19-010725

Advanced Development of Desorption Electrospray Ionization Mass Spectrometry for Intraoperative Molecular Diagnosis of Brain Cancer using Pathology Biopsies

NCT06387979

Document Date: 11/22/2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **November 22, 2024**
Not to be used after: **November 21, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Advanced Development of Desorption Electrospray Ionization Mass Spectrometry for Intraoperative Molecular Diagnosis of Brain Cancer using Pathology Biopsies

IRB#: 19-010725

Principal Investigator: Alfredo Quinones-Hinojosa, 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 see if it is possible to successfully analyze biopsy tissues utilizing DESI mass spectrometry during intraoperative procedures. You have been asked to take part in this research because you are scheduled to undergo surgery for the removal of a brain tumor.
What's Involved	Study participation involves allowing our study team to collect small portions of your resected tissue to be analyzed in parallel to your standard of care procedure and review information from your clinical outcomes.

	You will not have to take any additional assessments to participate in this study or make any additional visits to Mayo Clinic outside of the visits needed as part of your clinical care.
Key Information	Your participation in this study is completely voluntary. Alternatively, you may choose to have your surgery and not take part in the research.
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.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

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.

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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:** Dr. Alfredo Quinones-Hinojosa **Phone:** (904) 956-3435 **Institution Name and Address:** Mayo Clinic Jacksonville 4500 San Pablo Rd S. Jacksonville, FL 32224
▪ 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
▪ 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.

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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 scheduled to undergo brain tumor removal surgery.

Why is this research study being done?

Researchers at Mayo Clinic are interested in studying new ways to diagnosis and treat patients with brain cancer. This includes looking for ways to identify cancerous vs. noncancerous tissue during brain tumor resection in the operative setting.

Information you should know

Who is Funding the Study?
This study is funded by the National Institutes of Health.

How long will you be in this research study?

Your active participation in this study will be for the duration of your surgical procedure. Being in the study does not require any extra visits beyond the routine clinic appointments. We will follow you in your medical record for up to 5 years after your procedure to evaluate recovery and outcomes. Your samples will also be stored for up to 5 years after your procedure.

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

This is not a treatment study. You are already scheduled to have brain surgery as part of your standard clinical care. Your pre-surgical evaluation, surgery and any follow-up will not be affected by your participation in this study.

If you agree to be in this study, we will ask you to do the following things:

- Allow us to collect and analyze small portions of your resected tissue during the surgery that you will undergo for routine clinical purposes.
- Allow us to use remnants of materials used within the normal course of surgery, including but not limited to cotonoids, paper, taquiderme ®, after their use for research purposes.
- Allow Purdue researchers to attend your surgery.
- Collect personal health information about your diagnosis, treatment, recovery, and outcomes after your procedure from your medical record.
- Allows us to share collected samples with Purdue University investigators involved in the study.

We are collecting the radiological images and information for research purposes.

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. No information will be given to you or to your doctor about the specific studies of your brain tumor tissue related to this study.

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

We do not expect any additional physical risk or discomfort as a result of this study. The risks of brain surgery have been given to you in a separate hospital consent form. This study will not influence any clinical decisions and will not affect your treatment.

The DESI MS analysis procedure has no significant risks as the tissue is analyzed once it is outside of your body. 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?

Taking part in this research study is voluntary. You may withdraw your consent at any time.

- If you wish to stop, please tell us right away

- Leaving this study early will not stop you from getting regular medical care at Mayo Clinic
- There may be other reasons to take you out of the study that we do not know at this time.

If you choose to withdraw consent no more information about you will be collected; however, information already collected about you for the research may continue to be used.

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?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

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

You won't benefit from taking part in this research study. This study is being to collect information. Results from this research study could benefit patients undergoing brain tumor surgery in the future.

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

You don't have to be in this study to receive treatment for your condition. You may receive treatment for your condition and not take part in this research.

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

There are no costs for the DESI MS analysis performed during your procedure. 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. You will have to pay for any costs not covered by your insurance.

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 or samples collected in this study, allowing the information or samples 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. The data collected for this study will be de-identified. Participants in this research study will be assigned a unique code to be associated with their data that is collected for the study. All data will be stored in a secured computer database and all paper documents will be stored in a locked file cabinet in a secured office accessible only to Mayo Clinic assigned research staff. If the results of the research are made public, information that identifies you will not be used.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

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.

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.
- Researchers involved in this study at other institutions.
- 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.

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.

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
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

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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 forever, unless you cancel it.

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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