UF | Institutional Review Board
UNIVERSITY of FLORIDA

***INFORMED CONSENT FORM***
***to Participate in Research, and***

***AUTHORIZATION***
***to Collect, Use, and Disclose Protected Health Information (PHI)***

## INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

## GENERAL INFORMATION ABOUT THIS STUDY

**1. Name of Participant ("Study Subject")**

_____

**2. What is the Title of this research study?**

PHOTOBIOMODULATION FOR THE MANAGEMENT OF TEMPOROMANDIBULAR DISORDER PAIN

**3. Whom do you call if you have questions about this Research Study (the "Study Team")?**

Principal Investigators: **Margarete Ribeiro-Dasilva**
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Office (352) 273-8626

**Roger B. Fillingim**
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Study Coordinator: Selenia Rubio**, Study Coordinator**
University of Florida, College of Dentistry
(352) 273-5590

Lab Manager: Eric Weber, Study Coordinator
University of Florida, College of Dentistry
(352) 273-7802

**4. Who is paying for this Research Study?**

The sponsor of this study is the National Institute of Dental and Craniofacial Research.

**5. In general, what do you need to know about this Research Study?**

This is a clinical trial to evaluate the effects of a treatment using red light (cold laser and LED), known as photobiomodulation, as a potential treatment of Temporomandibular disorder. If you agree to participate in this research, you will need to come to our facility for a total of 11 sessions during a 7-8 month period of time. Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

**a) In general, what is the purpose of the research, and how long will you be involved**?

The purpose of this research study is to learn about a possible treatment for temporomandibular disorder (TMD) pain.

This study will test the use of Photobiomodulation (PBM), which is a combination of two different types of light, low-level laser therapy (LLLT) and Light-emitting Diodes (LED). PBM has been used to treat different pain conditions for over 30 years. This study will test if this type of treatment is helpful for people with TMD pain. For the PBM treatment, you will be randomly assigned (like the flip of a coin) to receive either real or sham PBM. Sham PBM is similar to the real version, but the light that is applied is much lower in strength and is not expected to reduce your pain.

This study includes a pre-treatment visit, followed by 8 treatment visits over a 3-4 week period. You will have a post-treatment visit about one week later, and then there will be a follow-up phone interview at 1 month and 3 months. The last visit will be a follow-up visit 6 months after the treatment ends. Therefore, you will be involved in the study for 7-8 months.

**b) What is involved with your participation, and what are the procedures to be followed in the research?**

You are being asked to be in the study because you are between 18 and 99 years of age and have TMD symptoms.

As mentioned before, participation in this study will consist of eleven visits over 7-8 months.

At your first visit, we will make sure you are eligible to participate. We will perform a clinical exam to see if you have the type of TMD we are studying. We will measure your sensitivity to pressure in several areas of your face and body, and you will answer some questionnaires. If you are eligible to continue in the study, you will be asked to complete a daily symptom diary for one week before the next visit, which we call V1. During V1, we will confirm if you are still eligible. If so, we will draw a **Blood Sample** (approximately 4-8 teaspoons) for analysis of

biomarkers. At V1, we will randomize you to either active or sham PBM, and you will have the first treatment. This will be followed by seven more clinical treatment visits over the next several weeks. We will try to schedule two to three treatment visits per week if possible. At your fifth visit (V5), in addition to the treatment, we will perform the same procedures as the ones performed during clinic visit 1 (V1) including a blood sample. After the last treatment visit (V8), a Post-Intervention visit or visit 9 (V9) will be scheduled, which will include the same procedures as V5, but there will not be a PBM treatment nor a urine test (if applicable) at V9. We will ask you to complete Daily Symptom Diaries each day from V0 to V9. One month and three months after V9 you will receive a phone call and/or an email to answer some questionnaires. Finally, 6 months after V9, you will be invited to come for a clinical visit 10 (V10). At this visit, final assessments will be performed, which include answering questionnaires, a TMD exam, measurement of sensitivity to pressure in several areas of your face and body, and a final blood draw.

**c) What are the likely risks or discomforts to you?**

- **TMD Examination and Pressure Tests.** Two types of assessments will be performed that may produce transient discomfort: the TMD examination, and tests for Pressure Pain Threshold (PPT). None of these assessments is expected to result in lasting discomfort or damage to affected tissues. Brief redness or tenderness of the skin is possible after these tests. However, if you feel the pain is greater than you wish to tolerate, you can stop the procedure at any time.

- **Blood Collection.** Risks of drawing blood include discomfort at the site of the puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. We reduce these risks by using sterile needles, alcohol swabs, application of pressure to your arm after removing the needle, and use of trained staff who are experienced in collecting blood samples.

- **Questionnaires**. You may experience discomfort from being asked personal questions about your health history, symptoms, or feelings. You are free not to answer those questions.

- **PBM therapy.** PBM may produce mild discomfort such as feelings of warmth or heat at the application site, redness, itching, dryness, and dry mouth. If you feel uncomfortable, you can stop at any time. Because the light from the device could possibly harm your eyes and your vision, you will be provided with goggles to protect your eyes from the light. If you experience sensitivity to the heat from the probe, we will temporarily remove the probe from your skin and it will be kept around 15 mm away from the skin. If the discomfort continues, the treatment will not be applied to the affected area.

- **Violation of Confidentiality.** The risk of violation of confidentiality exists because human participants are providing personal information, including biological data. Strategies to minimize this potential risk include collecting only

minimal identifying information, using unique study codes for participants, and storing data collection documents on secure, password-protected servers or in a locked private office within locked filing cabinets. Password-protected computers will be used, and only individuals involved in the study will have access. Compliance with all IRB regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed.

- To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

**d) What are the likely benefits to you or to others from the research?**

You may or may not benefit from receiving the PBM, but it is possible that you may experience decreased pain and improved jaw movement. Also, this research may help other people in the future by helping to find treatments that reduce TMD pain. The study PBM therapy will not be provided to you once your participation in the study has ended.

**e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?**

The other option to taking part in this study is not participating.

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.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

## WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

**6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?**

Regular medical care for your TMD and other medical conditions will continue to be given by your regular doctors, nurses, and other providers. This study does not offer any additional medical care.

**7. What will be done only because you are in this Research Study?**

You have already completed a brief telephone or in-person screening to find out if you meet the initial criteria to be in the study. During today's visit (V0), we will collect more health information, including a clinical exam to make sure that you are still eligible for the study. If you are still eligible for the study, the next eight visits (Visits 1-8) will involve PBM therapy that may help with the pain.

The procedures that will be performed during the 11 visits of the study (named visits V0 – V10) are outlined in Table 1. Details of the procedures listed in the table are described below. Risks or discomforts associated with any of the procedures are explained in section 5c of this form. The visits will last different amounts of time because they involve different procedures. Here is a breakdown of how long we expect each visit to last:

Table 1: Schedule of events

| Procedures | Pre-Screening (Day –49 to -7) | Baseline (Day -21 to -7) – Visit 0 | Visit 1 (Day 0) | Visits 2 (Visit 1 + 4 Days ± 3 days), 3 (Visit 2 + 4 Days ± 3 days), 4 (Visit 3 + 4 Days ± 3 Days), | Mid-intervention Visit 5 (Visit 4 + 4 Days ± 3 Days) | Visits 6 (Visit 5 + 4 Days ± 3 Days) ,7 (Visit 6 + 4 Days ± 3 Days), 8 (Visit 7 + 4 Days ± 3 Days) | Visit 9 – Post Intervention Assessment Visit *(Visit 8 + 5 Days* ± 9 Days ) | 1- and 3-Month Post-Intervention Follow-Up Assessments | Final Study Visit - Visit 10 (Visit 9 + 180 Days ± 30 Days) | Premature Discontinuation |
|---|---|---|---|---|---|---|---|---|---|---|
| Verbal consent to pre-screen | X | | | | | | | | | |
| Obtain written consent for study participation | | X | | | | | | | | |
| Collect demographic information | | X | | | | | | | | |
| Obtain and review health history | | X | X | X | X | X | X | | | X |
| Record concomitant medications and therapies | | X | X | X | X | X | X | X | X | X |
| Perform a urine pregnancy test in female participants of childbearing potential | | X | X | X | X | X | | | | |
| Jaw Functional limitation Scale | | X | | | X | | X | | X | X |
| Perform DC/TMD examination | | X | | | X | | X | | X | X |
| Review eligibility/continuation criteria | | X | X | X | X | X | | | | |
| Administer Psychological Questionnaires (PHQ15, Perceived Stress Scale, Pain Catastrophizing | | X | | | | | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Scale, PROMIS Anxiety/Depression) | | | | | | | | | | |
| Administer PEG | | X | | | X | | X | X | X | X |
| Administer the Pressure Pain Threshold test (PPT) | | X | | | X | | X | | X | X |
| Collect physical measurements, vital signs, and skin tone | | X | | | | | | | | |
| Dispense new electronic or paper Daily Symptom Diaries (DSD) | | X | X | X | X | X | X | X | X | X |
| Collect DSD if in a paper form and review DSD | | X | X | X | X | X | X | X | X | X |
| Blood draw | | | X | | X | | X | | X | X |
| Intervention Expectations Questionnaire | | | X | | | | | | | |
| Pre and Post-Intervention Questionnaire | | | X | X | X | X | | | | |
| Intervention Experiences Questionnaire | | | | | | | X | | | X |
| Assess and record AEs | | | X | X | X | X | X | X | X | X |
| PBM Intervention | | | X | X | X | X | | | | |

**Description of Procedures – Visit 0 (V0) (~2-3 hours)**

1. **Informed Consent**: You will be given a copy of the **Consent Form** and have it explained to you by a staff member so that you understand the purpose of the study and what your participation involves.
2. **Medical history and brief physical exam measurements, including vital signs and skin tone:** A medical history and brief physical exam will be completed, and we will measure your height, weight, and blood pressure. We may find out that you have health issues or medication use that would mean you are not eligible for the rest of the study. We will also measure the skin tone of two areas (cheek and upper part of your back), because the effect of PBM may be affected by your skin tone.
3. **Pregnancy Test-** If you are a woman who can get pregnant, we will do a urine pregnancy test nine times during the study (V0 to V8), because you should not

be in this study if you are pregnant. If your test is positive in any of these sessions, the PBM treatment will be stopped, but you can continue to do the other measures that are part of the study, if you would like. The study sponsor will pay for the test.

4. **Concomitant medication**: We will also collect information about any medication that you may be taking.
5. **Questionnaires**: We will ask you to fill out questionnaires to help us understand your health, pain, and other physical symptoms. Some of the questionnaires ask how you are feeling either right now or in the recent past, while others ask how you generally feel. You do not have to answer any questions that you do not want to. Some of these questionnaires can be completed at home either on paper or online and returned at the clinic visit or via a prepaid return envelope. Some of these questionnaires will be completed during your clinical visit.
6. **Clinical Examination**: We will do a clinical exam to better understand your facial pain. During the exam, a clinical examiner will do some measures while you are at rest and while you move your jaw. The examiner will also apply pressure to different places on your face, jaw, neck, shoulders, arms, back, and legs. You will be asked to tell the examiner if you feel pain at each spot.
7. **Pressure Sensations**: To measure your sensitivity to pressure, we will use a handheld device with a small (less than ½ inch wide) rubber tip to apply pressure to your head, face, shoulder, and arm. The pressure will slowly increase, and you will be asked to tell the examiner when you begin to feel discomfort or mild pain. As soon as you tell us you feel pain, the pressure will be removed.
8. **Daily Symptom Diary**: During the study, you will be asked to complete a symptom diary each day. The diary will ask you questions about your pain. It will take about 5-10 minutes each day.

**Description of Procedures – Visits 1 and 5 (V1 and V5) (~1 hour)**

In V1, if you are eligible, you will be randomized to receive either PBM or sham intervention. The following procedures will be done at V1 and V5.

1. Review of the medical history and concomitant medication: In all the sessions, we will review your medical history and concomitant medication to ensure that nothing has changed between sessions.
2. **Blood Samples**: We will draw blood at **V1** and **V5**. This blood will be used for finding biomarkers, such as chemicals that might be related to your TMD pain or to the effects of PBM treatment. The samples will be stored in one of the researcher's laboratories at the University of Florida. When we store the blood samples, they will not be labeled with your name. The samples will be labeled with a number and that number will only be linked to your name in a separate locked file, which is kept by Dr. Ribeiro-Dasilva and her research staff.

**PBM Therapy** -You will receive approximately 45 minutes of either active or sham PBM therapy.

The PBM therapy will be delivered two to three times per week, ensuring a total of eight sessions within three to four weeks.

3. **Questionnaires -** We will ask you to fill out questionnaires to help us understand your pain during the treatment and other physical symptoms.
4. **Daily Symptom Diaries:** We will review your responses for this diary that will ask you questions about your pain

**Description of Procedures – Visits 2-4 and 6-8 (V2-V4 and V6-V8) (~1 hour)**

During these visits, if you are a woman, a pregnancy test will be performed. Then we will do the following:

1. Review Medical History
2. Complete questionnaires
3. Review daily Symptom Diaries
4. Perform PBM treatment or sham intervention
5. You will complete Daily symptom diaries between visits

**Visits 9 and 10 (V9 and V10) (~1 hour)**

1. During these visits, we will repeat the same tests we did during V5, including the TMD examination and pressure sensation, except we will not review your medical history or perform a urine pregnancy test for women. At these sessions, we will also collect a blood draw to measure the change in your biomarkers throughout treatment, and you will fill out some questionnaires. However, these sessions will not include PBM or Sham treatment.

**Daily Symptom Diary (DSD) -** We will ask you to complete a daily diary of your pain symptoms during the week leading up to V10. Again, it should take 5-10 minutes to complete every day.

**More information about the treatment**

You will receive either active or sham PBM therapy. PBM therapy is similar to light therapy where a red and near-infrared light is placed over muscles or joints to improve pain. The sham therapy feels like and is performed in the same way as the active PBM, but sham light does not have any clinical effects. During the PBM treatment (V1-V8), both you and the study staff will wear goggles to protect the eyes from the light emitted by the laser.

If you decide to take part in this study, you will be randomly assigned (much like the flip of a coin) to receive either active treatment or sham treatment. The sham stimulation is like a placebo. A placebo is a treatment that looks like and is given in the same way as an actual treatment but produces no known benefit, for example a sugar pill, or an injection of saline (salt water). A placebo is used in research studies to show what effect a treatment has compared with taking nothing at all. If you are

assigned to receive a placebo, you will not receive the benefits of the active stimulation if there are any, nor will you be exposed to its risks, which are described below under "What are the possible discomforts and risks?" Studies have shown, however, that about 1 in 3 persons who take a placebo do improve, if only for a short time. You and the principal investigator, and other persons doing the study will not know whether you are receiving placebo or active treatment, but that information is available if it is needed. Also, you will have a 50% chance of receiving active stimulation and a 50% chance of receiving placebo stimulation. In the remainder of the description of what will be done, both the active light therapy and the placebo will be called "study treatment."

PBM therapy may or may not have any benefit. Some people may notice a slight warmth or redness in the area, but it should not be painful at all, and it should not last long. If this bothers you, the stimulation can be turned off. Remember, you can stop the research study at any time if you no longer want to participate. You will not know which group you have been assigned to while participating in the research, but you may find out after the research study is completed.

There will be three different lasers that will be applied to the skin around your jaw, neck, and shoulder area. At each site, the laser light will be applied for 30 – 60 seconds and will then be moved to another site.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

**8. What identifiable health information will be collected about you and how will it be used?**

The Research Team will collect the following identifiable health information:

- Medical and mental health history
- Physical examination findings
- Results of functional and sensory tests
- Biomarkers measures in your blood
- Responses to questionnaires
- Telephone interviews
- Your Social Security number for compensation purposes

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other

professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

**9. With whom will this health information be shared?**

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state, and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by federal privacy law.

**10. How long will you be in this Research Study?**

Your participation in this research project will last about 7-8 months and will include 11 visits total to our testing center at the University of Florida. The visits last from 1 to 3 hours, depending on which visit it is. Thus, your total time commitment is expected to be 10-12 hours over a 7-8 month period.

This Authorization to use and share your health information expires at the end of the study unless you revoke it (take it back) sooner.

**11. How many people are expected to take part in this Research Study?**

If you decide to participate in this study, you will be one of approximately 130 people in this research study.

## WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

**12. What are the possible discomforts and risks from taking part in this Research Study?**

- The pain testing procedures may be uncomfortable or unpleasant. You will experience some temporary discomfort from the pressure pain testing. However, if you feel the pain is greater than you wish to tolerate, you can stop any of the procedures at any time.
- The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely, an infection; and, uncommonly, faintness from the procedure. We reduce these risks by using sterile needles, cleaning the area thoroughly, applying pressure to your arm after we remove the needle, and using a trained technician or nurse experienced in collecting research blood draws.
- The physical exam procedures and activity tests may produce discomfort, and you can stop these procedures at any time.
- If you are a woman of childbearing potential, there may be unknown risks to the fetus. Therefore, before treatment, you must have a pregnancy test in order to rule out that you are pregnant. Because the treatment in this study might affect an unborn baby, you should not become pregnant while on this study. Since this treatment will not be given to any patients who are pregnant, all women of childbearing potential must take a pregnancy test prior to receiving any treatment on this study. We encourage all women enrolled on this study to use one of the effective birth control methods during treatment. These methods include total abstinence (no sexual intercourse), oral contraceptives ("the pill"), an intrauterine device (IUD), an etonogestrel implant (Implanon), or medroxyprogesterone acetate injections (Depo-Provera shots). If one of these cannot be used, using contraceptive foam and a condom are recommended. You must notify the study team if you become pregnant during the course of the study

**Other possible risks to you may include:** You may feel uncomfortable, upset or sad about answering some of the questions on the questionnaires. You do not have to answer those questions. Researchers will take appropriate steps to protect any information they collect about you. However, if the researcher believes it is in your medical best interest, they may share information with other health care providers so that they can help you.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the

person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

**13a. What are the potential benefits to you for taking part in this Research Study?**

You may or may not benefit from participating in this study. A potential benefit is that light therapy could improve your pain. If the treatment does improve your pain, we do not know how much it will help. It is possible that any improvement in pain could be small and may not last very long.

**13b. How could others possibly benefit from this Research Study?**

The results of this study may help us to better understand whether treatments like PBM therapy can help reduce pain in people with Temporomandibular joint and muscle disorder (TMD). We may also learn more about how and why these treatments are helpful, which might help us to create better treatments for pain in the future.

**13c. How could the Research Team members benefit from this Research Study?**

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

**14. What other choices do you have if you do not want to be in this study?**

The other option to taking part in this study is not participating. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form. If you choose to not take part in the study, you may continue your regular clinical care.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

**15a. Can you withdraw from this study?**

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

**15b. Can the Principal Investigator withdraw you from this Research Study?**

You may be withdrawn from this Research Study without your consent for the following reasons:

a. You do not meet the eligibility criteria for the study
b. You have had too many side effects or an unexpected negative reaction to the study
c. You have failed to follow instructions
d. The entire study has been stopped
e. Also, if the study team believes that your continuing in the study could cause problems for you or for the study, you can be withdrawn.

## WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

**16. If you choose to take part in this Research Study, will it cost you anything?**

No. There will be no extra cost to you for participating in this Research Study. The sponsor will pay for all health care costs related to your participation, including all required study items, services and procedures described in this consent form. However, if you feel you have received a bill related to this study, please contact the Principal Investigator.

If you receive any healthcare at UF Health that is not related to this study, this care will be billed as usual.

**17. Will you be paid for taking part in this Research Study?**

You will be paid for your participation in this study. Payment amount varies depending on the session. Payments will be made after your last treatment visit. You will receive partial payment if you do not complete the entire study. Here is the breakdown of your payment.

| Visit | Amount |
|---|---|
| V0-Baseline testing | $50 |
| V1-Treatment Sessions only | $25 |
| V2-Treatment Sessions only | $25 |
| V3-Treatment Sessions only | $25 |
| V4-Treatment Sessions only | $25 |
| V5-Treatment Sessions + testing | $50 |
| V6-Treatment Sessions only | $25 |
| V7-Treatment Sessions only | $25 |
| V8- Treatment Session only | $25 |
| V9- Post-Treatment testing | $50 |
| Daily Symptom Diary ($10 for each completed week) | $50 |
| 1-Month Follow up (Questionnaires) | $25 |
| 3-Month Follow up (Questionnaires) | $25 |
| V10-Final Assessment and retention bonus | $75 |
| Total potential compensation | $500 |

If you are paid more than $199 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens must be processed through the University of Florida Payroll and

Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

**18. What if you are injured while in this Research Study?**

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

## SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

| Signature of Person Obtaining Consent and Authorization | Date |
|---|---|

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

| Signature of Person Consenting and Authorizing | Date |
|---|---|