RESEARCH APPLICATION

IRB Coordinator
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IRB Administrator
Kristin Ferguson, RN
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PART 1: ADMINISTRATIVE INFORMATION

Date of Application: __12/1/21_____

A. Research Title:		
Evaluation of standard TED stocking versus Reparel bioactive garment on postoperative leg swelling, pain, and dvt rates after hip replacement surgery.		
Other Sites Involved in Research:		
none		
B. Principal Investigator:		
Name and degree Alexander Sah	Title MD	
Address CJR Bldg, 2000 Mowry Ave	Phone Number 510-818-7249	email Address asah@sahortho.com
Co-Investigator: may share some of the duties of the PI, such as enrolling subjects, but does not have overall responsibility for the research.		
Name and degree	Title	
Address	Phone Number	email Address
Co-Investigator:		
Name and degree	Title	
Address	Phone Number	email Address
Additional Contact Person (if any):		
Name Marie Sabado-Bell	Title EA	
Address Same	Phone Number 510-818-7284	email Address marie@sahortho.com

C. Funding - Check all that apply**:**

1. Type of funding:	2. Source of funding:
[x] Contract/Grant [ ] Subcontract [ ] Drug/device donation [ ] Departmental [ ] Student project [ ] Other: ___ Have funds been awarded? [ ] Yes [ ] Pending [x] No	[ ] Federal Government [ ] Other Government (e.g., State, local) [ ] Industry (e.g. drug or device company) [x] Other Private [ ] Departmental funds [ ] Other **Specify name of funding source or grant title:** Reparel

3. Contact Person for financial matters:
Alexander Sah

4. If this research is federally funded, please submit one copy of one of the following documents (unless there is more than one grant or contract involved; in that case, submit one copy for each associated grant or contract). Please indicate which document you have attached:
[ ] The Research Plan, including the Human Subjects, Section E of your NIH grant.
[ ] For other federal proposals (contracts or grants), the section of the proposal describing human subjects work.
[ ] The section of your progress report if it provides the most current information about your human subjects work.

5. If there are any significant discrepancies between this application and the grant or contract or if this is a training grant please explain here:

none

6. Secondary sponsors: If there are multiple sources of funding for this research, please describe the additional funding:

none

D. Scientific Merit Review: This research has received or will receive scientific merit review from:

NA

E. Key Personnel: All key personnel including the PI and Co-Investigator must be listed below along with a brief statement of their qualifications and study role(s). Key Personnel may include the research coordinator, research nurse, data coordinator, and others involved in research.

Investigators and other personnel [and institution(s)]:	Qualifications:	Research role(s):
Alexander Sah, MD	MD	PI
Marie Sabado Bell	EA	Research coordinator

Petra Nicolas Meena Mistry	PA PA	Evaluator, investigator Evaluator, investigator
Kayla Cook	PA	Evaluator, investigator
Joseph Gomez Bryant Bonner	PA MD	Evaluator, investigator Evaluator, investigator
F. Drugs, Devices and Biologics:		
List any investigational drugs, biologics and IND Numbers:	Name	IND #
List any investigational devices and IDE Numbers:	Name	IDE #
[x] Non-Significant Risk Determination Request		
Who holds the IND/IDE?	[x] Sponsor [ ] Investigator	
Are investigational drugs or biologics controlled by a pharmacy?	[ ] Yes [x] No If Yes, identify the pharmacy/ies:	
Are investigational drugs, devices, or biologics (test articles) controlled by the Principal Investigator? (See FDA IND and IDE Guidance for information regarding test article control).	[ ] Yes [x] No If "Yes", describe your plan for control of the test article:	
List any approved drugs, biologics and/or devices being studied:		

G. Other Approvals/Regulated Materials: Does this research involve the use of the regulated materials listed below? If "Yes", additional approvals may be required. - Controlled Substances - Radiation - Human Embryonic Stem Cells – The WHHS IRB cannot approve stem cell research - Fetal Tissue – The WHHS IRB cannot approve research involving fetal tissue	[ ] Yes [x] No

PART 2: STUDY DESIGN

Complete items A-E using clear, concise, non-technical, lay language (i.e., the type of language used in a newspaper article for the general public) wherever possible. Define all acronyms.

Space limits are recommendations and should be adjusted as needed, but the total length for sections A-E should not exceed 5 pages.

A. Synopsis (Briefly summarize the research.) Space limit: quarter page

Study Description: This is a randomized prospective study comparing two postoperative leg sleeves. The novel bioactive sleeve (Reparel Leg Sleeve) will be compared to a regular TED stocking. The main hypothesis for this study is that postoperative use of a novel bioactive sleeve after hip replacement will decrease pain and improve patient reported outcome scores faster and more reliably than the control standard TED stocking. In order to test this hypothesis, approximately 50 patients scheduled for hip replacement will be randomized to one of two arms (bioactive sleeve on operative leg and TED stocking on other, versus bioactive sleeve on nonoperative leg and TED stocking on operative leg). The following standard assessment tools will be assessed: patient reported outcomes (VAS, HOOS JR, VR12, and HSS, Satisfaction, Forgotten Joint), study questionnaire. PROMs will fall under chart review activities.
Objectives:

Primary Objective: Assessing the effectiveness of a bioactive sleeve against a non-bioactive TED leg sleeve with regard to pain, swelling, and dvt rates.
Primary Endpoint: Patient reported outcome scores (VAS, HOOS JR, VR12, HSS, Satisfaction, Forgotten Joint).
Secondary Endpoints: Swelling evaluated by routine clinical evaluations. DVT rates monitored.
Study Population: This prospective study hopes to enroll approximately 50 male and female patients over the age of 18 years old and below the age of 90 years old. BMI must be below 40. Subjects volunteer for participation with elective hip replacement.
Description of Study Intervention: This is a device study using a novel bioactive sleeve which is assumed to mimic the effects of photobiomodulation in comparison to a placebo sleeve.
Study Duration: Study duration from when the study opens until the completion of data analysis is expected to be 24 months.

B. Purpose (Specify the hypotheses and/or objectives.) Space limit: half page

This prospective study will evaluate pain, swelling, dvt rates as well as narcotic use in post-operative total hip arthroplasty patients using novel non-compressive photobiomodulating stocking (NCPS) versus current standard of care gradient compression stocking (Thrombo-Embolic-Deterrent or TED hose). Disadvantages of standard TED stockings are difficulty of placement, and thereby compliance in the postoperative period. Current literature remains mixed regarding the effectiveness of these stockings in pain, swelling, and dvt reduction. This study will evaluate if NCPS is equivalent, or superior, in these outcome areas, and it may provide a new and comfortable way to reduce patient pain and swelling immediately following hip surgery.

C. Background (Summarize previous research. Explain the rationale for the proposed investigation and if applicable how this research differs from local standard of care.)

Space limit: one page

Total hip arthroplasty (THA) is one of the most common surgical procedures today. It is designed and proven to effectively reduce pain caused by end-stage osteoarthritis. Despite its achievements, post-operative swelling of the hip and leg is thought to be a contributor to pain and delayed rehabilitation.

Traditionally, a standard gradient compression stocking is applied to the leg after surgery to reduce this pain and swelling. However, due to ineffectiveness or patient non-compliance, compression stockings are often not entirely successful at preventing edema. The recently developed NCPS is a lower extremity garment comprised of a technical fabric that is thought to be able to prevent edema and reduce pain all in a comfortable, user-friendly manner. The purpose of this study is to determine if the NCPS is effective at improving post-operative pain, swelling, ROM and analgesic use associated with THA.

Pain and prolonged recovery time associated with post-operative swelling are two factors that contribute to patient dissatisfaction following THA. Swelling of the leg following THA is caused by intraarticular bleeding and inflammation of the periarticular tissues, which can lead to a decrease in functional performance including pain and delayed rehabilitation. Leg swelling can play a part in post-operative quadriceps strength following joint replacement. Ultimately, if post-operative swelling can effectively be reduced, patient recovery could be expedited and patient satisfaction could be improved.

Compression stockings have been utilized to attempt to reduce post-operative swelling. Compression works to prevent swelling by reducing the hydrostatic pressure in the leg. Reducing hydrostatic pressure prevents the capillaries from oozing and allows blood to move freely from the superficial to the deep venous system, subsequently allowing excess fluid to flow away from the interstitial space.

More recently, the use of gradient compression stocking following THA has come into question for its efficacy. While the application of external pressure from these gradient compression stocking is beneficial for a period, they are often unable to exert a sufficient amount of pressure long enough to prevent painful edema for an extended amount of time. These garments can show sufficient compression during the first few hours after surgery, but the pressure they applied dropped with time and required daily measurements and refitting to maintain appropriate and therapeutic compression. It's clear that compression stockings are not as effective as once thought when it comes to controlling pain and swelling post-operatively.

A potential solution to the problems posed by traditional compression stocking is the NCPG. The garment is comprised of a semi-conductive material ground to nanoparticles that are embedded into the fibers, formed into a three-dimensional woven fabric for optimized comfort. Instead of relying on compression, NCPS utilizes the body's own thermal energy to generate infrared energy. The infrared energy generated is reflected back at the body and modifies cellular activity at the level of the mitochondria through a process known as photobiomodulation. This process of photobiomodulation is hypothesized to improve swelling and tissue healing by increasing the activity of mitochondria and the availability of cellular energy in the form of ATP.

D. Design
1. (Check all that apply):

[x] Phase I [ ] Phase II [ ] Phase III [ ] Phase IV [x] Randomized [ ] Blinded

[ ] Behavioral [ ] Interventional

[ ] Multicenter: If so, is Washington Hospital the coordinating center or the primary grant holder?	[ ] Yes [ ] No

2. Additional description of *general* study design. Attach flow diagram if appropriate.
Space limit: half page

Inclusion Criteria

1. Age range: from 18 to 89
2. Primary unilateral Total Hip Replacement

Exclusion Criteria

1. Physical condition prohibiting use of leg stocking or garment
2. Allergy to silicone/polyester
4. Current DVT
5. History of Vascular Bypass Surgery on Operative Limb ie) Fem-Pop or Fem-Fem
6. Inability to follow standardized post op and rehab protocols
7. Lymphedema

Number of Research Participants

We will enroll 50 subjects throughout all sites involved in the study.

E. Data Analysis (How and by whom will data be analyzed?) Space limit: half page

PI and reparel sponsor will analyze subject questionnaires using statistical data analysis using the results provided by each subject and the PI. Study team will evaluate each criterion and analyze the results of each subject. Routine clinical evaluations will be summarized. The information will be statistically summarized using the criteria identified above and measuring based upon the subject's questionnaires

PART 3: PROCEDURES

A. List, in sequence, all research procedures, tests and treatments required for the research. Indicate which would be done even if a subject does not enroll in the research. Include a detailed explanation of any experimental procedures. Attach table if available.

1. PI will identify 50 subject candidates willing to participate in the study.
2. Subjects randomized to bioactive sleeve on one leg and TED stocking on other.
3. Routine clinical evaluations performed
4. Patient questionnaires completed
5. Questionnaires and data analyzed, summarized and results presented

B. List the specific locations where research procedures will be performed. Indicate how much time will be required of the subjects, per visit and in total for the research.

1. PI offices: Sah Orthopedics
2. Normal routine clinical followup, up to 5 minutes for questionnaires

C. Will any interviews, questionnaires, surveys or focus groups be conducted for the research? If "Yes," please list any standard instruments used for this research and attach any non-standard instruments. Note: All non-standard instruments must be approved by the WHHS IRB prior to use.	[x] Yes [ ] No

Interviews, questionnaires, surveys will be conducted for the research using oral and online communication.
Standard instruments:
Hoos Jr, Pain Score, Patient Questionnaire, Global 7, Forgotten Joint Score

Attached forms: Reparel Patient Questionnaire

D. Will subjects or their health care provider be given the results of any experimental tests that are performed for the research? If "Yes" please describe the tests, provide a rationale for providing subjects with the experimental test results and explain what, how and by whom, subjects and their health care provider will be told about the meaning, reliability, and applicability of the test results for health care decisions.	[ ] Yes [x] No

PART 4: ALTERNATIVES

A. Describe the alternatives to research participation that are available to prospective subjects.	
No participation nor research	
B. Is study drug or treatment available off-study? If "Yes", discuss this in the consent form.	[x] Yes [ ] No [ ] N/A

PART 5: RISKS AND BENEFITS

A. Risks and Discomforts

1. Describe the risks and discomforts of any investigational or approved drugs, devices and procedures being used or assigned for research purposes. Describe the expected frequency of particular side effects. If subjects are restricted from receiving standard therapies during the research, also describe the risks of those restrictions.

No expected discomforts from using bioactive sleeve garment compared to traditional TED stocking. Study to assess amount of leg swelling, discomfort, dvt rate versus traditional stockings. TED stocking will be used on either operative or non-operative leg in all cases. Literature suggests this alone has an anti-dvt effect. Therefore, expected risks rare and minimal.

2. Describe the steps taken to minimize the risks/discomforts to subjects (e.g., supportive interventions or special monitoring):

Patients have clinic support and staff availability as standard of care

B. Data and Safety Monitoring Plan (DSMP): ***All interventional studies involving more than minimal risk must include a DSMP.*** A DSMP is a plan established to assure that each research study has a system appropriate oversight and monitoring of the conduct of the research to ensure the safety of participants and the validity and integrity of the data.
Note: Most, but not all studies (i.e., non-interventional studies) undergoing WHHS IRB review will require a DSMP.

This is an interventional study and thus does require a DSMP [x] Yes

Describe the DSMP Plan:
Patients will be evaluated with routine postoperative phone calls at intervals within 1 week, 2 week, 4 weeks. In addition, clinical evaluations will occur at 2 week, 6 week, 12 weeks. Safety will be evaluated at each of the above mentioned followups.
PI will assess all data and clinical evaluations. Monthly and quarterly review of research conduct will be reviewed by PI to assure safety of study, and validity/integrity of data.

This is a non-interventional study and thus does not require a DSMP. [x] Yes

C. Adequacy of Resources:
Principal Investigators must have the necessary resources required to conduct the proposed research in a way that assures the rights and welfare of participants are adequately protected. Depending on the nature of the research study, investigators should consider the proximity or availability of critical resources that may be essential to the safety and welfare of participants. For example, the proximity of an emergency facility for care of participant injury, or availability of psychological support after participation, or resources for participant communication, such as language translation services. *Please describe below the resources you have in place to conduct this research in a way that assures protection of the rights and welfare of participants*. This includes having adequately trained research staff and data systems to support the study:

This is a non-interventional study and thus does not require a DSMP. [ ] Yes
Standard postoperative care and followup are provided for study patients as for our standard non-study patients. These resources are adequate and appropriate to assure protection of rights and welfare of participants. Study performed by staff trained and educated to perform research.

D. Confidentiality and Privacy: Privacy concerns people, whereas confidentiality concerns data. Specifically, confidentiality refers to the researcher's plan to handle, manage and disseminate the participant's identifiable private information. Privacy refers to a person's wish to control the access of others to themselves. **Address each of the following privacy issues questions 1-3 below**:

1. How will the investigator access information from or about participants?

This is a non-interventional study and thus does not require a DSMP. [ ] Yes
Information will be same information used for non-study patients with standard postoperative care. EMR will be used as routine for joint replacement patients.

2. How will the investigator maintain privacy in the research setting(s)?

All data will be in the privacy of the subject's home or office clinic. Confidentiality of participants Protected Health Information (PHI) will be protected through locked cabinets for participant records containing PHI. Investigators will utilize password protected programs and access to PHI will be limited to investigators only. Data collected from questionnaires and during testing will stored in a locked cabinet that is accessible only to study personnel. Participants will not be identifiable by name or description in publications of this study.

3. What are the consequences to participants of a loss of privacy (e.g., risks to reputation, insurability, and other social risks)?

No additional data or information collected that is not standard. Therefore, same risks of privacy loss as with any EMR system.

The following questions address confidentiality issues:

4. Identifiers: Please indicate all identifiers that may be included in the research records for the study. Check all that apply.

[x] Names [x] Dates [x] Address [ ] Phone numbers [ ] Fax numbers [ ] Email address	[ ] Social Security numbers [ ] Medical records numbers [ ] Health plan numbers [ ] Account numbers [ ] License/Certificate numbers [ ] Vehicle id numbers	[ ] Device identifiers/Serial numbers [ ] Web URLs [ ] IP address numbers [ ] Biometric identifiers [ ] Facial Photos/Images [ ] Any other unique identifier [ ] None of the 18 identifiers listed above

5. **Determining Whether HIPAA Regulations Apply to This Research**: Please answer the questions below for the identifiers marked in the above section. Check all that apply:

Are research data: [x] Derived from a medical record? [ ] Added to the hospital or clinical medical record? [x] Created or collected as part of health care? [x] Used to make health care decisions?	**HIPAA regulations apply.**
[x] Obtained from the subject, including interviews, questionnaires? [ ] Obtained from a foreign country or countries only? [ ] Obtained from existing research records?	**HIPAA regulations do not apply.**

If HIPAA regulations apply, you are required to obtain individual subject authorization or a waiver of authorization. This authorization requires a separate signature by the research subject.

6. Use and Disclosure of Protected Health Information: Please indicate to whom or where you may disclose any of the identifiers listed above as part of the study process. Check all that apply:
[x] The subject's medical record.
[x] The study sponsor: ***please indicate***: Reparel
[ ] The US Food & Drug administration (FDA)
[x] Others: ***please indicate***: IRB
[ ] A Foreign County or Countries
[ ] We do not plan to share any of the PHI listed above outside the research team.

7. Data Security: Identifiable data should be not be stored on laptops, PDA's or other portable devices. Please indicate how study data are kept secure Check all that apply:
[ ] Data are coded; data key is destroyed at end of study or ***provide date***: _____
[ ] Data are coded; data key is kept separately and securely
[ ] Data are kept in locked file cabinet
[ ] Data are kept in locked office or suite
[x] Electronic data are protected with a password
[x] Data are stored on a secure network

8. Describe any additional steps taken to assure that identities of subjects and any of their health information which is protected under the law is kept confidential. If video or audio recordings will be made as part of the research, disposition of these recordings should be addressed here and in the consent form.

NA	
9. Reportable Information: Is it reasonable and/or foreseeable that the study will collect information that state or federal law requires to be reported to other officials (e.g., child or elder abuse) or ethically requires action (e.g., suicidal ideation)? If "Yes," please explain below and include a discussion of the reporting requirements in the consent form.	[ ] Yes [x] No
E. Benefits: **1.** Are there potential direct benefits to research subjects? If "Yes," please describe below.	[x] Yes [ ] No
It is hoped that subjects... - Less pain, less swelling, comparable or lower dvt rates	
2. What are the potential benefits to society?	
Faster and more comfortable recovery after hip replacement surgery	
F. Risk/Benefit Analysis: How do the benefits of the research outweigh the risks to subjects?	
No risks or adverse events are anticipated as a result of the tests. There is minimal risk to the subject and maximum gains in improved strength, health and wellbeing.	

PART 6: SUBJECT INFORMATION

A. Number of Subjects:	
1. How many subjects will be enrolled at WHHS and affiliated institutions?	**50**
2. How many subjects will be enrolled at all sites (i.e., if multicenter research)?	0
3. How many people do you estimate you will need to consent and screen here (but not necessarily enroll) to get the needed subjects?	70

B. Types of Subjects: Check all that apply.	
[ ]	Children – Complete Part 6.H of the Application
[ ]	Subjects Unable to Consent
[ ]	Subjects with Diminished Capacity to Consent
[ ]	Subjects Unable to Read, Speak, or Understand English – **Complete Part 8.D of this application**
[ ]	Pregnant Women – **Complete Part 6.G of this application**
[ ]	Fetuses – **Complete Part 6.G of this application**

[ ]	Neonates – **Complete Part 6.G of this application**
[ ]	Prisoners
[x]	Inpatients
[x]	Outpatients
[x]	Healthy Volunteers
[ ]	Staff of WHHS or WHHS affiliated institutions,
[ ]	Students of WHHS

C. Eligibility Criteria:

1. General description of subject population(s):

Elective hip replacement patients.

2. Inclusion Criteria:

50 subjects age 18-89 years of age.
50% male and 50% female
All subjects will have comparable levels of joint arthritis that present imminent surgical options or may present future surgical options.
All subjects will be selected by the PI

3. Exclusion Criteria:

Subjects <18 or >90 years of age
Subjects determined to be of high risk to participate by PI

1. Physical condition prohibiting use of leg stocking or garment
2. Allergy to silicone/polyester
4. Current DVT
5. History of Vascular Bypass Surgery on Operative Limb ie) Fem-Pop or Fem-Fem
6. Inability to follow standardized post op and rehab protocols
7. Lymphedema

D. Determination of Eligibility: How (chart review, additional tests/exams for research purposes), when and by whom will eligibility be determined?

Subjects will be screened initially by PI/team, for eligibility
Consent obtained after participation confirmed.
Bioactive sleeve garment and TED stocking supplied at time of surgery
Routine clinical followup and questionnaires provided

E. Are there any inclusion or exclusion criteria based on *gender, race* or *ethnicity*? If "Yes," please explain the nature and rational for the restrictions below.	[ ] Yes [x] No

na

F. Populations Likely to be Vulnerable to Coercion or Undue Influence:
List subject groups who are likely to be vulnerable to coercion or undue influence, such as mentally disabled persons, economically or educationally disadvantages persons, or investigators' staff or students. ***For pregnant women, fetuses and neonates,* see section 6.G Below**): Note: For other vulnerable groups, separate, specific regulations may apply.
na
2. Explain why it is appropriate to include the groups listed above in this particular research:
na
3. Describe **additional** safeguards that have been included in the research to protect the rights and welfare of these subjects and minimize coercion or undue influence. For example, you might provide competence evaluations (specify) for the mentally disabled, payment amounts calibrated to be non-coercive for the financially disadvantaged, extra-careful evaluations of subjects' understanding of the research, advocates to be involved in the consent process, or use flyers to recruit subjects instead of directly approaching staff or students:
NA
G. Pregnant Women, Human Fetuses and Neonates: Identify all sections of 45 CFR 46 Subpart B under which you believe the research falls and provide study-specific information showing why the research falls within those sections:
na
H. Children Identify all sections of 45 CFR 46 Subpart D under which you believe the research falls and provide study-specific information showing why the research falls within those sections:
na

PART 7: RECRUITMENT

A. Any advertisements, whether posted or broadcast, and all correspondence used for purposes of recruitment require IRB review and approval before they are used. Check all that apply:	
[x]	Research investigators recruit their own patients directly and/or nurses or staff working with researcher's approach patients. ***Please explain in Section B below.***
[ ]	Research investigators send an IRB approved letter to colleagues asking for referrals of eligible patients interested in the research. The investigators may provide the referring physicians an IRB approved Information Sheet about the study to give to the patients. If

	interested, the patient will contact the PI, or, with documented permission from the patient, the PI may be allowed to talk directly with patients about enrollment. ***Attach letter for review.***
[ ]	Research investigators provide their colleagues with a "Dear Patient" letter describing the research. This letter can be signed by the treating physicians and would inform the patients how to contact the research investigators. The research investigators may not have access to patient names and addresses for mailing. ***Attach letter for review.***
[ ]	Advertisements, notices, and/or media used to recruit subjects. The IRB must first approve the text of these and interested subjects will initiate contact with research investigators**.** ***Attach ads, notices or media text for review. In Section B, please explain where ads will be posted.***
[ ]	Research investigators request a Waiver of Consent/Authorization for recruitment purposes. This waiver is an exception to the policy but may be requested in circumstances such as:
[ ]	Minimal risk research in which subjects will not be contacted (i.e., chart review only).
[ ]	Review of charts is needed to identify prospective subjects who will then be contacted. (Explain in Waiver form).
[ ]	Large-scale epidemiological research and/or other population-based studies when subjects may be contacted by someone other than personal physician. (Explain in Waiver form).
[ ]	Direct contact of potential subjects who have previously given consent to be contacted for participation in research. Clinic or program develops an IRB-approved recruitment protocol that asks patients if they agree to be contacted for research (a recruitment database) or consent for future contact was documented using the consent form for another IRB-approved research. ***Please explain in Section B below.***
[ ]	Research investigators recruit potential subjects who are unknown to them. Examples include snowball sampling, use of social networks, and direct approach in public situations. ***Please explain in Section B below.***
B. Provide detail in the space below (i.e., *how, when, where* and *by whom* are potential subjects approached).	
PI will select subjects from his subject pool to ensure they are appropriate for the study.	

PART 8: INFORMED CONSENT PROCESS

A. Check all that apply:	
[x]	Signed consent will be obtained from subjects and/or parents (if subjects are minors).
[ ]	Signed consent will be obtained from a legally authorized representative.
[ ]	Informed consent will not be obtained. **Complete Waiver of Consent in Section 8.E.**
B. In the space below, describe *how, where, when* and *by whom* informed consent will be obtained. How much time will prospective subjects be given to consider study participation? If special subject populations will be included, be sure to describe any additional plans for obtaining consent from particular populations.	
PI will discuss the protocol with each subject and provide an Informed Consent form. Subject may additionally contact sponsor to address additional questions.	

C. How will you make sure subjects understand the information provided to them?
Subjects will be provided with oral and written explanations of the protocol and expectation.
D. Subjects Who Do Not Read, Speak or Understand English.
1. If you will enroll subjects who are unable to read, speak or understand English, what method will you use to obtain consent? na

[ ]	*Preferred Method* – Consent form and other study documents will be available in the subject's primary language. Qualified interpreter able to discuss participation in the patient's language will be present, physically or via language line, for the consent process.
[]	*Short-Form* – A qualified interpreter will translate the consent form verbally and subjects will be given the Experimental Subject's Bill of Rights and the Short Form Consent in their primary language.

2. How will you maintain the ability to communicate with non-English speakers throughout their participation in the study?
Study will be focused on English speakers only.
E. Waiver of Consent:
A waiver of consent is requested: [ ] Yes [x] No If yes, the investigator certifies that the following criteria are met: • The research involves no more than minimal risk to the subjects. • The research could not practicably be carried out without the requested waiver or alteration. • If the research involves using identifiable private information or identifiable biospecimen, the research could not practicably be carried out without using such information or biospecimen in an identifiable format. • The waiver or alteration will not adversely affect the rights and welfare of the subjects. • Whenever appropriate, the subjects or legally authorized representative will be provided with additional pertinent information after participation.

PART 9: FINANCIAL CONSIDERATIONS

A. Payments to Subjects: 1. Will subjects receive payments or gifts for research participation? If "Yes," complete the following:	[ ] Yes [x] No
2. Payments will be (check all that apply):	[ ] Cash [ ] Check [ ] Other (describe below)
3. Please describe the schedule and amounts of payments, including the total subjects can receive for completing the research.	
na	

B. Cost to Subjects: Will subjects or their insurance be charged for any research procedures? If "Yes", describe those costs below and compare subjects' costs to the costs associated with alternative care off-study. Finally, explain why it is appropriate to charge those costs to the subjects.	[ ] Yes [x] No

C. Treatment and Compensation for Injury: Describe the procedures that will be followed if a subject is injured as a result of participation in the research study.

Should the subject feel discomfort while following the oral or written instructions, they should refrain from using the garments and consult with Dr. Sah. There is no compensation for injury as injury is not expected.

PART 10: BIBLIOGRAPHY

de Freitas, L. F., & Hamblin, M. R. (2016). Proposed mechanisms of photobiomodulation or low-level light therapy. *IEEE Journal of selected topics in quantum electronics*, *22*(3), 348-364.

Brennecka, G.L. (2016). Optical Response of Reparel Fabrics, 0.3 – 2.5 µm. Colorado School of Mines.

PART 11: ATTACHMENTS

Please list Attachments, Supplements and Appendices Indicate with an asterisk (*) any document that requires IRB approval. Reparel Questionnaire *	Version number(s) or date(s)

PART 12: INVESTIGATOR CERTIFICATION

Principal Investigator's Certification:

- I certify that the information provided in this application is complete and correct.

Investigator Signature Date 12/1/21

Alexander Sah, MD
Investigator Printed Name