RESEARCH SUBJECT CONSENT FORM

TITLE:	The Comparison and Combination of Semiconductor Embedded Therapeutic Elbow Sleeves and Platelet-Rich Plasma and Adipose-Derived Stem Cell (PRP+ASC) Injections for the Treatment of Lateral Epicondylitis: A Randomized, Double-Blinded, Placebo-Controlled Clinical Trial
PROTOCOL NO.:	2024-6 WCG IRB Protocol #20242832
SPONSOR:	Incrediwear Holdings, Inc. 3120 Thorntree Dr. Chico, CA 95973 United States
INVESTIGATOR:	Dr. Matthew Bayes, MD 17300 North Outer 40 Road, Suite 201, Chesterfield, MO 63005 United States
STUDY- RELATED PHONE NUMBER:	636-778-2900

Taking part in this research 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 any 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. You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

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 six months.

Why is this research being done?
The purpose of this research is to assess the effects of using the Incrediwear elbow sleeve independently and in combination with Platelet-Rich Plasma and Adipose-Derived Stem Cell

(PRP+ASC) injections for patients with ECRB tendinopathy (Extensor Carpi Radialis Brevis (ECRB) tendinopathy, also known as lateral epicondylitis or tennis elbow) on patient function, pain management, and rate of recovery.

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:

- If you choose to do so, you will receive PRP+ASC injection treatment for the condition (as part of your standard care treatment)
- You will have to use the Incrediwear elbow sleeve
- You will have your condition evaluated through questionnaires and a grip strength test
- You will maintain and complete the patient journal to document pain scores, pain medications taken, and device usage

Could being in this research hurt me?
The elbow sleeve can cause skin irritation such as dry skin, redness, and itching.

Will being in this research benefit me?
We cannot promise any benefits to you or others from your taking part in this research.

The most important benefits that you may expect from taking part in this research include possible decreased lateral elbow tendinopathy pain, increased elbow function, decreased pain and symptoms, and increased grip strength.

What other choices do I have besides taking part in this research?
Your alternative is to not take part in the research and continue your standard care treatments.

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 that taking part in this research should not increase your cost outside of the PRP+ASC injection cost. You will not be charged for the Incrediwear products.

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

DETAILED RESEARCH INFORMATION

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.

- If you do not understand, ask questions.
- Ask all the questions you want before you decide.
- A copy of this signed and dated consent form will be provided to you.

Why is this research being done?
To assess the effects of using the Incrediwear elbow sleeve independently and in combination with Platelet-Rich Plasma and Adipose-Derived Stem Cell (PRP+ASC) injections for patients with ECRB tendinopathy (Extensor Carpi Radialis Brevis (ECRB) tendinopathy, also known as lateral epicondylitis or tennis elbow) on patient function, pain management, and rate of recovery. We will compare patients with Incrediwear products, or placebo Incrediwear products with and without PRP + ASC injections during a 6-month period.

"Placebo Incrediwear" means the product has no therapeutic effect and is being used as a comparison in this study.

Ultrasound-guided PRP and adipose-derived stem cells (ASCs) injections is an approved treatment option for patients with chronic ECRB tendinopathy. However combination use of Ultrasound-guided PRP and adipose-derived stem cells (ASCs) injections with Incrediwear is considered as an Investigational treatment and not approved by U.S Food and Drug Administration.

Number of Subjects:
At least 80 subjects will take part in this research.

How long will I be in this research?
We expect that your taking part in this research will last 6 months.

What happens to me if I agree to take part in this research?
After your lateral elbow tendinopathy assessment, you be able to choose whether you'd like to receive PRP+ASC injection treatment for the condition as part of your routine medical care. Then, you will be randomly assigned to one of the study groupsbased on your choice of receiving the PRO+ASC injection. This assignment to one of the four groups is blinded and you will not be aware of the assigned group.

1. One group will receive active therapy without PRP + ASC injections (active semiconductor embedded arm sleeves)
    a. "Incrediwear only"
2. One group will receive active therapy with PRP + ASC injections (active semiconductor embedded arm sleeves after they have received PRP+ ASC injections)
    a. "Incrediwear with PRP+ ASC Injections"
3. One group will receive placebo therapy without PRP+ASC injections (identical arm sleeve absent of semiconductor fabric after they have received PRP+ASC injections)
    a. "Sham Incrediwear only"
4. One group will receive placebo therapy with PRP+ASC injections (arm sleeve absent of semiconductor fabric)
    a. "Sham Incrediwear with PRP+ASC Injections"

The products will be placed on you by the clinic staff according to the random assignment sent with your study packet.

- Study Screening/Enrollment appointment
    - Once your doctor confirms that you meet the inclusion criteria, you may be eligible to participate in the study.
    - Your doctor will discuss the study and possible risks/benefits of being in the research.
    - Your study packet will be sent by the clinical staff. The packet will include your study number assignment, the products assigned to your number and the patient study journal. You, your doctor, and clinical staff will not know which study group you are in.
- Weeks 1-24
    - Patient rates elbow tendinopathy pain, on a 0-10 VAS pain scale, Disabilities of the arm, shoulder, and hand scale, patient-rated tennis elbow evaluation scale and patient specific functional score. These will be collected or reported at Enrollment visit, Week 2, Week 4, Week 8, Week 12, and Week 24.
    - Patients will record pain medication type and quantity taken in a medication log daily.
    - Patients will record device usage in a device usage log daily.
    - Grip strength test measured by either the clinical staff or the doctor at the appointment. These will be collected at: Enrollment visit, Week 8, and Week 24.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Follow the study protocol for your study group.
- Maintain and complete the patient journal to document pain scores, pain medications taken, and device usage.
- Keep all appointments for follow up appointments with your doctor.
- Please report any change in medical status to your doctor and the research team.

Could being in this research hurt me?

- The elbow sleeve can cause skin irritation such as dry skin, redness, and itching.
- PRP + ASC injections can cause local injection site pain and skin reaction.
- Adverse events at the injection site could possibly include:
    - Bruising
    - Swelling
    - Pain
    - Decreased range of motion in the elbow
    - There may be risks or side effects that are unknown at this time.
    - Please promptly report any possible side effects to the investigator.

Will it cost me money to take part in this research?

Taking part in this research should not increase your cost outside of the PRP+ASC injection cost. Although approved, PRP+ASC is not covered by Medicare or most insurance plans. Check with your insurance carrier if this is a concern. You will not be charged for the Incrediwear products. You may keep these once the study data collection has been completed.

Will being in this research benefit me?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include decreased lateral elbow tendinopathy pain, increased elbow function, decreased pain and symptoms, and increased grip strength.

What other choices do I have besides taking part in this research?
This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research. If you decide not to take part in the research, you will have the standard of care.

What happens to the information collected for this research?
Your private information will be deidentified by the research staff before being shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the U.S. Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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 to the study team as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff will use the information they collect from you. 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 will receive your information. “Sponsor” means any persons or companies that are:

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

Your information may 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
- and 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?
For sites in California, Delaware, Indiana, Illinois, and Washington, this permission will be good until December 31, 2070. For all other sites, 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 and no longer protected by HIPAA authorization.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289, clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the
- research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?
If you are injured or get sick because of being in this research, call the study doctor immediately. The doctor will provide emergency medical treatment. Your insurance may be billed for this treatment.

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.

Can I be removed from this research without my approval?
The doctor or the study coordinator in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- The research is canceled by the IRB or the sponsor
- You are unable to use the products
- Non-compliance
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?
If you decide to leave this research, we ask that you contact the research team so that the investigator can remove you from the study.

Will I be paid for taking part in this research?
No, you will not receive payment for being involved in the research study

Statement of Consent:

1. I have read this consent form (or it has been read to me)
2. I have had the opportunity to ask questions and any questions I have asked have been answered to my satisfaction
3. I consent voluntarily to participate as a research subject in this study
4. I authorize the use and disclosure of my health information to the parties listed in the
5. authorization section of this consent for the purposes described above
6. By signing this consent form, I have not given up any of my legal rights

Signature of adult subject capable of consent	Printed name	Date

Subject # _____

Statement by the investigator/designee conducting informed consent discussion I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

Signature of person obtaining consent	Printed name	Date