Study on Allopregnanolone and Depression in Perimenopausal Women

Research Consent Form

NCT05329779

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Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: February 2021

Subject Identification

Protocol Title: Using Allopregnanolone to Probe Behavioral and Neurobiological Mechanisms that Underlie Depression in Women in Perimenopause

Principal Investigator: Natalie Feldman, MD

Site Principal Investigator:

Description of Subject Population: Healthy perimenopausal women ages 40 to 60 years

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study, we want to learn more about how allopregnanolone, the female hormone related to progesterone, affects the brain in perimenopausal women who are experiencing depression. We are studying this by giving women a form of allopregnanolone that is FDA

approved to treat postpartum depression as part of a clinical trial involving treatment with allopregnanolone or placebo. We are studying this female hormone in depression during the perimenopause because of its close connection to postpartum depression, which improves with allopregnanolone treatment. While allopregnanolone is made naturally in the brain, it can also be given as a medication, which is known as brexanolone, a medication made and distributed by Sage Therapeutics. Sage Therapeutics is providing the medication for this study. The National Institutes of Health (NIH) is providing funds to support this study focused on perimenopausal depression. Our goal is to identify effective treatments for depression that are specific to women during the perimenopause.

How long will you take part in this research study?

This study will take approximately 5 weeks to complete, from the time of consenting to the end of data collection if there are no delays in scheduling the in-patient visit.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen:

- Complete up to 4 in-person study visits, one of which is a 4-night inpatient stay on a research unit at Brigham and Women's Hospital, and up to 2 remote study visits
- Receive a 60-hour intravenous (IV) infusion of either allopregnanolone (given as the FDA-approved agent brexanolone) or placebo
- Complete up to 3 MRI scans
- Have recordings of your brain wave activity during sleep at night during the inpatient visit
- Have medical, psychiatric, and cognitive assessments and tasks
- Provide urine and blood samples
- Have vital signs and body measurements taken
- Complete questionnaires, surveys, diaries, and other tasks

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include close monitoring of depression symptoms as well as related emotional symptoms, sleep disturbance, hot flashes, and night sweats. Others with perimenopausal depression may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Important risks and possible discomforts to know about include risks related to:

- ***Receiving allopregnanolone (given as brexanolone) by IV infusion*** (most common side effects are sleepiness, dry mouth, altered or loss of consciousness, dizziness, and hot flushes)
- ***Possible worsening of clinical depression or new suicidal thoughts***
- ***MRI (***bothered by feelings of confinement or by the noise made by the magnet during the procedure)
- ***Blood draws*** (bruising, pain, infection, and fainting)
- ***In-dwelling IV for infusion administration*** (bruising, clotting, bleeding, pain, infection)

What other treatments or procedures are available for your condition?

There are other treatments or procedures available to treat depression. You will be informed of other treatment options for depression before enrollment in this study. Currently there are no medications approved to treat perimenopausal depression specifically.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Natalie Feldman, MD MSc is the person in charge of this research study. You can call her at [redacted] **M-F 9am-5pm.** You can also call [redacted] **M-F 9-5,** with questions about this research study.

You can also call the following study doctors with questions about this research study:

- [redacted]

In case of any **study-related emergency**, after hours you can contact any of the study doctors by calling [redacted] and asking the page operator to page the number above associated with the corresponding study doctor on this study.

If you have questions about the scheduling of appointments or study visits, call **the study coordinators at** [redacted].

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB office. You can call them at [redacted].

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed 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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Who will take part in this research?

We are asking you to take part in this research study because you are a healthy perimenopausal woman between the ages of 40 and 60 years old with depression. We are expecting about 80 women to take part in this research study.

What will happen in this research study?

All subjects will undergo the same procedures, which include an in-person screening visit, a four-night inpatient visit, a remote visit, and a follow-up in-person visit one-month later. After completing the screening procedures, you will be admitted to a research unit at Brigham and Women's Hospital (BWH), where you will stay overnight for 4 consecutive nights. You will be followed for one-month after that visit until you complete a follow-up visit at our outpatient research offices.

Most of the study procedures take place during the 4-night hospital admission. For 60 hours during the hospital stay, you will be given either allopregnanolone (as brexanolone) or placebo through an IV placed in your vein. Allopregnanolone is a hormone related to

progesterone that is naturally made in the brain. This is a chance selection study in which neither investigators nor subjects know whether the subject is receiving active drug or placebo (inactive drug). If you qualify for the study, we will assign you by chance (like a coin toss) to the brexanolone group or the placebo group. You and the study doctor cannot choose your study group. You will have 1 in 2 chance of being assigned to the brexanolone group. The placebo looks exactly like brexanolone, but contains no brexanolone. Placebos are used in research studies to see if the results are due to the study drug or due to other reasons. You will be monitored closely throughout the day and night of the inpatient stay and treatment with the study medication. Various tests will be performed during this visit. Brexanolone is FDA approved for postpartum depression, but brexanolone is not approved by the FDA to treat depression in perimenopausal women. This means that brexanolone is being used off-label in this study.

***Screening Visit*:** All interested subjects who appear eligible based on a telephone pre-screening will attend the screening visit in two parts: one remote (via Zoom) and one in-person at a BWH Center for Clinical Investigation (CCI) outpatient unit. At this visit, a study physician will first obtain written, informed consent from you, and then you will be assessed further for eligibility, including with a medical evaluation to ensure medical appropriateness for the study, and administration of interviews, questionnaires, and a safety screening. We'll ask you to complete self-administered questionnaires and surveys. If you are eligible, you will have vital signs and features measured. You will have one blood draw for eligibility/safety labs, including a pregnancy test, and for reproductive hormones (approximately 2 tablespoons). You will be asked to complete daily diaries monitoring your sleep, hot flashes, night sweat symptoms and menstrual bleed at home for up to 7 days.

Four-Night Inpatient Visit: You will be admitted to the CCI's inpatient research unit at BWH for four consecutive nights. You will have your own room and bathroom. Some of the rooms do not have windows. Some of the rooms do not have radios or televisions, but you will be allowed to bring your computer, cell phone, reading materials, and any other materials you would like for entertainment. During the time you are staying at BWH, we will schedule the timing of all your daily activities (eating, sleeping, etc.). A typical day will include breakfast, shower, lunch, dinner, and a snack, as well as any testing procedures specific to this study.

Your inpatient visit will include the following study procedures:

- Provide a urine sample for pregnancy test at admission, and a urine sample on morning void after first night stay (if you happen to wake overnight to void urine you'll be asked to provide a sample here, but will not be woken up for this purpose).
- An infusion by IV (allopregnanolone given as brexanolone or placebo) for about 60 hours

- Daily safety assessments
- Recordings of your brain waves during sleep, called polysomnography (PSG) studies
- Assessments of thoughts and depressive symptoms
- 5 blood draws, needlesticks done by a nurse(approximately 2.5 tablespoons at admission, approximately 1tablespoon first night and once a day thereafter)

Monitoring

Throughout the time of your inpatient visit, you may be monitored by a nurse or research tech on a closed- circuit television. If you are in a room with monitoring, the staff will be able to hear you through an audio/intercom system. We will watch and listen to you to make sure you are safe in the room. We will not make any video or audiotape recordings of you.

Study Rules

- You will have access to our library of recorded movies, books, magazines and newspapers. You are also allowed to bring your own materials for entertainment.
- During your scheduled PSG sleep studies, you may need to stay in bed in the dark for the entire night. We will give you a bedpan during that time, if you need it.
- Exercise will be limited to light stretching only during your wake times.

Interim Remote Visit: About two weeks after the inpatient visit, you will be asked to complete daily monitoring of your sleep, hot flashes, night sweats, and menstrual cycles, and to monitor for side effects and depressive symptoms.

Follow-Up In-Person Visit: About 1 month after the inpatient visit, you will have a final follow-up in-person visit, during which you will undergo:

- Side effect and safety monitoring
- Assessments of thoughts and depressive symptoms
- Blood draw (approximately 2.5 tablespoons)

MRI visits, if eligible: You may receive up to 3 one-hour brain MRI scans called resting-state functional MRIs / magnetic resonance spectroscopy. The first will occur between the screening and inpatient visit (as an additional visit), the second directly after you are discharged from your inpatient visit, and the third during your follow-up in-person visit.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

We can provide you with general information about how you responded to the treatment that you received during the study, but we will be unable to tell you whether you were treated with brexanolone or placebo because the treatment will remain double-blinded until all study subjects finish their participation. We will share information with you and/or your doctor (with your written permission) as results become available if we find out anything that might be important to your health. Examples include unexpected findings on the brain MRI scans or clinically abnormal laboratory values on blood tests that we perform. As all assessments are being conducted in the context of a research study, and not regular clinical care, all results need to be considered in this context and we may recommend that you seek follow-up clinical testing with the doctors involved in your routine clinical care.

Review of Medical Records from Hospital Admissions or Emergency Department Visits

Mass General Brigham has an electronic system that lets your study doctors know if you are admitted to a Mass General Brigham Hospital, or if you visit a Mass General Brigham Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example: list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

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

Potential Risks:

Allopregnanolone (given as brexanolone): In previous trials, brexanolone has generally been well tolerated. However, this drug is associated with some side effects that can occur during the intravenous infusion in the hospital, most commonly sleepiness, dry mouth, loss of consciousness ("passing out" or "fainting"), and flushing of the skin or face. In patients with post-partum depression treated with brexanolone, side effects occurring more commonly (in at least 10% of participants) were: sleepiness, dry mouth, and dizziness/feeling faint; side effects occurring less commonly (in <5% of participants) were: loss of consciousness, flushing, diarrhea, upset stomach, and mouth pain. Of note, even participants getting placebo had these side effects.

The treatment is given as an intravenous infusion in the monitored setting of the hospital because of the potential risk for serious side effects. Sedation (feeling very sleepy) serious enough that the infusion needed to be paused or stopped occurred in 5% of participants, and changes in consciousness (passing out) occurred in 4% of patients, although all of these patients fully recovered within an hour of pausing the infusion. The nurse will check on you for symptoms of excessive sleepiness every 2 hours while you are awake during this study. While in prior studies not everyone who had changes in consciousness experienced sleepiness beforehand, if you begin to feel like you cannot stay awake during normal waking hours, tell us right away; we may choose to lower the dose or stop the infusion until you are less sleepy. Because sedation may be accompanied by low levels of blood oxygen, we will track your blood oxygen levels continuously with a finger monitor during the infusion, and if your oxygen levels decline, the infusion will be stopped immediately and not be restarted.

Because of the sedation risk, you may have increased sleepiness or fatigue on the day of your discharge. This may increase the chance of errors and accidents on that day. Therefore, driving or use of heavy equipment is not advised during brexanolone treatment, on the day of your discharge, or until any sedation that may have emerged has resolved. You will not be allowed to drive home after the inpatient visit. We will offer you reimbursement to travel by taxi or private car (e.g., Uber or Lyft) from the inpatient unit to your home if you are unable to arrange a ride home. Since you may be sleepy, you should not plan to return to work or other responsibilities requiring full alertness on the day you are discharged from the inpatient visit.

Brain-active medications (e.g., opiates, benzodiazepines) and substances (e.g., alcohol, marijuana) may enhance the risk of sedation-related side effects and should not be used in combination with brexanolone.

Reproductive and Lactation Risks: Women who are breastfeeding and those who are pregnant are not permitted to participate in this study. We will test for pregnancy to make sure you are not pregnant at the beginning of the study. It is important to tell us right away if you are breastfeeding or think you may be pregnant at any point in the study. Effects of brexanolone on the fetus and on breastfed infants are not known but it might be harmful to a developing fetus. Brexanolone passes into breast milk at 1 to 2% of the maternal dose. Because limited amounts of the drug pass into breast milk, and since infants cannot easily absorb brexanolone taken by mouth, the amount of exposure to brexanolone in breastfeeding infants is thought to be low.

Assignment of placebo: The risk associated with placebo (inactive drug) includes the potential lack of clinical improvement which may be provided by the active treatment. Because many people who receive placebo will report a variety of side effects consistent with the expectation that side effects may occur, there are additional risks related to the perception of psychological and physical side effects that are common to those subjects assigned to the active drug.

Treatment delay: We are asking you to make no changes to any therapy that you are participating in throughout the trial. Given the duration of the trial, there is also a risk of delaying the start of established, alternative treatments.

Possible worsening of clinical depression or new suicidal thoughts: Depression may worsen as a result of natural symptom fluctuations that commonly occur in depression, in response to trial participation, or due to some other unknown cause. Likewise, suicidal thoughts may appear, and suicidal behaviors may occur.

While the risk of developing suicidal thoughts and actions during infusion of brexanolone or placebo is unknown, a potential serious side effect of any antidepressant medication can be an increased risk of developing suicidal thoughts or taking suicidal actions. This is most likely to occur in people under the age of 24 years. However, you should pay attention to any changes in mood, behavior, thoughts, or feelings, and tell us right away if you have worsening depression, new thoughts of suicide or dying, make any attempts to commit suicide, or have other unusual changes in behavior or mood.

MRI: As part of this study, you may have one or more "Magnetic Resonance Imaging" (MRI) scans. MRI does NOT use ionizing radiation like x-rays. Instead it uses strong

magnets and radio waves to make images of the inside of a person's body. The MRI scan should not cause you any pain. The MRI scan is not known to have any significant effect on health.

Although MRI is not known to have any significant effect on the fetus of a pregnant woman, the effect of such strong magnetic fields and radio-waves on fetal development has not been thoroughly studied. For this reason, the technologist will ask you if you could be pregnant. If you are or could be pregnant it is recommended that you should not have the MRI scan and you may not be able to participate in this study.

Because MRI uses strong magnets and Radiofrequency certain kinds of medical devices implanted in or on your body may be damaged by the MRI scan, malfunction during or after the scan or injure you during MRI. The MRI technologist will have you complete a safety questionnaire to make sure that you don't have any implanted device or other objects such as bullets or nails in your body that would make it unsafe for you to have an MRI scan. If you have such an implants, bullet, tattoos, etc. that would cause MRI to be hazardous to you, you may not be able to receive the MRI scan and you may not be able to participate in the study.

The MRI also produces loud beeping and hammering sounds when the scanner is operating. This is normal and you will be given earplugs and/or other ear protection to reduce the noise to safe levels.

The MRI scanner is a narrow tube and some people become uncomfortable inside the magnet. During the scan you will be able to talk with the MRI technologist through an intercom system, so that any discomfort or anxiety you are experiencing can be immediately addressed and the scanning stopped if needed.

Blood tests: The risks associated with blood tests are minimal and include skin discoloration from bleeding, pain, infection, and fainting spells.

In-dwelling IV for infusion of the study medication: The risks associated with an indwelling IV are minimal and include bruising, clotting, bleeding, pain, and infection.

Inpatient sleep study procedures (4-night admission to the CCI research unit): Admissions of this length may be psychologically stressful and inconvenient or disruptive to daily routines.

Polysomnography sleep study: A minor rash may develop from the tape or adhesives used to attach electrodes. You may experience reduced quality of sleep if the monitoring equipment makes sleep somewhat more difficult than usual.

Emotional distress from completing questionnaires: Answering questionnaires may be upsetting given the sensitive nature of the information that is collected, including questions about depression and other mental health conditions as well as suicidal and other psychological symptoms.

Loss of confidentiality: Should there be a breach of confidentiality regarding psychiatric diagnosis, MRI findings, sleep studies, psychologic symptoms, or neurocognitive performance, you might be exposed to discrimination.

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

You may benefit from the close monitoring of your depression symptoms as well as related affective symptoms, sleep disturbance, hot flashes, and night sweats. You may directly benefit from brexanolone administration since allopregnanolone has been shown to improve mood in women with postpartum depression.

In this study, treatment with allopregnanolone aims to provide a meaningful benefit to perimenopausal women through knowledge gained about the underlying brain changes in depression that occurs during midlife when women's hormones are changing during the perimenopause.

If any of the routine testing (e.g. brain scans, sleep study recordings, hormone levels, psychological questionnaires) that is done during your visits is considered abnormal, we will provide that information to you so that you can discuss it with your doctor. With your consent, we will provide this information directly to your doctor.

What other treatments or procedures are available for your condition?

There are a number of FDA-approved medications that can treat depression, including antidepressants (e.g., SSRIs, SNRIs). Menopause-dosing of hormone therapy (estrogen with or without progesterone) can improve depression, especially when hot flashes and night sweats are present, but this is not FDA-approved to treat depression and it is not recommended as the primary treatment when depression is severe.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be compensated for the time, effort, and study procedure risks involved in this intensive study. You will receive up to $1,000 upon completion of all study procedures. You will only be compensated for those procedures you have completed. Payment will be provided at the end of the study and will accumulate according to the following schedule:

- Screening Visit - $100 ($50 for remote, $50 for in-person)
- Pre-admission MRI visit, if MRI eligible - $100
- Four-Night Inpatient Visit - $500 ($125/night if you depart early during the Inpatient Visit)
- Post-admission MRI visit, if MRI eligible - $100
- Follow-Up In-Person Visit - $100
- If MRI is completed during Follow-Up In-Person Visit $100

Reimbursement for transportation home after the inpatient visit will be provided. Parking vouchers or reimbursement up to $25 will be provided for outpatient in-person visits.

We may use your blood tests and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your blood tests or information are used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

Please consider it is your obligation, in the event you feel impaired in any way, to cease activity that may cause injury to yourself, to others or to property as a result of participating in this study.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In this study, we may collect identifiable information about you from:

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

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other: Sage Therapeutics, Inc., who are providing study drug, only in the instance of a serious adverse event.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be

included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Permission to Contact for Future Studies at BWH

Do you give us permission to contact you in the future about additional studies involving women's hormones, sleep, or mental health in which you might be interested in participating? Please check the appropriate box.

☐ Yes ☐ No Initials_ _____

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

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

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: 12/02/25