# Informed Consent/Authorization for Participation in Research

**Title of Research Study:** Optimizing contrast dose and scanning parameters for detection of leptomeningeal disease

**Study Number:** 2025-1395

**Principal Investigator:** Rami Eldaya

_____ _____
Participant's Name Medical Record Number

## ***Key Information***

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

### *Why am I being invited to take part in a research study?*

You are invited to take part in a research study because you possibly have or are at a high risk of developing leptomeningeal disease (LMD).

### *What should I know about a research study?*

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

### *Why is this research being done?*

A major limitation in treatment of LMD is the lack of reliable diagnostic tools for detection of the disease, in particular early LMD. The goal of this clinical research study is to learn if gadopiclenol (a contrast agent) used during MRI scanning can help in the detection of early LMD.

**This is an investigational study.** The MRI scans used in this study are performed using FDA-approved and commercially available methods. The use of gadopiclenol in the detection of early LMD is investigational.

The study doctor will explain how the study contrast agent is designed to work.

## *How long will the research last and what will I need to do?*

You are expected to be in this research study for up to 6 months after the study MRI scans are performed. You will be asked to undergo an LMD-specific brain MRI scan with gadopiclenol contrast within a week (preferably within 48 hours) of routine brain MRI scans. Then, you will be followed-up for 6 months or until the confirmation of LMD (whichever comes first).

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

## *Is there any way being in this study could be bad for me?*

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

## *Will being in this study help me in any way?*

It cannot be promised that there will be any benefits to you or others from your taking part in this research. However, it is hoped that the information gained in this study will help to improve patient care through detection of early LMD. Future patients may benefit from what is learned.

## *What happens if I do not want to be in this research?*

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate.

# ***Detailed Information***

The following is more detailed information about this study in addition to the information listed above.

## *Who can I talk to if I have questions or concerns?*

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-745-2945.

This research has been reviewed and approved by the MD Anderson Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

## *How many people will be in this study?*

It is expected about 40 people will be enrolled in this research study. All will take part at MD Anderson.

## *What happens if I agree to be in this research?*

If you are found to be eligible to take part in this study and agree to take part, you will have brain MRI scans as part of your standard of care. Then, within a week (preferably within 48 hours) of your routine brain MRI scans, you will have LMD-focused brain MRI scans with gadopiclenol contrast. Specifically, MRI scans will be done immediately after a small amount of gadopiclenol is given through an IV catheter placed into a vein, and then at 10 and 30 minutes thereafter. Then, a second dose of gadopiclenol will be given, and MRI scans will be done immediately after. The MRI scans performed for research purposes will take approximately 50 minutes to complete.

You will be followed by routing clinical and imaging guidelines for 6 months or until the confirmation of LMD (whichever comes first).

## *What happens if I say yes, but I change my mind later?*

You can leave the research at any time; it will not be held against you. You may withdraw from participation in this study without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you decide you want to stop taking part in the study, please talk to the study doctor. If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

## *Is there any way being in this study could be bad for me? (Detailed Risks)*

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “discomfort from lying still”, “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

If you are concerned that you might be pregnant please let the MRI technologist know and a pregnancy urine test can be performed prior to the scan. If you prefer not to have MRI, please let the technologist know and you will be unenrolled in the study.

If you have allergic reaction to MRI contrast agents, you might experience similar reaction to Vueway. If you have a history of MRI contrast agent allergic reaction, please report to the MRI technologist the reaction type and severity prior to scan to determine if it is safe for you to have MRI contrast agent.

In patients with acute kidney injury or GFR less than 30, MRI contrast agents including Vueway might worsen your kidney function or case deposit of contrast in soft tissue (nephrogenic systemic fibrosis). If you have acute kidney injury or low GFR, <30, please let the technologist know to determine if the exam is appropriate for you.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

## *Will it cost anything to be in this study? Will I be paid to be in this study?*

The MRIs done as part of this study will be provided at no cost to you.

You and/or your insurance provider will not have to pay for certain research exams and procedures done that are covered by the study.

You and/or your insurance provider will be responsible for the costs of routine clinical services (such as diagnostic/therapeutic procedures, drugs, devices, laboratory assays, and other services that would ordinarily be ordered for medical care, regardless of whether or not you are participating in a study). There may be extra costs that are not covered by your medical plan that you will have to pay yourself.

Taking part in this study may result in added costs to you (such as transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the clinic/hospital more often than if you were not participating in this study.

If you have insurance, talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

## *What happens to the information collected for the research?*

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

## *Will my data be used for future research?*

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and Bracco Diagnostics or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.

## *Can I be removed from the research study without my permission?*

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- You become pregnant.
- The research is stopped by the FDA or the sponsor.
- You are unable to keep your scheduled appointments or follow the study directions.

## *What happens if I get hurt from being in this study?*

If you become injured or ill and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic). If you become injured or ill and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form)
- call the study doctor (Dr. Rami Eldaya, at 713-745-2945) or 713-792-2121 (24 hours)

A research-related injury is an illness directly caused by your participation in the study. A research-related injury does not include:

- injuries directly caused by the natural worsening (progression) of an underlying disease or medical condition, or
- injuries caused by you not following the instructions in this consent form.

You will not be reimbursed for expenses or receive any money from MD Anderson for this injury. Costs of treatment received because you become injured or ill will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

## *What else do I need to know?*

This research is being funded by Bracco Diagnostics.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

## Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)

- The IRB and officials of MD Anderson
- Bracco Diagnostics, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

## CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

## WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

## PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT