BU Charles River IRB
(Full Board and Expedited Review)

SECTION A: PROTOCOL AND CONTACT INFORMATION

Protocol Title:	Translation of Robotic Apparel for Alleviating Low Back Pain **NCT05736393**
Principal Investigator **(Name, degrees, licenses, etc.):** ☒ Mr. ☐ Ms.	Lou Awad, PT, DPT, PhD
Department/School:	Department of Physical Therapy, College of Health & Rehabilitation Sciences: Sargent College
BU Mailing Address:	635 Commonwealth Ave, Boston, MA 02215
Email:	louawad@bu.edu
Telephone:	6173583043
Additional Contact Person:	Johanna Spangler, Research Fellow
Email:	jospan@bu.edu
Telephone:	(717) 357-3702

☒ YES **(REQUIRED)**	I confirm that I qualify to serve as the Principal Investigator of this study and am in compliance with the following policies: http://www.bu.edu/researchsupport/compliance/human-subjects/

SECTION B: FUNDING

Provide information regarding **ALL** funding sources for this project, including existing funding, pending funding, and funding that has been applied for to support this research.

Please check all that apply:	
☒	This research is funded
☐	Funding has been requested Have you received Just In Time (JIT) Notification? ☐ Yes ☐ No NOTE: Once the funding has been awarded, submit an amendment to the IRB to add the funding source
☐	Research is not funded

If the research is funded or funding has been requested, it is REQUIRED that you complete the box below. If you don't have an award #, please state that in the box below. If you have multiple funding sources, add additional boxes as necessary.

Sponsor Name	National Institutes of Health
Title of Grant/Proposal	Development, Evaluation and Translation of Robotic Apparel for Alleviating Low Back Pain

Sponsor Award # **(REQUIRED)*** *If Award is pending, put "pending".		4UH3AR076731-02
YES	**NO**	
☐	☒	Is Boston University the Prime Awardee of the grant?
☒	☐	Is Boston University receiving a sub-award? Name of Prime Recipient: Harvard University
☐	☒	Is the research being supported by an Industry Contract or Clinical Trial Agreement?

***NOTES:**

- Provide a copy of the grant application, funding proposal, contract/agreement, scope of work, or sub-award agreement supporting the research. If an award is pending, once the funding has been awarded, submit an amendment to the IRB to add the funding source.
- If this research study is for your dissertation, provide a copy of your prospectus (if available).

SECTION C: CONFLICT OF INTEREST

☒ YES **(REQUIRED)**	I confirm that **ALL** those responsible for the design, conduct, or reporting of the proposed research, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms, submitted them to the COI office, and completed training as dictated at: http://www.bu.edu/researchsupport/compliance/conflicts-of-interest/, and as provided under *the Boston University Investigator Conflicts of Interest Policy for Research.* NOTE: You must provide a copy of the PI's COI submission confirmation email with your IRB application. Regardless of the study's funding status, completion of the financial interest disclosure forms is required. COI submission confirmation emails for all other study staff should be maintained at the research site.
Of the financial interest disclosure forms submitted, did you check "yes" to any of the questions on either the FIND1 or NONFIND1 form? ☐ Yes* ☒ No	

***If you checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

SECTION D: TYPE OF REVIEW

For Guidance regarding Type of Review please refer to the CRC IRB website

I. **FULL BOARD** ☒
Please refer to the CRC IRB website for Full Board submission deadlines and meeting dates.

II. **EXPEDITED** ☐

In order to qualify for expedited review, the study must be no more than minimal risk* **AND** must fall into one of the categories below. Check all that apply:

1. ☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. ☐ Collection of blood samples by finger stick, heel-stick, ear stick, or venipuncture as follows:
   a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. ☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings, saliva or cheek swabs, sweat, etc.

4. ☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples:
   - Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
   - Weighing or testing sensory acuity
   - Magnetic resonance imaging
   - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
   - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. ☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)

6. ☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

7. ☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: The IRB will make the final determination on the Type of Review

***Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

SECTION E: STUDY STAFF AND HUMAN SUBJECTS TRAINING

List **ALL** current members of the research team in the table below. Add more rows as necessary.

STUDENT RESEARCH:
The Faculty Advisor must be listed as a co-investigator in this section and must complete the Human Subjects training requirements. Faculty Advisors are responsible for reviewing the IRB application, agreeing to serve as the Co-PI for this study with the student and are responsible for the ethical conduct of this student's human subjects research. Faculty Advisors must sign this Application prior to it being submitted to the IRB.

BU CHARLES RIVER CAMPUS (CRC) INVESTIGATORS/STUDY STAFF
Note: Boston University Medical Campus (BUMC) investigators/study staff should be listed in the NON-BU INVESTIGATOR/STUDY STAFF section

Name, Degree, Department, School	**Study Role (e.g. co-investigator, research coordinator, research assistant, project manager, lab manager)**	**Human Subjects Training***
Louis Awad, PT, DPT, PhD Department of Physical Therapy, College of Health & Rehabilitation Science: Sargent College, Boston University	Principal Investigator	☒ CITI; Expires 1/24/2026 ☐ Other;** GCP Training Most Recent Date Completed: 1/23/2023
David A. Sherman, PhD, PT, DPT, ATC	Co-Investigator, Research Physical Therapist, Project Manager	☒ CITI; Expires 6/13/2025 ☐ Other;** GCP Training

Boston University Physical Therapy Center & Department of Physical Therapy, College of Health & Rehabilitation Science: Sargent College, Boston University		Most Recent Date Completed: 06/13/2022
Andy Nhiv, BSc Boston University Physical Therapy Center, College of Health & Rehabilitation Science: Sargent College, Boston University	Research Coordinator	☒ CITI; Expires 8/7/2026 ☐ Other;** GCP Training Most Recent Date Completed: 8/6/2023
Caleigh O'Brien, DPT, OCS Boston University Physical Therapy Center, College of Health & Rehabilitation Science: Sargent College, Boston University	Research Physical Therapist	☒ CITI; Expires 9/8/2026 ☐ Other;** GCP Training Most Recent Date Completed: 9/7/2023
Trace Sears, PT, DPT, FAAOMPT Boston University Physical Therapy Center, College of Health & Rehabilitation Science: Sargent College, Boston University	Research Physical Therapist	☒ CITI; Expires 9/8/2026 ☐ Other;** GCP Training Most Recent Date Completed: 9/7/2023
Diane Dalton, PT, DPT, OCS Boston University Physical Therapy Center & Department of Physical Therapy, College of Health & Rehabilitation Science: Sargent College, Boston University	Co-Investigator, Research Physical Therapist	☒ CITI; Expires 08/28/2025 ☐ Other;** GCP Training Most Recent Date Completed: 08/28/2022
James "Cam" Camerinos, DPT, PT; Boston University Physical Therapy Center & Department of Physical Therapy, College of Health & Rehabilitation Science: Sargent College, Boston University	Co-Investigator, Research Physical Therapist	☒ CITI; Expires 3/3/2025 ☐ Other;** GCP Training Most Recent Date Completed: 3/3/2022
Johanna Spangler Department of Physical Therapy, College of Health	Research Coordinator, Lab Manager	☒ CITI; Expires 9/11/2026 ☒ Other;** GCP Training

& Rehabilitation Science: Sargent College, Boston University		Most Recent Date Completed: 09/10/2023

- *For more information regarding the Human Subjects Training Policy, refer to the 'Training' section of the Policies & Guidance section IRB website.
- **If the investigator/study staff did not complete CITI, you must submit a copy of their training certificate.

NON-BU INVESTIGATORS/STUDY STAFF* ☐ **N/A**

Note: BUMC and BMC staff are considered non-BU staff and should be listed in this section. Add more rows as necessary. All the columns in the box below must be completed. In addition, you must complete the box that follows with a description of the activities for each staff member.

Name, Degree, Institution	Study Role	Staff Information	Will IRB Approval be Obtained from Non-BU Institution?
Conor Walsh, PhD Harvard John A. Paulson School of Engineering and Applied Sciences, Harvard University	Co-principal Investigator	1. Will this staff interact with subjects? ☐ Yes ☒ No 2. Will this staff have access to identifiable information? ☒ Yes ☐ No 3. Is the work that the staff will complete related to their role or coursework at their institution? ☐ Yes ☒ No	☒ Yes*; provide copy of IRB approval letter. *Waiting for cede approval ☐ No (provide reason):
Philipp Arens Harvard John A. Paulson School of Engineering and Applied Sciences, Harvard University	Co-Investigator, Engineering Project Lead	1. Will this staff interact with subjects? ☒ Yes ☐ No 2. Will this staff have access to identifiable information? ☒ Yes ☐ No 3. Is the work that the staff will complete related to their role or	☒ Yes*; provide copy of IRB approval letter. *Waiting for cede approval ☐ No (provide reason):

		coursework at their institution? ☒ Yes ☐ No	
Marija Bakoc Harvard John A. Paulson School of Engineering and Applied Sciences, Harvard University	Research Fellow	1. Will this staff interact with subjects? ☒ Yes ☐ No 2. Will this staff have access to identifiable information? ☒ Yes ☐ No 3. Is the work that the staff will complete related to their role or coursework at their institution? ☒ Yes ☐ No	☒ Yes*; provide copy of IRB approval letter. *Waiting for cede approval ☐ No (provide reason):
David Adam Quirk, PhD Harvard John A. Paulson School of Engineering and Applied Sciences, Harvard University	Co-principal investigator	1. Will this staff interact with subjects? ☒ Yes ☐ No 2. Will this staff have access to identifiable information? ☒ Yes ☐ No 3. Is the work that the staff will complete related to their role or coursework at their institution? ☐ Yes ☒ No	☒ Yes*; provide copy of IRB approval letter. *Waiting for cede approval ☐ No (provide reason):
Dionna Williams Clinical & Translational Research Core, Wyss Institute for Biologically Inspired Engineering, Harvard University	Clinical Team Research Director	1. Will this staff interact with subjects? ☒ Yes ☐ No 2. Will this staff have access to identifiable information? ☒ Yes ☐ No 3. Is the work that the staff will complete related to their role or	☒ Yes*; provide copy of IRB approval letter. *Waiting for cede approval ☐ No (provide reason):

		coursework at their institution? ☐ Yes ☒ No	
Sarah Sullivan Clinical & Translational Research Core, Wyss Institute for Biologically Inspired Engineering, Harvard University	Clinical Team Research Manager	1. Will this staff interact with subjects? ☒ Yes ☐ No 2. Will this staff have access to identifiable information? ☒ Yes ☐ No 3. Is the work that the staff will complete related to their role or coursework at their institution? ☐ Yes ☒ No	☒ Yes*; provide copy of IRB approval letter. *Waiting for cede approval ☐ No (provide reason):

*If IRB approval will be obtained from the affiliate site, only list the lead investigator from the affiliate on this form.

The box below must be completed. Include a summary for each staff listed in the above box. If any of the investigators listed on this form are not affiliated with BU, provide a summary of the study activities that they will conduct. If IRB approval is not being obtained at the affiliate institution, provide an explanation. **NOTE: Non-BU staff may be required to complete an Individual Investigator Agreement (IIA). The IRB will notify you if this form is required.**

1. Records and file maintenance
2. Development and maintenance of all study materials including the IRB and study forms
3. Serving as contact to and delivering files to regulatory bodies (e.g. IRB)
4. Training staff and study procedures
5. Data collection
6. Identification, screening, enrollment, and retention of participants
7. Monitoring and reporting of adverse events
8. Compliance with and accountability of study intervention administration
9. Data entry
10. Study Team Member
11. Data Analysis

Conor Walsh[1,2,3,7,8,10,11]
Philipp Arens[1,4,5,7,8,9,10,11]
Marija Bakoc[1,4,5,7,8,9,10,11]
David Adam Quirk[1,2,3,4,5,7,8,9,10,11]
Dionna Williams[1,2,3,6,7,8,10,11]
Sarah Sullivan[1,2,3,6,7,8,10,11]

REQUIRED GOOD CLINICAL PRACTICE TRAINING FOR NIH-FUNDED CLINICAL TRIALS

YES*	NO	NIH-FUNDED CLINICAL TRIALS
☒	☐	Is your study NIH-Funded AND meet the definition of a clinical trial as defined in the NIH policy? All investigators (both BU and Non-BU) have completed good clinical practice training.

SECTION F: LOCATION OF THE RESEARCH

YES*	NO	
☒	☐	Will this research take place at sites/locations other than Boston University? **Note:** If the research will take place at Boston University, state the location (Building and Room number):

*If **YES,** please complete the boxes below

NOTE: You are responsible for obtaining permission/letters of support for research conducted off-site. This may include locations such as schools, workplaces, community organizations, etc. You must submit the letters/documentation of support with this application.

Institution Name and Address (if known)	**Describe Involvement (recruiting, consenting, data analysis, etc.) of the site. If the site or the site staff is not involved (engaged)[1] in research procedures, state NONE.**	**IRB/Ethics Approval/Site Permission Attached? If no[2], explain the plan to obtain this approval. If the site is not engaged in the research, you do not need to complete the box.**
Harvard University, 150 Western Ave, Boston, MA 02134	Screening, informed consent, identifiable data access, data analysis, app management, exosuit data management, and writing.	SMART IRB submission will be started. Approval upon cede receipt.
Harvard University Medical School (Wyss Institute)	Screening, informed consent, identifiable data access, etc.	SMART IRB submission will be started. Approval upon cede receipt.
[1]Guidance on Engagement of Institutions in Human Subjects Research [2]If IRB approval will not be obtained at the site, describe the IRB oversight arrangements here:		

YES*	NO	
☒	☐	Is the off-site location requesting that the Boston University IRB review the protocol in place of local IRB review? If **YES**, complete the Single IRB Review Form "Boston University is Institution A"

YES*	NO	
☒	☐	Is the BU PI the lead investigator **OR** is BU the lead site for this research?

		Note: This box only needs to be completed if the off-site location is engaged in the research.

*If **YES**, provide the following information in this box:

- The plan for collection and management of data from all the sites:
  - Data will not be collected at Harvard University.
  - De-identified data from the exosuit and associated app will be stored on Harvard University servers.
  - All other data will be stored in and accessed via Boston University's REDCap or SharePoint servers.
- The plan for reporting and evaluating:
  - See **Section S** for plans for reporting and monitoring unanticipated problems, serious and/or continuing non-compliance, suspensions and terminations of research, interim results, and protocol modifications
- The name of the Principal Investigator from each site:
  - Boston University: Lou Awad
  - Harvard University: Conor Walsh
- If IRB approval will be obtained at the site, confirmation that you have a copy (or will obtain a copy) of the IRB approval letters and the IRB-approved protocols from each site
- If IRB approval will be obtained at the site, confirmation that the site IRB has a FederalWide assurance (FWA)

YES	NO	
☐	☒	Will this research be conducted outside of the United States? If **YES**, complete the International Research Form.

SECTION G: STUDY SUMMARY

Summarize the study in lay language (do not copy from the grant/scope of work/proposal, etc.). This summary should include the research design, purpose, objectives, research question, hypothesis, and any relevant background information.

Do not include a list of citations in this section. Please limit this section to no more than 300 words.

Low back pain (LBP) has a lifetime prevalence of 80%, with approximately 20% of individuals experiencing recurrent episodes or chronic LBP (cLBP). Unfortunately, the evidence for the effectiveness of most rehabilitative treatment is low. With an economic burden approaching $100-billion in the United States alone, the National Institutes of Health has invested millions of dollars in innovative technologies aiming to improve rehabilitative care for low back injuries. As part of this initiative, our collaborative network of expert clinicians, engineers, and researchers have developed and tested robotic apparel technology (exosuit) that supplements ergonomic and biomechanical training and can be utilized by clinicians in the treatment of individuals with LBP.

Failed rehabilitation, and thus progression from acute to cLBP, is thought to be caused by maladaptive motor control strategies, muscle hyperactivity, reduced movement variability, and development of fear-avoidance-beliefs. Our exosuit technology was designed to reduce exertion, encourage safe, varied movement strategies, and promote recovery through well-timed assistive forces to the trunk and hips during flexion postures and lifting tasks. The proposed project builds

on this work through use of our exosuit to augment traditional physical therapy care. In doing so, we will determine whether this technology can enhance rehabilitation after back injuries, interrupt the progression of acute to cLBP, encourage non-maladaptive movement strategies, and expedite the timeline of return to prior level of function.

To examine the effects of exosuit augmented physical therapy rehabilitation and reduce disability, we have designed a two-phase study. In the pilot phase, we will enroll up to 8 individuals into the protocol as a pilot sample. These individuals will be recruited from the same population as the larger trial protocol. After the pilot phase, we will register the larger trial and incorporate any indicated changes. After approval, we will enroll up to 100 individuals with LBP who are referred to or receiving physical therapy into a single arm clinical trial. We will evaluate changes in muscle activity, motor control, range of motion, pain, disability, and fear-avoidance beliefs and compare outcomes to a historical control group who received usual care. Comparison of our findings to historical outcomes data will be critical to the determination of effectiveness.

For the full protocol, participants will attend an in person screening, initial visit (1), 10 (2-11) sessions of physical therapy and a discharge visit (12). Participants will undergo a comprehensive biomechanical analysis on visits 1, 3, 6, 9 and 12, completing an extensive battery of surveys at visits 1, discharge, and 1-month post-discharge. Given the comprehensive data collection, a detailed description of study objectives, their corresponding outcome measures, and the proposed statistical analysis are formalized in our statistical analysis plan (Appendix V).

To determine the persistence of the biomechanical and psychosocial changes that participants might experience during exosuit-augmented therapy, participants who have completed the full protocol can join an optional longitudinal evaluation study. This study will involve completing our extensive battery of surveys at 3, 6, 9, and 12 months post-discharge. Additionally, if interested and still eligible at months 6 and 12, participants can complete an in-person biomechanical data collection to understand whether their motion has changed over time.

SECTION H: RESEARCH METHODS AND ACTIVITIES (Check all that apply)

☒	Collection of audio, video, digital, or image recordings
☐	Biological samples → Complete Biological Samples Form Examples: blood, hair, cheek swab, urine, tears, saliva, etc.
☐	Collection of data that may be sensitive and if disclosed could put subjects at risk for legal or social harms. (e.g. Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc.
☐	Coordinating Center/Lead Site
☐	Deception
☒	Devices → Complete Devices Form
☐	Drugs → Complete Drugs Form

☐	Ethnographic: The study of people in their own environment through the use of methods such as participant observation and face-to-face interviewing
☐	Focus Groups
☐	Genetics Testing → Complete Genetics Form
☐	MRI → Complete MRI Form
☐	Placebo
☐	Pregnancy Testing
☐	Randomization
☒	Surveys, interviews, questionnaires
☐	Secondary Data Analysis
☒	Other (please describe): Common clinical examination approaches will be used to measure the musculoskeletal system (e.g., range of movement, strength), sensorimotor function (e.g., balance, posture, walking), and functional ability (e.g., squatting, lifting, carrying). Additionally, non-invasive measurements of biomechanical function will be made using common movement analysis tools such as motion tracking sensors (e.g., inertial measurement units) attached to the exosuit. Additionally, information on LBP through existing medical records, clinical notes, and imaging results may be utilized, contingent upon authorization to disclose protected health information (PHI). The medical records and clinical notes, will allow us to examine the relationship between clinical characteristics and response to intervention.

SECTION I: PARTICIPANT POPULATION

Provide the Number of Participants to be Enrolled. If you have sub-groups or more than one arm, please separate out these enrollment numbers. Note: Please account for participants who may drop out or be withdrawn from the study. Anyone who signs a consent form is considered to be enrolled in the research regardless of whether they complete any study procedures.
We will enroll up to 8 individuals referred to physical therapy for LBP for the Observational Pilot Study We will enroll up to 100 individuals referred to physical therapy for LBP, anticipating a 20% drop out rate.

Check all categories that apply to your participant population:	
☒	Adults

☐	Children (< 18 years of age)
☐	Adults with Limited Decision-Making Capacity
☐	Non-English Speaking
☐	Prisoners
☒	BU Employees
☒	BU Students
☐	Wards of the state
☐	Other (please describe):

If a population other than 'Adults' has been checked, describe the additional safeguards that have or will be put in place to protect those individuals, and provide the rationale for including this population in the research study.

BU employees and students may be enrolled into this study only if ALL the following conditions are met:

- The student/employee is aware that participation in the study is completely voluntary and will not be used to sway benefits or employment status
- The student/employee has had ample time to read over the consent form
- The investigator taking informed consent must be someone other than the PI and must not be in a senior or supervisory role to the student/employee
- The investigator taking informed consent must be trained in taking consent

No BU employee, student, of staff who are direct members of the lab will be recruited in this interventional study.

Eligibility Criteria

Inclusion Criteria:

- Age 18-70*
- Diagnosis of LBP by a licensed medical provider or self-report of lower back pain (initially gathered through phone screening and confirmed during in-person screening visit)
- Self-reported LBP with bending or lifting
- Able to walk without an assistive device.*
- Willing and able to provide informed consent.*

- Provide HIPAA Authorization to allow communication with the primary healthcare provider (e.g., treating physical therapist) for communication (as needed) during the study period.
- Must consent to and undergo physical therapy examination with a research physical therapist and be assigned a Treatment-Based Classification (TBC) of movement impairment or control impairment.

Exclusion Criteria (exclusion criteria are the specific criteria which would disqualify an individual from participating in the study not simply the opposite of the inclusion criteria):

- Unable to attend all scheduled visits and 1-month phone follow-up
- Currently pregnant or likely to become pregnant within 6 weeks
- Having received surgery to address current LBP
- Having pain or symptoms below the knee that seems related to their current LBP
- Having current LBP lasting less than 2 weeks
- Diagnosed or self-reported neurological disorders effecting motor control (stroke, Parkinson's disease, etc.)
- Use of a pacemaker or other implanted medical devices
- Currently under treatment for cancer
- Skin issues / sensitivity that an exosuit could exacerbate (e.g., Epidermolysis Bullosa)
- Any other medical conditions that would preclude safe use of the exosuit device as determined by a physical therapist

SECTION J: RECRUITMENT

Provide a summary of the recruitment process, including who will recruit, when and where recruitment will occur, and how subjects will be identified

Submit all recruitment materials (e.g. advertisements, brochures, flyers, letters/e-mails, scripts, etc.) as separate documents in either Word or PDF format.

Only investigators, research assistants, and administrators with clinical appointments at the Boston University Physical Therapy Center may be involved in recruitment through the Boston University Physical Therapy Center.

Recruitment will be conducted primarily through the Boston University Physical Therapy Center (BUPTC) at the Ryan Center for Sports Medicine at Boston University. If a prospective patient reports lower back pain, BUPTC administrative staff will ask, "*Are you interested in learning more about research studies that may pertain to your condition?"*. The intake process is conducted via phone.

If a patient answers yes, consistent with the (Study Introduction Script). In that case, the patient will have the option to hear more about the study or have their contact information added to the Recruitment Screening List (Appendix S) with a description of the referring complaint (e.g., back pain) so that the study coordinator can call them back (Section 6.1). This registry will be housed on HIPAA-compliant BU Microsoft Teams/SharePoint in a shared folder between the BUPTC administrative staff and the BU members of the research team who

have clinical appointments at BUPTC. This is a secure, password-protected server authorized to store restricted data by BU IS&T Information Security team on the BU network, with access provided only to the investigators, research assistants, and administrators with clinical appointments at BUPTC. The study team at BUPTC will monitor this registry closely (at least daily) for individuals who may meet the inclusion/exclusion criteria and will initiate contact accordingly to describe the study (using IRB-approved script, **Appendix A**). We will target less than 24-hour delay to conduct the initial screening. However, we are requesting 3 days to initial contact if someone is added on Friday afternoon and research staff cannot call until Monday.

If the patient selects to hear more about the study, they will be transferred to the study coordinator(s). If the study coordinator is not available, to ensure scheduling with the appropriate physical therapist, the BUPTC administrator can inform the participant of the study using the language provided in the (Study Introduction Script). If the participant remains interested and has time, the BUPTC administrator can conduct the Phone Screening Form (**Appendix C**), completing a hard copy or electronic pdf version of the Form that will be uploaded to a secure Microsoft Teams Server or kept in a locked filing cabinet (hard copy). Otherwise, the patient's information will be added to the Recruitment Screening List for a research team member to conduct the Phone Screen at a convenient time.

If the patient's contact information is added to a registry **(Appendix S: Recruitment Screening List)** the potential participants will be contacted by a research team member with a clinical appointment at BUPTC. If individuals indicate they are interested or are transferred to the research coordinator, the research team member will proceed with the phone screen.

Individuals will be asked to answer questions for screening in the phone screening form (**Appendix C**) over the phone. Whenever possible, the phone screen will be conducted during the study interest phone call (i.e. the initial recruitment contact). However, the phone screen will be scheduled at a separate time if the potential participant is busy or would like time to consider their interest in the study. All participants who complete the phone screen will be assigned a screening ID, and responses will be recorded using the phone screening form (**Appendix C**).

Individuals who fail this screen OR who are not interested in the study will be returned to BUPTC admin staff for non-research / routine care. The study team will not retain their contact information, only the phone-screening template with an assigned screening ID.

If the participant is interested and willing to participate, the research team member will schedule the in-person visit to conduct the screening consent form and in-person screen (physical therapy exam). If the participant is eligible, a study team member will review the informed consent with the participant. If the participant needs additional time to think about the study and participation, they will be given a copy of the Informed Consent Form (ICF) document and can continue the intake process for the BUPTC in the meantime. The research team member will follow up with the potential participant at 1 week to learn if they are still interested and would like to participate. If the potential participant is still interested, the participant will be scheduled for a time to review the ICF either in person or remotely (via

zoom meeting or phone call). Please see section K for further details regarding the informed consent process. If the potential participant does not respond or indicates a lack of interest, recruitment concludes. Research staff and BUPTC administrative staff work closely together. This will be communicated verbally or via Microsoft Teams, our HIPAA compliant messaging platform. In the event of screen failure or disinterest, the individual will be contacted for scheduling by BUPTC staff on the same day.

Once the individual is screened, does not respond, or indicates a lack of interest, their information is removed from the registry.

We make the following commitments to BUPTC regarding recruitment procedures:

a. Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
b. No protected health information is to be removed from the covered entity by the researcher in the course of the review; and
c. The protected health information for which use or access is sought is necessary for the research purposes.

Recruitment may occur via email (e.g., using IRB-approved language [**Appendix A**]), IRB-approved flyers (**Appendix B**), or word of mouth through the following: (All investigators and research assistants may be involved in recruitment through these means)

a. Clinicians at clinics, centers, and institutions with whom the investigators have developed collaborating relationships (e.g., BUPTC, Ryan Center, Wyss Institute at Harvard University, and Boston Medical Center) may approach patients who they believe may be interested in participating in the study to inform them about the study (Email and/or Flyers).
    i. If these individuals are interested, they will be provided with a research flyer, which they can use to initiate contact with our study personnel.
b. Clinicians at rehabilitation clinics in the greater Boston area may be provided with IRB-approved recruitment materials that they can make available to their patients (Flyers).
    i. Individuals that are interested can then use the information in these materials to initiate contact with our study personnel.
c. Study investigators may be invited to speak about the study to relevant organizations, including recreational/social programs, support groups, etc. Study flyers will be left at or provided to these locations for distribution (Flyers).
    i. Individuals that are interested can then use the information in these materials to initiate contact with our study personnel.
d. Information about the study may also be distributed via the following methods with prior approval from site staff/managers (Flyers):
    i. Relevant buildings around Boston, at local businesses (e.g., coffee/sandwich shops), at local health or fitness centers.
    ii. Electronic posting on lab websites, research opportunities in clinical sites, and other relevant websites such as Craigslist or print papers such as the Boston Metro
    iii. Relevant social media sites or groups (e.g., Facebook)

In cases when interested individuals verbally indicate preference to be contacted by our research team, study personnel will contact them to provide more information about the study.

SECTION K: CONSENT AND ASSENT

Please refer to the consent and assent form templates on the IRB website when creating your consent/assent documents. The templates include the required elements of consent and will help to ensure that your consent/assent form meets the requirements of the federal regulations and the BU CRC IRB.

STUDENT RESEARCHERS must: 1) indicate in the consent form/information sheet/script that they are a student and 2) list the Faculty Advisor as a contact in the form/sheet/script.

Provide a summary of the consent process, including who will consent participants, when and where consent will occur. The summary should include, as appropriate, any waiting period between informing the prospective participant about the research and obtaining consent, such that the prospective participant or the legally authorized representative has sufficient opportunity to consider whether to participate, and steps taken to minimize coercion or undue influence.

Submit copies of all consent forms and scripts; materials should be submitted as separate documents in Word format.

Note: for guidance on Research Involving Persons with Limited Decision-Making Capacity to Provide Informed Consent, please see here.

Recruitment outreach + phone screen (if interested)

Potential participants will first undergo an initial phone or in-person screen (described in detail in "Section J: Recruitment") to determine eligibility for the study. This screen will take under ten minutes and will be conducted by the trained study personnel with clinical appointments at BUPTC (listed in Section E) or a BUPTC administrator (Section J: Recruitment). During this first conversation, the goals of the project will be clearly described, and the potential participant will be asked questions to ascertain whether they meet the study's inclusion/exclusion criteria. This will be recorded using the phone screening form (**Appendix C**).

If the participant meets the study criteria and remains interested in participating, they will be scheduled for a **Physical Therapy Examination**. A study team member will reach out to the patient to inform them of the following:

1. The Physical Therapy Examination will take place at the Boston University Physical Therapy Center (BUPTC) at the Ryan Center for Sports Medicine located at 915 Commonwealth Ave, Boston, MA 02215.
2. Prior to beginning the Physical Therapy Examination, study researchers will go through the **Screening Consent Form.**
3. If screening consent is obtained, participants will begin the Physical Therapy Examination. The Physical Therapy Examination is required of all BUPTC patients. It is also required to participate in this study. While the exam is performed in the context of care, it will inform study eligibility.

4. Physical therapy examination can take up to 60 minutes.
5. The physical therapy examination will result in the physical therapist making a determination of treatment-based classification based on the total of the exam findings.
6. The study team will use this classification to determine eligibility. I.e., if the treatment-based classification is motor control: movement impairment or motor control: control impairment, the individual will be determined eligible. Otherwise, the individual is ineligible.

7. If eligible based on the Physical Therapy Examination, the potential participant will be provided an opportunity to trial the back exosuit to help them determine their interest in the study. In order to complete this trial of the back exosuit, they must sign a **Risk and Release Form from both BU and Harvard institutions (two separate forms).** This device trial is optional and not required to proceed. If the participant remains interested in participating, study researchers will go through informed consent and a HIPAA authorization form with the participant after the examination and before any research procedures commence.
8. If the individual is not able to stay after the physical examination for informed consent, this will be rescheduled at a different time. The individual will be able to complete the informed consent process in-person or remotely (via zoom meeting or phone call).
9. After enrollment, a researcher will schedule participants for the next steps in the research procedures, including research visit 1, which will include routine physical therapy care, Exosuit Fit/Comfort, tuning and baseline assessments.
10. If the potential participant is determined ineligible for the research study, it will not impact their care at BUPTC. The participant will be asked on the Phone screening form if the research team can keep their contact information in a research registry for future outreach about potential studies. If they answer yes, the participant will be added to the research registry that will include screened and enrolled participants with contact information stored on a password protected Sharepoint folder accessible only to study staff.
11. The research team will update the screening log **(Appendix D: Screening Log)**.

Screening Consent

Upon arriving to the in-person screening, the individual and researcher will complete the Screening Consent Form electronically via REDCAP e-consent framework. Participants will also have the option to consent via paper copy, if preferred. Regardless of mode of consent, the screening consent form will be uploaded to Sharepoint in the participant's screening folder. If consent is not obtained, the research process will cease. Failure to obtain screening consent will not impact their care at BUPTC. If consent is obtained, the study physical therapist will begin the physical therapy examination.

Routine Physical Therapy Examination to Determine Eligibility

A licensed and credentialed physical therapist will conduct the Physical Therapy Examination. The examination will also serve as the primary entry into routine clinical care at the Boston University Physical Therapy Center. The physical therapist determination of

treatment based classification will be used to determine study eligibility. If the potential participant is determined **ineligible** for the research study, it will not impact their care at BUPTC. Study members will inform BUPTC administrative staff that the participant will not enroll in the research study so that BUPTC admin can coordinate scheduling with the individual for routine BUPTC clinical care. If the potential participant is determined to be **eligible** for the research study, study personnel will begin the informed consent process. Either way, the eligibility checklist (**Appendix E**) will be completed and screening log (**Appendix D: Screening Log**) will be updated.

Informed Consent

The informed consent process will be performed either in-person or remotely (zoom or phone call) depending on the participant preference; i.e. if they are able to stay to complete the first research visit after the physical therapy examination, they will complete it in person. If they cannot stay, it may benefit the participant to complete the informed consent procedure remotely. First, the informed consent document will be reviewed in detail with the participant. All procedures will be explained, and voluntary participation will be confirmed with signed consent prior to the initiation of data collection. Interested participants will be asked to sign the ICF. After signing the ICF, the team member will discuss the HIPAA Authorization Form (**Appendix F**) and the participant will be asked to sign. The HIPAA Authorization form allows for the physical therapist to communicate with the rest of the team members about this participant, as well as include clinical documentation in the REDCap participant file. This may take approximately 30 minutes. Participants will be offered the option to sign the informed consent form and HIPAA form electronically via REDCap e-consenting framework or via hard-copy. The study coordinator will ensure ICF completeness and provide copies of ICF and HIPAA Authorization to participant via a printed copy or electronically via BU secure email. Original copies will be uploaded into Sharepoint in the participant file, and a second copy may be stored on redcap if completed electronically.

If the participant needs additional time to think about the study and participation, they will be given a copy of the informed consent form (ICF) document and can continue the intake process for the BUPTC in the meantime. The Study Coordinator will follow up with the potential participant at 1 week to learn if they are still interested and would like to participate. If the potential participant is still interested, the consent visit will be scheduled to review the ICF to obtain signatures required to enroll in the study.

Once complete, the researcher and participant will complete the exosuit fit/comfort and baseline assessments, as described in **Section L**. Following those activities, the visit will end. The Enrollment Log (**Appendix G**) will be updated.

A Note on Physical Therapy Evaluation Notes Used in Screening:

1. All physical therapy examination notes will be recorded in the patient's electronic medical record at Boston University Physical Therapy Center.
2. If an individual is screened eligible AND they enroll in the study by providing informed consent and HIPAA Authorization, then the study team will keep a separate record of the PT evaluation in the participant's REDCap file under their Study ID number.

3. If an individual is screened ineligible OR they choose not to enroll in the study, then the study team will not keep a record of the PT evaluation. The study team will retain only the screening checklists, screening consent, and record in the screening log.

Indicate the consent and/or assent process and document(s) to be used in this study.
Check all that apply

Consent: Adults (≥18 years old); One of the following MUST apply	**N/A ☐**
☒	Consent Form/Information Sheet
☐	Verbal Consent (Script) **Note:** If written consent will not be obtained, complete the 'Waiver of Written Documentation Consent' box (Box 1) located further down in this section
☐	Consent will not be obtained **Note**: If consent will not be obtained, complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section

Assent of Children (≤ 18 years old); One of the following MUST apply	**N/A ☒**
☐	Assent Form **OR** Parent Consent Form/Information Sheet (older children may sign the parent consent form along with their parents as long as the consent form is written at the grade level of the subjects)
☐	Verbal Assent (Script)
☐	Assent will not be obtained; one of the following conditions must exist: 1. ☐ The capability of some or all of the children is so limited that they cannot reasonably be consulted; 2. ☐ The children are too young to provide assent; 3. ☐ The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research 4. ☐ The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. **(Complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section)**
Guidance on age requirements for obtaining assent: • **Parental Permission for minors under 6 years old** • **Verbal assent for minors 6-11 years old** • **Written assent from minors ages 12-17 (unless verbal consent is approved for the parents/adult subjects**	
Parental Permission; One of the following MUST apply	**N/A ☒**

☐	Parental Consent Form
☐	Parental Verbal Consent (Script) **Note:** If written consent will not be obtained, complete the 'Waiver of Written Documentation of Consent' box (Box 1) located further down in this section
☐	Parental permission will not be obtained; **one of the following conditions must exist:** 1. ☐ The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). 2. ☐ The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. **(Complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section).**

Consent: Adults with Limited Decisional Capacity to Consent (≥18 years old) N/A ☒ **Describe the consent and/or assent process for enrolling adults with limited decisional capacity to consent to research. Including how decisional capacity will determined, and who will serve as Legally Authorized Representative.**
Assent will be obtained from: ☐ All Subjects ☐ Some participants, specify: ☐ No participants. If no participants will assent, provide a rationale:

☐	Consent will be obtained from the subject's Legally Authorized Representative (LAR) **(REQUIRED).** **Who will serve as LAR:**

CONSENT OF NON-ENGLISH SPEAKING SUBJECTS N/A ☒ **Describe the process for obtaining consent from non-English speaking subjects. List the individual who will serve as the interpreter and their qualifications.** **NOTE:** A copy of the translated consent along with the Attestation Form for Translation of Consent must be submitted. The Attestation Form can be located on the IRB website.

BOX 1—WAIVER OF WRITTEN DOCUMENTATION OF CONSENT

WAIVER OF WRITTEN DOCUMENTATION OF CONSENT N/A ☒ **Either Criteria 1 or 2 must be met in order to qualify**	**Yes**	**No**

☐ **Criteria 1**		
The research is **NOT** FDA Regulated	☐	☐
The only record linking the subject and the research would be the consent document	☐	☐
The principal risk would be potential harm resulting from a breach of confidentiality	☐	☐
Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject's wishes will govern	☐	☐
A written statement/information sheet will be provided to subjects. **If NO**, provide rationale for not providing this information:	☐	☐
☐ **Criteria 2**		
The research is **NOT** FDA Regulated	☐	☐
The research presents no more than minimal risk of harm to subjects	☐	☐
The research involves no procedures for which written consent is normally required outside of the research context	☐	☐
A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information:	☐	☐
☐ **Criteria 3**		
The research is **NOT** FDA Regulated	☐	☐
The research presents no more than minimal risk of harm to subjects	☐	☐
The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm	☐	☐
There is an appropriate mechanism for documenting that informed consent was obtained	☐	☐
A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information:	☐	☐

BOX 2—WAIVER OR ALTERATION OF CONSENT

NON-FDA REGULATED STUDIES

WAIVER OR ALTERATION OF CONSENT N/A ☐ **45 CFR 46.116 Waiver or alteration of consent. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents ALL of the criteria listed below:**	**Yes**	**No**
The research involves no more than minimal risk to the subjects;	☐	☐
The waiver or alteration will not adversely affect the rights and welfare of the subjects;	☐	☐
The research could not practicably be carried out without the waiver or alteration;	☐	☐

If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;	☐	☐
Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information:	☐	☐
Provide the justification/rationale for why this study meets the above criteria for waiving or altering consent (REQUIRED):		

FDA-REGULATED STUDIES

Per FDA guidance issued in July 2017, the IRB may waive or alter informed consent requirements for certain minimal risk clinical investigations when the IRB finds and documents ALL of the criteria listed below:	**Yes**	**No**
The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;	☒	☐
The waiver or alteration will not adversely affect the rights and welfare of the subjects;	☒	☐
The clinical investigation could not practicably be carried out without the waiver or alteration	☒	☐
Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information:	☒	☐
Additional Comments: waiver of consent for the purpose of accessing medical records for recruitment		

SECTION L: STUDY PROCEDURES

In the box below provide a detailed description of the study procedures to be performed (preferably in sequential order). Be sure to specify which procedures are for research purposes and which procedures are part of standard of care, if applicable. Be sure to include the following information:

- **Methods of data collection**
- **Details regarding research activities/procedures/interventions**
- **Number, frequency, duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)**
- **Time required from each subject**
- **Use of equipment (eye-tracker, treadmill, sensors, etc.). Provide a brief description of equipment that will be used in the study.***

*Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit Appendix C: Device Form.

Submit copies of all surveys, interview questions, assessments, screening scripts, etc. that will be used during the conduct of this study; materials should be submitted as separate documents in either Word or PDF format.

Pilot Sample .

We will first run a small pilot of the described clinical trial. These individuals will be recruited from the same population as the described protocol. The objectives of the pilot are similar and will utilize the same recruitment/enrollment procedures as the described protocol. However, the pilot study will only include study procedures up through research visit 1 (including biomechanical assessment and remote surveys). The data acquired in the pilot may reveal necessary changes to the protocol including recruitment and data collection procedures.

We are anticipating enrollment of a small sample (n =8, inclusive of the 100 maximum enrollment requested). Following completion of the pilot phase, we will make indicated updates to the procedures in the form of any IRB amendment, register the larger trial on clinicaltrials.gov, and await final approval prior to beginning the full clinical trial phase.

This trial is registered on clinicaltrials.gov (NCT05736393).

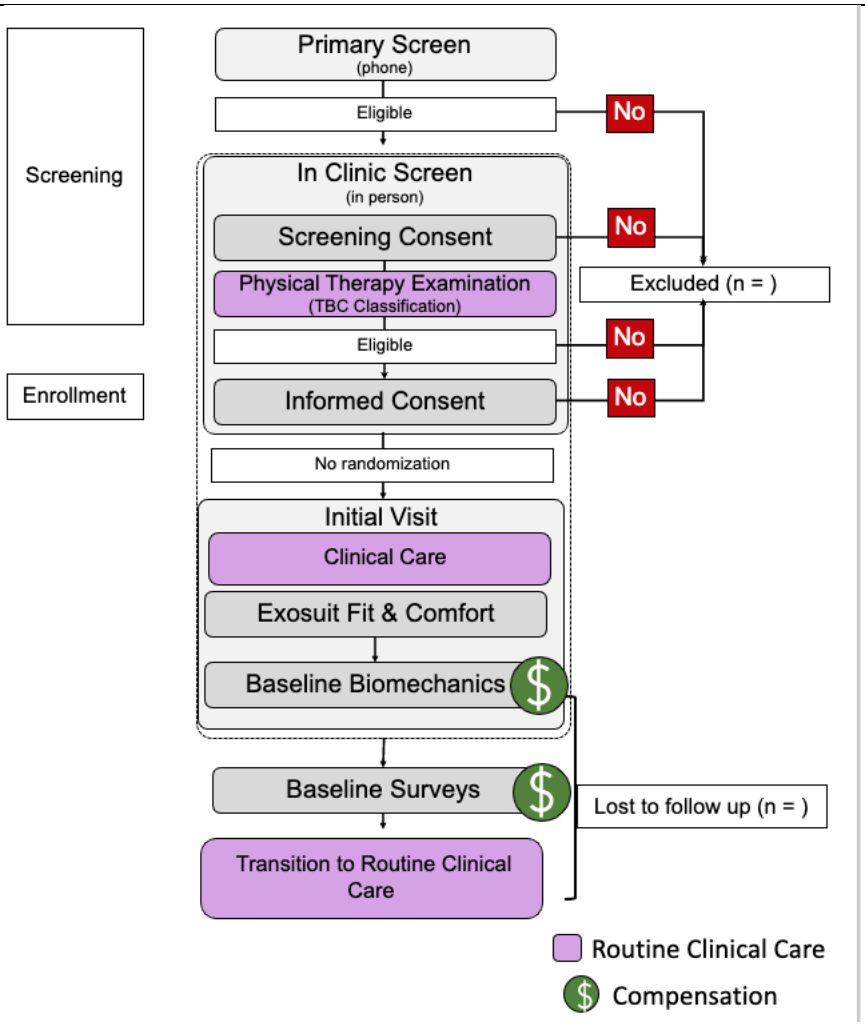


Figure 1: Observational Pilot Study Flow Diagram

Single Arm Clinical Trial: Exosuit-Augmented Physical Therapy

General Study Visit Procedures:

Figure 2 provides an overview of the study flow. We will enroll individuals referred to physical therapy care for LBP at BUPTC.

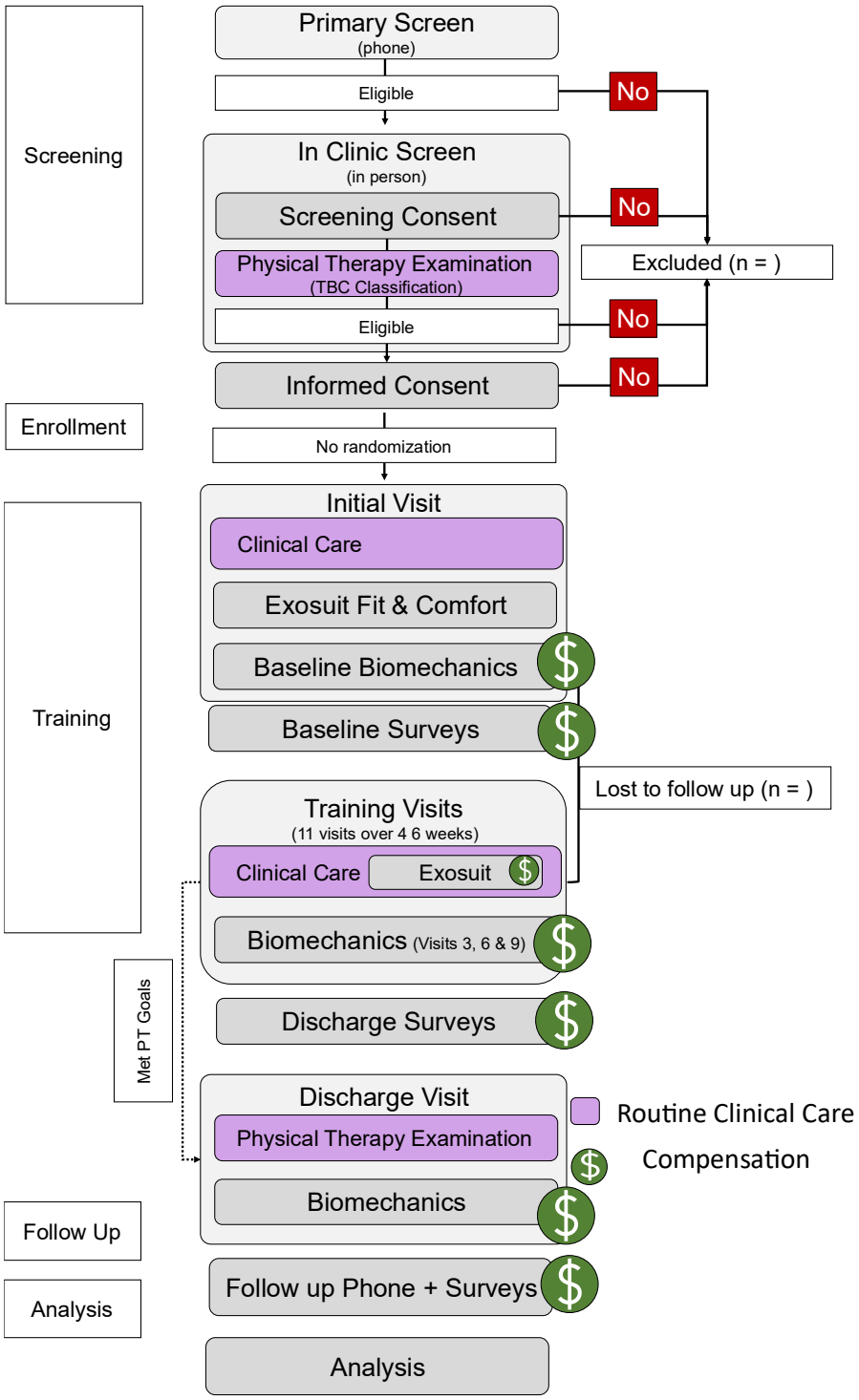


Figure 2: Study Flow Diagram

Overview

Following the determination of eligibility and completion of the informed consent process, the research study will follow each participant through a course of physical therapy rehabilitation with a portion of the care augmented with the use of the investigational device (exosuit).

Each visit will include routine physical therapy care (equivalent to what would be provided outside study enrollment). These non-research procedures will be documented through the Boston University Physical Therapy Center's HIPAA Compliant Electronic Medical Record. These services are provided by a credentialed and licensed physical therapist who is also a member of the research team.

Each visit will also include exosuit-augmented physical therapy. The participant will wear the exosuit during a portion of their routine physical therapy session for assistance during activities such walking, lifting, carrying, squatting, stooping, and sitting. These activities will be selected based on participant reported functional limitations stemming from their back pain, and current goals in physical therapy. The research physical therapist will lead the visit and determine which activities are most appropriate based on open-ended patient interviews.

All visits will:

- Take place at the BUPTC.
- Be conducted under the supervision of trained IRB-approved investigators.
    - A credentialed (Doctor of Physical Therapy [DPT]) and licensed (Massachusetts Board of Allied Health Professionals) physical therapist will be at every visit. They will:
        - Design, prescribe, and deliver routine physical therapy care (non-research procedures, exosuit not in use)
        - Actively monitor the participant during exosuit donning, use, and doffing
        - Design, prescribe, and deliver research-related physical therapy care while participant is wearing the exosuit.
    - Optionally, one engineer may attend visits to actively monitor the exosuit technology for appropriate fit and functionality and ensure data quality.
- Include rest periods for the participants as needed/requested by the participant.
- Not exceed 1-hour of exosuit active wear time.

All study documents such as screeners, surveys, questionnaires, data from participant motion, self-reported medical information, in-session clinical documentation, and any notes from study visits will be kept on a BU's secure REDCap server.

The study is comprised of the following procedures and visits:

(1) Phone Screen (via phone)
(2) Physical Therapy Examination (screening consent, physical therapy examination)
(3) Consent and baseline visit (informed consent, PT clinical care, exosuit fit & comfort, baseline biomechanical assessment) (1 visit)
(4) Patient-Reported Outcome Measures – Intake (web-based, independent)
(5) Training Visits (up to 10 sessions and 1 discharge visit over 6 weeks)
(6) Patient-Reported Outcome Measures – Discharge (web-based, independent)
(7) Post Assessment (1 visit, performed on final training visit)

(8) Follow-Up Assessment (via phone and electronic surveys)
The following table outlines the timeline of data collection (Table)

Table: Timeline of Procedures

Visit Description	Screening		Treatment and Follow-Up													
	Phone	PT Exam	V1	Surveys	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	Surveys	V12	Follow-Up
Eligibility Screen	X	X															
Screening Consent		X															
Physical Therapy Exam		X															
Optional Device Demonstration		X															
Informed Consent		X	X														
HIPAA Authorization			X														
Video Consent			X														
Demographics			X														
Exosuit Fit & Comfort			X		X	X	X	X	X	X	X	X	X	X		X	
Biomechanical Assessment**			X			X			X			X				X	
Surveys				X											X		X
Clinical Care†			X		X	X	X	X	X	X	X	X	X	X		X	
Exosuit Augmented Care†					X	X	X	X	X	X	X	X	X	X		X	
Study Completion																	X
Remuneration in $$			45	45	20	45	20	20	45	20	20	45	20	20	45	45	45

*Informed consent may happen on the same day as the PT exam, remotely after the PT exam and before v1, or on v1 before research procedures begin.
**Please see section on Early Discontinuations. In the event of early discontinuation, biomechanical assessment will take place on final visit (i.e., on V10 instead of V12). Participants will not complete more than 5 biomechanical assessments. For scheduling or technical issues the biomechanical assessment (Visit 3, 6, or 9) can be scheduled 1 visit before or after the intended visit.
†Not included in observational pilot trial.

The following section will outline procedures for assessments (Baseline, Training Visit, Post, and Follow-Up Assessments) (Table).

Table: Summary of Visit Schedule and Activities

Timepoints	Location	Activities at Timepoint
Phone Screen	Phone	Initial contact with research team or front desk personnel, phone screening, and scheduling of Physical Therapy Examination.
Physical Therapy Examination and Consent Visit	Clinic	Screening consent, Physical therapy examination, eligibility checklist, optional device demonstration.
Research visit 1	Clinic	Informed consent*, HIPAA authorization*, video consent form*, exosuit fit & comfort, baseline biomechanical assessment.
Patient-Reported Outcome Measures – Intake	Web-based, Independent	Survey based assessment done remotely using standardized questionnaires.
Training Visits (v2-v11)	Clinic	Key surveys, routine clinical care, exosuit augmented functional training, suit-based biomechanical assessments
Patient-Reported Outcome Measures – Discharge	Web-based, Independent	Survey based assessment done remotely using standardized questionnaires.

Post Assessment (v12)	Clinic	Physical therapy examination, discharge assessment, exosuit fit & comfort, baseline biomechanical assessment.
Follow-Up Assessment	Phone + Web-based	Phone-based interview regarding clinical status. Electronic surveys.
*Informed consent, HIPAA authorization and video consent may happen at the screening visit, remotely between screening and research visit 1, or at the beginning of research visit 1 before study procedures begin.		

A Note on the Exosuit Device

Details and supporting evidence regarding the exosuit device are provided in the device cover letter accompanying this application as well as in two supporting manuscript proofs (UNDER REVIEW). In brief, the exosuit is a soft active system which provides minimal movement restriction and adaptively applies assistance to a wearer depending on a task such as lowering, lifting, or walking. The device is lightweight (2.7kg) and easy to wear (average 36s donning time). In healthy individuals, the device was shown to reduce peak back extensor activation amplitudes by 18% without abdominal coactivation while performing a complicated, 1- hour-long simulated order picking task, including lifting, carrying and walking *(Science Robotics Manuscript Submission included)*. In a small sample of individuals with low back pain (*Pain Medicine Manuscript Submission included)*, it had similar biomechanical benefits, as well as perceptual benefits of ease of movement, lower fear of movement, and lower pain. Figure 3 is reproduced from an published manuscript (Chung et al, 2023, Pain Medicine), which describes how the exosuit works in detail.

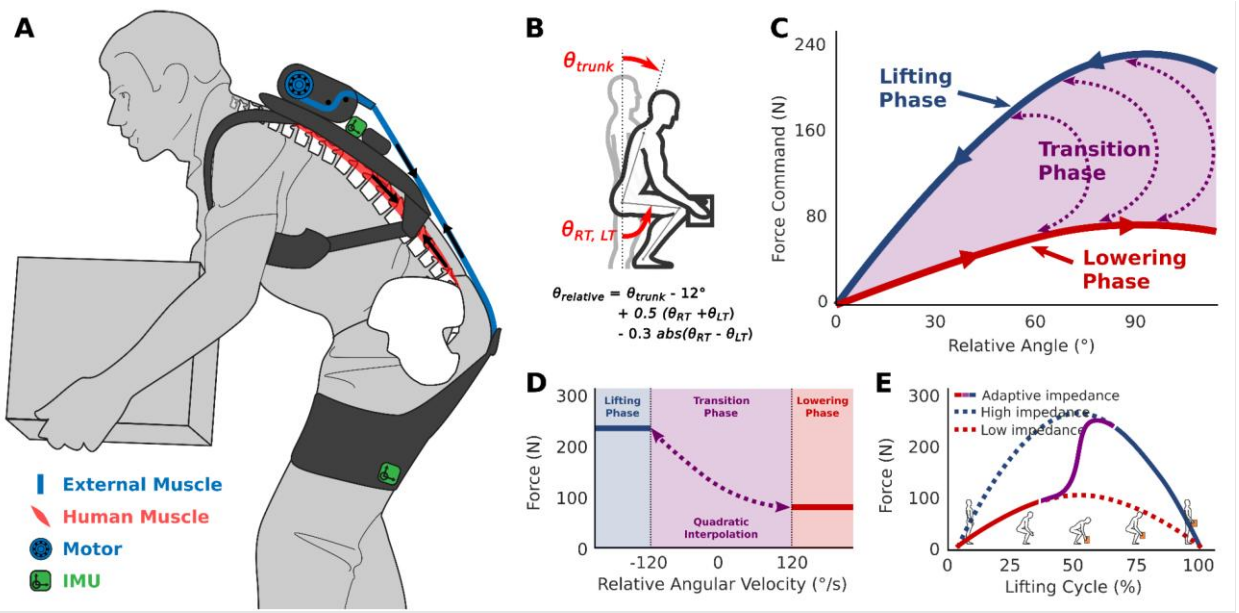


Figure 3: Back exosuit and adaptive impedance controller. (A) Back exosuit acts as an external muscle by applying assistive force to the user using a motor and a ribbon cable, via an IMU-informed controller. (B) The exosuit controller is informed by IMU-measured relative angle between the trunk and the thighs. (C) Assistive forces generated by the exosuit were commanded with an impedance function dependent on the relative angle and phase of motion. (D) Movement phase was classified using angular velocity thresholds. At a given angle, lifting assistance and lowering assistance are calculated first, then the transition assistance is quadratically interpolated between them. A wide interpolated transition phase of 120 °/s was chosen to prevent mistriggering and ensure smooth transition. (F) Considering the adaptive impedance modulation strategy in the time domain (solid line), our controller was designed to make a smooth transition between a low impedance state when lowering and a high impedance state when lifting.

Phone Screening (Phone)

The first contact with an interested individual will take place over the phone (**up to 10-15 minutes**). The primary screening does not count toward the total number of sessions. The study will be explained by either the front desk personnel or a member of the research team if present in detail and any questions the individual has will be answered. If the individual maintains interest in participation, they will be asked the questions from Appendix A: Study Introduction Script to determine consideration for the study.

In situations when researcher or front desk personnel and interested participant are in the same location, the participant may opt for an in-person primary screen for convenience.

Clinical Screening (In-Person)

If the results of the initial participant screening suggest the individual may qualify for the research study, the individual will be scheduled for in-person clinical screening. This in-person visit may last up to 3 hours.

Screening Consent

Upon arriving to the in-person screening, the potential participant will be approached for screening consent prior to initiating physical therapy examination.

Physical Therapy Examination

The clinical screening will begin with a routine physical therapy examination. This physical therapy examination is consistent with the standard of care for all people with complaints of low back pain initiating care at BUPTC. Therefore, the examination will not include any research procedures. It will be carried out without deviation from normal examination procedures and will be used to initiate and develop a plan of care for the potential participant's lower back pain regardless of study eligibility or enrollment. Physical therapy examination can take up to 60 minutes. Examination procedures included in this initial examination may include (Please find further elaboration in **Appendix H: Description of Routine Physical Therapy Care**):

(1) The physical therapist uses questionnaires and risk-stratification tools to formulate hypothesis related to pain classification, level of acuity/irritability and level of disability.
    a. These questionnaires are embedded in BUPTC Intake Paperwork (**Appendix J**.)
(2) History of present illness and past medical history is obtained via patient interview to further clinician's hypothesis on likely TBC
(3) Patient expectations and goals, related to care and outcomes, are identified, and discussed.
(4) Physical examination is conducted including but not limited to:
    a. Test of function including quantitative and qualitative analysis of movement
    b. Repeated movement testing
    c. Neurological screen, including standard testing typically performed at a doctor's visit (e.g., neurodynamic testing, sensory testing, reflex testing, muscle performance testing)
    d. Lumbar/Hip Mobility Assessment, including joint mobility assessment of the lumbar spine and hips, hip passive range of motion, and muscle length assessments.

e. Movement Coordination Classification Tests, including assessment of transverse abdominis activation/relaxation, assessment of lumbar multifidi activation, and prone instability test

(5) Clinician uses information gathered in steps 1-4 to determine appropriate TBC
(6) Review of physical exam findings, plan of care, and prognosis are shared with the patient, which helps build therapeutic alliance and aid in development of the plan of care aligned with their goals.
(7) Education that is relevant to the individual patient's level of irritability/acuity and current functional and participation limitations may be provided
(8) Follow up visits are scheduled/confirmed.
(9) All procedures are within the physical therapist's practice act as detailed in Chapter 112 of the Massachusetts General Laws, Sections 23A - 23Q (Physical Therapy Practice Act).

Note on Physical Therapy Examination Data: As part of routine clinical care, the physical therapist is required to document patient interaction and examination details in the Electronic Medical Record for liability and insurance purposes. These data will be stored in the Electronic Medical Record according to the BUPTC Initial evaluation notes (**Appendix I**). Should the individual qualify, a HIPAA authorization will be obtained and a copy of these notes may be transferred to the research team by Boston University HIPAA-compliant SharePoint server and uploaded to REDCap. Key features of these data may also be extracted and entered directly into REDCap (see *HIPAA Authorization*). In addition to this HIPAA authorization, the Notice of Privacy Practices is provided to all participants as part of the standard intake paperwork completed by all people seeking care at the Ryan Center regardless of study involvement. This notice describes how medical and health information is collected and stored, how it may be used and disclosed, and how the participant can obtain access to this information (**Appendix J**). This medical and health information will also include the Patient Specific Functional Scale (PSFS) and other surveys that are collected as a part of routine clinical care at intake and throughout the trial.

Optional: Device Demonstration

1. Eligible participants will have the opportunity to briefly try on the back exosuit in-clinic and under the supervision of a researcher. Either shortly after the physical therapy examination, or shortly before signing the informed consent form.
2. Before the demonstration, a trained study team member will go through the Risk and Release Form with the potential participant and answer any questions.
    1. **Consent,** the participant will proceed to a device demonstration
        1. **E-Consent:** They will be asked to electronically sign a version of the Risk and Release Form on REDCap. The participant will have their signed copy printed and physically delivered to them or digitally delivered via BU secure e-mail.
        2. **Paper Consent:** They will be asked to sign two copies of the Risk and Release Form (i.e., one for our record and one for them to keep).
    2. **Decline:** If the participant is not interested, the study team member will remind them this step is not needed for a participant to advance to the study consent process.

3. After signing the risk and release form, a trained researcher will fit the potential participant with the Back Exosuit, power on the device, and place the device in setting 2 (Exosuit Augmented Physical Therapy Guide: Section 1 and 3). The potential participant can bend with the device to get a idea of how it feels in order to better inform their interest in enrolling in the study.

Informed Consent

Following determination of eligibility, a member of the research study staff will obtain written consent (in-person) for the study. From this point on, the researcher will make it clear that the Physical Therapy Examination performed in the context of their care has stopped, and the clinician is now engaged in his capacity as a researcher. The researcher will explain the study procedures in detail and answer any questions the participant may have. We will then proceed to explain study visit details, including confirming eligibility criteria.

HIPAA Authorization

After reviewing the consent form and enrolling in the study, participants will be asked to sign a HIPAA Authorization to Disclose Protected Health Information for Research Purposes. This will allow direct communication between with the participant's physical therapist and the rest of the research team to secure recent physical therapy visit notes and clinical progress, if needed during the study. The participant will be able to authorize what protected health information will be disclosed to us. This HIPAA authorization will allow for copies of routine clinical notes documented in the BUPTC to be uploaded to REDCap to support research-related procedures.

Video Consent

If during the informed consent, the participant indicates that they are willing to be photographed and videotaped during study participation, they will be asked to sign a video consent form. This is not required for study participation, nor does it guarantee that the researchers will elect to photographic or videotape the participant during their enrollment in the study. Any photos or videos will be used in research training documents (to members of the study team), in teaching and in-services (at Boston University Physical Therapy Center), and in research dissemination (at scientific conferences and events) and are not being collected directly as study outcomes.

Research Visit 1: Baseline and Training Visit 1 (In-Person)

Note: Informed Consent, HIPAA authorization and Video Consent may occur immediately following the PT examination (screening), remotely between screening and research visit 1 (v1) or at the beginning of v1 based upon participant's preference.

Exosuit Fit & Comfort

The following standard language will be used to describe the use and role of the exosuit to participants. Similar language appears in the informed consent document and user manual.

The exosuit applies assistance in parallel with your muscles. It responds to your movements by combining motion tracking sensors with robotic actuators. The device will not restrict your natural movements. It will however assist you in bending and lifting tasks by reducing your muscular effort by as much as 30%. This research study is investigating whether this assistance supports your back and hips, improves lifting form and postures, or lowers pain and soreness during exercise.

The device is worn like a backpack. A ribbon serves as an external muscle to reduce the load and effort during lifting. We will use this device during 20-40 minutes of physical therapy exercises during each visit over the next 4-6 weeks. Once it is fit and adjusted to your comfort, the physical therapist will control the level of assistance the device provides similarly to how they would progress or regress an exercise. You may start with more assistance and wean down over the course of the study.

There is a user manual available to you.

Interested participants will be provided the user manual (**Appendix K**).

The physical therapist will then work with the patient to don the exosuit, which is worn like a backpack. Prior to beginning, the physical therapist will ensure the exosuit is powered OFF and the batteries are installed properly. They will then help the patient put the shoulder straps over each shoulder and adjust straps to ensure comfortable fit with the exosuit high on the back. They will then untangle the thigh wraps and pass them to the participant to fasten the thigh wraps around each thigh. They will then be instructed on how to use the Boa cables to tighten to comfort.

Once donned, the participant will stand upright while the physical therapist turns the exosuit on. The exosuit will then go through pre-tensioning and default to slack mode. Slack mode means the device does not actively assist the participant. The only difference between slack mode and active mode is the device does not assist the participant's motions in slack mode. Therefore, it feels no different than wearing a 6-pound backpack (2.7 kg). The physical therapist will then encourage the participant to familiarize themselves with the exosuit (**Appendix L**: Section 3.4). They will be allowed to move freely for up to 5 minutes in slack mode prior to beginning study procedures- i.e., standing, walking, performing self-selected movements such as stretching. Exosuit assistance will then be tuned to the participants preference. The participants assistance level will be recorded in the exosuit log.

Baseline Biomechanics Assessment (**Appendix L**: Section 4)

This is the first instance of research-related data collection. The exosuit records kinematic data from three on-board IMU (inertial measurement units) sensors as well as 5 additional IMUs that are placed on the participant prior to completing the biomechanical assessment. The researchers will leverage these data collection instruments during biomechanical assessments. The app will enable acquisition of annotated data. The app, which was designed by members of the research team, contains no identifiable data (e.g., all data is labelled with participant ID only). All data will be shared with team members at BU. All data is uploaded automatically and securely to a password-protected, Cognito authenticated, limited access, encrypted Amazon Web Services (AWS) S3 cloud database managed by the Harvard Move Lab. All biomechanical assessments will be completed in slack suit mode, some biomechanical assessments will be repeated in active suit mode. All biomechanical task are depicted and further described in **Appendix L**: Exosuit Augmented Physical Therapy Guide.

IMU Placement: see **Appendix L** page 32-33 for specific placement instructions

1. Participant should be prone on a patient bed in a comfortable position for placing the IMUs on the spine and standing with a neutral stance for placement on the R and L thigh.
2. Order of placement is as follows: C7, T12, L5, Right and Left Thigh

3. IMUs are secured in this order:
    a. Identify the correct spinous process or midpoint of the leg
    b. Dry and shave the identified area if necessary
    c. Place the first piece of medical grade double sided tape over the identified area
        i. Use a finger or erasable marker to keep place
    d. Place IMU in the center of the double-sided tape
    e. Finally, place the second piece of Cover-Roll over the entire IMU
4. The IMUs are then plugged into the exosuit

Suit Tuning and usage: see **Appendix L** : Section 4

1. The physical therapist inform the participant to stand still and will power on the device placing the exosuit into into slack mode ('Slack Suit')
2. The PT will select the lowest button placing the device into App-Controller Mode
3. The PT will work with the participant to tune the device using using manual tuning (Appendix L: Section 2.4) on regular PT treatment visit days and using preference learning (Appendix L: Section 3) on visits that include a biomechanics assessment.
4. Baseline biomechanical assessment will be initiated on the App proceeding as follows:

Outcome Test	Test Name	# Reps	Approximate Time
Walking Speed	10-meter walk test	1	1 minute
Dynamic Reach Distance	Dynamic Reach Test	3	1.5 minutes
Power	5x sit to stand	1	1.5 minutes
Static Range of Motion	Static Range of motion (side bend, rotation)	2-3	2 minutes
Dynamic Movement Velocity	Dynamic Range of Motion (flex-Ext, rotation, side-bend)	15	3 minutes
Static Range of Motion	Static Range of motion (flex-extension)	3	1 minute
Strength – Deadlift	**Dynamometer Pull**	**2**	**4 minutes**
Strength – endurance Power	**Incremental Postural Lifting Strategy Test**	**< 24**	**12 minutes**
Strength – endurance Power	**Asymmetric Continuous Dynamic Lifting Test:**	**<90**	**11 minutes**
	Total Time		**~37 minutes**
Tasks completed in both actuated and slack conditions are identified **in bold**. Approximate time includes maximal estimated time with rest time.			

Full task instructions are provided in Appendix L (Section 4.0)

a. Active Range of Motion Test [Axial Rotation, Lateral Flexion, and Back Extension]
    i. Instructions: Have the participant move as far as comfortable in all cardinal planes (Left-Right Side Bending, Left-Right Rotation and

Extension) and hold at the end range for a second. Two repetitions will be performed in each direction.

b. Active Range of Motion Test [Flexion]
    i. Instructions: Ask the participant move as far as comfortable in flexion and hold at end range for a second. Three repetitions will be performed.
    ii. The research physical therapist will provide clinical notes based on the "Range of Motion Clinical Notes" in Appendix M2.
c. Dynamic Range of Motion Test
    i. Flex-Ext Instructions: Ask participants to move "as fast as comfortable" into flexion and extension for 5 repetitions.
    ii. Rotation Instructions: Ask participants to move "as fast as comfortable" into left and right rotation for 5 repetitions.
    iii. Side-Bend Instructions: Ask participants to move "as fast as comfortable" into left and right side-bending for 5 repetitions.
d. Dynamometer Pull
    i. Set-up: An external dynamometer device (Baseline® Analog Gauge Push-Pull Dynamometer, Global Industrial Inc.) will be anchored to the floor. Participant will hold handles and assume a comfortable stooped position. This device is depicted in **Appendix L** (page 41).
    ii. Instructions: Ask participants to gradually pull against handles "with straight arms and without shrugging," by "standing up and lifting the device". Instruct them build up to as strong a pull as possible and to hold for about 3 seconds. Allow a minute rest and repeat (2 reps total).
e. 5 Times Sit To Stand
    i. Instructions: Ask participant to sit in a chair with arms crossed over chest. Time participant as they stand-up and sit-down 5 times as fast as comfortable.
f. Dynamic Reach
    i. Instructions: Ask participant to reach as far as possible forward without losing their balance. Record reach distance using standardized measuring tape on wall. Repeat 3 times.
g. 10-Meter Walk Test (Fast-Walking Speed)
    i. Instructions: Ask participant to walk a distance of 10-meters as fast as comfortable. Record time it takes.
    ii. Standard Language: "I will say ready, set, go. When I say go, walk as fast as you safely can until I say stop"
h. Incremental Postural Lifting Strategy test:
    i. Please see **Appendix L page 42** for specific instructions.
    ii. The participant will lift a box from the floor to a table height (4 times or for 20 seconds, whichever comes first) with incremental increases of 5 lbs in weight (begin at 8 lbs for women and 13 lbs for men). The participant will proceed to the next weight if they continue to lift with proper form and are willing to proceed. A brief rest break will be provided between levels to take clinical notes. The task will terminate at level 6 ensuring the maximum weight lifted does not exceed 33lbs for women and 38 pounds

for men. Before moving to the next condition, about 2 minutes of rest will be provided.

iii. The research physical therapist will score this test based on the "Progressive Postural Lifting Exam Clinical Score" in Appendix M2.

i. Asymmetric Continuous Dynamic Lifting Test:
   i. Please see **Appendix L page 43** for specific instructions
   ii. The participant will start with a neutral stand with a weighted box (5 lbs less than the highest level completed during the incremental postural lifting test in the slack exosuit condition) placed 25 degrees to their right on an raised aerobic step. When prompted to start, the participant will lift the box from the step, stabilize at waist height in neutral, and lower the box to the left on a step approximately 25 degrees to the left. The participant will proceed to continue lifting the box right to left and left to right as many times as possible in 2 minutes and 30 seconds. The participant can take a rest or stop at any time. Before moving to the next condition, about 2 minutes of rest will be provided.

5. Following these procedures, the participant will doff the exosuit and the initial study visit will end.
6. Participants will receive $45 remuneration for completing this visit.

Note on the occurrence logistical and technical issues: If there are technical or logistical issues preventing completion of planned procedures, additional fit & comfort or biomechanical assessment sessions may be scheduled up to additional 2 visits (i.e., total of 3 visits). Examples of logistical issues include but are not limited to scheduling of participant or issues with transportation. Examples of technical issues include but are not limited to device-related troubleshooting, inadequate charge of batteries, or Bluetooth connection issues with the onboard sensors rendering inability to collect data.

Note on the occurrence logistical and technical issues that would affect the biomechanical assessment: If logistic or technical issues are identified before a scheduled biomechanical assessment on visit 3, 6 or 9 a research team member can reschedule **one visit before** or **one visit after** the intended biomechanical assessment date. If logistic or technical issues are identified during a scheduled biomechanical assessment on visit 3, 6 or 9, a research team member can reschedule for **one visit after** the intended biomechanical assessment date If rescheduling exceeds this threshold of one additional visit, the biomechanical assessment should be skipped.

Patient-Reported Outcome Measures – (Virtual: Baseline, Discharge, Follow-up)

(1) Participant will complete the following patient-reported outcome measures related to their LBP using REDCap
   1. BACPAC Minimum Demographics Survey *only completed at baseline timepoint
   2. BACPAC Minimum Pain inventory
   3. Pain, Enjoyment, General Activity (PEG)
   4. PROMIS 4a – Pain interference
   5. PROMIS 6b – Physical Function

6. PROMIS 4a - Depression
7. PROMIS 4a - Anxiety
8. Modified PROMIS Sleep Disturbance + Duration
9. Pain-Catastrophizing Scale (PCS-6)
10. Patient Health Questionnaire (PHQ-2)
11. Generalized Anxiety Disorder (GAD-2)
12. Tobacco, Alcohol, Prescription medication, and other Substance (TAPS 1) Tool
13. Usability Questionnaire- QUEST Full
14. Photo Series of Daily Activities (PHODA)**
15. Modified Oswestry Disability Index**
16. Numerical Pain Rating Scale**
17. Optimal Screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF)

(2) This will be done remotely using a computer or their personal cellular device.
(3) They will receive a link to complete these surveys from the *Participant List* Function in REDCap.
(4) Participants will complete these within 48 hours of the first visit, discharge visit or follow-up phone calls.
(5) Note surveys marked with an ** will be completed on the follow-up survey only.
(6) Full list of instruments in **Appendix M** (inclusive of surveys completed at home and in the clinic)

Outcome Measure	Construct Measured	# Items
BACPAC Minimum Demographics Survey	Socioeconomic Factors LBP Pain History	15
BACPAC Minimum Pain Inventory	General and back pain	9
Pain, Enjoyment, General Activity (PEG)	Pain	3
PROMIS 4a – Pain interference	Quality of Life	4
PROMIS 6B – Physical function	Function	6
Modified PROMIS 6a Sleep Disturbance + Duration	Sleep	9
PROMIS 4A – Anxiety	Anxiety	4
PROMIS 4a – Depression	Depression	4
Pain-Catastrophizing Scale (PCS-6)	Pain Catastrophizing	6
Patient Health Questionnaire (PHQ-2)	Depression	2
Generalized Anxiety Disorder (GAD-2)	Anxiety	2
Optimal Screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF)	Negative Mood, Fear avoidance, and Coping	17
Tobacco, Alcohol, Prescription medication, and other Substance (TAPS 1) Tool	Substance Use	4
Photographic Series of Daily Activities	Fear of Movement	8
Usability Questionnaire: Quest Light and Quest Full	Device Usability	12
Modified Oswestry Disability Index	Disability	11
Body Discomfort Map	Discomfort	3
Numeric Rating Scale Task Effort	Effort	1
Numeric Rating Scale Task Discomfort	Discomfort	1
Numeric Pain Rating Scale	Pain	2

(7) Participants will receive $45 remuneration for completing these surveys.

Training Visits (In-person)

(1) Frequency of Visits & Length of Trial:

a. Participants will complete up to 10 training visits and 1 discharge visit within 6 weeks of entering the study. This is an average of 2 visits per week, including the initial visit.

b. Visit frequency is up to clinical decision making of the study physical therapist and participant availability.

c. Every effort will be made to achieve higher frequency of visits for the first few weeks (up to 3x/week for weeks 1, 2, and 3) followed by lower frequency of visits thereafter (e.g., 1-2x/week for weeks 4, 5, and 6).

d. Study completion will be determined by utilization of visits, not calendar days spent within the study. In other words, there are no requirements to continue through to the 6th week. If a participant completes the 10 training visits and 1 discharge visit in 4 weeks, they will be discharged from the study.

e. Visits will be schedule as frequently as 3 times per week, or as infrequently as 1 times per week.

f. If the participant has not completed 10 training visits within six weeks of enrollment, they will be scheduled for their discharge visit.

g. *Flexibility in the event of cancellations and scheduling conflicts:* If the participant has not completed 10 training visits and 1 discharge visit within 8 weeks of enrollment, they will be discharged from the study.

(2) Structure of Training Visits

a. Each training visit will last between 45 and 90 minutes and include patient-reported outcome measures (surveys) and routine physical therapy care (described in #4 below) with a portion of that care augmented by the exosuit. Exosuit activities are visible in **Appendix L: Exosuit Augmented PT Guide, Section 5**.

b. Every 3rd visit, the biomechanical assessment may be repeated.

(3) Patient-Reported Outcome Measures

a. The participant will complete the following patient-reported outcome measures once they arrive at each study visit:

Table: Patient Reported Outcome Measures – Training Visits

Outcome Measure	Construct Measured	# Items	Approximate Time
Pain, Enjoyment, General Activity (PEG)	Pain	3	1 minute
Modified Oswestry Low Back Pain Disability Questionnaire (mODI)	Disability	10	3 minutes
Numeric Pain Rating Scale (NPRS)	Pain	2	1 minute
		Total:	6 minutes

b. These surveys will be scored and reviewed contemporaneously to gauge participant's pain levels, functional limitations, and progress in the context of current goals.

(4) Routine Physical Therapy Care -

a. The participant and physical therapist will begin each visit with subjective review of current condition and patient goals, followed by physical therapy treatment (Detailed in **Appendix H**).

b. This may include manual therapy, patient education, impairment-based exercise prescription, and functional training, or other therapies as detailed in Chapter 112 of

the Massachusetts General Laws, Sections 23A - 23Q (Physical Therapy Practice Act):

i. **Manual therapy (0-20 minutes).** Joint mobilizations/manipulations, soft tissue mobilization and manual muscle stretching
ii. **Muscle activation/relaxation exercises (0-20 minutes).** Transversus Abdominis, lumbar multifidi and pelvic floor musculature contract/relax and activation training, diaphragmatic breathing
iii. **Acquisition exercises (0-20 minutes).** Lower extremity range of motion, clamshells, bridging, bird-dog, supine hook-lying flies, prone Y/T
iv. **Mobility exercises (0-20 minutes).** Hook-lying lower trunk rotation, side-lying "open book" rotation, cat/Camel, hook-lying pelvic rocking/tilting, Child's Pose stretch, sitting lumbar flexion, sitting lumbar flexion with ball rolls
v. **Functional exercises (20-40 minutes).*** Bending/lifting tasks requiring spinal flexion (stoop lift), squatting, squat-lifting, hinging and dead lifting, lateral/rotatory chops.

*These activities will incorporate the use of the exosuit device. A list, including pictures, of potential exercises performed with the exosuit on and active can be found in **Appendix L**. These procedures may take 20-40 minutes of each session.

c. All care will be delivered under the supervision of research physical therapists, who are licensed to practice in the Commonwealth of Massachusetts in alignment with the patient goals regardless of use or non-use the exosuit Other research personnel may also be present during study procedures.
d. These procedures are determined through clinical decision making by the physical therapist and are up to their discretion.
   i. That is to say the specific exercises conducted at each study visit, and ultimately the parameters of each exercise (e.g., number of repetitions, number of sets, amount of load), is at the discretion of the research physical therapist. A typical exercise is performed for 1 to 5 sets of 4 to 30 repetitions, with fewer sets occurring with higher repetitions and vice versa. These procedures may take up to 80 minutes of each training visit.
e. Documentation of this session will occur in the BUPTC's Electronic Medical Record. Notes will be transferred to REDCap for use in the study according to HIPAA Authorization.

(5) Notes on Non-Clinical Use of Exosuit
a. Participants will don the exosuit under the physical therapist supervision.
b. Participants and physical therapists will conduct fit & comfort checks prior to turning on the device.
c. Using the app-controller, the physical therapist and participant will work iteratively to tune the adjustable parameters. Parameter settings will attempt to maximize participant comfort while also maximizing the participant's comfortable range of motion and movement velocity during functional bending and lifting tasks. On biomechanical assessment visits device tuning will be aided with a preference learning algorithm.

d. Biomechanical Assessments will be done while wearing the exosuit and are done for research purposes only.
e. Participant will doff the exosuit after completing functional exercise and any other research procedures (Biomechanical Assessments).

(6) Biomechanical Assessment **(Study visits 3, 6, 9, and 12 (discharge))**
a. Biomechanical assessment will be repeated on 4 occasions (typically study visits 3, 6, 9, and 12) as described above.
b. If the participant is eligible for early discontinuation, a biomechanical assessment will take place on the last scheduled visit.
c. During the biomechanical assessment, when prompted by the exosuit application– the following surveys will be collected.

Table: Patient Reported Outcome Measures – Biomechanical Assessment Surveys			
Outcome Measure	Construct Measured	# Items	Approximate Time
Numeric Rating Scale (NRS) – Task Effort	Effort	1	0.25 minutes
Numeric Rating Scale (NRS) – Total body discomfort	Discomfort	1	0.25 minute
		Total:	30 seconds

(7) Data Collection
a. Kinematic data will be collected during exosuit-augmented functional training at each training visit and during the Biomechanical Assessments using the sensors on the exosuit.
b. These data will be aggregated to calculate an overall workload for each participant for each session (i.e., number of minutes of exercise, number of flexion/extension repetitions, total work delivered by the suit) to allow the study staff to keep track of each participant's reps and workload as they proceed through the study.
c. The physical therapist will document the sets and reps of each exercise, as well as the participant response in REDCap.
i. During specific tasks in the biomechanical assessment, the physical therapist will be prompted through the exosuit app with the following questionnaires to supplement clinical notes:

Table: Clinical Outcome Measures – Biomechanics assessments			
Outcome Measure	Construct Measured	# Items	Approximate Time
ROM clinical notes – flexion	Quality of Movement	4	3 minutes
Progressive Postural Lifting Exam Clinical Score	Quality of Movement	10	3 minute
		Total:	6 minutes

(8) Post-visit Surveys:
a. The following surveys will be completed at the end of all study visits:

Table: Patient Reported Outcome Measures – Training Visits Post			
Outcome Measure	Construct Measured	# Items	Approximate Time
Body Discomfort Map	Discomfort	3	1 minute
Numeric Pain Rating Scale (NPRS)	Pain	1	1 minute
		Total:	2 minutes

b. The following surveys will be completed additionally following all biomechanics assessment visits:

Table: Patient Reported Outcome Measures – Training Visits Post			
Outcome Measure	Construct Measured	# Items	Approximate Time
Usability Questionnaire – QUEST Light*	Usability	9	5 minutes

PHODA	Fear/avoidance	4	2 minutes
		Total:	7/8 minutes*

*Light Usability questionnaire will only be completed after the biomechanical assessment (typically on visits 3, 6, and 9).

(9) Scheduling & Follow-Up
   a. Prior to leaving each training visit, the physical therapist will work with the participant schedule the following visit.
   b. There is no planned follow-up between sessions, however the participant is encouraged to contact members of the research team if questions arise.
   c. Overall progression through the study will be tracked for each participants via REDCap.

(10) Participants will receive remuneration for completing treatment visits
   a. Participants will receive $20 in remuneration for treatment visits with the exosuit (typically visits 2, 4, 5, 7, 8, 10, and 11)
   b. Participants will receive $45 in remuneration for treatment visits with the exosuit that involve a biomechanical assessment (typically visits 3, 6, 9 and 12)

Patient-Reported Outcome Measures – Discharge (Virtual)

(1) Participant will complete patient-reported outcome measures related to their LBP using REDcap (List Below).
(2) This will be done remotely using a computer or their personal cellular device.
(3) They will receive a link to complete these surveys from the *Participant List* Function in REDCap.
(4) Participants will complete these within 48 hours preceding the final study visit.
   1. BACPAC Minimum Pain inventory
   2. Pain, Enjoyment, General Activity (PEG)
   3. PROMIS 4a – Pain interference
   4. PROMIS 6b – Physical Function
   5. PROMIS 4a - Depression
   6. PROMIS 4a - Anxiety
   7. Modified PROMIS 6a Sleep Disturbance + Duration
   8. Pain-Catastrophizing Scale (PCS-6)
   9. Patient Health Questionnaire (PHQ-2)
   10. Generalized Anxiety Disorder (GAD-2)
   11. Tobacco, Alcohol, Prescription medication, and other Substance (TAPS 1) Tool
   12. Usability Questionnaire- QUEST Full
   13. Optimal Screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF)

Table: Patient Reported Outcome Measures - Discharge			
Outcome Measure	Construct Measured	# Items	Approximate Time
Pain, Enjoyment, General Activity (PEG)	Pain	3	1 minutes
Pain Interference (PROMIS-6)	Quality of Life	6	2 minutes
PROMIS Sleep Disturbance + Duration	Sleep	8	3 minutes
Pain-Catastrophizing Scale (PCS-6)	Pain Catastrophizing	6	3 minutes
Patient Health Questionnaire (PHQ-9)	Depression	9	4 minutes
Generalized Anxiety Disorder (GAD-2)	Anxiety	2	1 minutes

Optimal Screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF)	Negative Mood, Fear avoidance, and Coping	17	5 minutes
Tobacco, Alcohol, Prescription medication, and other Substance (TAPS 1) Tool	Substance Use	4	2 minutes
Photographic Series of Daily Activities	Fear of Movement	4	2 minutes
Full Usability Questionnaire	Device Usability	9	3 minutes
Modified Oswestry Disability Index	Disability	11	5 minutes
		Total:	32 minutes

(5) Participants will receive $45 remuneration for completing these surveys.

Post Assessment – Final Training Visit (In-person)

The final training visit and discharge visit will follow the same procedures as every other training visit, including the biomechanical assessment, with the following exceptions:

(1) Physical Therapy Examination:
   a. The study physical therapist may conduct components of a physical examination, known as a reassessment.
   b. This is considered routine clinical care.
   c. This routine care will include collecting the Patient Specific Functional Scale (PSFS).
   d. Data from this reassessment will be documented in the BUPTC Electronic Medical Record, shared, and uploaded to REDCap via HIPAA Authorization.

(2) Scheduling & Follow-Up
   a. Prior to leaving, the physical therapist will work with the participant schedule the 1-month follow-up phone call.
   b. There is no planned follow-up until that phone call, however the participant is encouraged to contact members of the research team if questions arise.
   c. If the participant has not met clinical goals and would like to continue non-research related physical therapy, the study coordinator will connect them with the BUPTC Administrative Staff.
   d. The participant will be responsible for organizing and scheduling continued care outside of the trial.

Follow-Up Phone Call (Phone)

(1) Four-weeks after post-assessment, participants will be contacted via phone to complete a follow-up assessment with the study staff.
(2) If participants do not answer the phone, a voicemail will be left requesting a call back. An email will also be sent to request a call-back.
(3) The study staff member will use the follow-up assessment script (**Appendix O:** Study follow-up assessment) to guide the conversation surrounding ongoing pain and limitations, and general clinical progress since post-assessment. These data will be entered into REDCap. The Patient Specific Functional Scale (PSFS) will be completed during this follow-up phone call and is included in **Appendix O**).
(4) The participant will be asked to complete the following surveys after the phone-call.
(5) Participants will receive $45 remuneration for completing this phone call and survey.
(6) List of instruments:
   1. BACPAC Minimum Pain inventory
   2. Pain, Enjoyment, General Activity (PEG)

3. PROMIS 4a – Pain interference
4. PROMIS 6b – Physical Function
5. PROMIS 4a - Depression
6. PROMIS 4a - Anxiety
7. Modified PROMIS 6a Sleep Disturbance + Duration
8. Pain-Catastrophizing Scale (PCS-6)
9. Patient Health Questionnaire (PHQ-2)
10. Generalized Anxiety Disorder (GAD-2)
11. Tobacco, Alcohol, Prescription medication, and other Substance (TAPS 1) Tool
12. Modified Oswestry Disability Index
13. Photo Series of Daily Activity
14. Usability Questionnaire- QUEST full
15. Patient Global Impression of Change
16. Patient Specific Functional Scale
17. Numerical Pain Rating Scale
18. Patient Global Impression of Change
19. Optimal Screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF)

Early Discontinuations

It is possible that individuals enrolled in the study will experience rapid clinical progress (whether associated with the exosuit use or not) and achieve all physical therapy goals prior to 6th week of study interventions. For these participants, early discontinuations will be considered if:

(1) The study physical therapist agrees that all clinical goals have been met (i.e., participant is able to return to unrestricted participation in activities of daily living).
(2) The study physical therapist agrees that this individual would be discharged from non-research related physical therapy care.
(3) The participant demonstrates ≥50% improvement on the MDQ and PEG scales from baseline at 2 consecutive training visits.

Participants who achieve these milestones, will complete the discharge surveys and post assessment visit, as well as 1-month follow-up phone call and follow-up surveys from last visit.

Photo/Video data.

Photos or videos may be taken as participants complete research activities to allow offline analyses by investigators who were not at study visits and for use in publications or presentations. We will make every attempt possible to avoid capturing participants' faces. We will not collect photo or video data if participants did not sign a Video Consent Form which describes possible use of the data in future research presentations.

a.

SECTION M: RISKS

Describe any expected risks to subjects. Consider physical, psychological, social, political, legal, economic, or other risks that are related to the study.
There are some risks to participating in this study. We have categorized the risks by procedures and devices.

Clinical Interview, Questionnaire, and Survey Risks

Participants may feel emotional or upset when answering some of the questions. Participants do not have to answer any questions that make them feel uncomfortable.

General Physical Therapy Risks

Participants are eligible for this study because LBP currently limits their level of function. This research study is offered to study the effects of augmenting physical therapy with an exosuit device. By enrolling in this study, they will receive routine physical therapy examination and treatment as would typically be prescribed based on their symptom presentation. This may include activities such as physical examination, manual therapy, impairment-based exercise prescription, and functional training, or other therapies as detailed in Chapter 112 of the Massachusetts General Laws, Sections 23A - 23Q (Physical Therapy Practice Act). All care participants receive will be delivered under the supervision of physical therapists licensed to practice in the Commonwealth of Massachusetts. The functional training portion of this therapy may incorporate the use of the exosuit device. Although the research team may use physical therapy documentation generated during routine clinical care, this is only to contextualize research-related procedures regarding their clinical case.

As with traditional physical therapy, there is no guarantee that the proposed course of treatment will improve the participant's condition. It is possible, although unlikely, that the course of treatment may cause additional pain or discomfort or aggravate their condition. Participants will have the opportunity to ask questions, and or discontinue any portion of treatment.

Exosuit Risks

The device fits like a backpack over the shoulders, weighs 6-pounds, and straps to each thigh. As with any assistive device, there is a length of time required to feel comfortable wearing it. Participants will be given as much time as they need to feel comfortable while wearing the suit.

The 6-pound device rests comfortably on the torso- the device adds some compressive forces to the spinal column- e.g., similar to a light backpack.

Participants may experience minor redness, chafing, rubbing, blistering, swelling, numbness, or tingling due to the tightness of the exosuit. These are only temporary effects and should disappear over time. The person conducting the exosuit fittings and exercise training will inspect the skin on participant's legs and shoulders prior to and after each study visit. If they are uncomfortable or wish to stop at any time during the study, they are able to do so.

Individual electronic devices/sensors/modules of the exosuit will be safety certified by staff engineers, being put through a safety-checklist before being applied and worn by participants in our study. The motor controllers have built-in safety measures to detect shorted or unconnected phases and cut power to the system. We have also designed an emergency stop switch that can be used by the operator to instantly cut the power to the motor phases in case of unexpected error. Any assistance participants experience from the exosuit will be less than what a healthy adult can naturally exert.

It is also possible, but unlikely, that the external surfaces of the body-worn actuator could overheat and cause a burn in the event of accidental contact with the participant's skin. The body-worn actuator has built-in safety measures to detect and prevent incidents of overheating,

and the actuator is separated from them by an insulating layer and their clothing to minimize any accidental contact.

Some of our systems are powered by batteries which, if shorted, could have a risk of fire. In order to lessen this risk, the batteries are protected by a fuse to minimize the effects of a short. The battery connector geometry is designed so that the batteries can only be connected in the correct orientation, and battery charging and setup will only be performed by trained research staff.

Exercise Training Risks

As with any exercise, there is the possibility that abnormal responses could occur. The exercise training programs have the following risks. These risks include nausea, shortness of breath, fatigue, muscle cramps, or muscle soreness (sometimes lasting days after a testing session), as well as unexpected changes in blood pressure, irregular heart rate, fainting, or joint injury. Rare risks associated with exercise could include heart problems or hospitalization. The licensed physical therapist will supervise each participant throughout each visit and is trained and licensed to monitor the participants' response to exercise. They may provide guarding during exercise to ensure participants do not lose their balance or fall. They may monitor your blood pressure or heart rate or other vital signs during the study visits. Should participants experience symptoms indicative of poor tolerance to exercise, the physical therapist will discontinue or modify the activity accordingly.

Exercising with Exosuit

When participants are wearing the exosuit, it is possible that they could experience a fall while performing the tasks. In the passive 'slack suit' mode, the device will not be providing any active assistance, so the risk of exercise in this mode of testing is like what participants would experience in their daily life. While the exosuit is active, it will provide external assistance to participants during movement. Any assistance they experience from the exosuit will be less than what a healthy adult can naturally exert. It is possible that this assistance occurs when they are not expecting it, which may result in unsteadiness. Loss of balance or experiencing a fall during exercise are possible risks within this study. However, research personnel will be present to provide additional support, guarding and/or monitoring during the tasks.

It is also possible that participants may become anxious while using the suit as some participants may perceive them as novel and unfamiliar. They are free to end testing or procedures that cause anxiety or discomfort at any time, this will not affect any remuneration they are entitled to.

Back Pain

It is possible that the exosuit related study activities could provoke the participants' LBP. If this occurs, they and the study physical therapist will have the freedom to make clinical determination on whether to modify the intensity of study procedures or discontinue exosuit use.

Skin Irritation

During the biomechanical assessment, we will place five inertial measurement unit sensors on the participant's skin at the base of the neck, mid-back, and lower back. These sensors must be adhered to the skin with tape. In the presence of body hair, we may shave and debride the skin with a dry razor to ensure participant comfort when removing the tape. It is

possible that either the tape or shaving may cause skin irritation. If it occurs, this will be mild and is expected to resolve in <15 minutes.

Study Withdrawal

Participants are allowed to withdraw from the study at any time. Doing so will not influence their ability to seek continued care at Boston University Physical Therapy Center. However, continued care at Boston University Physical Therapy Center will be scheduled with a different provider, which may influence the therapist-patient relationship, as well as the time course of their recovery due to potential scheduling delays.

Sanitation Plan

Body-worn exosuit components are sprayed with household disinfectant (e.g., Lysol) immediately after use. Exosuit components are machine washable, and sensors and actuator units are wiped down with disinfecting wipes, if needed.

Loss of Confidentiality

The main risk of allowing us to use and store participants' information for research is a potential loss of confidentiality. To lessen this risk, participant data will be labeled with a code and keeping the key to the code in a password-protected computer. All medical information and notes will be stored in a way that protects their protected health information (HIPAA compliant servers).

Describe the plan to minimize risks. Include in the description the availability of any medical or psychological resources.

The PI and co-investigators have extensive experience with clinical research involving individuals with LBP. Many of the investigators have a clinical background in physical therapy and are credentialed and licensed in the State of Massachusetts. Other study personnel and students have training in CPR and first aid. All the aforementioned risks will also be mitigated through the following:

- Potential participants will be provided with the consent form and ample time to read it and ask questions. The research team will address any concerns. Participants will be told that participation in the study is completely voluntary, and they have the right to withdraw from the study at any time.
- Adequate rest periods and water will be provided to optimize comfort and reduce fatigue. Rest periods will be allowed whenever requested by the participant, during down-time between exercises or during exercise set-up, or at the discretion of the research physical therapist. This applies to both non-exosuit and exosuit training.
- Total exosuit wear time per session will be limited to 75 minutes.
- Trained investigators may monitor vital signs and check for symptoms of distress at each study visit. Procedures will be halted as physiologic signs clinically warrant activity cessation. Any findings out of the ordinary will be reported to the participant's primary healthcare provider (e.g., treating physical therapist), concluding the study visit procedures.
- All participants are free to end testing or procedures that cause anxiety or discomfort at any time, this will not affect any remuneration to which they are entitled.

- The exosuit features onboard safety features to prevent malfunction or injury related to its use. These are outlined in the attached user-manual for device review.

SECTION N: BENEFITS

Describe the potential benefits to subjects related to the study. State if there are no direct benefits. NOTE: Compensation and/or course credit are not considered benefits.

Participants will receive routine physical therapy prescribed evidence-based exercise and manual therapy as part of this research study. Such physical therapy care is likely to benefit the participant. There is no known direct benefit to wearing the exosuit. This study will help determine whether an exosuit offers benefit to participants during physical therapy.

Describe the potential benefits to society and/or others related to the study

The project will facilitate the development and clinical translation of exosuit augmented functional training interventions that may improve LBP recovery. In short, this project will test new technology that extends the abilities of clinicians in treating LBP.

SECTION O: COSTS/PAYMENTS

YES	NO	
☒	☐	Are there any costs to subjects as a result of participating in this study? **If YES**, provide a description of the costs: Participants will be responsible for any upfront or out-of-pocket costs related to routine physical therapy care. These costs will be associated with care documented and billing through the BUPTC Electronic Medical Record and will only occur for activities that are not done for research purposes (e.g., activities that are routine clinical care). This will include the physical therapy examination (excluding consent, exosuit fit/comfort, and baseline biomechanical assessments) and clinical care during each training visit (excluding research-related exosuit research procedures [i.e., donning/doffing, fit & comfort, biomechanical assessment, etc.]). Participants may also be responsible for any upfront costs related to traveling to Boston University (e.g., parking).
☒	☐	Will subjects be compensated for participating in the study? Compensation may include cash, checks, gift cards, lotteries, course credit, etc. Payments should be prorated to compensate subjects for time and procedures completed **If YES**, provide a description of the compensation: Participants can receive up to $500 for participation in this study. The compensation structure is as follows (Table). Compensation will be provided in the form of an Amazon.com gift cards. Table: Financial Remuneration Structure Baseline Biomechanical Assessment — $45 Baseline Surveys — $45 Treatment Visit 2 — $20

		Biomechanics Assessment Visit 3 — $45 Treatment Visit 4 — $20 Treatment Visit 5 — $20 Biomechanics Assessment Visit 6 — $45 Treatment Visit 7 — $20 Treatment Visit 8 — $20 Biomechanics Assessment Visit 9 — $45 Treatment Visit 10 — $20 Treatment Visit 11 — $20 Discharge Surveys — $45 Discharge Biomechanical Assessment — $45 Follow-Up Phone Call & Surveys — $45 If a participant is discharged early due to the success of the intervention, this will affect their overall compensation because of missed treatment visits. However, all participants will be asked to complete discharge surveys prior to their final training visit, a discharge biomechanical assessment at the final training visit, and follow-up phone call & surveys 1-month after the final training visit; these visits have a higher remuneration rate than typical treatment visits. Alternatively, if the participant drops out or fails to follow-up, they will only receive compensation for completed study visits.
☐	☒	Will identifiable information be sent to Accounts Payable, Post Award Financial Operations, etc. for payment purposes? **If YES**, this information must be disclosed in the consent form.

SECTION P: CONFIDENTIALITY OF DATA

	YES	NO
Are you using BU-managed computers?	☒	☐
Are you using any non-BU managed computers (e.g. personal computer)? If yes, confirm that the non-BU managed computer(s) have the following:	☒	☐
• A current and supported Operating System	☒	☐
• Malware Protection (e.g. Microsoft Defender, BU Crowdstrike – no cost)	☒	☐
• Encryption enabled (i.e. turned on)	☒	☐
• Automatic screen lock to password/code at 15 minutes or less	☒	☐

For guidance on securing computers, please see here: https://www.bumc.bu.edu/it/infosec/safe-computing/

Describe how data will be stored (e.g. paper, electronic database, etc.)
Research participants will be informed that all data collected for study purposes will be held in strict confidence and used for research purposes only. Records may be paper or electronic. **Electronic Documents -** Screening information: Screening documents, including screening checklist, screening consent, and screening log will be kept in electronic format and stored in both a secure SharePoint folder and secure REDCap database that only the research team has access to. This is a secure, password-protected server authorized to store restricted data by BU IS&T Information Security team on the BU network, with access provided only to the investigators, research assistants, and administrators with clinical appointments at BUPTC. Electronic Consent Forms: including ICF, HIPAA Authorization, and Video Consent Forms will be kept in electronic format and stored in a both a secure REDCap Project and SharePoint folder that only the research team has access to. This is a secure, password-protected server authorized to store restricted data by BU IS&T Information Security team on the BU network, with access provided only to the investigators, research assistants, and administrators with clinical appointments at BUPTC. Screening Logs: will be kept in electronic format and stored in a secure SharePoint folder that only the research team has access to. This is a secure, password-protected server authorized to store restricted data by BU IS&T Information Security team on the BU network, with access provided only to the investigators, research assistants, and administrators with clinical appointments at BUPTC. Data Safety Monitoring Forms: All DSMP forms will be created and maintained electronically. These will be stored on BU SharePoint servers. HIPAA Protected Health Record: N/A. BUPTC's current practice is to scan all paper documents (i.e., intake paperwork) into the electronic medical record. This is not study related. Only digital copies from the electronic medical record will be accepted (see REDCap below). **Paper Documents** – ICF and HIPAA Authorization: Including ICF and HIPAA documents that are completed on paper. The paper originals will be scanned and uploaded to both REDCap and SharePoint servers. The paper originals will then be stored in a locked lockbox within a locked room. This lockbox is only accessible to research team members. Documents will be stored here temporarily (up to 2 weeks) prior to be transferred by Sarah Sullivan or Ada Huang to the Wyss Institute. Here documents will be stored in a locked filing cabinet which requires an ID Badge to enter and has security guard monitoring. **Photos/Videos** – Photos and videos will be kept in electronic format and stored in a secure SharePoint folder that only the research team has access to. This is a secure, password-protected

server authorized to store restricted data by BU IS&T Information Security team on the BU network, with access provided only to the study team..

REDCap - Electronic forms of study documents such as screeners, surveys, questionnaire, data from functional training, HIPAA protected medical information, in-session clinical documentation, medical provider communication, and any notes generated related to the study will also be uploaded and kept on a secure REDCap server.

De-Identified Participant ID Number – Data collected during this research will be labeled using a de-identified participant ID number.

Research Data – Data will be de-identified and stored on a secure, password-protected server with access limited to the research team. De-identified (Coded) Exosuit Mobile Application data will be automatically submitted to a password-protected, Cognito authenticated, limited access, encrypted Amazon Web Services S3 cloud database managed by the Harvard Move Lab. Digital copies of exosuit data files will be downloaded from the cloud and uploaded to REDCap at regular intervals following data collection. All other study data will be entered or uploaded directly to REDCap or BU SharePoint as described above. Research data will not be shared or copied into the participant's medical record.

YES	NO	
☒	☐	Will you collect identifiable information? (e.g. names, social security numbers, addresses, email addresses, telephone numbers, photo/video/voice etc.). **If YES**, complete the box below.

Describe the coding system that will be used to protect the information including who will have access to the code. Coding systems are used to: 1) protect the confidentiality of the research data and 2) allow the investigator to link subjects to their responses. Each subject is assigned a unique study ID at the beginning of the study. A separate document (key) should be maintained that links the names of the subjects to the study ID numbers.

To ensure confidentiality of all data collected, each subject will be assigned a unique alphanumeric code. Only the PI and designated research personnel associated with the project will have access to the master-code with the corresponding identifiers. The master-code will be housed on a password-protected network drive.

Protected health information, including physical therapy examination notes and clinical notes, will be obtained through HIPAA Authorization between BUPTC and the research team. Virtual transfer will occur through HIPAA-compliant servers (SharePoint) and uploaded to Boston University's HIPAA-compliant REDCap server.

YES	NO	
☒	☐	Will you share data with others outside of the study? **If YES**, complete the box below.

Describe how data will be transferred and how confidentiality will be maintained (e.g. identifying information will not be sent outside, etc.):

NIH Heal Initiative
This study is part of the NIH HEAL Initiative, which focuses on understanding and developing new treatments for addiction and pain. Participant data could be used for this and other NIH

HEAL Initiative studies insofar as it provides evidence of whether an intervention (exosuit) can reduce the development of LBP. Stored data could also be made widely available to other researchers. The shared data may be used indefinitely for research unrelated to this study or the HEAL Initiative without asking for additional consent.

Data will be stored securely at Boston University or at sites NIH selects for this study. Participant name and other personally identifying information will not be kept with the data. Data will be stored with or without a code that links to identifying information. If the data has a code, the key to the code will be kept at Harvard in a separate, secure area and will not be shared outside of the Boston University research team.

Describe how you will maintain the confidentiality of the data (e.g. locked cabinet, password-protected files, encryption, etc.). Note: Confidentiality refers to the researcher's agreement with the participant about how the subject's identifiable private information will be handled, managed, and disseminated.
Only the PI and a few designated research personnel can access identifiable research data. The PI and all study personnel (listed in section E) will have access to all coded data housed on a password-protected secured network drive. No names or identifiers of subjects will be contained on paper forms. BU REDCap (our HIPAA-compliant and secured study database) or BU SharePoint (our HIPAA-compliant and secured study server) will store names and identifiers. BU REDCap will be used for data collection and will be accessible to approved study personnel. BU SharePoint will contain copies of signed ICF documents and the ID Code List. No identifiable data will be shared with non-study personnel, including students, professional colleagues, outside institutions or study sponsors.

Under the BU Data Classification Policy, personally identifiable health information (e.g., email address, phone number, picture or video recording of face) is classified as Restricted Use, and human subject data with identifiers limited to dates, city, and Zip Code is classified as Confidential.

Please identify where you will store Restricted Use data: for example, in BU REDCap; on a BU Restricted Use network drive; on a BU managed computer or server; on paper in a locked cabinet/office, or other services cleared for Restricted Use data by BU Information Security.
• BU REDCap • BU SharePoint / BU 365 • BU managed computers or servers until made accessible on either BU REDCap or BU SharePoint servers (i.e., temporary local storage during the process of uploading documents).
Please identify where you will store Confidential data: for example, using a non-BU, third-party app but with anonymous accounts setup by research project; BU network drive; IS&T/Research Computing, Shared Computing Cluster 4 (SCC4); BU managed computer; or other services cleared for Confidential data by BU Information Security.
• BU REDCap • BU SharePoint / BU 365 • BU managed computers until made accessible on either BU REDCap or BU SharePoint servers (i.e., temporary local storage during the process of uploading documents).

YES	NO	
☐	☒	**Will subjects setup accounts (e.g., personal email address) for a non-BU, third-party app that is not listed on the** BU Information Security **website?** Note: BU Information Security needs to complete a security review before the research protocol is approved. Send an email to buinfosec@bu.edu with the name of the vendor/app and an email address of someone at the vendor/app who can answer security questions.
If YES, please list the name(s) of the non-BU, third party apps:		

For further assistance and/or access to resources regarding information security, please refer to the BU Information Security website**,** the Boston University (BU) Record Retention Policy and the IRB's Guidance Page for information on data management.

SECTION Q: CERTIFICATE OF CONFIDENTIALITY

In 2017 the NIH updated its policy for issuing **Certificates of Confidentiality.** Under the policy, all **eligible** research studies funded by the NIH are automatically issued a certificate of confidentiality. Investigators whose research is not funded or supported by the NIH may request and obtain from the NIH a Certificate of Confidentiality. Investigators who request and receive Certificates must follow the NIH and PHS policies governing such certifications.

YES	NO	
☒	☐	Is your research funded by the NIH and eligible for a Certificate of Confidentiality?
☐	☐	If your research is not funded by the NIH, will you be applying for a Certificate of Confidentiality?

SECTION R: PRIVACY

Describe how you will protect the privacy of subjects (e.g. where will consent procedures take place, if interviews or other interventions, where will these procedures take place)

Recruitment and screening procedures conducted through the BUPTC will be limited to investigators, research assistants, and administrators with clinical appointments at BUPTC.

Privacy of participants will be protected by conducting all in-person interactions in a semi-private or private space within the BUPTC located at the Ryan Center for Sports Medicine. No personally identifiable information will be discussed in common areas. Interviews where protected health information is discussed will occur in private space – e.g., standard practice at our clinic is that all sensitive conversations take place in private rooms. Other aspects of care, such as exercise therapy, often requires larger areas and utilizes equipment in the open part of the clinic where other patients are in view. Isolating the participant to a private room for the entirety of their session will deprive them of the access to space/equipment others with their condition utilize when under non-research care. Participants will therefore complete all study

procedures in the BUPTC clinic space. They will be able to be seen by other patients and BUPTC staff (non-study personnel). It is important to note that clinicians do not discuss protected health information when others can hear.

Protected Health Information – Any medical records and imaging files obtained during the course of the study will be handled only through HIPAA-compliant servers at Boston University (e.g., SharePoint and REDCap).

SECTION S: MONITORING STUDY DATA

How will data be monitored? **Note:** The Data and Safety Monitoring Plan should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied.	
☒	Principal Investigator
☐	Monitor/Monitoring Group
☐	Data and Safety Monitoring Board (DSMB) Note: The DSMB Charter must be submitted with this Application. For more information regarding a DSMB, please refer to the NIH website.

Describe the plan for monitoring study data. This should include a description of how data will be collected and analyzed as the project progresses to assure the appropriateness of the research, its design, and subject protections.

Dr. Awad and Dr. Walsh will be responsible for data safety and monitoring, reviewing and approving all enrollment and DSMP reports and attending DSM meetings. Study staff will submit all correspondence to the IRB for SAEs, UPs, and protocol breaches. The PI will notify the entire research team of changes made by the IRB, including updates to changes in screening or re-consenting.

NIAMS is responsible for independent oversight of data and trial safety monitoring. They have appointed Navitas Clinical Research, Inc. (NCR), a contract research organization, to serve as the Executive Secretary to NIAMS. Navitas is responsible for communicating between the research team and the NIAMS. The Executive Secretary is responsible for all communication between the research team and the study's independent Safety Officer (Jon D. Lurie, M.D., M.S.).

The Clinical Research Manager, Sarah Sullivan, will oversee communication between the research team and the NIAMS, including enrollment and DSM reports. Ms. Sullivan will ensure new reports are drafted in a timely manner and internally review these reports with Drs. Awad and Walsh.

Selected research team members will identify and log safety events, notifying the clinical research manager of SAEs and UAPs to activate reporting protocols. Select research team members will populate study templates for enrollment and DSM reports using data from various logs.

Report generation: Approximately two weeks prior to the submission date of enrollment or DSM reports, a research team member will update report templates using the most up-to-date data from the sources listed below. This report will be submitted to the Clinical Research Manager.

Study enrollment status: Will be recorded using data collected in the Screening and Enrollment Log and ID Code List, including participants screened, enrolled, status and those who completed or exited the study.

Study duration and data quality tables will be completed using the survey completion log as part of our data quality check and adverse event checks.

Data of safety assessments: Safety events (adverse, serious) recorded in the individual adverse event log as a part of AE reporting will utilize metadata fields to populate aggregate event reports for the DSM report.

Statement of Compliance
The study will be conducted in compliance with the protocol, International Council for Harmonization/Good Clinical Practice requirements (ICH/GCP), and applicable state, local and federal regulatory requirements.

Safety Reporting
This study will use the definitions and guidelines for event collection and reporting as outlined in this section. The following definitions reflect Boston University's protocol for adverse events and serious adverse events. When such events occur, the investigators will provide a report to the IRB of Boston University, the NIAMS Program Officer (PO), and the study Safety Officer (SO) via NCR.

Definitions

(1) Unanticipated Problem Involving Risks to Subjects or Others
   a. Any incident, experience or outcome that is:
      i. unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and the informed consent document, and the characteristics of the subject population being studied
      ii. related or possibly* related to participation in the research
      iii. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

   **Possibly Related*: There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research

(2) Adverse Event
   a. Any untoward or unfavorable physical or psychological occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease temporally associated with the subject's

participation in the research, whether considered related to the subject's participation in the research.

(3) Serious Adverse Event
   a. Any adverse event that:
      i. Results in death
      ii. Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
      iii. Results in patient hospitalization or prolongation of existing hospitalization
      iv. Results in a persistent or significant disability/incapacity
      v. Results in a congenital anomaly/birth defect
      vi. Based upon appropriate medical judgement may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

(4) Unexpected Adverse Event
   a. Any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity or frequency of which is not consistent with either:
      i. The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in:
         1. The protocol-related documents, such as the IRB-approved protocol, any applicable investigator brochure, and the current IRB-approved informed consent document.
         2. Other relevant sources of information, such as product labeling and package inserts
      ii. The expected natural progression of any underling disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

(5) Unanticipated Adverse Device Effect
   a. Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of the subjects.

(6) Adverse Device Events
   a. Any adverse event that is related or possibly related to the device.

Reporting Requirements

Reporting of Adverse Events, Serious Adverse Events, and Unanticipated Problems will follow specific procedures based on the NIAMS and the IRB of Boston University

The following procedures refer to NIH Policy of reporting to the NIAMS and SO:

Adverse Event Reporting

All AEs (regardless of expectedness or relatedness) will be reported in the DSM report to the NIAMS and the Safety Officer through Navitas.

Serious Adverse Event (SAE) and Unanticipated Problem Reporting
The research team will report all SAEs (regardless of expectedness or relatedness) and unanticipated problems to the NIAMS and the Safety Officer through Navitas within 48 hours of becoming aware of the event, even if the report is incomplete. Follow-up reports will be submitted as needed.

Protocol Deviation Reporting
The research team will report any protocol deviation that impacts participant safety to the NIAMS and the Safety Officer through Navitas within 48 hours of becoming aware of the event. The research team will report protocol deviations that do not impact participant safety in the DSM report.

Serious or Continuing Noncompliance Reporting
The research team will report serious or continuing noncompliance to the NIAMS Program Officer and Grants Management Specialist within 3 business days of IRB determination. This will include a copy of the IRB submission and determination.

Suspension or Termination of IRB Approval Reporting
The research team will report any suspension or termination of IRB approval (including the reason for suspension or termination) to the NIAMS Program Officer and Grants Management Specialist within 3 business days of receiving the IRB notification.

<u>The following procedures refer to reporting to BU IRB</u>
Adverse events, serious adverse events, unanticipated problems, and major deviations (Schedule: within 5 working days of discovery):

(1) The following events must be reported to the IRB **within 5 working days** of discovery:
   a. Adverse events that are unanticipated (in terms of nature, severity, or frequency, related or possibly related, and suggest that there is an increased risk to subjects or others than was previously known
   b. Any event or problem that is unanticipated (in terms of nature, severity, or frequency, related or possibly related, and suggest that there is an increased risk to subjects or others than was previously known
   c. Breach of confidentiality
   d. Suspension or termination of the research study by the Sponsor or other agency
   e. Incarceration of a research subject enrolled into the study
   f. Study staff misconduct
   g. Medication or laboratory error regardless of whether subjects experienced harm
   h. Death of a research subject if the death is related or possibly related to the research study
   i. New information (e.g., interim analysis, safety monitoring report, publication, or other finding) that suggests that there are new or increased risks to subject or others
   j. A complaint by a research subject or others that suggests that rights, welfare, or safety of a subject has been adversely affected

k. Any other problem that suggests that the research places subjects or others at an increased risk for harm or adversely affects the rights, welfare, or safety of subjects or other

(2) The IRB will decide if the unanticipated problem constitutes serious and/or continuing noncompliance. Serious adverse events may need to be submitted at a timeline that corresponds with funding institution (i.e., NIAMS: within 48 hours).

(3) Submission of Unanticipated Problem/Adverse Event:

a. The Principal Investigator is responsible for submitting the unanticipated problem/adverse event using the Event Form. Unanticipated problems and adverse events that are unexpected and related must be reported within 5 working days upon discovery.

b. The Principal Investigator must submit all unanticipated problems and adverse events to the Sponsor and other applicable agencies as required; reports to Federal oversight bodies will be handled by the IRB Office.

(4) The researcher who discovers the event will put together documentation of event using an electronic version of the BU Charles River IRB Event Reporting Form (**Appendix P**). The study PI will review, obtain additional information if needed, and finalize the report. The study PI will send the report to BU IRB.

Notification to Study Staff

(1) Once the report has been submitted to the NIAMS and SO, the study PI will send a copy of the report to the rest of the research team.

(2) Once the Event Form is submitted to the IRB, the PI will email a copy of the completed Event Form to the rest of the research team. Further, once a determination by the IRB has been achieved, the rest of the team will be notified of the outcome.

(3) Copies of NIAMS reports and IRB Event Forms will be stored in secure SharePoint, which will be accessible to research team members.

(4) When the event is related to participant safety, the study PI will immediately (within 48 hours or sooner) communicate the event as well as safety considerations to the research team through email.

If a deviation in data collection/usage, adverse or unanticipated event involving risks to participants or others, or a breach in confidentiality is suspected or found, the incident will be reported to the IRB either immediately, within 5 business days via an RNI, or at continuing review depending on the severity of the event.

Monitoring of Adverse Event

Primary Method

All events will be recorded in the Training Visit Clinical Notes, and transcribed into REDCap documentation. If the event is determined to be a serious adverse event (SAE) – **Appendix R:** Serious Adverse Event Form will be completed. Researchers will be trained to prompt the participant to report AEs before, during and after a training visit using the AE Checklist (found in Appendix L: Section 7).

Event Record-Keeping

When a training visit is completed, the research team member will:
(1) Record any new event in the Master Adverse Event Log (Appendix Q)
(2) Identify resolved events: If a previous AE was identified, without an end date, the research team member will:
a. Ask the participant about the event and log an AE stop date if appropriate.

SECTION T: HIPAA
Health Insurance Portability and Accountability Act

YES*	NO	

☒	☐	Is this research being conducted in a covered entity?
		The following BU CRC Departments are considered covered entities:
		• Sargent College Rehabilitation Services
		  ○ Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation
		  ○ Sargent Choice Nutrition Center
		• The Danielsen Institute
		• Boston University Health Plan
		*If YES, contact the IRB office for assistance.
		
		We have submitted two HIPAA-related protocol documents:
		1. Partial HIPAA Waiver for the purpose of recruitment
		2. HIPAA Authorization for the approval of communication and records sharing between BUPTC and the research team.

SECTION U: FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT (FERPA): FERPA is the_federal law that protects the privacy of student education records. Research funded by the Department of Education or research conducted in educational institutions that receive funds from the Department of Education (for research or other purposes) must comply with FERPA.

YES*	NO	
☐	☒	Does this study involve collection of information from student school/university records? *If YES, refer to the following websites for guidance on FERPA: • http://www.bu.edu/researchsupport/compliance/human-subjects/ • http://www.bu.edu/reg/general-information/ferpa/ • http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html **If FERPA applies, you must complete the box below:**
In accordance with FERPA, written consent must be obtained to access student records. The consent must: • Specify the records that may be disclosed • State the purpose of the disclosure • Identify the person or class of parties to whom the disclosure can be made		
☐ YES **(REQUIRED)**		I confirm that I will comply with the FERPA policy that is in place at the educational institution where I am conducting my research. This includes, if

	applicable, the requirements for written agreement when requesting a waiver of consent for personally identifiable information. **If an agreement is required, this agreement must be submitted to the IRB.**

SECTION V: PROTECTION OF PUPIL RIGHTS AMENDMENT (PPRA):

PPRA is a federal law that affords certain rights to parents of minor students with regard to surveys that ask questions of a personal nature. Research funded by the Department of Education or research conducted in educational institutions that receive funds (for research or other purposes) from the Department of Education must comply with the PPRA.

YES*	NO	
☐	☒	Does PPRA apply to this study? If YES, refer to the following websites for guidance: • http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html • http://www.bu.edu/researchsupport/compliance/human-subjects/ **If PPRA applies, you must complete the box below:**
In accordance with PPRA, written parental consent must be obtained prior to subject's participation in the study.		
☐ YES **(REQUIRED)**		I confirm that I will comply with the PPRA policy that is in place at the educational institution where I am conducting my research.

SECTION W: CLINICAL TRIALS REGISTRATION:

The Food Drug and Administration Amendments Act (known as FDAAA 801) requires that "applicable clinical trials" be registered and have results reported on clinicaltrials.gov. In addition, the International Committee of Medical Journal Editors (ICJME) and the National Institutes of Health (NIH) also have requirements for registration. Please see box below to determine if your study requires registration in accordance with either FDAAA 801, ICJME, or NIH.

YES	NO	FDAAA 801 Requirements
☒	☐	Does your study meet the definition of an applicable clinical trial (ACT) and require registration **AND** results submission in accordance with FDAAA 801? ACTs include: • Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation • Trials of devices (see note): 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric post-market surveillance required by FDA **Note:** If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval**.** NCT #: NCT05736393 Following IRB review, the protocol will require review by the funding agency and independent safety officers. Given there may be changes made during the review period or even after approval prior to enrollment (i.e., via subsequent IRB modifications) that would affect the CT.gov submission, we are requesting

		delay of registration to within 21 days of the first enrolled participant in the clinical trial. This is in accordance with rules set forth by the NIH and clinicaltrials.gov.
YES	**NO**	**ICMJE Requirements**
☒	☐	Does your study meet the definition of a clinical trial and require registration in accordance with ICMJE? **Note:** If your study meets the requirement for registration, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval. NCT #: NCT05736393 Following IRB review, the protocol will require review by the funding agency and independent safety officers. Given there may be changes made during the review period or even after approval prior to enrollment (i.e., via subsequent IRB modifications) that would affect the CT.gov submission, we are requesting delay of registration to within 21 days of the first enrolled participant in the clinical trial. This is in accordance with rules set forth by the NIH and clinicaltrials.gov.
YES	**NO**	**NIH Requirements**
☒	☐	Does your study meet the definition of an applicable clinical trial and require registration **AND** results submission in accordance with NIH? For more information on this policy please refer to: • NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information • Checklist **Note:** If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval. NCT #: NCT05736393 Following IRB review, the protocol will require review by the funding agency and independent safety officers. Given there may be changes made during the review period or even after approval prior to enrollment (i.e., via subsequent IRB modifications) that would affect the CT.gov submission, we are requesting delay of registration to within 21 days of the first enrolled participant in the clinical trial. This is in accordance with rules set forth by the NIH and clinicaltrials.gov.

Certification / Signatures

- By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
- I agree to conduct the describe research in an ethical manner.
- I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
- I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
- I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
- I agree to comply with any relevant HIPAA and FERPA regulations if applicable.
- I verify that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms and completed training as dictated at http://www.bu.edu/orc/coi/forms/, and returned the forms to the Office for Research Compliance COI Unit. **NOTE: If anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

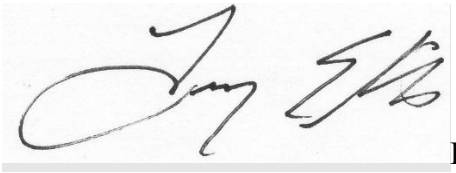
Principal Investigator Signature:  Date: February 15, 2023

FACULTY Research:

The Department Chair signature is required: This application must be signed by the Department Chair for all faculty researchers. If the PI is the Department Chair, then signature by the appropriate Dean is required. Department Chair signature is not required for student research.

By signing this form you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, that they are qualified to serve as the PI for this study, that they have the adequate resources, and the research utilizes acceptable practice for the discipline**.**

Department Chair Printed Name: Terry Ellis, PhD, PT, NCS

Department Chair Signature:  Date: February 16, 2023

STUDENT Research

Student research: Student research must be signed by the faculty advisor AND the designated School IRB pre-reviewer (if applicable) PRIOR TO submission to the IRB. Students should check with their School to determine if School IRB pre-review is required. Students must submit a copy of their dissertation with the IRB Application

By signing this form, you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student's human subjects research.

Faculty Advisor Printed Name: enter text

Faculty Advisor Signature: Date:

School Review Name, if applicable: enter text

School Reviewer Signature: Date:

Submission: Electronic signatures are acceptable, as are emails confirming the certification information. This form can be completed, signed, scanned and submitted to the IRB at irb@bu.edu. Faxed documents and handwritten materials are not accepted. Be sure to include all relevant attachments.