UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND

March 20, 2024

MEMORANDUM FOR MAJ BRADLEY H. CORNELL, DPT, 1ST SPECIAL FORCES GROUP

SUBJECT: USU Institutional Review Board (IRB) (FWA 00001628; DoD Assurance P60001) Approval of Amendment to Protocol USUHS.2023-126 for Human Subjects Participation

The Amendment ref# 970086 for your Minimal Risk human subjects research protocol USUHS.2023-126, entitled "***Assessing the Impact of Post-Exercise Photobiomodulation Application on Performance, Recovery, and Behavioral State in Trained Special Operator Population,***" was reviewed and approved for execution on March 19, 2024 by Edmund Howe, M.D., J.D., Chair IRB under the provision of 32 CFR 219.110(b)(1)(ii). This approval will be reported to the USU IRB scheduled to meet on March 28, 2024.

This action approves the following changes to the protocol:

1. Adding USASOC maintenance of de-identified research data for future use.
2. Included risks associated with counter-movement jump and strength testing.
3. Minor edits to protocol and study documents to correct typos and improve clarity and general understanding.

Documents Reviewed:

1. EIRB Modification Form - (Version 1.0)
2. EIRB Protocol Template - (Version 1.3)
3. ICF (English) - (Version 1.3)
4. Appendix D Baseline Data Collection CRF - (Version 1.1)
5. Appendix E Follow-Up Data Collection CRF - (Version 1.1)
6. Appendix F Activity Log CRF - (Version 1.1)
7. Appendix I Protocol Adherence CRF - (Version 1.1)
8. Appendix J Study Completion CRF - (Version 1.1)
9. Appendix K Data Collection Schedule - (Version 1.1)
10. Appendix L Strength Testing SOP - (Version 1.1)
11. Appendix M Screening Script - (Version 1.1)
12. Appendix N Screening Log - (Version 1.1)
13. Appendix O Master List - (Version 1.1)
14. Appendix P Study Flyer - (Version 1.1)
15. Appendix T PBM Dose Calculation Spreadsheet - (Version 1.1)

As a reminder, it is your responsibility to ensure all applicable protocol-related approvals, including any required approvals from external/collaborating sites involved (whether considered engaged or not engaged in research), have been obtained prior to initiating study activities.

Authorization to conduct protocol USUHS.2023-126 will automatically expire on January 16, 2027. If you plan to continue data collection or analysis beyond this date, then HRPP approval for continuation is required. Please submit an EIRB Periodic Administrative Report for approval to the HRPP Office 60 days prior to the expiration date.

SUBJECT: USU Institutional Review Board (IRB) (FWA 00001628; DoD Assurance P60001) Approval of Amendment 970086 to Protocol USUHS.2023-126 for Human Subjects Participation

You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding this IRB action or questions of a more general nature concerning human participation in research, please contact Yaw Adomako-Ankomah, PhD at 301-295- 0428 or yaw.adomako-ankomah.ctr@usuhs.edu.

ADOMAKO-ANKOMAH.YAW.1541043442 Digitally signed by ADOMAKO-ANKOMAH.YAW.1541043442 Date: 2024.03.20 09:32:25 -04'00'

Yaw Adomako-Ankomah, PhD, CIP
IRB Analyst
USU Human Research Protection Program

EIRB Protocol Template (Version 1.3)

1.0 General Information

***Please enter the full title of your study:**

Assessing the Impact of Post-Exercise Photobiomodulation Application on Performance, Recovery, and Behavioral State in a Trained Special Operator Population

***Please enter the Protocol Number you would like to use to reference the protocol:**

Photomedicine Project 14: PBMT for Performance Enhancement in SOF
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◆	**R and E** - Uniformed Services University of the Health Sciences (USUHS)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Cornell, Bradley Heyward, DPT MAJ

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

HAGER, NELSON ALLEN
Associate Investigator
Hughes, Nicholas Runte

Associate Investigator
O'Hagan, Riley Nicholas
Associate Investigator
Schroeder, Jeremy Daniel, DO LTC
Associate Investigator
Sims, Donald Cornell
Associate Investigator

B) Research Support Staff

Carper, Moriah C
Non-engaged Administrator
GABLER, GEOFFREY MARK
Research Coordinator
Karikari, Nana-King Ahwoi
Research Coordinator
Lucio, Whitley B
Non-engaged Administrator
MCKEE, Samantha Jade
Research Coordinator
Metzger, Elizabeth C
Non-engaged Administrator
Ory, Rian Lyndzie, MS
Non-engaged Administrator
Rossi, Robert M, MPH
Research Coordinator
Vega, Rakayla Bregina
Research Coordinator

3.3 *Please add a Protocol Contact:

Carper, Moriah C
Cornell, Bradley Heyward, DPT MAJ
HAGER, NELSON ALLEN
Hughes, Nicholas Runte
Lucio, Whitley B
Metzger, Elizabeth C
O'Hagan, Riley Nicholas
Ory, Rian Lyndzie, MS
Sims, Donald Cornell
Vega, Rakayla Bregina

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * What department(s) will be associated with this protocol?

	Other

4.2 * Is the IRB of record for this study an IRB/HRPP that does NOT use EIRB? If Yes, complete the application according to the IRB/HRPP Determination.

If your Projects or Protocols are under the oversight of another IRB that does use EIRB, stop this submission and contact the core site and request an invitation as a performing site.

If your Project or Protocol is now being submitted for the first time to an IRB that does use EIRB, continue with this application and answer the questions to be reviewed by the IRB.

Answering yes means the board of record is an IRB that does NOT use EIRB.

○ Yes ◉ No

4.3 * Is this protocol research, expanded access, or humanitarian use device?

◉ Yes ○ No

4.4 * What type of protocol is this?

- ☐ Behavioral Research
- ☑ Biomedical Research
- ☑ Clinical trial (FDA regulated)
- ☐ Educational Research
- ☐ Expanded Access
- ☐ Humanitarian Use Device (HUD)
- ☐ Psychosocial Research
- ☐ Oral History
- ☐ Other

4.5 Are you conducting this project in pursuit of a personal degree?

○ Yes ◉ No

4.7 * Is this human subjects research? (As defined by 32 CFR 219) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

◉ Yes ○ No

4.8 * Do you believe this human subjects research is exempt from IRB review?

○ Yes ◉ No

5.0

Personnel Details

5.1 Does the Principal Investigator have a Permanent Change of Station (PCS) Date or Estimated Institutional Departure Date (EIDD)?

○ Yes ◉ No

5.2 List any Research Team members without EIRB access that are not previously entered in the protocol:

No records have been added

5.3 Are any Contractors or Subcontractors involved in this study? If yes, please list them and describe their role.

◉ Yes ○ No

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Carper, Moriah C Role on Protocol: MIRROR Regualtory Affairs Coordinator	540-267-6654	moriah.carper.ctr@usuhs.edu	The Geneva Foundation / USUHS
Ory, Rian L Role on Protocol: MIRROR Regualtory Affairs Manager	909-904-5034	rian.ory.ctr@usuhs.edu	The Geneva Foundation / USUHS
Lucio, Whitley B Role on Protocol: MIRROR Sr. Regualtory Affairs & Data Manager	202-375-8831	whitley.lucio.ctr@usuhs.edu	The Geneva Foundation / USUHS
Metzger, Elizabeth C Role on Protocol: Photomedicine	252-562-2419	emetzger@genevausa.org	The Geneva Foundation / USUHS

Scientific Program Manager			
Name: (Last, First, M.I.) Hughes, Nicholas Role on Protocol: Associate Investigator, Research Physical Therapist	Phone Number: 206-351-7583	Email Address: nhughes@genevausa.org	Associated Institution: The Geneva Foundation / THOR3, 1st SFG
Name: (Last, First, M.I.) Sims, Donald Role on Protocol: Associate Investigator	Phone Number: 510-593-0402	Email Address: donald.c.sims3.ctr@army.mil	Associated Institution: THOR3, 1st SFG
Name: (Last, First, M.I.) Gabler, Geoffrey Role on Protocol: Research Physical Therapist	Phone Number: 253-968-2083	Email Address: ggabler@genevausa.org	Associated Institution: The Geneva Foundation / JBLM
Name: (Last, First, M.I.) Rossi, Robert Role on Protocol: Research Coordinator	Phone Number: 253-968-2083	Email Address: rrossi@genevausa.org	Associated Institution: The Geneva Foundation / JBLM
Name: (Last, First, M.I.) McKee, Samantha Role on Protocol: Research Assistant	Phone Number: 253-968-2083	Email Address: smckee@genevausa.org	Associated Institution: The Geneva Foundation / JBLM
Name: (Last, First, M.I.) Karikari, Nana-king Role on Protocol: Research Assistant	Phone Number: 253-968-2083	Email Address: nkarikari@genevausa.org	Associated Institution: The Geneva Foundation / JBLM

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Hager, Nelson Role on Protocol: Photomedicine Sr. Medical Advisor	425-218-1833	nelson.hager.ctr@usuhs.edu	The Geneva Foundation / USUHS

5.4 Will you have a Research Monitor for this study?

- ○ Yes
- ◉ No
- ○ N/A

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

○ Yes ◉ No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
: Other USUHS Award Number HU00011920056	: Research Development Testing and Evaluation (RDT&E) funds Photomedicine	250000

Total amount of funding:

250000

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

All personnel engaged in research must complete and attach a Conflict of Interest (COI) form.

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

(•) Yes ( ) No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
Army	THOR3, 1st SFG, USASOC	Lead site			: IIA	: USUHS IRB #1
P&R	USUHS	Coordinating center	FWA00001628	05/04 /2026		: USUHS IRB #1

Other:

Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added					

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

( ) Yes (•) No

8.4 Is this an OCONUS (Outside Continental United States) study?

( ) Yes (•) No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

( ) Yes ( ) No

9.0 Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

Photobiomodulation, Photomedicine, Performance Enhancement, Quadriceps, Special Operations

Readiness

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

Military demands require for Special Operations Forces (SOF) populations to be physically fit, ready for deployment at any time. To meet this requirement, Special Operators ("Operators") train regularly to reach peak performance. This training can be taxing on one's body, as it is nearly always recovering. To provide elite performance and recovery coaching, the United States Special Operations Command (SOCOM) initiated Tactical Human Optimization Rapid Rehabilitation and Reconditioning (THOR3), in 2009: a program for Special Forces to provide wholistic wellness and health to Operators through mental, physical, nutrition, spiritual, and cognitive programming. Ultimately, the goal of THOR3 is to optimize physical and mental health performance, consequently increasing operational longevity and warfighter readiness. THOR3 focuses on providing evidence-based interventions, tracks data of Operators' performance, and is on the cutting-edge of performance enhancement in the DoD with elite trainers and providers. Thus, this program is at the tip-of-the-spear for initiatives to increase strength, conditioning, and recovery (Wyatt, 2017).

A pioneering performance and recovery enhancement tool is Photobiomodulation therapy (PBMT). PBMT is a noninvasive treatment where a device that emits low level lasers is applied to a body area to enhance recovery and improve performance (Dompe, 2020). Studies in athletes have shown performance (improved maximum voluntary contraction, sprint time, CMJ height, fatigue index, time on pitch, VO2max, volume and time to anaerobic and aerobic threshold appearance) and recovery (decreased inflammatory and oxidative stress markers, delayed onset muscle soreness) benefit with both pre-and post-workout application of PBMT (Ailioaie, 2021).

When applied to the lower body pre-exercise, PBMT has been found to prevent increase of /decrease creatine kinase (CK) activity, a biomarker of muscle damage. This reduction, as compared to placebo, has been observed after cycling tests (Junior, 2009; Junior, 2011), eccentric exercise (Baroni, 2010; Vanin, 2016; De Paiva, 2016; Antonialli, 2014; de Oliveria, 2017), and running tests (Tomazoni, 2019). A case-control study with identical twins participating in a workout regimen also showed that PBMT application post-exercise reduced creatine kinase (CK) (Ferraresi, 2016). Transferring this observation to other activities, PBMT has also shown to decrease/prevent increase of CK in sports performance such as volleyball, (Ferraresi, 2015) and futsal (De Marchi, 2019). Compared to other modalities, namely, cold-water immersion (Junior, 2011), or cryotherapy (De Paiva, 2016), PBMT was significantly more effective in positively altering CK activity. Similarly, pre-application of PBMT has also shown to reduce lactate after sprint/running tests (Pinto, 2016; Tomazoni, 2019), eccentric exercise (Baroni, 2010; de Oliveria, 2017) futsal matches (De Marchi, 2019), and cycling tests, in which it also more effectively reduced lactate as compared to other modalities (Junior, 2011). Alike results have been noted for Interleukin-6 (IL-6) (Vanin, 2016; de Oliveria, 2017; Tomazoni, 2019), and carbonylated proteins indicative of an oxidative stress environment (De Marchi, 2019; Tomazoni, 2019; Ferraresi, 2016). Taken together, these results suggest that PBMT is protective against muscle damage.

Performance metrics have also shown improvement with PBMT. Maximum voluntary contraction (MVC) has been found to increase/decrease to a lesser extent after an eccentric exercise routine when PBMT was applied pre-workout, as compared to placebo (Baroni, 2010; Antonialli, 2014, Vanin, 2016). Maximum involuntary contraction (MVIC) also increased with application of PBMT prior to an eccentric exercise program (de Oliveria, 2017; De Paiva, 2016). PBMT application can also increase the number of maximum repetitions (de Brito, 2014), torque (De Carvalho, 2020; Baroni, 2015; Dornelles, 2019), and CMJ performance (Dornelles, 2019). Succinctly, Rossato et al. (2020) found that application of PBMT decreases fatigue while maintaining or increasing performance, thus enabling athletes to output the same total work with the availability to complete additional sets. Pre-application of PBMT prior to a futsal match also significantly increased the time players were able to stay on the pitch (De Marchi, 2019). Thus, PBMT is effective at increasing performance metrics across a variety of outcomes.

Self-reported behavioral effects related to physical performance also show positive effects from PBMT. PBMT application has been found to reduce self-reported delayed-onset muscle soreness (DOMS) and self-reported fatigue. A randomized, double-blinded, placebo-controlled clinical trial found that PBMT decreased DOMS as compared to placebo and cryotherapy alone, or the

combination of cryotherapy and PBMT (De Paiva, 2016). Other similar studies found a significant difference in decreased DOMS as compared to placebo (Antonialli, 2014; de Oliveria, 2017; Ferraresi, 2016). During sprint tests, in a randomized, crossover, double-blind, placebo-controlled clinical trial conducted with rugby players, PBMT decreased self-perceived fatigue post sprint test (Pinto, 2016). PBMT is effective in reducing perception of fatigue and soreness, even when compared to an equivalent placebo.

Outside of self-reported fatigue or DOMS, there is less information on the potential behavioral effects of PBMT focal application (e.g., quadriceps). Studies, however, have shown that transcranial application of PBMT has a role in recovery of brain injury and disorders (e.g., traumatic brain injury, Parkinson's disease, and Alzheimer's), psychological disorders (e.g., anxiety and depression), and cognitive enhancement in both healthy and cognitive declining populations (Hamblin, 2016).

Taken as a whole, PBMT is a promising avenue for increasing overall performance by enhancing recovery processes, self-reported DOMS and fatigue, and potentially positively affecting behavioral health in the Special Operator population. We will conduct a single-blinded randomized-control trial with sham control to investigate the effectiveness of providing PBMT post physical training in a SOF population, thus translating this cutting-edge research to application in the THOR3 setting.

9.3 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions /hypotheses

Aim 1: Describe physiologic effects of PBM application post-exercise in SOF operators undergoing THOR3 coach led training
Aim 2: Describe behavioral effects of PBM application post-exercise in SOF operators undergoing a THOR3 coach led training

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

Randomized, single-blind, sham control trial

9.5 Target Population:

Describe the population to whom the study findings will be generalized

Active-Duty Service Members, combat/tactical Athletes such as police officers and firefighters, collegiate athlete populations

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

Military demands require for SOF populations to be physically fit, ready for deployment at any time. SOF are responsible for executing specific missions and objectives that may be outside of the capacity of conventional forces, thus filling a necessary void in the nation's defense. Increasing performance and/or recovery of these Special Operators will contribute to their individual warfighter readiness and collectively positively influencing operational longevity.

10.0

Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

Study activities will occur at Joint Base Lewis-McChord (JBLM) within the 1st Special Forces Group (SFG). Study activities, including recruitment, will occur in the THOR3 Clinic area or other applicable 1st SFG areas.

Recruitment, Pre-Screening (before consent), Study Introduction & Informed Consent: Potential participants will be identified via three methods:

1. Participants may self-refer to participate in the study if they become aware of the study by study flyer (Appendix P) or word of mouth. Interested potential participants will be able to contact a member of the study team via phone or email.
2. Mass briefs at THOR3 coach-lead trainings.
    - Briefings will occur at regular intervals, about every 3 weeks, for each training class at the 3 Operator focused training sessions. In the course of a month, there will be about 4 briefings.
    - Briefings will take no more than five (5) minutes. The briefs will be scheduled to occur prior to the coach led session. Consenting procedures will not occur during these informational briefs.
    - Leadership would only include the OIC of THOR3, not Group Leadership. Every effort will be made to ensure there is not undue coercion.
    - "Thank you for taking a few minutes to listen to this brief. We are conducting a research study to assess utilizing light therapy to increase recovery post training. There is the possibility that it can decrease inflammation, soreness, and fatigue and thus increase performance. We will ask you to complete a baseline visit, where we collect some self-reported demographic and health information, and measure your height, weight, and body fat. We will also ask you to complete a strength test and a counter movement jump. We will assign you an Oura Ring to wear for the duration of the study. This visit will take about 45 minutes. Then for 3 weeks, we will ask to provide light therapy 3 times a week after THOR3 coach led training. You will be randomly assigned to an active treatment or sham treatment group. Each group will wear headphones and blackout glasses. These sessions should take 20 minutes. Each week we will ask you to complete a countermovement jump, and fill out some questionnaires. These visits will take about 15 minutes. We will also ask you to fill out a daily pain questionnaire, and complete an activity log, which will take about 5 minutes. At the end of the three weeks, we will test your strength and counter movement jump again and ask you to fill out final questionnaires. This will take about 25 minutes. You will be compensated at each weekly visit, for a total of 150 USD. If you are interested in participating or in learning more about the study, please see a member of the research study team."
3. Study advertisements (Appendix P) will be posted in THOR3 and 1st SFG areas that operators frequent.

If a potential participant expresses interest in learning more about the research study, a member of the research staff will briefly introduce the study, express the voluntary nature of participation, assess interest in participating, and screen the potential participant for eligibility. Eligibility will be determined in person (individually, with a study team member) using the Inclusion/Exclusion Case Report Form (CRF) (Appendix A). Additionally, the potential participant may be provided with a study flyer.

Pre-screening conversations may also take place over the phone, should a participant contact the study team, using the Screening Script (Appendix M). Potential participants who meet initial eligibility per the Screening Script and express interest in participating will be asked to come to the THOR3 area to confirm final eligibility with an authorized study team member.

If the potential participant meets eligibility criteria and expresses interest in participating, an authorized study team member will assess whether the individual is comfortable with a group consent or an individual consent discussion. In accordance with the individual's preference, the authorized study team member will initiate the formal consent discussion and, if applicable, obtain informed consent (as outlined in Protocol Section 13.4).

If a potential participant would like additional time to review the consent form, study procedures, risks and benefits, etc. they will be provided with a consent form to take home and, if applicable, they may return at a later date to have any and all remaining questions answered and to finish the consent process.

The research team will keep a password-protected electronic Screening Log (Appendix N), containing initials, date of birth (DOB) and eligibility/ineligibility status, in a secure folder on a secure drive, accessible only by authorized users. This log is needed to avoid any duplicative screening of individuals. This log, therefore, will include initials and dates of birth (DOBs) for those that screened formally and informally. Screening IDs will be different from study IDs that are assigned post-consent.

Participants that consent to participate will be added to a Master List (Appendix O) that will match the participants unique study ID with their name and other direct identifiers. The Master List will be stored in a password-protected electronic document on a common access card (CAC)-enabled server; only on-site study team members will have access to this file. This coded study ID will be used on all research data collection forms in place of the participant's name, Department of Defense (DoD) ID, or other protected identifier.

Contact Information Data Collection (post-consent):
Immediately following consent, the participant will complete an Intake CRF (Appendix B). The Intake CRF will collect participant contact information (full name, preferred phone number, email address, etc.).

With the exception of the Consent Form, the Intake CRF is the only paper research form that will contain participant identifying information. The Intake CRF will be kept with the signed consent forms (in a locked cabinet inside of a locked room) and stored separately from all other paper research forms.

Demographics, & Baseline Data Collection:
Prior to receiving study treatment, participants will complete a Demographics CRF (Appendix C) which collects relevant demographics including: personal demography, military and employment demography, and study-specific demography.

Additionally, participants will complete a Baseline Data Collection CRF (Appendix D) that collects: relevant medical history, military & work status, validated self-report measures, and study-specific measures. The following study-specific measures will be collected by a study team member:

- Fitzpatrick Skin Phototype
- Height, weight, and body fat composition (measured by bioelectrical impedance with InBody 770)
- Measurements of the participant's quadriceps to calculate the appropriate PBMT dose. (See Appendix S for PBM dosing information).
- Assessments of both legs:
    - CMJ, assessing jump height, time to take-off, RSImod, Eccentric Deceleration Impulse, Countermovement Depth, Concentric Impulse, Movement Start to Peak Power, and any asymmetries, and
    - Isometric and isokinetic dynamometer testing, assessing isolated strength in the lower body (i.e., unilateral Peak Torque and Rate of Force Development of quadriceps and hamstrings).
    - Processes for these tests can be found in the Appendices L and W. CMJ data will be output from the Force Decks software and recorded directly by the study team to the Appendix D and E CRF tables at each test iteration.

Each participant will be assigned an Oura Ring at baseline. Participants will be instructed to wear the Oura Ring for the duration of the study. The Oura Ring will continuously measure sleep quality, heart rate, blood oxygen saturation percentage (SpO_2) levels, and activity. Oura Ring data will be securely stored in OuraTeams with access only for research team members.

Randomization:
Participants will be randomized to a study arm using a computer-generated randomization model prepared by the study biostatistician, to assign participants 1:1 across both study arms (THOR3 training + sham PBMT, or THOR3 training + PBMT).

Study Treatments (THOR3 training + sham PBMT, THOR3 training + PBMT):

Participants will be blinded to the study arm they are assigned to and will be unblinded at the conclusion of the final study visit.

Participants will be asked to refrain from using perfumes or plant extracts (e.g., St John's Wort) in the treatment areas, as this use can increase photosensitivity.

THOR3 Coach-Lead Training
All participants will be enrolled in the THOR3 coach-lead training program as a standard daily exercise regimen, focusing on muscle strength, endurance, and stamina. This program will proceed without interference from the study. Activity during the THOR3 program will be documented (e.g., exercises, reps, etc.) on Appendix G THOR3 Training Program Log CRF. A study team member will export the training schedule from Bridge Athletic and will insert the information into Appendix G and ask the participant to confirm what training they completed.

Photobiomodulation Treatment (PBMT)
PBMT will be delivered at 40W. A member of the study team will use the quadriceps measurements of the treatment area to calculate the PBMT treatment time (approximately 5-20 minutes). PBMT treatment will be provided up to 3 times a week, for 3 weeks. Participants will be asked to engage in 3 sessions per week; however, due to operational demands, we understand that they may not be able to attend all sessions and will then aim to minimally have them attend 2 sessions per week.

PBMT will be provided by a trained study team member. Training for the PBMT will be conducted by a LightForce representative. PBMT will be delivered using the LightForce® XLi 40W device with the Smart Hand Piece technology, created by LiteCure, LLC/DJO (New Castle, DE) which has a built-in accelerometer in the hand piece that controls the speed of light delivery to the treatment area. The LightForce® XLi therapy laser is an FDA cleared device for the treatment of pain. The trained team members will use the Smart Hand Piece technology, which achieves effective treatments and improves dosing accuracy by assessing the operator's speed and providing real-time visual (red – amber – green light) and sensory feedback. The Smart Hand Piece is calibrated to shut-off when moving too slowly, and warn the operator when moving too fast by vibrating. (See LightForce Brochure). The therapy is delivered through a flexible optical fiber threaded through the hand piece, which contains a rolling glass massage ball. PBMT will be delivered at specified J/cm2 and applied to the quadriceps area.

In order to facilitate participant blinding to their randomized study group, all participants (regardless of their assigned study group) will be asked to wear blackout glasses and headphones during their treatment.

Sham PBMT Arm:
Sham PBMT will be provided by a trained study team member. Sham PBMT will be delivered in the same manner as indicated for the PBMT process above, but the device will stay in standby mode (i.e., the treatment mode will not be turned on). As infrared light is invisible to the naked eye, the only visible difference between treatment and standby modes is the presence of a few tiny amber lights (these lights are on during treatment mode).

The inclusion of sham PBMT will ensure all participant treatment procedures remain the same, with the exception of emission of photons (active treatment), thus, allowing for contribution of any differences between groups to be credited to the use of PBMT.

Follow-Up Data Collection:
Follow-up data will be recorded on Appendix E Follow-up Data Collection CRF.

Regardless of study arm assignment, all participants will be asked to log their daily activity and pain (Appendix F Activity Log CRF) and wear the Oura Ring for 3 weeks.

Weekly Follow-Up:
Participants will follow-up with a study team member once a week to:

- turn in the activity log and Oura Ring data,
- be assessed for any adverse events (AEs),
- complete CMJ measurements just prior to THOR3 training session, and
- complete a DOMS questionnaire.

3-Week Follow-Up:
Participants will follow-up with a study team member for a final study visit to:

- turn in the final activity log and Oura Ring,
- be assessed for any adverse events (AEs),

- complete CMJ and lower body strength assessments,
- complete a follow-up questionnaire, and
- be unblinded to their study treatment.

Participants will not be held responsible for lost or damaged Oura Rings.

Study participation will end after the completion of the 3-week follow-up visit.

Data may be captured in-person or remotely (e.g., entered directly into REDCap using a personalized coded link with no log-in required, verbally over the phone with a study team member, etc.), as applicable. Reminder phone calls, texts, and/or emails will be sent to participants at their preferred contact method indicated on the Intake CRF (Appendix B).

Missed Appointments and Study Removal:
If a participant misses a scheduled appointment, they will be contacted to reschedule in order to maintain the treatment plan of their assigned study treatment group. In the event that a participant misses an appointment, study staff will make one attempt to reschedule each day on three separate days (for three total attempts to reschedule). If the participant cannot be reached or does not respond/reschedule, they will be removed from the study due to non-compliance.

Additional Information - MIRROR/USU:
This research study is being conducted as part of Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation (PM&R) at the Uniformed Services University (USU).

MIRROR is focused on advancing musculoskeletal injury (MSI) rehabilitative care within the military healthcare system in order to reduce the burden MSIs have on military readiness and to ultimately enhance the operational capabilities of the armed forces. MSIs affect approximately 800,000 service members annually and result in 25 million days of limited duty. These conditions are the primary reasons for medical discharge/downgrade and result in 34% of medical evacuations from theatre. MIRROR was developed as a means to study risk factors of common MSIs, generate prevention strategies, optimize treatments, and establish return-to-duty criteria that is based on scientific evidence rather than case-specific clinical judgment alone.

MIRROR involves interdisciplinary and inter-service partnerships, the DoD, and several major academic medical centers. To ensure military mission focus and scientific relevance, MIRROR is guided by a steering committee composed of members from the Joint Program Committees (JPCs) at the U.S. Army Medical Research and Development Command (USAMRDC), military operational leaders, and experts in musculoskeletal medicine from the military and civilian communities. MIRROR aims to be the world's leader in military relevant musculoskeletal injury care research.

Currently, 40+ research projects are being deployed at more than 20 military and civilian treatment facilities nationwide.

MIRROR/USU is serving as a Coordinating Center for this study and will also be providing remote regulatory support. Staff from MIRROR/USU will not interact with human subjects and will not have access to the Master List during the conduct of this study. Deidentified research data will be shared with MIRROR/USU and maintained indefinitely for possible use in future research.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

Please see Appendix K Data Collection Schedule.

The local study team will obtain the information necessary to complete the study CRFs directly from the participant.

Outcome Measures & Functional Assessments:

- Defense and Veteran's Pain Rating Scale (DVPRS) basic - captures pain
- Visual Analogue Scale (VAS) - measures delayed onset muscle soreness
- Borg Perceived Exertion and Elloumi scale for behavioral health
- Quick Physical Activity Rating (QPAR) scale

- Activity log to record activity and a training log that records the THOR3 training workout for all associated participants.
- Percent body fat, height, and weight
- CMJ measurements to assess performance (deceleration/concentric impulse, peak force production, rate of force production, any asymmetries) via jump plates
- Isokinetic dynamometer to measure isolated strength.
- Oura Ring will continuously measure sleep, heart rate, Sp02, and activity.

Appendix A Inclusion Exclusion CRF:
Verifies that the potential participant meets eligibility criteria for study participation.

- Inclusions/exclusion criteria
- Documentation of informed consent
- Final eligibility status
- Randomization documentation

Appendix B Intake CRF:
Obtains sufficient contact information in order to locate and track the participant during study participation.

Appendix C Demographics CRF:
Characterizes the participant's demographics and relevant medical and work history. This information may have a significant effect on functional outcomes.

- Personal demography
- Military & employment demography
- Study-specific demography

Appendix D Baseline Data Collection CRF:
Collects relevant baseline research data.

- Self-reported medical history
- Current military & work status
- DVPRS
- QPAR
- VAS
- Borg Perceived Exertion Scale
- Elloumi fatigue scale
- Fitzpatrick Phototyping Scale
- Body measurements
- CMJ
- Isometric/Isokinetic Strength

Appendix E Follow-Up Data Collection CRF:
Collects relevant follow-up research data.

- VAS
- Borg Perceived Exertion Scale (3-week follow-up only)
- Elloumi fatigue scale (only at 3-week follow-up)
- CMJ
- Isometric/Isokinetic Strength (3-week follow-up only)
- Adverse Event (AE) assessment

Appendix F Activity Log

- Daily activity
- Daily DVPRS

Appendix G THOR3 Training Program Log CRF:
Documents THOR3 training completed (reps, sets, load) for each study visit.

Appendix H Protocol Adherence CRF:
Documents protocol adherence for each study visit.

- AE assessment
- PD assessment

Appendix J Study Completion CRF:
Documents participant study completion status.

- Study completion status
- AE assessment
- PD assessment

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

○ Yes ◉ No

10.14 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for this Study:

Include in this section the plan for acquiring data (both electronic and hard copy), access during the study, data/specimen storage and length of time stored, shipment/transmission, and the plan for storage and final disposition at the conclusion of the study. Describe any data agreements in place for accessing data within and/or outside of your institution (e.g., Data Sharing Agreement, Data Use Agreement, Business Agreements, etc.)

Data Capture Methods:
The local study team will collect data directly from the study participant (including in person, mail, email, or over the phone) and record it on study CRFs. The completed CRFs will serve as source documents for this study.

Participants may enter their coded data directly into REDCap using a personalized survey link (no log-in required). In these cases, the completed REDCap forms will be printed and added to the participant's research record to serve as a source document.

Electronic Data Entry:
The study team will enter non-personally identifiable data from the paper CRFs into REDCap. Please see Appendix U for additional information on REDCap.

Data Storage & Access:
The ICF and Intake CRF will be stored separately from the coded paper research forms. All paper research forms and source documents will be stored in a locked cabinet inside of a locked room within the THOR3 area.

The coded electronic research data for this study will be stored in REDCap, housed on a Department of Defense (DoD) server and maintained by USU IT. No PII will be entered into REDCap. The local study team will maintain the electronic master list separately from the coded electronic research data in a secure, password protected document on a computer and network that requires CAC access and will only be accessible by local research staff.

Access to the electronic coded research data will be governed strictly on an individual-by-individual basis within REDCap. Individual data access as well as privileges will be clearly delegated, audited, and monitored by MIRROR/USU. Staff from MIRROR/USU will not have access to the paper research records or any identifiable research data.

All research data and forms (both paper and electronic) will only be accessible by authorized study staff, authorized staff from MIRROR/USU (coded data entered into REDCap only, as described above), the IRB of record, the USASOC HRPP, and applicable governmental agencies as part of their duties and in accordance with federal law.

There will be appropriate data sharing agreements in place.

At study closure, study documents will be securely transported to USU Department of PM&R and Military Emergency Medicine (MEM) for record retention. ICFs will be maintained for a period of 6

years following study closure and then securely shredded. Paper research forms will be maintained for a period of 5 years following study closure and then securely shredded. The master list connecting unique study ID to participant identifiers will be destroyed at study closure. The electronic coded research data will be maintained indefinitely as described below in Protocol Section 10.15.

Is this a data repository?

○ Yes ◉ No

10.15 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for Future Research:

If the study involves collecting, storing, or banking human specimens, data, or documents (either by the Investigator or through an established repository) for FUTURE research, address. How the specimens/data will be used, where and how data/specimens will be stored (including shipping procedures, storage plan, etc.), whether and how consent will be obtained, procedures that will fulfill subjects' request as stated in the consent, whether subjects may withdraw their data/specimens from storage, whether and how subjects may be recontacted for future research and given the option to decline, whether there will be genetic testing on the specimens, who will have access to the data/specimens, and the linkage, the length of time that data/specimens will be stored and conditions under which data/specimens will be destroyed.

Consent for Future Use of Data:
The ICF for this research study states that de-identified research data will be shared with MIRROR /USU and the United States Army Special Operations Command (USASOC) and will be maintained indefinitely for possible use in future research. By consenting to participate in this research study, participants agree to allow us to maintain their de-identified research data indefinitely for possible use in future research.

Participants will not be given the option to opt out of us retaining their de-identified research data indefinitely for possible future use. The ICF states, "If you do not want your deidentified data collected as part of this research study to be kept for use in future research studies, you should not sign this consent form."

Long Term Data Storage & Access:
The de-identified electronic dataset will be maintained by MIRROR/USU and the study team indefinitely or as long as it is practicable to maintain.

De-identified electronic research data will be securely transmitted from local study teams to the MIRROR /USU via REDCap or the DoD secure access file exchange (SAFE) application (or other permissible safe data sharing system). REDCap utilizes Secure Sockets Layer (SSL) in addition to other safeguards on its web server to maintain secure communication with end-users (see Appendix U). DoD SAFE uses a TLS (Transport Layer Security) protocol when files are uploaded and downloaded.

Once received, the electronic de-identified research data will be stored within an encrypted, access controlled, password protected electronic data capture and management system housed on a DoD-compliant server.

Access to the de-identified research data will be governed strictly on an individual-by-individual basis within the secure electronic data capture and management system. Individual data access as well as privileges will be clearly delegated, audited, and monitored by MIRROR/USU. Any future research using retained data will require a research protocol to be approved by an Institutional Review Board or other authorized official responsible for protecting human subjects of research.

We will also ask participants for permission to store their identifiable contact information for the purposes of being contacted to participate in future research studies. Participants will be provided the option to opt-in or opt-out of the storage of their contact information. All participants that opt in to the storage of contact information for the purposes of being contacted to participate in future research studies will have their name and contact information retained at study closure. The local study team will securely maintain the contact information indefinitely, or as long as it is practical to maintain. The PI will be responsible for ensuring secure storage and destruction, as applicable.

Any future research using retained data will require a research protocol to be approved by an Institutional Review Board or other authorized official responsible for protecting human subjects of research.

Data Withdrawal from Storage:
Participants may request to have their data withdrawn at any time before their personal identifiers have been removed. Once their data has been de-identified (when the study master list is destroyed at study closure), it will be impossible for the researchers to locate their specific study data.

Is this a data repository?

(•) Yes ( ) No

If Yes, provide the name of the Repository

USU OCIO REDCap

Who will have access to the Repository?

MIRROR/USU, study team members, and investigators, as appropriate

What data type will be stored in the Repository?

- [ ] Protected Health Information
- [ ] Limited Data Set
- [x] De-identified Data

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any sub-group analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis

Descriptive statistics will report location and scale in terms of mean and standard deviation for normally distributed variables, median and interquartile intervals for ordinal metric variables, and in terms of proportion and size for categorical variables. Descriptive statistics will be reported for baseline demographic and clinical characteristics at an overall level and by initial treatment group.

Outliers will be removed if determined to be erroneous based on relevant clinical expertise. Confounding will be principally controlled by randomization. In regards to the treatment of missing data, Oura Ring data will be analyzed despite presence of missing data at any point; with regards to non-continuous outcomes, data will be analyzed only if baseline and the 3-week follow-up are both present. In the event of missing data for a mid-point follow up (i.e., not baseline or the 3-week follow up), said patient will still be included in all models.

Statistical analyses will use generalized additive models predicting the change in outcome measures at 3 weeks relative to baseline for all measures except Oura Ring data. Oura Ring data will be aggregated by averaging readings across each 24-hour period and will be modeled using multi-level models incorporating random effects. Sensitivity analyses will be performed on longitudinal data for each outcome metric and will include multi-level models incorporating random effects as well as control variables to account for any differences explained by a selection of patient characteristics (such as body weight, etc.).

11.2 Sample Size:

Within one performance site, and assuming roughly 20% attrition and accounting for screen

failures, we are requesting to enroll up to 116 (58 per arm) participants in order to evaluate a final sample of 85 (42-43 per arm).

11.3 Total number of subjects requested (including records and specimens):

116

11.4 If you are recruiting by study arm, please identify the arms of the study and how many subjects will be enrolled in each arm

Across one performance site, up to 116 patients will be randomized 1:1 to the two treatment arms (PBMT and Sham PBMT).

11.5 Please provide a justification for your sample size

Due to the accepted feasibility/pilot nature of this study, we understand that the proposed study may not be appropriately powered. Assuming a moderate effect size of .15 and a significance level of 5%; in the event we are able to enroll 116 participants (85 post-attrition) we will achieve 80% power. If we are able to enroll 135 participants (108 post-attrition), we will achieve 90% power. Power was calculated using the linear multiple regression module within G*Power (Erdfelder, Faul, & Buchner, 1996).

11.6 Data Analysis Plan: Complete description: Background, Objectives, Design, Step by Step how the project is going to be done, Data analysis plan:

Descriptive statistics will report location and scale in terms of mean and standard deviation for normally distributed variables, median and interquartile intervals for ordinal metric variables, and in terms of proportion and size for categorical variables. Descriptive statistics will be reported for baseline demographic and clinical characteristics at an overall level and by initial treatment group.

Statistical analyses will use generalized additive models predicting the change in outcome measures at 3 weeks relative to baseline for all measures except Oura Ring data. Oura Ring data will be aggregated by averaging readings across each 24-hour period and will be modeled using multi-level models incorporating random effects. Sensitivity analyses will be performed on longitudinal data for each outcome metric and will include multi-level models incorporating random effects as well as control variables to account for patient characteristics. Exact selection of control variables will be guided by observed differences within final collected data as well as relevant clinical expertise.

Hypothesis tests will be two-tailed and statistical significance will be considered at the putative threshold (alpha=0.05). Any secondary P-values will be subject to a false discovery rate adjustment in keeping with best statistical practices. Multilevel models will incorporate random effects to account for repeated measures, using distribution families and link functions appropriate for the outcomes of interest, determined using quantile-quantile (QQ) plots analyzed for best model fit. All statistical analyses will be performed using the R Programming language.

12.0 Participant Information

12.1 Subject Population:

Active-duty, male, SFG (18-series) personnel, between the ages of 18-45 (inclusive) years old

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [ ] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [ ] 45-54
- [ ] 55-64
- [ ] 65-74
- [ ] 75+

18-45 (inclusive)

12.3 Gender:

- [x] Male
- [ ] Female
- [ ] Other

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen
- [x] Active Duty Military Personnel
- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons
- [ ] Educationally Disadvantaged Persons
- [ ] Physically Challenged (Physical challenges include visual and/or auditory impairment)
- [ ] Persons with Impaired Decisional Capacity
- [ ] Prisoners
- [ ] Pregnant Women, Fetuses, and Neonates
- [ ] Non-English Speakers
- [ ] International Research involving Foreign Nationals - Headquarters Review is necessary

You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e.

12.5 Inclusion Criteria:

Order Number	Criteria
1	Active-Duty Special Forces Personnel (18-series)
2	Between the ages of 18-45 years old (inclusive)
3	Male
4	Able to read and understand English language for consent purposes
5	Able to commit to study intervention and follow-up
6	Able to participate in THOR3 coach-lead training, without restriction

12.6 Exclusion Criteria:

Order Number	Criteria
1	Obese (body fat $\geq$ 25%)
2	Cardiovascular disease
3	Use of select medications: • statins (e.g., Atorvastatin/Lipitor, Fluvastatin, Lovastatin, Pitastatin, Pravastatin, Rosuvastatin/Crestor, Simvastatin/Zocor), • diuretics (e.g., Microzide, Lasix, Aldactone, Midamor), or • antihypertensive agents
4	Female
5	Tattoo in treatment area
6	Diagnosis with porphyria (light induced allergy) or photosensitive eczema
7	Current use of medications associated with sensitivity to heat or light (e.g., amiodarone, chlorpromazine, doxycycline, hydrochlorothiazide, nalidixic acid, naproxen, piroxicam, tetracycline, thioridazine, voriconazole),
8	Use of pacemaker/underlying cardiac disease
9	Diagnosis of autoimmune diseases
10	Albinism
11	Peripheral neuropathy

13.0 Recruitment and Consent

13.1 Please describe the recruitment process, including how subjects will be identified and selected for the study.

Study activities will occur at Joint Base Lewis-McChord (JBLM) within the 1st Special Forces Group (SFG). Study activities, including recruitment, will occur in the THOR3 area or other applicable 1st SFG areas.

Recruitment, Pre-Screening (before consent), Study Introduction & Informed Consent: Potential participants will be identified via three methods:

1. Participants may self-refer to participate in the study if they become aware of the study by study flyer (Appendix P) or word of mouth. Interested potential participants will be able to contact a member of the study team via phone or email.
2. Mass briefs at THOR3 coach-lead trainings.
    - Briefings will occur at regular intervals, about every 3 weeks, for each training class at the 3 Operator focused training sessions. In the course of a month, there will be about 4 briefings.
    - Briefings will take no more than five (5) minutes. The briefs will be scheduled to occur prior to the coach lead session. Consenting procedures will not occur during these informational briefs.

- Leadership would only include the OIC of THOR3, not Group Leadership. Every effort will be made to unsure there is not undue coercion.
- "Thank you for taking a few minutes to listen to this brief. We are conducting a research study to assess utilizing light therapy to increase recovery post training. There is the possibility that it can decrease inflammation, soreness, and fatigue and thus increase performance. We will ask you to complete a baseline visit, where we collect some self-reported demographic and health information, and measure your height, weight, and body fat. We will also ask you to complete a strength test and a counter movement jump. We will assign you an Oura Ring to wear for the duration of the study. This visit will take about 45 minutes. Then for 3 weeks, we will ask to provide light therapy 3 times a week after THOR3 coach led training. You will be randomly assigned to an active treatment or sham treatment group. Each group will wear headphones and blackout glasses. These sessions should take 20 minutes. Each week we will ask you to complete a countermovement jump, and fill out some questionnaires. These visits will take about 15 minutes. We will also ask you to fill out a daily pain questionnaire, and complete an activity log, which will take about 5 minutes. At the end of the three weeks, we will test your strength and counter movement jump again and ask you to fill out final questionnaires. This will take about 25 minutes. You will be compensated at each weekly visit, for a total of 150 USD."

3. Study advertisements (Appendix P) will be posted in THOR3 and 1st SFG areas that operators frequent.

If a potential participant expresses interest in learning more about the research study, a member of the research staff will briefly introduce the study, express the voluntary nature of participation, assess interest in participating, and screen the potential participant for eligibility. Eligibility will be determined in person (individually, with a study team member) using the Inclusion/Exclusion Case Report Form (CRF) (Appendix A). Additionally, the potential participant may be provided with a study flyer.

Pre-screening conversations may also take place over the phone, should a participant contact the study team, using the Screening Script (Appendix M). Potential participants who meet initial eligibility per the Screening Script and express interest in participating will be asked to come to the THOR3 area to confirm final eligibility with an authorized study team member.

If the potential participant meets eligibility criteria and expresses interest in participating, an authorized study team member will assess whether the individual is comfortable with a group consent or an individual consent discussion. In accordance with the individual's preference, the authorized study team member will initiate the formal consent discussion and, if applicable, obtain informed consent (as outlined in Protocol Section 13.4).

If a potential participant would like additional time to review the consent form, study procedures, risks and benefits, etc. they will be provided with a consent form to take home and, if applicable, they may return at a later date to have any and all remaining questions answered and to finish the consent process.

The research team will keep a password-protected electronic Screening Log (Appendix N), containing initials, date of birth (DOB) and eligibility/ineligibility status, in a secure folder on a secure drive, accessible only by authorized users. This log is needed to avoid any duplicative screening of individuals. This log, therefore, will include initials and dates of birth (DOBs) for those that screened formally and informally. Screening IDs will be different from study IDs that are assigned post-consent.

13.2 Compensation for Participation:

Participants may receive up to $150 for participation in this research.

Participants will be compensated at the following intervals:

- $50 USD gift card for completing the activity log and turning it in at the 1-week follow-up
- $50 USD gift card for completing the activity log and turning it in at the 2-week follow-up
- $50 USD gift card for completing the activity log and turning it in at the 3-week follow-up

Eligible participants will be compensated through the Greenphire platform. Participants will be registered in the Greenphire platform upon confirmation of final eligibility. Once registered, the participant will be classified as a (1) non-active duty, or (2) active-duty employee category, and a Greenphire debit card will be assigned to them. Participants will be given an envelope containing their debit card and all information needed to access their funds, and they will be

instructed to retain that card for the duration of their study participation. At the various compensation intervals indicated above, an assigned user will verify the study visit was completed and will issue a stipend through the Greenphire system, which will electronically release funds to the assigned debit card.

If needed, a Greenphire debit card can be mailed to a participant. In this case, a participant will be registered into the appropriate employee category, the debit card will be assigned (but not activated) and will be mailed to the participant. Stipends will be issued only after the participant confirms receipt of the card.

DHA-AI 3200.01 indicates active-duty service members may receive additional compensation for the completion of a daily health diary when completed off-duty. In accordance with DHA-AI 3200.01 the following definitions of on-duty and off-duty will apply to active duty-service member study participants:

- An individual is on-duty when they are expected or required to perform the duties of their assigned job or position.
- An individual is off-duty if the individual is not scheduled to perform any work that may arise during the period.

13.3 Please describe the pre-screening process. If no pre-screening, enter Not Applicable in the text editor

If a potential participant expresses interest in learning more about the research study, a member of the research staff will briefly introduce the study, express the voluntary nature of participation, assess interest in participating, and screen the potential participant for initial eligibility using the Inclusion/Exclusion CRF (Appendix A). Pre-screening conversations may take place over the phone using the Screening Script (Appendix M).

13.4 Consent Process: Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

Consent (individual and group) will be obtained in accordance with principles of Belmont Report and Common Rule guidelines.

The potential participant(s) will be given a copy of the ICF to read before the informed consent discussion with an authorized study team member. Sufficient time will be given to the potential participant to understand the study purpose, study procedures, time commitments, potential risks and benefits, and the types of information that will be collected and used by the research team if they agree to participate in the study.

Questions can be raised by the potential participant(s) at any time. The potential participant(s) will be reminded that their participation is completely voluntary and that they may withdraw from the study at any time without penalty. Their decision to participate, or not, will not affect their access to health care that they are otherwise entitled to and it will not affect their military position.

Formal consent, as represented by the act of signing a dated, IRB-approved ICF for the study will occur after: confirming eligibility using the Inclusion/Exclusion CRF, a thorough review of what is involved in the study (including all available study treatments as well as blinding and randomization processes), and all questions have been answered. Informed consent will be obtained in person and may include consenting as a group, based on the participants' comfortability and scheduling. Each individual will be asked for their preference for a group or individual consent discussion, and the individual's preference will be utilized. A copy of the signed consent form will be given to the participant and the original will be securely stored. No Legally Authorized Representatives will be utilized.

Every effort will be made to eliminate the perception of authority. When applicable, the study investigators will be in civilian clothes instead of uniform and will not utilize or display their military rank when introducing themselves. Some potential participants may be patients of the study PI or AI. In these cases, the consent conversation will be initiated by non-provider study staff to prevent any misconception of coercion or undue influence.

In the event that there are significant new findings that may affect participants' willingness to continue in the study, an information sheet will be provided to all current and past participants, and the ICF will be amended for future participants.

Following completion of informed consent, a unique study ID will be generated. This coded study ID will be used on all research data collection forms in place of the participant's name, Department of Defense (DoD) ID, or other protected identifier. No PII will be entered into REDCap.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

- (•) N/A
- ( ) Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

Participant Withdrawal:
Participants may contact a member of the study team in writing to formally withdraw from the study.

Participants may withdraw from the study at any time without penalty. Participants will be informed that withdrawal will not affect their access to health care that they are otherwise entitled to and it will not affect their military position.

If a participant withdraws from the study, we may retain and analyze all coded/de-identified data collected up to the time of withdrawal if the data is necessary to maintain the integrity of the study. However, no further data will be collected after the date of withdrawal.

Withdrawal Without Participant Consent:
A participant may be withdrawn from the study without their consent if remaining in the study might be dangerous or harmful to them, the military mission requires it, they lose their right to receive medical care at a military hospital, the study is canceled, they fail to adhere to the protocol and/or therapy plan, or if they display inappropriate behavior towards study personnel.

Participants will be asked to return all study materials at the time of study withdrawal. Participants will be contacted up to three times for each contact method (e.g., call, text, email, or in-person interactions) to retrieve the study materials. Once all attempts are exhausted, no further contacts will be made.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach

of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

The risks associated with PBMT are minimal. PBMT is used by a variety of healthcare practitioners for painful clinical conditions. Mild discomfort may be experienced during the treatment, the treatment should not feel "hot", but participants should notify the study team member if they feel any uncomfortable warming. Individuals with neuropathies or difficulty distinguishing changes in skin temperature are at higher risk. Potential research-related risks include damage to eye structures, headaches post-procedure, uncomfortable skin heating or erythema/redness, which are both very rare.

The risks associated with the counter-movement jump and strength testing are minimal risks that may be experienced in everyday life, including loss of balance, fall, discomfort, or injury.

Additionally, any time information is collected for a study, there is a small risk of breach of confidentiality.

14.2
Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

All available measures to minimize risks will be taken in accordance with standard clinic protocols.

Protective eyewear will be worn by all participants and study team members during PBMT and sham PBMT treatment sessions to avoid potential eye damage. Along with the Laser Safety Officer (LSO), the PI will ensure that the treatment space meets all regulatory requirements for utilization of a treatment laser, including appropriate signage and use of laser blocking screens to absorb any potential scatter/refraction of light outside of the treatment area.

In the rare occurrence that participants experience uncomfortable warmth over the treatment area during PBMT, the treatment will be modified or stopped.

All available measures will be taken by research staff to protect participant confidentiality. See Protocol Section 14.3 for additional information on confidentiality protections.

All participants will be evaluated for AEs at each follow-up visit. All AEs, regardless of severity, will be reported to the PI and the IRB according to the guidelines stated in Protocol Section 16.0.

14.3
Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e. g., child or spouse abuse

Upon consenting for the study, participants will be assigned a unique study ID. With the exception of the ICF, Intake Form, and electronic Master List, all research data (both paper and electronic) will be identified using this unique study ID only.

Paper research forms and source documents will be stored in a locked cabinet inside of a locked room, accessible only by local research staff designated and authorized by the PI. The paper Intake CRF and ICFs will be stored separately from the coded paper research forms.

The electronic Master List will be stored separately from the coded electronic research data in a secure, password-protected electronic document on a computer and network that requires CAC access.

The coded electronic research data for this study will be stored in REDCap, an encrypted, access controlled, password protected electronic data capture and management system housed on a DoD server and maintained by USU IT. No PII will be entered into REDCap.

MIRROR, which is based out of the Department of PM&R at USU, is serving as the data coordinating center for this research study. As such, authorized staff from MIRROR/USU will have access to the coded research data that is entered into REDCap. Authorized staff from MIRROR /USU will not have access to the electronic Master List.

All research data and forms (both paper and electronic) will only be accessible by authorized study staff, the IRB of record, the local research office, and applicable governmental agencies as part of their duties and in accordance with federal law. These duties include making sure that research participants are protected.

Any research data shared with an approved agency for review will be linked only to the participant's unique study ID. If the research data is used in scholarly presentations or journal articles, the investigators will protect the anonymity of individual participants and report only aggregate data (e.g., group means) where appropriate. Participants will not be individually identified in any publication or presentation of research results.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

We cannot guarantee that participants will benefit from participation in this research study. The aim of this study is to improve performance and recovery. All participants will still receive standard THOR3 coach-lead training.

14.5 Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

Consent conversations and follow-up research activities will take place in a private setting (e.g., over a private phone line, in a closed clinic room, investigator's office, etc.) to minimize the potential opportunity to be overheard or inadvertently witnessed. Each individual will be asked for their preference for a group or individual consent discussion, and the individual's preference will be utilized. Information being collected will be limited to only the minimum amount of data necessary to accomplish the proposed research.

No uniformed service members or supervisors will be present during consent discussions.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the

results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

Because information regarding participant health may be required to be reported to appropriate medical or command authorities, participants will not have the option to opt out of receiving the results of incidental findings from this research.

The PI will review all incidental findings and determine whether or not the incidental finding should be reported to the participant. The PI will utilize guidance provided by the Office of Human Research Protections (OHRP) Attachment F - Recommendations on Reporting Incidental Finding. Specifically, the PI will consider whether the findings are validated and actionable, and if they have potential implications for a participants physical and mental wellbeing. The PI will assume responsibility for notifying participants of incidental findings, explaining the findings, implications, and recommendations for next-steps to follow-up with their clinical care team. The CSC/CSU surgeon will also be notified.

In cases involving military personnel, information regarding their health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- (●) DSMP
- ( ) DSMB
- ( ) Both
- ( ) Not Applicable

A DSMP should describe the plan to monitor the data to verify that the data are collected and analyzed as specified in the protocol. Include who will conduct the monitoring, what will be monitored, and the frequency of monitoring. It should also include the plan to ensure the safety of subjects

Participant Safety Monitoring Plan:
To ensure the safety of participants the PI will:

1. Monitor the conduct of the protocol per the approved study plan and ensure protection of human participants. This may involve periodic review of research files of enrolled participants.
2. Review and keep abreast of AEs and protocol deviations (PDs) that occur during the research.
3. The PI will review and sign AE/PD logs and continuing review (CR) progress reports.
4. If there is concern about the welfare of enrolled participants, the PI will stop the research study in progress, remove individual participants from a study, and take whatever steps necessary to protect the safety and well-being of research participants until the IRB can assess the situation.
5. Ensure that all study team members keep current required human subjects research trainings which require renewal every 3 years.

If an AE or PD occurs, it will be evaluated by the PI and appropriate actions will be taken as outlined in Protocol Section 16.0. In the case of an emergency, first responders will be called. In order to address the challenge of early identification of an increased risk of a known AE, all AE data will be tracked and evaluated.

Participants can elect to withdraw from the study at any time. Participants may also be taken out of the study at any point if it is determined to no longer be safe for them to continue with the study. If a participant elects to drop out of the study or is withdrawn for safety reasons, they will be encouraged to seek care with their healthcare provider, if applicable, and the CSC/CSU surgeon will be notified.

Data Monitoring Plan:
Data will be collected and stored in both paper CRF and electronic format as described previously in Protocol Section 10.14 Data Management. In addition to data quality and data validation checks done continually by REDCap for electronic format data, authorized MIRROR staff will perform routine checks of the coded electronic data entered into REDCap to ensure that data has been properly input and that data entry is consistent with expected values. The local PI will ensure that paper research forms and the electronic Master List are completed and securely stored in accordance with stated protocol procedures.

Please see Protocol Section. 14.3 Confidentiality Protections and 14.5 Privacy for Subjects for additional information regarding how we will protect participant privacy and confidentiality throughout this study.

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

AEs & Unanticipated Problems:
All AEs will be recorded by the study team using an AE Log. The PI will promptly review and assess events to determine severity and relatedness to research activities.

All Serious Adverse Events (SAEs) that are at least possibly related to study participation and all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) will be reported to the IRB and USASOC HPD via telephone or email within 24 hours of discovery, and a complete written report will be submitted via EIRB within 5 business days. The written report will be provided to the USASOC HPD at the time of submission.

All expected AEs and all SAEs that are not possibly related to study participation will be reported to the IRB and USASOC HPD at the time of CR or study closure (as applicable).

Protocol Deviations:
All PDs will be recorded by the study team using a PD log. The PI will promptly review and assess events to determine severity.

All major PDs will be promptly reported to the IRB and USASOC HPD via telephone or email within 24 hours of discovery, and a complete written report will be submitted via EIRB within 5 working days. The written report will be provided to the USASOC HPD at the time of submission.

All minor/administrative PDs will be reported to the IRB and USASOC HPD at the time of CR or study closure (as applicable).

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

(•) Yes ( ) No

Please describe:

HUMAC® NORM™ Testing & Rehabilitation System will be used to measure isometric and isokinetic strength.

InBody770 will be used to measure height, weight, and body fat composition.

Oura Ring will be used to measure measure sleep quality, heart rate, blood oxygen saturation percentage (SpO2) levels, and activity.

VALD ForceDecks will be used to measure countermovement jump measurements (jump height, time to take-off, RSImod, eccentric deceleration impulse, countermovement depth, concentric impulse, movement start to peak power).

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- [ ] Drugs
- [ ] Dietary Supplements
- [ ] Biologics
- [x] Devices
- [ ] N/A

18.3 Device Details:

- [x] Are device(s) in this research being used in accordance to the approved labeling?
- [ ] Are device(s) in this research being used in a manner other than its approved labeling?

When adding a device indicate in the details section of the device if the use is either used in accordance to the approved labeling or in a manner other than it's approved labeling

View Details	Device Name
⊟	LightForce® XLi therapy laser

Manufacturer/Supplier of Device	LiteCure, DJO Global, Envois
Where will the Devices Be Stored	In the research area
Will Devices be supplied at no Cost	No
Is this a HUD (HDE)	No
HDE Number	N/A
Who holds the IDE	N/A
IDE details	N/A

18.4 Reporting Requirements for FDA-regulated research under IND and IDE:

Describe the process for complying with FDA regulatory requirements for adverse event reporting and adverse device effects reporting to the sponsor

The PI will be responsible for reporting any unanticipated adverse effects and unanticipated problems to the manufacturer and FDA for the device.

18.5 Sponsor (organization/institution/company):

☑ N/A

If applicable, provide sponsor contact information:

N/A

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- ○ Registration is not required
- ◉ Registration pending
- ○ Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- ◉ Registration is not required
- ○ Registration pending
- ○ Registration complete

20.0 References and Glossary

20.1 References:

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20.2 Abbreviations and Acronyms:

Adverse Event (AE)
Case Report Form (CRF)
Centimeter (cm)
Common Access Card (CAC)
Continuing Review (CR)
Countermovement Jump (CMJ)
Creatine Kinase (CK)
Date of birth (DOB)
Defense and Veteran's Pain Rating Scale (DVPRS)
Defense Health Agency Administrative Instruction (DHA-AI)
Delayed Onset Muscle Soreness (DOMS)
Department of Defense (DoD)
Electronic Institutional Review Board (EIRB)
Exempli Gratia (E.g.)
Etcetera (etc.)
Food & Drug Administration (FDA)
Identification (ID)
Id Est (I.e.)
Informed Consent Form (ICF)
Interleukin-6 (IL-6)
Institutional Review Board (IRB)
Information Technology (IT)
Joint Base Lewis McChord (JBLM)
Joint Program Committee (JPC)
Joule (J)
Laser Safety Officer (LSO)
Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR)
Musculoskeletal injury (MSI)
Maximum Involuntary Contraction (MVIC)
Maximum Volume of Oxygen Consumption (VO2max)
Maximum Voluntary Contraction (MVC)
Military Emergency Medicine (MEM)
Office of Human Research Protections (OHRP)
Office of the Chief Information Officer (OCIO)
Oxygen Saturation Percentage (SpO2)
Photobiomodulation Therapy/Treatment (PBMT)
Photobiomodulation (PBM)
Physical Medicine & Rehabilitation (PM&R)
Point of Contact (POC)
Principal Investigator (PI)
Protocol Deviation (PD)
Quantile-Quantile (QQ)
Research Electronic Data Capture (REDCap)
Secure Access File Exchange (SAFE)
Secure Sockets Layer (SSL)
Serious Adverse Event (SAE)
Special Forces Group (SFG)
Special Operations Command (SOCOM)
Special Operations Forces (SOF)
Tactical Human Optimization, Rapid Rehabilitation and Reconditioning (THOR3)
TLS (Transport Layer Security)
Ultraviolet (UV)
Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)

Uniformed Services University (USU)
Uniformed Services University of the Health Sciences (USUHS)
United States Army Medical Research and Development Command (USAMRDC)
United States Army Special Operations Command (USASOC)
Visual Analogue Scale (VAS)
Watt (W)