ClinicalTrials.gov Cover Page

Title: Effects of Light on Melatonin and Contractions in Pregnant Women **NCT #:** 01863446

Last IRB review date: Sept 25, 2022. Consent forms last versions (1) 1- day study Dec 20, 2017; (2) 2-day study Dec 2, 2016

Submit date: October 18, 2023

Protocol

Subject Selection

A total of 100 participants will be selected who are at 35-41 weeks of pregnancy. Inclusion criteria include nulliparity and age between 18 and 35. Women with clinical or histological chorioamnionitis, rupture of membranes >12h, abnormal vaginal discharge, or positive uterine cultures for β-strep, gonorrhea, trichomonas or syphilis will not be considered. Women who are color blind or on any medication that affects the sympathetic nervous system (e.g., beta-blockers) or with a BMI >35 pre-pregnancy will be excluded.

Subject Enrollment

Participants will be recruited by at the Brigham and Women's Hospital clinical practices and advertising. Clinicians will acquire from their patients written or verbal consent-to-approach to be contacted by study staff for participation in the study. Study staff will also recruit through internet and newspaper advertising, flyers and the BWH Center for Clinical Investigation's Research Study Volunteer Program (RSVP for Health). Women will meet with study staff at least 24 hours before the inpatient study to review inclusion/exclusion criteria, receive answers to questions about the study protocol and sign the consent form.

Participants will be randomized at admission to blue/green wavelength or red wavelength light by the investigator or her designate. We will encourage women to participate in Protocol 2; if they decline, we will offer enrollment in Protocol 1.

Study procedures

The study will begin at least one week before the inpatient admission. Dr. Klerman or her study representative will meet with the prospective volunteer to review the study, answer questions and have the volunteer sign the consent form. At that time or approximately one week before the inpatient admission, Dr. Klerman or her designate will (i) give the volunteer a wrist-worn activity and light exposure monitor (actigraph) to wear through the end of the inpatient stay; and (ii) give the volunteer a sleep/wake log to complete. If the volunteer does not wish to wear the actigraph, Dr. Klerman or her designate will meet with her at least 24 hours before the inpatient to review the procedures and sign the consent form. For Protocol 1 only, all subjects will be asked to collect their urine at home for the 24 hours immediately before starting the inpatient experiments. Instructions for collection of the urine samples will be provided to the participants.

The inpatient experiments will be conducted in the inpatient Center for Clinical Investigation (CCI) on pod 9A or 9B of the BWH Towers. These facilities are staffed 24-hours per day and the nurses and technicians are trained in all the procedures to be performed except uterine tocometry and fetal monitoring. Since the uterine contraction data are collected and used only for research purposes and not for diagnosing maternal or fetal distress, the data collection will be monitored either by a non-clinician member of the research team or an Obstetrical nurse or ObGyn resident or fellow. Fetal assessment will be conducted by the physician-investigator at admission prior to the start of the study interventions.

Participants will be admitted in the afternoon and kept in dim light (<15 lux). An IV will be inserted into a forearm vein if blood sampling will occur. A small amount of heparin will continuously flow through the IV line to keep it patent, per BWH CCI guidelines, and as previously approved for other IRB Protocols (e.g., 2007P-000566). Hematocrit or hemoglobin levels will be checked; if values are below 30% (Hematocrit) or

10.8 (Hemoglobin), only saliva sampling will occur. Uterine tocometry will occur starting ~6 hours before habitual bedtime through ~10 hours after habitual bedtime. An external uterine tocometer will be applied.

We will collect blood approximately every 30 minutes and saliva approximately every 60 minutes and questionnaires about uterine contractions and subjective alertness will be given. Blood samples will be collected through an IV catheter. Saliva samples will be collected by having participants spit into a test tube. Starting at most 3 hours before their habitual bedtime, participants will be exposed to up to 5,000 lux blue/green or red light source (Protocol 1: random assignment at admission; Protocol 2: all women will be exposed to red light) for four hours. Therefore, participants will go to sleep approximately 2 hours after their usual bedtime. During this time, we will try to standardize posture (request that she remains seated) and timing of bathroom breaks (request that the bathroom use be at a specified time) across all participants; the participant, however, may change posture and use the bathroom at any time she desires. We will collect all urine samples produced in the CCI. The samples will be used to assay melatonin metabolites. Room lights will remain at < 15 lux until they go to sleep (approximately 2 hours after their habitual bedtime) when lights will be turned off. During sleep, tocometer and (if more than 5 contractions per hour) fetal monitoring and IV sampling will continue but saliva collection and questionnaires will end. The tocometer and fetal monitor will remain until the participant awakens. For Protocol 1 only, sleep will be monitored using polysomnography. Surface electrodes are taped and/or glued to specific locations on the subject's face, head and torso in order to allow the recording of brain wave activity (EEG), horizontal and vertical eye movements (EOG), heart rate (ECG), and muscle activity (EMG). The recordings will be collected on an ambulatory digital recorder. The digitized data will be used for both spectral analysis and sleep stage scoring. Additionally, surface electrodes may be used around the abdomen to record uterine muscle activity externally. Approximately eight hours later, participants will be awoken. For Protocol 1, the IV and actigraphy will be removed and the participant will be discharged. The total amount of blood to be withdrawn should be ~28 ml (14 hours *2/hour*1 ml/sample). For Protocol 2, the IV and wrist-worn activity and light monitor will remain. The participant will be free to do as she wishes within the BWH room until 2 pm. At 2 pm, the events of the first night will be repeated. The experimental light will be randomized to red or blue/green light upon admission; this design enables each women to be their own control (i.e., red light exposure on night 1). Upon awakening from the second night, the IV and wrist-worn activity and light monitor will be removed. The total amount of blood to be withdrawn should be ~<50 ml (28 hours*2/hr*1 ml/sample except we will not take samples during 10 am-2 pm).

Approximately two weeks after due date, we will review the medical records to determine the date and clock time of delivery and date and clock time of onset of labor. We will use this information to monitor whether the study might have any effect on these measures.

Biostatistical Analysis

Primary analyses

Blood, urine and/or saliva samples will be sent for assay for melatonin and other sleep, circadian rhythm, and pregnancy-related hormone concentrations.

A trained technician, nurse or physician will review the tocometer reading and count the number of contractions per 30 minutes after excluding artifacts.

The actigraph will be reviewed for sleep/wake times and light exposure.

Secondary analyses

Statistical analyses will be performed for each of the measures collected every 30 minutes: number of contractions from tocometer, melatonin concentration, number of contractions from questionnaires, subjective alertness from questionnaires.

For Protocol 1:

1. mixed-model longitudinal analyses with light exposure condition (i.e., red vs. blue/green) as the fixed conditions and participant as the random condition;
2. 3-way ANOVA in the 2 hours before light exposure begins vs. 2 hours after light exposure in the 2 lighting exposure conditions.

For Protocol 1:

1. mixed-model longitudinal analyses with light exposure condition (night 1 vs. night 2) as the fixed conditions and participant as the random condition;
2. 3-way ANOVA in the 2 hours before light exposure begins vs. 2 hours after light exposure in the 2 lighting exposure conditions.

Protocol Title: Light and Melatonin Effects on Pregnancy

Principal Investigator: Elizabeth B Klerman MD PhD

Site Principal Investigator:

Description of Subject Population: Healthy pregnant women - One Night Study

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.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. 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.

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.

Why is this research study being done?

The purpose of this study is to examine the effect of light on pregnant women's uterine contractions and alertness. Light is known to decrease levels of the hormone melatonin that may affect uterine contractions near the end of a pregnancy. We are asking you to take part because you are a healthy pregnant woman. We expect 100 pregnant women to participate in the study.

How long will I take part in this research study?

The expected time to complete this study is approximately one week at home and then less than one day at the Brigham and Women's Hospital (BWH). You will stay in a room at the BWH from approximately 2 pm on one day through approximately 9 am the next day.

What will happen in this research study?

At least one week before your inpatient stay we will meet with you. We will discuss the study with you and answer questions you may have. If you agree to participate, you will sign this consent form.

Approximately one week before your inpatient stay we will meet with you. We will then give you an actigraph, a wrist-worn device that will monitor your activity and light exposure levels. You will wear this all the time day and night except when you are in the bath, showering, or in a pool. We will also give you a sleep/wake diary to complete about when you sleep (night or day) for the week. You will be asked to collect urine samples at home for the 24 hours immediately before starting the inpatient stay. We will give you instructions for how to do this.

On the day of your inpatient stay, at approximately 2 pm, you will come to the BWH. You should bring your urine samples. We will record your height, weight, blood pressure and heart rate. We will ask some questions about your pregnancy and measure the baby's heartrate. Starting about 4 hours before you usually go to sleep, we will put a strap around your stomach to monitor uterine contractions; the strap will remain for approximately 16 hours. We will put an IV tube into your arm; the IV tube will allow us to draw blood samples approximately every 30 minutes. The IV tube will remain until you leave the next day. A sterile solution with small amounts of heparin will flow slowly through the IV tube to keep the tube open. We will ask you to provide saliva samples by spitting into a test tube approximately every 60 minutes. We will collect all urine that you produce during your inpatient stay. We will also ask you to complete questionnaires approximately every 30 minutes about how alert you feel and about any uterine contractions you feel. You will complete these questionnaires and the saliva collection until you go to sleep and then again after you awaken the next day.

During the study, we will monitor your sleep using polysomnography (PSG), which measures brain electrical activity using electroencephalograph (EEG), eye movement using electrooculograph (EOG) and muscle-movement activity using electromyograph (EMG) and heart rate using electrocardiograph (ECG). EEG measures your brain waves so we can see what your brain is doing when you are asleep and awake. EOG and EMG measures eye movements

and muscle-movement activity which changes depending on your sleep and wake states and allows assessing the different stages of sleep. For the PSG recordings, we will:

- wash your head and face with special soap and with alcohol
- put small electrodes (sensors) with wires attached to them on your scalp, face and chin which will be used to measure EEG, EOG and EMG.
- attach the sensors with tape or with special glue.
- put 2 sensors on your chest for ECG.

We may also apply small electrodes around your abdomen to record uterine muscle movement.

A few hours before you usually go to sleep, we will turn on some lights in the room. The lights appear normal, red or blue/green. The lights will remain on for approximately 4 hours. During this time, we may ask you to stay seated; if you need to change positions you can. We may also ask you to have a bathroom break at specific times so that the posture pattern is the same for all participants. After that time, the lights will return to their previous appearance and brightness. We will collect all urine samples produced during your time at the BWH.

At approximately 2 hours after your usual bedtime, we will turn off all lights and you can try to go to sleep. The IV will remain in your arm and the strap will remain around your stomach. Approximately eight hours later, we will awaken you, turn on the lights, remove the IV, remove the actigraph, and give you a final questionnaire. The study will then end. We recommend that you not drive home after the study ends; we will pay for transportation or you should arrange for someone to pick you up.

The blood, saliva, and urine samples will be tested for the amounts of melatonin and other sleep, circadian rhythm, and pregnancy-related hormones.

There are video cameras and audio intercoms in the research area. These are for safety monitoring only; no recordings will be made. You cannot use any of your personal light-emitting electronic devices including your mobile phone, computer or tablet while you are in the study room. You will not have access to the internet or phones while you are in the room.

We will review your medical records approximately two weeks after your due date (1) on what dates and at what clock time did your labor begin and (2) on what date and clock time your baby was born. We want to know this information to monitor whether your study visit may have affected the time and date of delivery.

We reserve the right to end your participation at any time. You retain the right to end your participation at any time.

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

1) The risks of light exposure at night are reduced sleepiness when awake and increased problems falling asleep. There are no known risks of light exposure related to pregnancy. The light levels you will see are less than those outdoors during the day.
2) There may be some discomfort or bruising on initial insertion of the catheter into a vein, but wearing the catheter should not be painful. To help keep the venipuncture site clean, a portion of the forearm hair may be cut before insertion of the IV catheter. Occasionally, there is a black and blue mark at the site of the IV insertion, which may last a couple of weeks; and, rarely, a small scar may remain permanently at the venipuncture site. There is also the possibility of fainting during or after the procedure.
3) There may be some side effects from the use of heparin; such as bleeding.
4) There is a rare possibility of developing a small blood clot, inflammation, or local infection around the vein where the catheter is inserted, or in rare cases a generalized infection spread through the bloodstream as a result of the IV tube.
5) Occasionally, mild discomfort may occur from the IV tube in the vein. If this happens, we will either reposition it or remove it entirely, asking permission before any subsequent reinsertion.
6) The amount of blood drawn should not significantly alter blood volume, although there may be a small decrease in the red blood cell concentration (hematocrit). However, the total amount of blood drawn over the course of the study (less than 100 ml) is less than the amount normally drawn during a ~ 1 hour blood donation. Hematocrit levels will be checked before the study starts.
7) You will be able to read paper-based materials and listen to music; you will not be allowed to use any electronic devices that might emit light (e.g., TV, laptop, tablet, mobile phone while receiving the experimental light exposure.
8) After the experimental light exposure, you may experience something called an after-effect. This is a temporary condition that will last for a few minutes afterward, in which items viewed in white light may be tinted with the complementary color (i.e., a greenish tint after red light exposure). After a few minutes, color vision will return to normal. Such exposure to light of a specific color has no known long-term effects on color vision.
9) The tape and paste used to apply and remove the electrodes for EEG may cause some minor discomfort and/or skin irritation. The glue used to hold electrodes to the scalp may leave a flaky material in your hair for several days.

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

There are no immediate benefits from participating in this research study. You may experience a temporary decrease in the number and/or strength of uterine contractions or you may not. You may feel more alert and/or less sleepy or you may not.

If light does reduce the number and/or strength of contractions, then it may be a relatively safe, inexpensive and easy to use method for decreasing uterine contractions for pregnant women before their labor and delivery of the baby begins.

What other treatments or procedures are available for my condition?

There are no other treatments or procedures for normal term uterine contractions in healthy pregnant women.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners 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.

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. 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 I do if I 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 I be paid to take part in this research study?

You will be paid $25 for wearing the actigraphy and completing the sleep/wake diary for approximately one week and $500 for completing the 24 hour urine collection and the overnight stay. We will also reimburse your reasonable travel and/or parking costs.

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

The study funds will pay for the study related costs.

Although 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 I am injured as a result of taking part in this research study?

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 next section of this consent form.

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

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

Elizabeth B Klerman MD PhD is the person in charge of this research study. You can call her at 617-732-5500 at any time.

If you have questions about the scheduling of appointments or study visits, call Wendy Chan at 617-525-3201 or 617-525-7254 M-F 9-5.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health 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 health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers

- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health 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 health 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 health 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 information for any mailing or marketing list. However, once your information is shared outside Partners, 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 health information.

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 identifying 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 health 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 health 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.

You have the right to see and get a copy of your health 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)

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: 18 Dec 2017

Protocol Title: Light and Melatonin Effects on Pregnancy

Principal Investigator: Elizabeth B Klerman MD PhD

Site Principal Investigator:

Description of Subject Population: Healthy pregnant women - 2-day study

About this consent form

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Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. 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.

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.

Why is this research study being done?

The purpose of this study is to examine the effect of light on pregnant women's uterine contractions and alertness. Light is known to decreased levels of the hormone melatonin that may affect uterine contractions near the end of a pregnancy. We are asking you to take part because you are a healthy pregnant woman. We expect 40 pregnant women to participate in the study.

How long will I take part in this research study?

The expected time to complete this study is approximately one week at home and then two nights (including the day in between) at the Brigham and Women's Hospital (BWH). You will stay in a room at the BWH-from approximately 2 pm on one day through approximately 9 am two days later.

What will happen in this research study?

Approximately one week before your inpatient stay we will meet with you. We will discuss the study with you and answer questions you may have. If you agree to participate, you will sign this consent form. We will then give you an actigraphy, a wrist-worn device that will monitor your activity and light exposure levels. You will wear this all the time day and night except when you are in the bath, showering, or in a pool. We will also give you a sleep/wake diary to complete about when you sleep (night or day) for the week.

On the day of your inpatient stay, at approximately 2 pm, you will come to the BWH. We will record your height, weight, blood pressure and heart rate. We will ask some questions about your pregnancy and measure the baby's heartrate. Starting about 4 hours before you usually go to sleep, we will put a strap around your stomach to monitor uterine contractions; the strap will remain for approximately 16 hours between approximately 4 pm and 8 am. We will put an IV tube into your arm; the IV tube will allow us to draw blood samples approximately every 30 minutes. The IV tube will remain until you leave two days later. A sterile solution with small amounts of heparin will flow slowly through the IV tube to keep the tube open. We will ask you to provide saliva samples by spitting into a test tube approximately every 60 minutes when you are awake. We will also ask you to complete questionnaires approximately every 30 minutes when you are awake about how alert you feel and about any uterine contractions you feel. You will complete these questionnaires and the saliva collection until you go to sleep and then again after you awaken the next day.

A few hours before you usually go to sleep, we will turn on some lights in the room. The lights appear normal, red or blue/green. The lights will remain on for approximately 4 hours. During this time, we may ask you to stay seated; if you need to change positions you can. We may also ask you to have a bathroom break at specific times so that the posture pattern is the same for all participants. After that time, the lights will return to their previous appearance and brightness.

At approximately 2 hours after your usual bedtime, we will turn off all lights and you can try to go to sleep. The IV will remain in your arm and the strap will remain around your stomach.

Approximately eight hours later, we will awaken you, turn on the lights, stop blood and saliva collection, and remove the tocometer strap.

You will then be free to do as you want in the room until approximately 2 pm that day. Starting at 2 pm, we will repeat all the events that we did on the first night. The lights may be the same or different.

On the next morning, when we awaken you, we will also remove the IV and the actigraph, and give you a final questionnaire. The study will then end. We recommend that you not drive home after the study ends; we will pay for transportation or you should arrange for someone to pick you up.

We will collect all urine samples produced during your time at the BWH. The blood, saliva, and urine samples will be tested for the amounts of melatonin and other sleep, circadian rhythm, and pregnancy-related hormones.

There are video cameras and audio intercoms in the research area. These are for safety monitoring only; no recordings will be made.

You cannot use any of your personal light-emitting electronic devices including your mobile phone, computer or tablet while you are in the study room from 2 pm until the next morning on both days. You will not have access to the internet or phones while you are in the room from 2 pm until the next morning on both days.

We will review your medical records approximately two weeks after your due date (1) on what dates and at what clock time did your labor begin and (2) on what date your baby was born. We want to know this information to monitor whether your study visit may have affected the time and date of delivery.

We reserve the right to end your participation at any time. You retain the right to end your participation at any time.

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

1) The risks of light exposure at night are reduced sleepiness when awake and increased problems falling asleep. There are no known risks of light exposure related to pregnancy. The light levels you will see are less than those outdoors during the day.
2) There may be some discomfort or bruising on initial insertion of the catheter into a vein, but wearing the catheter should not be painful. To help keep the venipuncture site clean, a

portion of the forearm hair may be cut before insertion of the IV catheter. Occasionally, there is a black and blue mark at the site of the IV insertion, which may last a couple of weeks; and, rarely, a small scar may remain permanently at the venipuncture site. There is also the possibility of fainting during or after the procedure.

3) There may be some side effects from the use of heparin; such as bleeding.
4) There is a rare possibility of developing a small blood clot, inflammation, or local infection around the vein where the catheter is inserted, or in rare cases a generalized infection spread through the bloodstream as a result of the IV tube.
5) Occasionally, mild discomfort may occur from the IV tube in the vein. If this happens, we will either reposition it or remove it entirely, asking permission before any subsequent reinsertion.
6) The amount of blood drawn should not significantly alter blood volume, although there may be a small decrease in the red blood cell concentration (hematocrit). However, the total amount of blood drawn over the course of the study (less than 100 ml) is less than the amount normally drawn during a ~ 1 hour blood donation. Hematocrit levels will be checked before the study starts.
7) You will be able to read paper-based materials and listen to music; you will not be allowed to use any electronic devices that might emit light (e.g., TV, laptop, tablet, mobile phone from 2 pm until the next morning on both days.
8) After the experimental light exposure, you may experience something called an after-effect. This is a temporary condition that will last for a few minutes afterward, in which items viewed in white light may be tinted with the complementary color (i.e., a greenish tint after red light exposure). After a few minutes, color vision will return to normal. Such exposure to light of a specific color has no known long-term effects on color vision.

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

There are no immediate benefits from participating in this research study. You may experience a temporary decrease in the number and/or strength of uterine contractions or you may not. You may feel more alert and/or less sleepy or you may not.

If light does reduce the number and/or strength of contractions, then it may be a relatively safe, inexpensive and easy to use method for decreasing uterine contractions for pregnant women before their labor and delivery of the baby begins.

What other treatments or procedures are available for my condition?

There are no other treatments or procedures for normal term uterine contractions in healthy pregnant women.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners 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.

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. 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 I do if I 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 I be paid to take part in this research study?

You will be paid $25 for wearing the actigraphy and completing the sleep/wake diary for approximately one week, $250 for the first night and $525 for the 2nd night. We will also reimburse your reasonable travel and/or parking costs.

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

The study funds will pay for the study related costs.

Although 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 I am injured as a result of taking part in this research study?

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 next section of this consent form.

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

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

Elizabeth B Klerman MD PhD is the person in charge of this research study. You can call her at 617-732-5500 at any time.

If you have questions about the scheduling of appointments or study visits, call Dr. Klerman at 617-732-5500 x33947 M-F 9-5.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health 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 health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health 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 health 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 health 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 information for any mailing or marketing list. However, once your information is shared outside Partners, 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 health information.

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 identifying 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 health 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 health 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.

You have the right to see and get a copy of your health 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)

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: 18 March 2016