ERCHONIA® PPL
21

APPENDIX B: INFORMED CONSENT FORM

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	An Evaluation of The Erchonia® PPL Laser as a Pre-Treatment Adjunct to Enhance Standard Erchonia Red Laser Therapy for the Temporary Relief of Nociceptive Musculoskeletal Pain
PROTOCOL NO.:	None WCG Protocol # 20253018
SPONSOR:	Erchonia Corporation
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

[21]RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

How long will I be in this research?

We expect that your taking part in this research will last 2 days.

Why is this research being done?

The purpose of this research is to evaluate a new light-based study device known as the Erchonia® PPL, which emits low-level blue laser light. The goal is to determine whether applying this blue light prior to the standard Erchonia red laser treatment can provide greater relief from nociceptive musculoskeletal pain in the neck and shoulders compared to using the

red laser treatment alone. The red laser therapy is already cleared by the U.S. Food and Drug Administration (FDA) for temporarily relieving chronic neck and shoulder pain associated with musculoskeletal conditions.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include a Screening (day 1 visit) where they will ask information about your neck and or shoulder pain, medication use, do a simple physical examination of your neck, shoulder and spine and review medical history and imaging. Pre-Treatment Phase (day 1 visit) ask questions and have you rate the level of your pain in your neck and or shoulder on a 0-100 scale and do a test to see how you move back and forth and from side to side. Treatment Phase (day 1 visit) there is a single treatment with the study device Erchonia® PPL and standard Erchonia red light therapy. The session takes about 18 minutes. You will be seated in a chair and fitted with special glasses to block the laser light from your eyes. The light will shine across your neck, shoulder, head and back area, the Erchonia® devices will not touch your skin. While the doctor is doing the study treatment, he or she will gently move your arms about. Then at the Post-Treatment Phase (at home) 24 hours and again at 48 hours after your treatment you will need to record the information on the forms given to you at the test site rating the level of your pain in your neck and/or shoulder on the 0-100 scale and rate how satisfied you are with the outcome of the treatment administration.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include possible eyesight damage from long term exposure to laser light. This is unlikely since you will have eyesight protection during the treatment and there is one treatment. Because this study is investigational it is possible that you will not get any improvement in the pain in your neck and/or shoulder or that it may even get worse.

Will being in this research benefit me?

Your neck and/or shoulder pain may lessen while you are in this study; however, this cannot be promised. The results of this study may help people to lessen neck and/or shoulder pain in the future.

What other choices do I have besides taking part in this research?

Instead of being in this research there is other care available to you, such as rest; medications to relieve pain and muscle spasms; heat applications; massage; exercise; spinal manipulation; and surgical procedures; as well as alternative options including acupuncture; biofeedback; traction, transcutaneous electrical nerve stimulation (TENS); and ultrasound. The study doctor will discuss these with you. You do not have to be in this study to be treated for your neck and/or shoulder pain.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is; you must not take any medications or do any treatments to help with any neck and/or shoulder pain you may be experiencing during the post-treatment phase.

This research does NOT involve the collection of identifiable private information or identifiable biospecimens.

DETAILED RESEARCH INFORMATION

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the study doctor or staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- This study involves experimental (investigational) device procedures that are being tested for a certain condition or illness. An investigational device is one that has not been approved by the U.S. Food & Drug Administration (FDA).

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What device and procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

This study is being conducted to evaluate a new light-based device known as the Erchonia® PPL, which emits low-level blue laser light. The goal is to determine whether applying this blue light prior to the standard Erchonia red laser treatment can provide greater relief from

nociceptive musculoskeletal pain—particularly in the neck and shoulders—compared to using the red laser treatment alone. The red laser therapy is already cleared by the U.S. Food and Drug Administration (FDA) for temporarily relieving chronic neck and shoulder pain associated with musculoskeletal conditions.

PROCEDURES

- If you agree to take part in this study, you will be one of about 43 people taking part.
- If you agree to take part in this study, you will get the study treatment with the active PPL and standard Erchonia red light therapy meaning it will be turned on.
- To take part in this study, you must agree to not take any medicines or try any other treatments to help with your neck and shoulder pain, until your part in the study is over.
- The study takes 48 hours (2 days) to complete.
- The study process is as follows:

Screening Visit (Visit 1)

If you are interested in taking part in this research study, we will conduct a screening visit at the test site. At this visit, we will review this informed consent document. Then we will:

- Get information about your neck and/or shoulder pain.
- Get information about your other medical history, including information about other current medical conditions you may have.
- Get information about medicines you are taking for your neck and/or shoulder pain.
- Do a simple physical examination of your neck, shoulder and spine.
- Review your previous medical records and diagnostic tests (like x-rays, MRIs, CT Scans, etc.) that relate to your neck and/or shoulder pain if any such information is available.
- Ask you to rate the level of your pain in your neck and/or shoulder on a scale from 0 to 100, where '0' means 'no pain' and '100' means 'worst pain imaginable'.

The screening phase lasts about 20 minutes.

Pre-Treatment Phase (Visit 1)

The pre-treatment phase will start once you have successfully completed the screening visit, and we can confirm that you are still eligible for this study. At this visit, we will:

- Get some more information about your neck and/or shoulder pain.
- Get information about medications you are taking right now for any reason.
- Get information about your age, gender and ethnicity.
- Ask you to rate the level of your pain in your neck and/or shoulder on the 0-100 scale as you did during the screening visit.
- Do a simple test to see how you move back and forth and from side to side.

The pre-treatment phase visit lasts about 10 minutes.

Treatment Phase (Visit 1)

The treatment phase will start once you have successfully completed the pre-treatment phase, on the same day.

There is a single treatment administration with the Erchonia® PPL and standard Erchonia red light therapy. The treatment session takes about 18 minutes. You will be seated comfortably in a chair and fitted with special glasses to block the laser light from your eyes. The light will shine across your neck, shoulder, head and back area, but the Erchonia® devices will not

touch your skin. While the doctor is doing the study treatment, he or she will gently move your arms about.

You will be asked not to take any medication or do any other treatments to help with any neck and/or shoulder pain you may experience for the next 48 hours.

Immediately after the treatment with the Erchonia® lasers, we will:

- Ask you to rate the level of your pain in your neck and/or shoulder on a scale from 0 to 100, as you did during the screening and pre-treatment phases.
- Do the simple test to see how you move back and forth and from side to side as during the pre-treatment phase.
- Ask you to rate how satisfied you are with the outcome of the treatment administration with the Erchonia® treatment on a five-point scale

Post-Treatment Phase (At Home)

At 24 hours and again at 48 hours after your treatment with the Erchonia® PPL and standard Erchonia red light therapy, you will need to record the following information on the forms given to you at the test site. You will need to:

- Rate the level of your pain in your neck and/or shoulder on the 0-100 scale.
- Rate how satisfied you are with the outcome of the treatment administration with the Erchonia® treatment on a five-point scale as you did immediately after the treatment administration.

- ➢ You must not take any medications or do any treatments to help with any neck and/or shoulder pain you may be experiencing during the post-treatment phase.
- ➢ You must return the complete 24-hour and 48-hour forms to the test site as you have been instructed.
- ➢ Your part in the study is then over.

RISKS AND DISCOMFORTS

****ALL SITES:** The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes without appropriate documentation will be reverted during Board review.

[START]

The only known or anticipated risk with the use of the laser device is that long term exposure to laser light could cause damage to eyesight. As a precaution, when you are given the treatment with the Erchonia® PPL and standard Erchonia red light therapy, you will be fitted with special darkened protective glasses to block out the light.

No adverse events have been noted during prior clinical trials using the Erchonia® Lasers. However, the complete risk profile or anticipated risks with the use of the Erchonia® Lasers is not known. It is possible that you will not get any improvement in the pain in your neck and/or shoulder or that it may even get worse.

Women who are pregnant or nursing a child may not take part in this study. If you are trying to get pregnant, you should not volunteer for this study.

[END]

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

Your neck and/or shoulder pain may lessen while you are in this study; however, this cannot be promised. The results of this study may help people to lessen neck and/or shoulder pain in the future.

COSTS

It will not cost you anything to be part of the study. Erchonia Corporation, the sponsor of this research, will provide use of the Erchonia® PPL and standard Erchonia red light device to do the study treatment free of charge. The cost for all study-related procedures and measurements will also be covered by Erchonia Corporation. Nothing will be billed to you or to your insurance company.

PAYMENT FOR PARTICIPATION

You will not be paid for your part in this research study.

ALTERNATIVE TREATMENT

If you decide not to enter this study, there is other care available to you, such as rest; medications to relieve pain and muscle spasms; local heat applications; massage; exercise; spinal manipulation; and surgical procedures; as well as alternative options such as acupuncture; biofeedback; traction, transcutaneous electrical nerve stimulation (TENS); and ultrasound. The study doctor will discuss these with you. You do not have to be in this study to be treated for your neck and/or shoulder pain.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Institutional Review Board (IRB).

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and

- to see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission. 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.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

[21]If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate, or you may leave the study, at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

The sponsor, Erchonia Corporation, will pay for this research study.

[21]The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

QUESTIONS

Contact [21]the study doctor and/or staff at the number(s) listed in this document for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study treatment, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Institutional Review Board (IRB)
Telephone: [21]855-818-2289
E-mail: [21]clientcare@wcgclinical.com

The IRB is a group of people who independently review research.

The IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact[21] the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____

Signature of Subject [21](22 years and older) Date

Signature of Person Conducting Informed Consent Discussion Date

For Sites in California

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

[21]The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2060.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____
Signature of Subject **Date**