Mass General Brigham

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

Subject Identification

Protocol Title: Genetic Basis of Atypical Circadian Rhythms

Principal Investigator: Jacqueline Lane, PhD

Site Principal Investigator:

Description of Subject Population: People ages 22-95 with and without atypical circadian rhythm disorders

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.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, "you" always refers to the person who takes part study.

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 study we will test at home collections of dim light melatonin onset (DLMO) saliva samples. DLMO collections help assess your circadian rhythms. DLMO samples are usually collected on site at a circadian clinic, or at home with an assistant. This study will test DLMO samples completed self-directed by a participant collected at home.

How long will you take part in this research study?

You must be eligible to participate in this study. You completed a screen for study eligibility online. If you are interested, you may choose to participate in this study. To participate in this study, you must provide consent. You may provide consent by signing this form. Once you do, you are enrolled in the study.

From enrollment, it will take approximately 4 weeks to complete the study. During the 4 weeks, we ask for the following:

- Provide saliva samples collected in dim light
- Keep a daily sleep log
- Provide at-home activity tracking using wearable devices that we will provide
- Fill out questionnaires

More specifically, study duration can be broken down to the following approximate uninterrupted time commitments, including time to read instructions and prepare:

Activity	Approximate Time Commitment
Questionnaires	2 questionnaires, approximately 30 minutes
Daily sleep log	15 minutes, daily
Dim light saliva samples	8 hours, twice (approximately 16 hours), on separate days overlapping bedtime

The study is a self-directed, home-based study. This study doesn't require in-person visits. If enrolled in this research study, we ask that you avoid traveling across time zones while you are in the study.

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

You must provide consent to participate in this study. If you do, you will receive:

- Access to an online site for sample collection scheduling
- Access to online study material
- A study kit mailed to your home address

You will need to send the study kit material and samples back to us at the end of the study. We will provide shipping instructions and prepaid shipping labels at no cost to you.

Why might you choose to take part in this study?

You will not directly benefit from taking part in this research study. Others 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. Please take time to consider them. Risks and possible discomforts include the following:

- Sleep loss
- Acute increased gum sensitivity, risk of minor gum bleeding from hourly dim light melatonin saliva sample collection
- Skin irritation from wearable technology
- Side effects from refraining from alcohol, caffeine, nicotine, recreational drugs, specific foods, and/or melatonin
- Loss of confidentiality
- Length and time commitment required for study participation

Please see section “What are the risks and possible discomforts from being in this research study?”. This section includes detailed information on risks and possible discomforts.

When considering study participation, keep in mind study length. Including time to ship the study kit, the total study length is approximately four weeks. This requires some commitment to following and maintaining study protocol.

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.

Dr. Jacqueline Lane, PhD, is the person in charge of this research study. You can call her at 617-643-3067, Monday through Friday, 9AM-5PM with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call a study coordinator at (857) 265-6742 or email us at **circadiastudy@mgh.harvard.edu.**

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 857-282-1900.

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

Why is this research study being done?

We are doing this research to test at-home, self-directed instructions and collections of dim light melatonin onset (DLMO) samples. We will use this information to improve our work and future research.

Who will take part in this research?

Adults with suspected or confirmed atypical circadian rhythms, healthy adults.

We will recruit approximately 10 adults to take part in this research study. The research study will be self-directed, and home based. It will not require in person clinic visits.

What will happen in this research study?

You were screened and found eligible for consent. To participate in this study, you need to sign this consent form. No study procedures will occur until you have signed this consent form. The study procedures require 4 parts to be completed remotely:

1. Dim light melatonin saliva sample collections
2. Completion of about 4 weeks of daily sleep logs
3. Activity tracking
4. Two study questionnaires

Additionally, to participate in this study you will need to receive an at-home study kit, mailed to your address on behalf of the study. It will contain study collection materials, wearable technology, and material for return shipping

PART 1: Dim Light Melatonin Saliva Sample Collection

We will also ask you to collect dim light melatonin onset (DLMO) saliva samples. These samples will be collected on two separate days, separated by about 3-7 days. Samples will be collected over 8 consecutive hours. A total of 9 samples will be collected per DLMO collection. The collection will start about 6 hours before your usual bedtime. The collection will end about two hours after your usual bedtime. We will ask you to schedule your collection dates at the

beginning of the study using our secure study scheduling site. We will provide you instructions and a link to our scheduling site. You will need to schedule your sample collection dates before we ship a study kit to you.

You will need to collect DLMO samples in dim light conditions. Dim light conditions are dark with very little light. During this protocol, you will need to dim any electronics present in the room, such as a smartphone or television, to the dimmest possible setting. Certain electronics, such as laptops and tablets, will not be allowed during the collection. We provide instructions and tools for monitoring your light exposure.

The dim light melatonin saliva sample collection will be assessing your naturally occurring melatonin levels. Since melatonin levels can be altered by certain products, we ask you to refrain from using alcohol, caffeine, recreational drugs, nicotine and tobacco products, melatonin supplements, and to avoid certain foods for about 24 hours around your collection start time. We will also ask you to refrain from using certain products, like lip balm and toothpaste, during the saliva sample collections in an effort to protect sample integrity. We provide a comprehensive list in our instructions to aid you in preparation for sample collection.

We require tracking of the dim light melatonin saliva sample collection time. To make this easy, we will provide you a bottle with a time stamp lid containing collection swabs. We will send you timed reminders for sample collection through text, if you consent to receiving text. At each reminder, opening the tracker vial will record the time a collection swab is removed. We provide instructions on how the timed reminders will work. You may contact study staff if you need immediate help during your dim light melatonin saliva sample collection.

PART 2: Daily Sleep Log

You will need to keep a daily sleep log. This daily log will include questions about your sleep and sleep/wake timing. You will complete this daily log for the duration of the study, approximately 4 weeks.

PART 3: Activity Tracking

You will need to wear an activity tracker (Actiwatch) on your wrist. You will need to wear this for the duration of the at home portion of the study, approximately 4 weeks. The Actiwatch tracks your activity, light exposure, and sleep.

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.

At the completion of this research study, we would like to store and be able to use and share your identifiable samples and health information with researchers at Partners for other research related. If we share your samples and/or health information with other researchers outside of Partners, we will label the samples and information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your sample and/or information. We will keep the code in a password protected file.

Because these samples and/or health information are identifiable, we are asking your permission to store, use and share them for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing of the samples and health information for other research.

Do you agree to let us store and use your samples and health information for other research?

☐ YES ☐ NO Initial _____

Will you get the results of this research study?

You should not expect to get information about the results of the research study or the results of your individual participation in the research study. We and the researchers involved in the study will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we or the researcher could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

Study Communication via Text Message (Short Message Service)

Text messages by mobile/cell phones are a common form of communication. This study involves sending you text messages that are relevant to the research study. This study will use text messaging service to communicate with study participants.

Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. If you want to receive communications by unencrypted texts despite these risks, MGB/Partners HealthCare will not be held responsible for any interception of messages sent through unencrypted text message communications.

Below are some important points about texting in this research study:

- Please do not text us any information about your health. This is to protect your privacy. If you need to tell us anything related to your health, please call us instead.
- Should you opt to receive text messages to your personal mobile phone number, you will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and MGB/Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts. Participants will not be responsible for text message fees sent to the provided study smart-phone.
- Text messages will only be read during regular business hours or during scheduled at-home procedures, to provide additional support to participants. Texts sent on nights or weekends will not be read until the next business day, unless to provide support or guidance to participants completed an at-home study procedure.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from MGB/Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from MGB/Partners Healthcare is a separate process as well.
- It is your responsibility to update your personal mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Please select one of the following options:

☐ YES I consent to receive text messages related to this study to both my personal mobile/cell phone number .

☐ NO I do not consent to receiving any text messages related to this study to my personal mobile/cell phone number for text messages.

Study Communication via Unsecured Email

This study may communicate with you via email. The Partners standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare.

However, this study uses "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.

I have had the chance to ask questions about the use of unencrypted email with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted email communications associated with this research study.

Please select one of the following options:

☐ YES I consent to receive unencrypted email communications.

☐ NO I do not consent to receive unencrypted email communications.

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

Risks are minor in this research study, and are limited to the following:

1. Sleep loss
2. Acute increased gum sensitivity, risk of minor gum bleeding from hourly dim light melatonin saliva sample collection
3. Skin irritation from wearable technology
4. Side effects from refraining from alcohol, coffee, or melatonin
5. Loss of confidentiality

The outlined risks and possible discomforts are further outlined below:

1) Sleep Loss

You will complete dim light melatonin saliva collections. During this you may experience slight sleep deprivation. This is because the collection continues for about two hours past your bedtime. However, collection dates are based on your schedule. We do not foresee long-term effects from the dim light melatonin saliva collection.

2) Risk of Gum Sensitivity and Bleeding

The dim light melatonin saliva collection requires you to provide multiple saliva samples. These samples are provided within an 8-hour window. During this collection, you may experience increased gum sensitivity. You may experience slight gum bleeding. This may be from providing saliva collections within a short time frame. If you experience either, we anticipate that the effects will not be long-lasting.

3) Risks of Wearable Technology

The wristbands of the activity tracker may cause skin irritation. This may be from wearing the wristband too tightly. It may also be from skin that is not completely dry under the wristband. Soft medical tape may be worn under the wristband. This is provided in the at-home kit. If irritation persists or worsens, we advise you to remove the device and contact the study team.

4) Side Effects of Refraining from Alcohol, Caffeine, Recreational drugs, Nicotine and Tobacco products, Melatonin Supplements

For the dim light melatonin saliva sample collections, we ask that you refrain from consuming alcohol, caffeine, recreational drugs, nicotine/tobacco products, and certain foods that alter melatonin levels, and/or melatonin supplements for approximately 24 hours prior to the start of your collection protocol. We will supply a list of foods to refrain from consuming as part of the dim light melatonin saliva sample collection instructions. There are no expected side effects from refraining from these foods, however, it may require some planning depending on how often you consume the food items we specify. If you use alcohol, caffeine, recreational drugs, nicotine/tobacco products, and/or melatonin supplements regularly, this may cause some side effects from withdrawing your consumption. These side effects may include but are not limited to the following: headache, fatigue, sleep loss, low mood, irritability, fatigue. However, you may consume these products after study collection, thereby minimizing the length in time in which you may experience these side effects.

5) Loss of Confidentiality

It is possible that a mistake could lead to a loss of confidentiality. The study doctors and staff will make every effort to make sure that your private information is protected. However, a gap in security due to human error may make that information available to others. We will do our best to ensure none of your results from this study become part of your medical record.

We will also make sure no results shared with other investigators contain personal identifying information. However, much like fingerprints, it is possible to identify someone if certain data are put together. While we use very strict data security measures to protect your privacy, there is always a small risk that your data may lead to you being re-identified. As technology advances, there may be new ways of linking data back to you that we cannot foresee today. Like other medical information, this may one day affect your insurability or employment. While this risk is very small we cannot guarantee that it does not exist.

There may be other risks that are not known at this time.

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

There are no benefits from being in this study.

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?

Yes. You may receive up to $270 for participating in the study. You will receive $270 as follows:

- $90 for each completed dim light melatonin saliva sample collection ($10 per collected sample, up to $180)
- $15 per week of activity tracking and daily logging (up to $60)
- $20 dollars for return shipping completed kit within 5 business days of sample collections
- $10 for questionnaire completion

Your compensation is dependent upon returning study materials. Additionally, compensation will be withheld if the wearable activity monitor is not returned. If the wearable activity monitor is lost or stolen, a Lost or Stolen Study Device Report will need to be completed. The form may be accessed through the study portal. Once the form is reviewed and accepted by study staff, compensation will be released. Once you complete the study and returned study materials are received by study staff, we will mail checks to your home address. We will use the home address you provided us during recruitment. It may take 6-8 weeks after study completion for checks to be mailed. We require your social security number or tax ID number for compensation.

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. You may have questions about costs to you that may result from taking part in the research. In that case, 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.

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:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, 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 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.

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)

Consent Form Version: 06/03/2021