Consent to Participate in Research

Study Title: Light Therapy As a Non-Pharmacologic Intervention to Decrease Anxiety in Pregnant Women with Opioid Use Disorder

Principal Investigator: Heather Miller MD

Sponsor and/or Funder: Center for Pain and Addiction, University of Arizona

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. This consent contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

You are being invited to participate in a study about the anxiety-reducing effect of light therapy in pregnant patients with opioid use disorder. During the study, you will be exposed to an LED light for 2 hours every day from the time you are enrolled in the study until you are 36 weeks pregnant (or deliver, whichever comes first).

Why is this study being done?

Opioid use disorder during pregnancy is a complex medical problem. There are currently evidence-based pharmacologic interventions, such as methadone and suboxone, that are shown to improve prenatal care and pregnancy outcomes; however, many pregnant patients desire to try alternative methods to help maintain sobriety. Anxiety is known to increase at baseline as pregnancy progresses. This study is designed to investigate the possibility of reducing pregnancy anxiety scores in pregnant women with opioid use disorder by exposure to certain colors of light.

What will happen if I take part in this study?

If you decide to participate in this study, you will be asked to sign this consent form. Before you are included, the following criteria must be met.

Inclusion Criteria:

1) Pregnant women between 20 – 32 weeks gestation with a diagnosis of opiate use disorder receiving care through Banner University Medical Center North Mothers Over Medicine (MOMs) Clinic, a high-risk pregnancy clinic for women with substance use disorder complicating pregnancy

Exclusion Criteria:
1) Inability to speak or understand English
2) Incarcerated individuals
3) Age <18 yo

Once you have signed the informed consent form and have met all eligibility criteria to participate, the following procedures will be conducted. During the initial baseline visit, we will collect several pieces of data from you that are considered part of the routine care. We will also ask you to fill out a survey on childhood experiences. We will administer a questionnaire (the State-Trait Anxiety Inventory - STAI) to assess your anxiety level at time of entry into the study.

You will be randomly assigned to the active treatment group or control group. In other words, you will have a 50/50 chance (like a coin flip) of being assigned to the color of light being investigated or the control-colored light. Twenty-six identical pieces of papers will have either a red or a green dot in the center and folded in half. The papers will be placed in a container and you will be asked to pick a paper without looking. If you draw a paper with a red dot, you will be assigned to the control group. If you draw a paper with a green dot, you will be assigned to the active treatment group. You will be unaware of which group you were assigned to until the end of the study. The overall randomization ratios will be 1:1. Each group will have 13 patients.

You will be asked to locate a dark room in your house after you receive the study light. You will place the provided LED strip near you on a flat surface and turn it on for two hours a day until 36 weeks or time of delivery, whichever comes first. You have the freedom to pick anytime during day or night to use the light. We will ask you to be as consistent as possible with the time you choose. You can engage in any activity to pass the time as long as it does not involve exposure to another light from an outside source (computers, TV, smart phones, tablets, etc…). You will be asked to fill out the surveys mentioned above. When you return your study light, you will be asked to perform the STAI survey once again.

Co-interventions:
You are allowed to receive usual care, including co-interventions, as deemed necessary by the treating physician.

How long will I be in this study?

You will be in this study for approximately 4-16 weeks. The study start date and the outcome assessment timeline will begin the day of your baseline visit. The study is expected to start when you are enrolled and receive a light, and will end at 36 weeks or when you deliver your baby, whichever occurs first. At time of study completion, we will ask you to return the light.

How many people will take part in this study?

Up to 26 subjects will be enrolled in this study.

What benefits can I expect from being in this study?

You may notice decreased anxiety or increased calm as a result of using light therapy consistently.

What risks, side effects or discomforts can I expect from being in the study?

There have been no reported side effects of exposure to these wavelengths of light. There is virtually no risk known.

What other choices do I have if I do not take part in this study?

You may choose not to participate in this study without penalty or loss of benefits to which you are otherwise entitled. Whether or not you choose to participate, you will have access to regular prenatal care.

When may participation in the study be stopped?

Your participation is voluntary. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona or Banner Health. If you choose to discontinue participation, you are asked to contact the Principle Investigator in writing. Contact information is under "Who can answer my questions about the study" at the end of this document.

The study may be stopped by the investigator for any of the following reasons:

1) Violation of any of the inclusion criteria.
2) Aggressive behavior towards the clinic staff.
3) Development of new or discovery of already existing medical condition(s) that was not there during the initial screening if such condition(s) may interfere with the study.
4) Sustaining an injury that may interfere with accurate gathering of the data.
5) Any situation that hinders your access to assigned light and follow-up appointment.

What happens if I am injured because I took part in this study?

The study intervention is considered to be minimal risk. If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study. You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

What are the costs of taking part in this study?

There should be no cost other than your time. You will take your surveys and receive/turn in lights during your regularly scheduled prenatal visits.

The LED lights and services performed for research only, will be provided at no charge to you or your insurance company. Routine medical care performed while participating in study will be billed to you and/or your insurance company. This will include (but is not limited to) physical exam, routine lab work, administration of medications, and the treatment of side effects.

Not all insurance companies are willing to pay for services performed in a clinical trial. You will be responsible for any charges that your insurance does not cover including regular co-payments and deductibles. Please speak with your insurance company to find out what you may be financially liable for.

Will I be paid for taking part in this study?

You will receive a $50 gift certificate of your choosing at completion of the study, after you take the final STAI survey and turn in your study light.

Compensation for participation in a research study is considered taxable income for you. We are required to obtain your name, address, and Social Security number for federal tax reporting purposes. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes.

Will my data or specimens be stored for future research?

No data or specimens will be stored for future research.

Will my specimens be sold for commercial profits?

No data or specimens will be sold for commercial profit.

Will I hear back on any results that directly impact me?

You will not receive any clinically relevant results discovered about you and/or the general subject population.

Will Whole Genome Sequencing be done with my specimen?

No Whole Genome Sequencing will be done with your specimen.

Will my study-related information be shared, disclosed, and kept confidential?

It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose

your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- *Banner University Medical Group and Banner Health*
- The University of Arizona (UA) and the UA Institutional Review Board
- The sponsor and/or funder supporting the study, their agents or study monitors
- Your primary care physician or a specialist taking care of your health.

If you agree to take part in this study, a copy of this signed informed consent form will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Information learned from the procedures described in this consent form
- Demographic information
- Date of birth
- Obstetric history
- Opiate replacement therapy
- Opiate use during admission for delivery (both maintenance therapy and therapy for acute pain)
- Past medical and surgical history
- Current medications
- Radiological images
- Allergies

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for

participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, and genetic information (e.g., genetic testing). The study staff may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

What do I need to know if I decide to cancel my authorization?

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under “Who can answer my questions about the study” at the end of this document.

Will access be limited to my research study record during this study?

You will not have access to the research information developed as part of this study until it is completed.

Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact Heather Miller, M.D. at 520-626-6636 or hlmiller@obgyn.arizona.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact

the Human Subjects Protection Program Director at 520-626-8630 or online at http://rgw.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Heather Miller, M.D. at 520-626-6636 or hlmiller@obgyn.arizona.edu.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at 602-839-4583 or BHResearchCompliance@bannerhealth.com.

To cancel your authorization for access to PHI you must notify the *Principal Investigator* and/or *Research Team* in writing at the following address:

Heather Miller, M.D.
Department of Obstetrics & Gynecology
1501 N. Campbell Ave.
Tucson, AZ 85724

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.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form.

Printed name of subject	Signature of subject	Date

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent	Date