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

Consent Approval Date: 10-16-2023

Protocol Number: 2020P001191

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
10/15/2024
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

Subject's Name:
Title of Research Protocol: Fremanezumab, migraine and sleep
Principal Investigator: Rami Burstein, PhD
Protocol Number: 2020P001191

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 suffer from migraine.

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.

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Why is this research being done?
The purpose of the study is to understand how a new class of drugs, which was recently approved by the FDA, prevents migraine. Until now, it was believed that drugs that prevent migraine act in the brain, but because the size of the components of this new class of drugs is too large to enter the brain, it is unclear how exactly they work.

How long will the research last and what will I need to do?
We expect that you will be in this research study for 4 months.

You will be asked to provide information about your health, your migraine headache, and your sleep.

If you are enrolled in the study, you will be asked to do the following:

- In the first visit at the headache clinic, we will ask you to fill a few questionnaires about your headache and sleep. Your answers will help us determine your eligibility to participate in the study.
- You will then be asked to fill 2 daily diaries, one about your migraine and headache and another about your sleep. You will need to fill these diaries each day during your 4 months' participation in the study. Filling these diaries should take you less than 4 minutes.
- A month after this first visit, you will come to the Clinical Research Center to review your headache and sleep diaries with the study team and then receive an injection of the study drug, fremanezumab (it is also called Ajovy), into your skin. The next two visits will function the same, each one a month after the previous one.
- After being on the study treatment for three months, you will come back to the headache clinic to conclude your study participation. In this final visit, we will review your e-diary and summarize the study.

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

Is there any way being in this study could be harmful to me?
In general, the most common side effect of the study drug, fremanezumab, is skin reactions near the injection site.

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 include future improvements in understanding migraine and how to treat it better.

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.

You will still be able to receive fremanezumab, even if you decide not to participate in the study, if your doctor decides to treat you with the drug. Otherwise, your alternative to participating in this research study is to not participate.

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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 Drs. Sait Ashina, MD and is funded by Teva Pharmaceuticals. The funding agency in this study, Teva Pharmaceuticals, 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. Ashina (a co-investigator on the study) are paid consultants to Teva Pharmaceuticals.

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 this study is to understand better how fremanezumab works. Specifically, we are trying to determine whether this drug prevent the start of the next migraine attack by improving your sleep.

Fremanezumab is approved by the Food and Drug Administration (FDA) for the prevention of migraine. We would also like to learn if fremanezumab improves your sleep.

The knowledge is useful as it can lead to the development of new medications for the treatment of migraine using drugs that work outside the brain to stop the headache and inside one small part of the brain that we think can start a headache.

The drug we will study is fremanezumab, a drug that prevents migraine.

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STUDY PARTICIPANTS

You are being asked to participate in this study because you suffer from migraine (>8 days per month).

Approximately 100 people will take part in this study 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 4 months. In the first month, we will follow your headache frequency and sleep quality. In the following 3 months, you will receive the fremanezumab. This study does not involve the use of placebo. A placebo is an inactive pill that looks like the study drug, but a placebo contains no active medication. If you chose to participate in the study, you are guaranteed to receive the active study drug (fremanezumab).

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

- During the study, you will come to Beth Israel Deaconess Medical Center (BIDMC) 5 times, twice to the Comprehensive Headache Center and three times to the Clinical Research Center.

- <u>During visit 1 (day 0)</u>, you will learn about the study and if you agree to participate, will give your consent, fill out a questionnaire, and undergo a headache related physical examination. This examination will include checking your vital signs, weight, height, blood pressure, and pulse.

    - You will then complete screening for the study by providing a routine medical and headache history, while also confirming a diagnosis of chronic or high-frequency episodic migraine. The headache history will focus on triggers, warning signs, and symptoms that accompany the headache, as well as headache location, intensity, frequency, and duration.

    - Next, we will determine whether it is safe for you to use fremanezumab.

    - If you are eligible to participate in the study, we will ask you to fill a headache questionnaire and a questionnaire about your sleep. We will then teach you how to fill a daily e-diary for sleep and a daily e-diary for headache. You will have to fill these diaries each day for 4 months. It should take you 5 minutes or less to fill these diaries each day. The diaries may be completed on a cell phone or a personal computer with internet access and the research team will check with you weekly to ensure proper documentation of migraine and sleep.

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- You will also undergo Quantitative Sensory Testing (QST) to determine mechanical pressure and heat pain thresholds. To determine your pain threshold to touch, we will press your skin with flexible nylon fibers and ask you to report if and when you start feeling pain. To determine your pain threshold to heat, a small device, called a thermode, will be attached to your skin. The device is capable of heating the skin as needed. Skin temperature will be increased slowly from 32°C/89.6°F until you start to feel a pain sensation, at which moment you will be able to immediately stop the device by pushing on a small button. If you do not stop the heat stimulus before it reaches 50°C/122°F, the device will automatically shut off and return the temperature to 32°C/89.6°F within a second. The computer will record the temperature at which you stopped the device. For your comfort and safety, the device will automatically switch itself off at upper temperature cutoffs. This is repeated three more times each and the average of the four recorded temperatures is considered to be your threshold.

- Visit 1 will last 90 minutes.

- In visit 2 (which we will schedule for you 30 days after your first visit), you will visit the Clinical Research Center (CRC) so that we can review your headache and sleep e-diaries and then administer your first treatment of the study drug. This visit will last 30 minutes.

- The treatment is 225 mg (dissolved in 1.5 ml solution) fremanezumab (also called AJOVY). The therapeutic effects of each injection will last 30 days.

  - Prior to being started on the study treatment, subjects of child-bearing potential will undergo pregnancy testing.

- In clinic visits 3 and 4 (day 60 and 90), you will return to the CRC to review your headache and sleep diaries and receive your second and third injections of the study drug, respectively.

- In clinic visit 5 (which we will schedule you 1 month after your 3rd and last fremanezumab treatment = study day 120), you will return to the headache clinic to summarize your experience, review your e-diaries for a final time, and discuss any feedback that you may have about your experience with fremanezumab. This visit will last 30-60 minutes.

A schedule of events for the study is provided below:

Study Timeline	Day 0: Screening (Headache Center)	Day 30: Initial dose (CRC)	Day 60: Second dose (CRC)	Day 90: Third dose (CRC)	Day 120: Study conclusion (Headache Center)
Informed	X				

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consent					
Physical examination	X				X
Vital signs	X				X
Review of medical and headache history	X				X
QST	X				X
Administration of e-diary	X				
Review of e-diary		X	X	X	X
Review of inclusion/ exclusion criteria		X			
Drug administration		X	X	X	
e-diary completion	X				

Individual Research Results

Most medical information obtained in research studies is only for research and have no clear meaning for health care. The research testing done in this study is just a stepping stone to learning more about migraine and how fremanezumab works to prevent headaches.

While you should not expect to receive any results from the research testing, if we find that research results from your images are of high medical importance, we may attempt to contact your medical provider to discuss the results. In some situations, follow up studies might be needed. You and your medical insurer may be responsible for the costs of these tests and any follow up care, including deductibles and co-payments. It is possible that you will never be contacted with individual research findings. This does not mean that you don't have or won't develop an important health problem.

Information and Biological Samples

Your information and biological samples will be used and shared with the sponsor and 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

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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 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.

Storing of Identifiable Information and Samples for Future Use
At the completion of this research, we would like to store any remaining sample(s) and information collected from or about you for this research for possible future use. Your sample will be stored with identifiers, such as your name or medical record number. The remaining samples and information may be stored indefinitely and may be used for future research on migraine and ways to prevent it. The research staff will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified by the other researchers or institutions.

If you have questions about storing samples or information, or would like to request that samples or information be removed from storage, please let us know. It is not always possible to remove samples or information from storage or to retrieve samples or information that have/has already been sent to other investigators.

I agree to allow my samples and information to be stored and used for future research as described above: (please check and initial one to indicate your choice)

_____ YES _____ NO

RISKS AND DISCOMFORTS

QST:
The equipment used for the QST is safe, non-invasive, and used by health providers and researchers to measure skin and nerve sensitivity and pain. The machine that tests for heat and cold pain thresholds is FDA approved, poses minimal risk, and no lasting discomfort. The heat machine

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is controlled by you and can be stopped immediately by you at any time. At this temperature range and for this duration of time, there is minimal risk of a burn.

Fremanezumab treatment:
The most common adverse reaction of treatment with fremanezumab are skin reactions near the injection site, which include injection site pain, redness (erythema), and itching.

Less common adverse reactions, such as rash, hives (urticaria), and shortness of breath (dyspnea) have also been reported with fremanezumab in clinical trials. If a serious or severe adverse reaction occurs, treatment with fremanezumab will be discontinued and you will be treated with an appropriate therapy.

In some cases, your immune system may cause the study drug to be ineffective, meaning that you will not be able to benefit from this treatment.

Reproductive risks:
Because of the effects of this study medication on the developing fetus is not known, you may not participate in this study if you are pregnant.

For the duration of the study, if you are engaged in sexual activity that could cause you or your partner(s) to become pregnant, you and your partner(s) must agree to use a highly effective method of birth control or abstain from sexual activity that could cause you or your partner(s) to become pregnant.

The methods of highly effective birth control for this study are below:
1. Contraceptive implant, such as Nexplanon or Implanon
2. Levonorgestrel or copper intrauterine device (IUD), such as Mirena, Skyla, ParaGard or Liletta
3. Permanent female sterilization, such as tubal ligation or Essure with confirmed tubal occlusion
4. Male partner(s) has had a vasectomy more than three months before study enrollment
5. Oral contraceptives pill, patch or ring
6. Injectable contraception, such as Depo Provera
7. Consistent use of a barrier method, such as diaphragm with spermicide or condoms

Additionally, you may not participate in this study if you are breastfeeding.

If you believe you have become pregnant while participating in this study, you must inform your study doctor immediately.

If you are a man capable of fathering children, you must use adequate contraception while participating in this study. For the purposes of this study, adequate birth control means:
1. Use of a condom

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2. Your partner must use an approved method of birth control as listed above.

Loss of confidentiality

There is the potential for loss of confidentiality by participating in this study. Every effort will be 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

It is not possible to predict whether you will benefit directly from participation 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 following options:

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It is important to note that it is possible to get fremanezumab at BIDMC and other health care institutions, as it is an FDA-approved drug for the prevention of migraine, even if you do not take part in the study. Please be aware that not all doctors may agree to prescribe this drug for you and not all health insurance companies will pay for the drug when it is prescribed for migraine prevention, as different insurers use different criteria before approving payment.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this 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 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 fremanezumab administration or physical exams that are part of this research study.

Payments to You:

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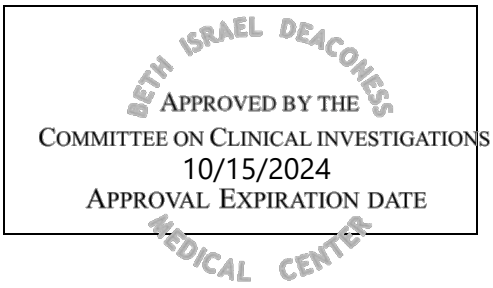

Participants will receive $60 for each study visit that they complete. Those completing all 5 visits will receive $300 from BIDMC.

For this study, compensation will be provided through an electronic payment card (like a pre-paid debit card) called the ClinCard Program. The ClinCard Program is provided to BIDMC by a third-party company called GreenPhire. You will be issued a Greenphire ClinCard, which is a debit card that funds are loaded onto in connection with you taking part in this study. The study staff will provide you with additional information about how ClinCard works, including terms and conditions for the use of ClinCard. In order to complete your payments, Greenphire will need to process certain personal information about you: your name (required), birth date (required), address (required), and contact details (cell/mobile phone number and/or email address- optional for study related communications). This information will be collected from you by the staff in clinic and given to Greenphire. By agreeing to receive reimbursement for this study, you are authorizing the release of this information to Greenphire. By providing this information, Greenphire will be aware that you are enrolled in a clinical trial at BIDMC. Please allow up to three business days for payments to be credited to your ClinCard.

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

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

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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, 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, Teva Pharmaceuticals 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 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

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- 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
- Greenphire
- 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 to 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 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

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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.

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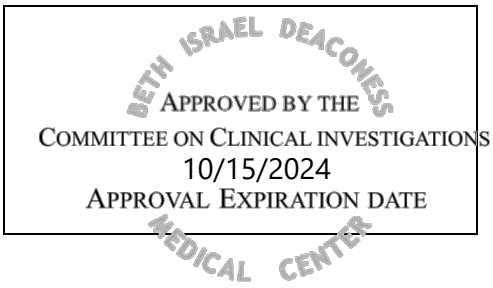
Principal Investigator's Name: Rami Burstein, PhD
Protocol #: 2020P001191



_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

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.

Subject's Name:
Title of Research Protocol: Fremanezumab, migraine and sleep
Principal Investigator's Name: Rami Burstein, PhD
Protocol #: 2020P001191

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: _____