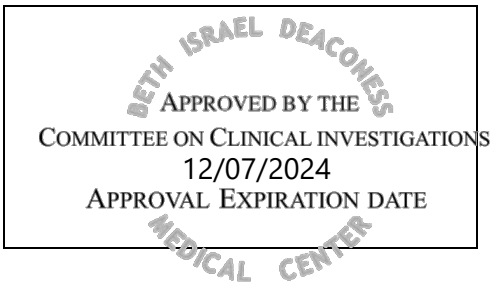
**For CCI Use Only**
**Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:**

Consent Approval Date: 01/05/2024

Protocol Number: 2019P001081




# INFORMED CONSENT FORM TO TAKE PART IN A DRY RUN OF A MRI SCAN

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| **Subject's Name:** |
| **Title of Research Protocol: Novel insight into migraine pathophysiology and galcanezumab mechanisms of action** |
| **Principal Investigator: Rami Burstein, PhD** |
| **Protocol Number: 2019P001081** |

## 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?***
We invite you to take part in a research study because you are a healthy volunteer.

***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.
- Your participation is completely voluntary.
- 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.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

***Why is this research being done?***
This study protocol includes scanning sequences that are not routinely ordered at BIDMC. In order to ensure that the sequences can be carried out smoothly, we are seeking to do a test run of the scanning procedures for the study before we begin to enroll subjects into the main research study.

***How long will the research last and what will I need to do?***
You will be asked to participate in this research study for once for a test run that will last one hour. You will be asked to undergo a MRI (magnetic resonance imaging) scan at BIDMC's research MRI center.

More detailed information about the study procedures can be found under ***"*DESCRIPTION OF STUDY DETAILS*".***

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***Is there any way being in this study could be harmful to me?***
Potential risks associated with MRI include the chance of metallic objects entering the scanner room, claustrophobia, possible heating and/or twitching sensations, and skin burns.

More detailed information about the risks can be found under ***"RISKS AND DISCOMFORTS".***

***Will being in this study help me in any way?***
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include an efficient MRI scanning procedure.

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

Participation in research is completely voluntary. You can decide to participate or not to participate.

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

## DETAILED INFORMATION SECTION

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

## DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Rami Burstein, PhD and is funded by Eli Lilly. The funding agency in this study, Eli Lilly, is paying Beth Israel Deaconess Medical Center (BIDMC) to perform this research. BIDMC and the study doctors have interests in this research project or in the funding agency as follows: Dr. Burstein and Dr. Sait Ashina (a co-investigator on the study) are consultants to Eli Lilly.

## WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Rami Burstein at (617) 735-2832.

## PURPOSE

The purpose of the MRI Test Scan is to standardize the scan methods used at all the imaging sites that might participate in Eli Lilly's study and to ensure that the scan images may be transmitted electronically. The quality of the images obtained from these test scans will be checked at BIDMC. This will allow any scan quality or transmission problems to be identified and resolved before the main study starts.

Your participation in this MRI Test Scan is voluntary and you are free to decide if you want to take part. This MRI examination does not entitle or commit you to participate as a subject in the main research study or in any future clinical study conducted by Eli Lilly.

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**STUDY PARTICIPANTS**
You have been asked to be in the study because you are a healthy adult (>18 yrs old).

Approximately 1 person will take part in this test run at Beth Israel Deaconess Medical Center.

**DESCRIPTION OF STUDY DETAILS**
If you agree to be in this study, you will be in this research study for about an hour.

After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include: a safety form so that the research team can be sure it is safe for you to go into the MRI machine. If the team determines, after reviewing your Safety Form, that it is unsafe for you to enter the MRI, you will not have the MRI.

2. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:
   - The procedure includes a research MRI scan. MRI is a method of taking pictures of the brain and of the blood flow in the brain, using a large magnet and radio signals.
   - Prior to the procedure, you will change into a hospital gown and remove all metal and metallic objects.
   - You will be asked to lie down on a platform that can slide into the magnet. An MRI imaging coil, which is made from special wires that are covered in plastic, will be placed around your head. Foam pads will be placed around your head to limit head movement during the scan.
   - During the scan, you will be asked to lie still on your back for about [xx] to [xx] minutes. You will hear a loud knocking or hammering noise while the MRI is taking pictures, but the process itself will be painless. You will be given disposable earplugs to use to help make the noise less noticeable.
   - During the procedure, you will be in constant contact with the MRI technologist through an intercom. If at any time during the scan you feel too uncomfortable to continue, no matter what the reason, the procedure will be immediately stopped and you will be removed from the MRI scanner.
   - We may be interested in re-evaluating you at another time in the future. In that case we would have the study team contact you to see if you would like to discuss the possibility of undergoing additional evaluations.
   - Certain studies of the brain may require speaking, listening to sounds or instructions, watching flashing or changing pictures and/or patterns of shapes, or moving your fingers in a regular sequence when instructed to do so. Performing these tasks

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changes the activity of regions in your brain much the way moving your legs exercises the muscles. Certain MRI techniques can image these changes in your brain. Testing or improving these techniques can require scanning of subjects performing these tasks. If you are asked to participate in such a study, the procedure of scanning will be the same except that we may position a screen, which you can view from inside the scanner, or instruct you in the finger movements beforehand. We will instruct you through the intercom of the scanner when we would like you to move or stop moving your fingers or when you should view the screen. Performing these tasks should not be uncomfortable or stressful for you.

**Individual Research Results**
Most tests done on samples in research studies are only for research and have no clear meaning for health care.

The research MRI scans performed for this study are different from those that would be used for a clinical evaluation and are not meant to detect or diagnose medical problems. No images or clinical interpretation of the images will be provided to you or included in your medical record. If a suspicious finding is observed, the finding will be reported to the study PI and to the MRI Research Medical Officer. If the finding is confirmed as suspicious and requiring follow up, the PI or an MD co-investigator will contact you and explain any recommendations. If you would like, this investigator will also communicate the recommendation to your primary care provider with a medical explanation of the finding.

**Information and Biological Samples**
Your information and biological samples will be used and shared with the researchers involved in this study to conduct the research. The consent form provides information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. For example, your samples and information may be used to develop a new product or medical test to be sold. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further

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explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

**RISKS AND DISCOMFORTS**
As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

**MRI Procedure:**
MRI is a safe and painless procedure for most people. However, it is not safe for people who have pacemakers, some ear implants, shrapnel injuries, or some types of metal or electric devices in their body, such persons will not be allowed to participate in the study. You must tell the study doctor or study staff about any operations you have had and any metal you may have in your body, so it can be decided whether it is safe for you to proceed with the scan. We will also require that all people involved with the study remove all metal from their clothing and all metal objects from their pockets. For your own safety, you will not be allowed to bring any metal objects into the magnet room at any time.

With any radiofrequency (RF) coil, there is a risk of skin burns if the coil is used improperly. The MRI staff at Beth Israel Deaconess Medical Center is fully trained in the proper use of these devices. In normal operation, some subjects could experience warmth or heating. This should not be uncomfortable, but please let us know if it is.

When very high-speed methods are used for imaging, some people experience a mild twitching sensation. This should not be uncomfortable, but let us know if you experience this sensation since we can modify the imaging method to eliminate it.

Fast imaging has been done for several years and no serious side effects have been encountered. At scan speeds much higher than those that are capable with our scanner itis possible to induce irregular heartbeats. However, the system operates well below the threshold of potential ill effects in the heart.

Some people get a feeling of claustrophobia (fear of small places) while lying in the MRI scanner because the sides and top of the scanner are very close to your face and body. If you suffer from claustrophobia, then we ask that you do not participate in the study. The technologist performing the scan will have voice contact with you constantly while you are in the MRI scanner. If you feel the need to be removed from the MRI scanner at any time, then the scan will be stopped immediately.

If you are pregnant or become pregnant, this MRI may involve risks to the embryo or fetus which are currently unforeseeable.

<u>Loss of confidentiality</u>
There is the potential for loss of confidentiality by participating in this study. Every effort will be

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made to protect the confidentiality of your identifiable information.

**CONFIDENTIALITY**
Information learned about you during this research program will be maintained confidentially by the research staff as described in this form.

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, and by the drug manufacturer, Eli Lilly, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD
A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

**POSSIBLE BENEFITS**
There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

**OTHER AVAILABLE OPTIONS**
Taking part in this study is voluntary. Instead of being in this study, you have the option to not enroll in the study.

**IF YOU DECIDE NOT TO TAKE PART IN THE STUDY**
Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess

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Medical Center.

**INVESTIGATORS RIGHT TO STOP THE STUDY**
The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

**COSTS AND/OR PAYMENTS TO YOU**

**Costs Covered by Study**
You will not be charged for the MRI scan that is part of this research study.

**Payments to You:**
Participants will receive $150 for the completed MRI scan.

In addition, you will be reimbursed for the following: travel (if you take Uber, a taxi, or any other means/services of transportation) or parking (if you drive by yourself). The amount of reimbursement will be based on receipts for these expenses but will not exceed $40 per visit.

It may take up to 8 weeks for you to receive payment by check.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

**Cost of Research Related Injury:**
If you are injured as a direct result of your participation in this study, you should contact the Investigator at the number provided under the section “Who to Call if You Have Questions” in this form. You will be offered the necessary care to treat your injury. We reserve the right to bill your insurance company or the sponsor, if appropriate, for the care you get for the injury. We will try to get these costs paid for, but you may be responsible for some of them. You may be responsible for all co-payments and deductibles required under your insurance. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

**OTHER IMPORTANT INFORMATION**

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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.

**AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION**

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

**Description of Protected Health Information [PHI]**

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable, as well as any new information generated as part of this study. This is your Protected Health Information.

**People/Groups at BIDMC Who Will Share and Use Your Protected Health Information**

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

**People/Groups Outside of BIDMC To Whom Your Protected Health Information Will Be Disclosed (Shared) and Who May Use Your Protected Health Information**

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- The funding source and/or sponsor of this study, Eli Lilly, and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions.
- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this

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research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

**Purpose: Why We Are Using and Sharing Your Protected Health Information**
The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

**No Expiration Date – Right to Withdraw Authorization**
Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization Dr. Rami Burstein at 3 Blackfan Circle, Room 649, Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the

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Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

**Refusal to Sign**
Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

**Right to Access and Copy your PHI**
If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

**ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS**
You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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**THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.**

## CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

***The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.***

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

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PRINT INVESTIGATOR'S/Co-Investigator's NAME

***A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.***

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## THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

***If the subject is able to speak and understand English but is not able to read or write***

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

***If the subject is able to understand English but is not physically able to read or write or see***

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

***If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.***

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____