphylaxis or hypersensitivity to fluorescein. a commonly used dye so doctors can better see the structure of an organ. Your doctor will discuss the risks of blood draws, x-ray, and the standard of biopsy procedure as these tests and procedures are part of your standard clinical care. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. Participating in the study will not change the means by which a bronchoscopic biopsy is obtained, nor the type of tools used. The device will guide proceduralists where within the lung to take the biopsy. This study is only being done to gather information. You may choose not to take part in this study. You won't need to pay for tests and procedures which are done just for this research study. You won't be paid for your participation in the study.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Sebastian Fernandez-Bussy, MD **Phone**: (904) 953-6320 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Road Jacksonville, FL 32224 **Co-Principal Investigator:**David Abia Trujillo, M.D., M.B. **Phone:** (904) 953-2861 **Co-Principal Investigator:**Janani Reisenauer, MD **Phone:** (507) 538-2422 **Study Team Contact:** Thoracic Surgery Clinical Research Unit **Phone:** (507) 293-0807 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu

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If you have questions about …	You can contact …
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://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.

A description of this research study will also be available on: www.mayo.edu/research/minnesota This web site will not include information that can identify you. You can search this web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are going to have a biopsy of lung lesions using robotic bronchoscopy.

Why is this research study being done?

This research is being done to evaluate the feasibility of using nCLE (Needle-based Confocal Laser Endomicroscopy), a laser light to create 'real-time' microscopic images of tissue in a smart needle that may allow for real-time cancer detection during bronchoscopy.

Information you should know

Who is Funding the Study?

The study is funded by Mauna Kea Technologies. Mauna Kea Technologies will provide the device and funding to cover the cover the costs of running the study.

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Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in the study up until 1 month after your bronchoscopy is completed. The study team will contact you by the phone to follow up any adverse event. Then, the study staff will review your medical records and collect data about your medications, doctor visits (primary care and specialist visits), procedures and other medical record information related to your health for up to 30 days.

What will happen to you while you are in this research study?

Before taking part in any research activities, you will be asked to sign this informed consent form.

You will be randomized into this trial. Randomization is by chance, like a flip of a coin. For this study the randomization is based on if the nCLE device will be used in the standard of care bronchoscopy with tissue biopsy. Half of the subjects will be assigned to have a nCLE procedure (real-time' microscopic imaging) added to the standard of care robotic bronchoscopy with tissue biopsy.

The other half of the subjects will be assigned have the standard of care robotic bronchoscopy with tissue biopsy. You or your doctor will not be able to choose which procedure you are assigned to.

If you agree to be in the study, before the biopsy procedure you will be asked to participate in the following:

- You will have a standard of care physical exam and will be asked about your medical history, demographics such as your age, ethnicity, gender, and race, and we will review your medications. You will also have a standard of care routine chest scans (CT scan and/or x-ray) Routine blood tests
- Standard of care urine pregnancy test for women of childbearing potential

One month after the procedure:
You will be asked about any side effects you may have one month after your procedure.

Follow Up
You may return for standard of care routine follow up visits to see how you are doing. At 7 days post-procedure the study team will contact you to follow up any adverse event. Then, the study staff will review your medical records and collect data about your medications, doctor visits (primary care and specialist visits), procedures and other medical record information related to your health for up to 30 days.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

nCLE Risks

- Poses no additional risk than standard of care biopsy
- Hypoxia
- Respiratory failure
- Bleeding at puncture site
- Pneumothorax
- Infection including pneumonia, bronchitis, or mediastinitis
- Sore throat
- Fever

If you are randomized to the nCLE arm (real-time' microscopic imaging) you may have an increase of the biopsy procedure and sedation time of up to 10 minutes.

There is a small risk of allergic reaction, anaphylaxis or hypersensitivity to fluorescein, a commonly used dye so doctors can better see the structure of an organ. In patients without a known allergy to fluorescein, beta-blocker use, or pregnancy, the use of fluorescein is safe. Pregnancy is exclusionary. A pregnancy test will be performed as part of standard of care if you are a female able to become pregnant.

Fluorescein Risks

- Nausea
- Vomiting
- Dizziness
- Faint
- Localized reactions
- Urticaria

Standard of Care Risks

Your doctor will discuss the risks of blood draws, x-ray, and the standard of biopsy procedure as these tests and procedures are part of your standard clinical care.

Unforeseeable Risks

Some side effects may not be known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety. In addition, the Principal Investigator, Mauna Kea Technologies (the study sponsor providing the device) or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Mauna Kea Technologies will offer to pay for medical treatment of research-related injuries directly resulting from the proper application of the study device. Mauna Kea Technologies may not offer to pay for several reasons. Mauna Kea Technologies may not offer to pay if they conclude the injury happened because you did not follow the study directions or the injury resulted from your actions. Mauna Kea Technologies may not consider the worsening of an existing health condition to be a research-related injury. In the case of injury resulting from your participation in this study, you do not lose any of your legal rights to seek payment by signing this form. Contact the Principal Investigator, who can help you obtain this reimbursement.

If Mauna Kea Technologies will pay for research-related injury costs and you are eligible for Medicare, federal law requires Mauna Kea Technologies to inform the Centers for Medicare & Medicaid Services (the agency responsible for the Medicare program). Information, such as your name, date of birth, sex, and Medicare ID number (if you have one), may need to be shared with the Centers for Medicare & Medicaid Services.

What are the possible benefits from being in this research study?

This study may not make your health better. However, others with lung lesions undergoing biopsy may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Use of the needle based confocal laser endomicroscopy device

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Your name or protected health information will not appear on the study forms. Instead, you will be assigned a participant identification number. Additionally, the study forms will be filed in your participant folder in a locked room or locked files that are not accessible to the public or will be stored on a database with firewalls and password protection. Only approved study personnel can access the paper or computer files. The sponsor will use the data from this study to carry out the purposes of the research study which may include support for marketing applications, publications, and development of educational materials.

If the results of the research are made public, information that identifies you will not be used.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Mauna Kea Technologies GDPR

As a part of this research, records that contain information or data about you and your health (i.e. protected health information ("PHI") under US laws / health personal data under EU laws) will be shared with individuals and organizations that conduct or watch over this research, including the manufacturer (Mauna Kea Technologies) of the technologies we use.

In addition to this research, Mauna Kea Technologies may further reuse your personal information or data including demographic data and tissues specimen images for its own purposes. Mauna Kea Technologies will be exclusively allowed to do so, after that your information or data have been duly de-personalized in accordance with European General Regulation No. 2016/679 of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data as amended as well as, where appropriate, any local laws applicable to Mauna Kea Technologies ("GDPR").

More precisely, the purposes for which Mauna Kea Technologies may reuse your de-personalized information or data are the following:

- To conduct further research or clinical trials
- To ensure high standards of quality, performance and safety of technologies developed in full or in part by Mauna Kea Technologies including technologies based on artificial intelligence or machine learning functionalities
- To train its staff members, partners or customers on technologies developed in full or in part by Mauna Kea Technologies
- To support any regulatory filing with the relevant authorities in order to obtain approval for the commercialization of technologies developed in full or in part by Mauna Kea Technologies including technologies based on artificial intelligence or machine learning functionalities

Mauna Kea Technologies will only retain your de-personalized information or data for as long as necessary to fulfil the above-mentioned purposes, including for the purposes of satisfying any specific legal requirements and, beyond, for a period not exceeding the applicable statutory limitation periods.

Subject to Mauna Kea Technologies' reasonable best efforts to re-identify you as prescribed under GDPR, you have the rights to:

- **Request access** to your de-personalized information or data.
- **Request rectification** of your de-personalized information or data (e.g. where it is incomplete or inaccurate), including by means of providing a supplementary statement.
- **Request erasure** of your de-personalized information or data, where there is no legitimate reason for us continuing to process it.
- **Request the withdrawal** of your consent to the collection and the use of your de-personalized information or data at any time (without this withdrawal affecting the lawfulness of any processing that took place prior to the withdrawal).
  In case of withdrawal, all activities previously carried out will cease, unless the processing operations are based on other lawful grounds, in particular legal obligations to which Mauna Kea Technologies is subject to.
- **Object to processing** of your personal data unless we will be permitted to continue such processing and/or for the establishment, exercise or defense of legal claims;
- **Request the restriction (suspension)** of processing of your personal data (e.g. if you want Mauna Kea Technologies to establish its accuracy or the reason for processing it);
- **Request the portability** of your de-personalized information or data.
- **Define guidelines** for the post-mortem use of your de-personalized information.

If any, you also have the right to lodge a complaint at the relevant supervisory data protection authority (i.e. the French Data Protection Authority called the CNIL, headquartered at 3 Place de Fontenoy, TSA 80715, 75334 PARIS CEDEX 07, France – website: https://www.cnil.fr/en/home).

Unless otherwise stated in this consent form, these rights can be exercised directly with us, by contacting the research team at the mentioned contact details. You will not be required to pay a fee to exercise any of these rights. However, we may charge a reasonable fee for acting on any subject access request which is manifestly unfounded or excessive. Alternatively, we may refuse to comply with any such request.

In addition, in certain circumstances, we may need to request specific information from you to help us confirm your identity and ensure your right to exercise any of your rights. This is another appropriate security measure to ensure that personal data is not disclosed to any person who has no right to receive it.

Based on the above, you confirm by checking the box below that:

I have been duly informed of the different purposes for which Mauna Kea Technologies will reuse my de-personalized information or data and I hereby agree freely to such reuses.

☐ Yes ☐ No Please initial here: _____Date: _____

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.

- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building, PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature