UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Bright Light Treatment At Home To Improve Symptom Management of Fibromyalgia Syndrome

Company or agency sponsoring the study: National Institute of Health
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Helen Burgess, Ph.D., Department of Psychiatry, University of Michigan
Study Coordinator: Muneer Rizvydeen, Department of Psychiatry Sleep

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The purpose of this study is to determine the effect a morning light treatment has on improving symptoms in people with fibromyalgia syndrome (FMS). FMS is a syndrome characterized by chronic widespread pain. The light treatment will be administered using a wearable light device that is already commercially available and safe.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Inclusion Criteria

- People 18 years or older
- With chronic widespread pain
- Physically able to travel to the laboratory
- Must understand English well enough to participate

Exclusion Criteria

- If you are a woman of child-bearing potential, you should not be pregnant or trying to get pregnant, or breastfeeding
- Those with severe hearing or memory problems

- A history of eye surgery or photosensitizing medications (medications that make your eyes light sensitive)
- Cardiovascular disease (heart and blood vessel problems, blood pressure ≥140/90 mmHg)

3.2 How many people are expected to take part in this study?
We expect to enroll 80 subjects in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

1) Height, Weight, Vision, Alcohol and Drug Tests: After you are enrolled in the study, we will drug test you (see below) and will measure your height and weight, take your blood pressure, and test your eyesight.
2) WatchPAT: After that you will receive a WatchPAT device which consists of a wrist monitor and finger probe. You will wear the WatchPAT device for 1 night of sleep and return it to the lab the next day. The WatchPAT device is FDA approved to assess the severity of any sleep disordered breathing you may have.
3) Wrist Activity Monitor: After the WatchPAT night, you will be required to wear a wrist activity monitor, which looks like a wrist watch, for the entire study, even when sleeping or showering. It will record your movements and tells us when you are asleep. After the light treatment starts (see below), we will download data from the wrist monitor to confirm you are waking at the assigned light treatment time and not napping in the 4 hours after the light treatment.
4) Sleep at Home: When you sleep at home, you will be asked to follow your usual bed and wake times. It is very important your sleep schedule is not influenced by special events (for example: weddings, vacations, concerts, exams, etc.).
5) Daily Sleep and Medication Questionnaires: You will be required to complete a sleep and medication questionnaire every day.
6) Questionnaires: During some of the laboratory visits you will be asked to complete questionnaires about your pain and physical function, sleep and mood.
7) Light Treatment at Home: After the first week in the study, we will give you a Re-timer® device so you can start your light treatment the next morning and continue the light treatment for 28 days (4 weeks). You will be randomly (by chance) assigned to receive 1 of 2 different light treatments. You will be told the set time to start your light treatment every morning, which will be close to your usual wake time, or up to 1 hour earlier to accommodate your morning schedule. We will provide you with an alarm clock to help you wake up on time to start the light treatment. The light treatment goes for 1 hour and it is important you do not nap in the 4 hours after the end of the light treatment. We will contact you every day during the light treatment to see if you are having any problems with the light treatment. During the laboratory visits we will download data from the Re-timer® and you will receive feedback on your adherence with the light treatment.
8) Alcohol Breath Test: We will breathalyze you during the study (you will blow into a meter that measures the alcohol in your body). If you test positive, indicating the presence of alcohol, you will be dropped from the study, but this information will be kept confidential.
9) Recreational Drugs: You must refrain from taking recreational (street) drugs during the entire study. You will be asked to give a urine sample on the day you start the study, to test for

common drugs of abuse. If it is positive, indicating the presence of drugs, you will be dropped from the study, but this information will be kept confidential.

10) Menstrual Cycle: We need to keep track of where you are within your menstrual cycle during the study. When you enroll in the study we will ask you when your last menstrual period started. If you do not start your menstrual cycle during the study, we will follow up with you after the study has ended to find out the start date of your next menstrual cycle. We need to know this for research purposes only, in order to analyze the data properly. If you are menopausal we will not need to ask you about your menstrual cycle.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled laboratory visits, and report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?

This study is 37 days long. There will be 7 laboratory visits which will vary between 1-3 hours long. The first visit will be a screening visit to determine if you meet the study inclusion criteria. If you do, there will be 6 more laboratory visits. The morning light treatment is 1 hour long and will need to occur every morning at a fixed time, for 28 days (4 weeks).

4.3 When will my participation in the study be over?

Your participation will be over after your last laboratory visit.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information may be shared with the National Institute of Health.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- Some of the questionnaires may ask you very personal information about your physical and mental health and this may be uncomfortable for you.
- The WatchPAT device consists of a wrist monitor and finger probe that you will wear for 1 night. The finger probe fits snugly and you may wake during the night feeling some pressure on your finger. Most people are able to wear the WatchPAT for an entire night of sleep.
- The light treatment at home may shift your circadian (body clock) and you may experience symptoms of "jet-lag" like those experienced by jet travelers. These symptoms may include an upset stomach (nausea and/or diarrhea), fatigue, sleepiness, and/or headache. The Re-timer®

device is safer than sunlight because it does not contain any UV light. Your pain may get better or worse during the study.

The researchers will try to minimize these risks by:

- Providing a quiet space, free from observers, when completing the questionnaires. We will also explain the meaning of confidentiality as it relates to this study.
- Providing a comfortable setting with trained study personnel if you experience discomfort.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, you may find that the light treatment at home improves your pain. Others may also benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
There may be other ways to treat your FMS, including medication or other experimental treatments. Your doctor can tell you more about these other treatments, their risks, and their possible benefits. You should have this discussion about the risks and benefits or other alternatives prior to making your decision about whether or not you wish to take part in this research study.

You have the right to withdraw from the study at any time. If you wish to withdraw, please let any of the research staff know that you wish to withdrawal. Any data already collected will be kept on file.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
You may withdraw from this study at any time. There are no penalties for doing so and withdrawing will not pose any dangers to you. There is no harm associated with choosing to withdraw from this study. However, research staff may conduct an exit interview as to why you are choosing to withdraw, which could cause minor inconvenience.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
If you complete the entire study, you will be paid a total of $670 for your study participation. This payment includes reward for participation in addition to covering costs associated with traveling to the 7 laboratory visits. Payment may take up to a week to be processed. The payment will be reported to the Internal Revenue Service. We will collect your social security number when you begin the study in order to process your payment. We will need all the equipment returned before we process any payment for you.

The schedule of payments is as follows:

- You will be paid $50 when you complete the 1 night wearing the WatchPAT device and return the WatchPAT device to our research staff.

- Thereafter, you will be paid $100 for each week of the study you complete, with an extra $50 payment on your last laboratory visit.
- You will be paid a $10 travel stipend for each laboratory visit to cover costs associated with travelling to the laboratory.

If we have to drop you for not following the rules (for example: failing the breathalyzer or drug tests, taking off wrist monitor or not completing the light treatment every day) you will only be paid for your time in the study during which you followed the study rules.

8.3 Who could profit or financially benefit from the study results?
There is no current expectation that the investigators or the University of Michigan will benefit financially from the study results. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Study records that contain patient names will have access limited to the Principal Investigator and the immediate research team that is collecting the data. Confidentiality will be preserved by coding all study data with a unique identifying research number, and referring to this number in all analyses. You will not be identified in any reports on this study. The master list with both names and identifying numbers will be kept by the Principal Investigator in a secure location at the University of Michigan, while the remaining information, with only identifying numbers, will be kept in another secure location at the University of Michigan. Each data set will be kept secure and confidential in the manner required by federal, state, and local law.

We will do everything we can to keep others from learning about your participation in the research. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute of Nursing Research which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. I f you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document**.**

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission does not expire unless you choose to cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Helen Burgess, PhD
Mailing Address: Department of Psychiatry, Rachel Upjohn Building
4250 Plymouth Road
Ann Arbor, MI 48104-2700
Telephone: 734-615-8303

Study Coordinator: Muneer Rizvydeen
Mailing Address: Department of Psychiatry, Rachel Upjohn Building
4250 Plymouth Road
Ann Arbor, MI 48104-2700
Telephone: 734-764-1320

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a signed copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent to Participate in an Optional Sub-study: Use of an Apple Watch to identify sleep stages

We are also conducting an add-on study looking at the use of an Apple Watch plus an app to help us identify different stages of sleep using information already collected by a smart watch (e.g. heart rate). This information will help us better understand how bright light treatment affects the underlying sleep architecture in patients with fibromyalgia. This add-on study is completely optional. You can be in the main FibroLight study without consenting to this add-on study.
If you say yes to being in this add-on study you will be asked to wear an Apple Watch and install an app on your phone. The app was developed by the researchers to analyze the heart rate and accelerometer data already collected by the Apple Watch. You will wear the Apple Watch and enter information about your exposure to light into the app for the entire 5 weeks of the main study. On some nights you will press a button on the watch to indicate when you're going to bed. You will be paid $40 per week that you wear the watch and use the app (up to $200 total) *in addition to* the money from the main study.

Being in this add-on study does not involve extra risk beyond the main other than the increase in burden to you: there is the potential annoyance at having to wear a smart watch for the entire study and the time associated with daily logging in the app. If you decide that wearing the watch and using the app proves too burdensome, you may withdraw from the add-on study while staying in the main study.

The data we collect from the Apple Watch and app will be coded, just like the data from the main study. Data from the main study will combined with data from this add-on study, and the researchers who analyze the Apple Watch and app data will not have access to your identifying information.

If you agree to being in this add-on study, please check the appropriate box below and sign and date in the Sig-C box.

Sig-C

Consent to Participating in an Add-on Study –Apple Watch to identify sleep stages
This project involves wearing an Apple Watch and using an app to help researchers better understand how sleep in patients with fibromyalgia. I understand that it is my choice whether or not to take part in this add-on study. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to take part in the optional add-on study.

_____ No, I do not agree to take part in the optional add-on study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____