Research Title: Objective Dynamic and 3D Knee Assessment Medical Device to Improve Recovery and Accelerate Return to Readiness in Service Members with Knee Pain

NCT Number: 06517056

Document Date: 2/10/2025

EIRB Protocol Template (Version 1.9)

1.0 General Information

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

Objective Dynamic and 3D Knee Assessment Medical Device to Improve Recovery and Accelerate Return to Readiness in Service Members with Knee Pain

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

EMOVI
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

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

Yes

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◆	**P and R** - Womack Army Medical Center (WAMC)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Goss, Donald Lee, PhD, PT

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Maldonado, Carlos J, PhD
Associate Investigator
Rochester, Kelsey Lee

Associate Investigator
Tucker, Caitlin Johanna
Associate Investigator

B) Research Support Staff

Lucio, Whitley B
Non-engaged Administrator
Ory, Rian Lyndzie, MS
Non-engaged Administrator

3.3 *Please add a Protocol Contact:

Goss, Donald Lee, PhD, PT
Rochester, Kelsey Lee
Tucker, Caitlin Johanna

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

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

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

4.0 Project Information

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

	Physical Therapy

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

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

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

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

○ Yes ◉ No

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

◉ Yes ○ No

4.4 * What type of protocol is this?

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

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

○ Yes ◉ No

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

◉ Yes ○ No

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

○ Yes ◉ No

5.0 Personnel Details

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

○ Yes ◉ No

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

No records have been added

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

◉ Yes ○ No

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Rochester, Kelsey L. Role on Protocol:	910-907-8531	kelsey.l.rochester.ctr@health.mil	Geneva Foundation

Associate Investigator			
Name: (Last, First, M.I.) Tucker, Caitlin J. Role on Protocol: Associate Investigator	Phone Number: 910-907-8531	Email Address: caitlin.j.tucker.ctr@health.mil	Associated Institution: Geneva Foundation
Name: (Last, First, M.I.) Goss, Don Role on Protocol: Principal Investigator	Phone Number: 910-907-8531	Email Address: donald.l.goss.ctr@health.mil	Associated Institution: Geneva Foundation

5.4 Will you have a Research Monitor for this study?

- ○ Yes
- ◉ No
- ○ N/A

6.0 Data/Specimens

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

○ Yes ◉ No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
: Military Operational Medicine Research Program (MOMRP) (JPC-5)	: Research Development Testing and Evaluation (RDT&E) funds	766000

Total amount of funding:

766000

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

○ Yes ◉ No

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

8.0 Study Locations

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

◉ Yes ○ No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
Army	Tripler Army Medical Center	Performance site	FWA00003575	05/20/2027	: IAIR	: NMCP IRB
Army	Womack Army Medical Center	Lead site			: CRADA	: NMCP IRB

Other:

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

8.3 Are there international sites?

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

○ Yes ◉ No

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

○ Yes ◉ No

Select the area of responsibility:

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

○ Yes ○ No

9.0 Study Details

9.1 Key Words:

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

Knee pain
Biomechanics
Kinematics
Military
Return to duty

9.2 Background and Significance:

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

Physical training and sports-related activities account for 50-90% of injuries in the military, while almost half (i.e., 45%) of these injuries are due to running activity (Hauret et al., 2015). Daily training, particularly for soldiers serving in combat, often consists of high volumes of distance running and/or carrying heavy loads (Jones & Hauschild, 2018). Although there are numerous pathologies associated with running, the knee is the most frequently injured joint (Hauret et al., 2015). Specifically, patellofemoral pain syndrome (PFPS) is the most common running-related pathology, as it accounts for 16-21% of all running- related injuries (Molloy et al., 2020). The high incidence of patients with residual symptoms and chronic deficits suggests that there are significant gaps in the way service members with PFPS are managed.

With the lack of validated objective functional assessment tools to support clinical decision, health care providers (HCPs) must rely on subjective visual assessment of the knee movement to formulate a plan of care. The accuracy and reliability of observational gait analysis is notoriously poor, as even experienced examiners using videotape analysis reported only poor to moderate reliability. While current diagnostic modalities (e.g., X-ray, MRI) providing information about structure in static, non-load-bearing and non-functional conditions, are useful to rule out red-flag conditions (e.g., fractures, bony abnormalities), they demonstrate poor correlation with PFPS symptoms and limitations to guide HCPs in personalized treatment interventions. Objectively quantifying the mechanical function of the knee joint and identifying the underlying biomechanical causes of PFPS are necessary to provide effective and efficient personalized therapeutic interventions. It is important to mention that objective functional data already demonstrated its value in a civilian population with knee osteoarthritis and after knee replacement surgery.

To benefit the military population, biomechanical assessment tools to identify root causes of PFP on an individual patient level must be useful in garrison, deployed, and other austere settings. Robust gait

laboratories exist in the MHS, but they are not practical to evaluate routine knee conditions. In fact, the use of these facilities for clinical care is not feasible as they are expensive, scarcely located at only a few key military treatment facilities (MTFs), time consuming and lack a method or providing clinical interpretation of findings at the point of care (Mukaino et al., 2018; Simon, 2004).
To address this gap in biomechanical and diagnostic testing for PFP, we are proposing to use a validated objective functional assessment of the knee at the point of care in military personnel. This testing is known as a 'Knee Kinesiography" exam which accurately and objectively assess the knee function during weight-bearing activity. This examination includes the use of the KneeKG® system (Emovi Inc., Canada – FDA cleared), which has been validated against traditional gait laboratories to objectively measure 3D knee movement through biomechanical markers linked to knee pathologies (Lustig et al., 2012).

A Knee Kinesiography exam enables HCPs to provide participants with immediate diagnostic information and design intervention strategies to address the identified biomechanical deficits. Knee joint kinematics are calculated during a 45-second bout of treadmill walking and biomechanical deficiencies are automatically detected and flagged in an instant report. These biomechanical markers of abnormal function consist of those specifically identified as having a causative or associative role in PFPS, including altered tibiofemoral rotation (Salsich et al., 2007), knee valgus collapse (Tibiero et al., 1987; Powers et al., 2003), decreased knee flexion during loading (de Oliveira Silva et al., 2015), and others. The exam takes 10-15 minutes to complete.

The HCP can then design a personalized home exercise program guided by this information and an application with detailed validated exercises targeting the different biomechanical markers.

Recent results confirmed that targeted exercises based on the Knee Kinesiography exam can also improve biomechanical markers compared to standard care for knee osteoarthritis (Cagnin et al., 2019).

Therefore, there is interest to assess the value in adding a knee kinesiography exam in the management of PFP.

9.3
Objectives/Specific Aims/Research Questions:

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

The purpose of this study is to assess the effectiveness of using a 3D medical assessment device versus usual care to help guide clinical decisions about the management of PFP. The objective is to determine if gathering objective biomechanical data from a three-dimensional (3D) motion capture device leads to more precise and optimal care, ultimately improving physical function and other outcomes compared to participants who receive routine care that is not guided by information from this device.

Specific Aim 1: Test the effectiveness of rehabilitation guided by the KneeKG functional assessment device for improving the primary outcome of PROMIS Physical Function at 3 months compared to usual care.

Hypothesis 1: We hypothesize that participants that receive care guided by the KneeKG motion capture device will have significantly greater improvements in physical function compared to participants that receive usual care.

Specific Aim 2: Test the effectiveness of rehabilitation guided by the KneeKG motion capture device for improving the secondary outcome (PROMIS Pain Interference, Anterior Knee Pain Scale, Global Rating of Change, Perceived Military Readiness) at 3 months compared to usual care that is not informed by KneeKG data.

Hypothesis 2: We hypothesize that participants that receive care guided by the KneeKG motion capture device will have significantly greater improvements in physical function and accelerate their return to readiness compared to participants that receive usual care.

Specific Aim 3: Assess how well treatment provided in the informed by group addressed specific biomechanical impairments identified by the KneeKG. The treatment effectiveness will be assessed by a linear mixed effects model to analyze the between-group difference in all secondary outcomes at 3 months.

Specific Aim 4: Conduct a qualitative assessment of acceptability, feasibility, and utility of the KneeKG device from physical therapists practicing in this setting. This will help summarize perceptions about value and characterize best-use practices.

9.4 Study Design:

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

This is a randomized clinical trial investigating the use of the Emovi Knee Kinesiography information in the treatment of anterior knee pain in physical therapy.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

Active duty service members age 18-50 complaining of atraumatic anterior knee pain

9.6 Benefit to the DoD:

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

Patellofemoral pain syndrome accounts for approximately 16-21% of running-related injuries across the military (Molloy et al., 2020). If this method of knee assessment proves to be beneficial, results and best practices could be shared across the DoD in an effort to improve management of patellofemoral pain in this setting.

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

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

Participants will be recruited from primary care and physical therapy clinics at participating sites. Authorized study personnel will search electronic medical records (Genesis) to identify potential study participants diagnosed with knee pain. After consent and enrollment, participants will complete baseline measures and then receive a Knee Kinesiography exam. The participant will be entered into the KneeKG system using a unique participant identifier. After the knee kinesiography exam with the KneeKG, participants will be randomized 1:1 into one of two different treatment arms: 1) KneeKG informed care or 2) usual care without any information from the KneeKG.

Knee Kinesiography Exam with KneeKG:

Knee mechanics during gait is assessed with a Knee Kinesiography exam. The participant will walk for 5 minutes on a commercial treadmill at their comfortable speed. Three-dimensional (3D) knee kinematics are captured on each leg using the KneeKG system (Emovi, Canada). With this validated FDA cleared medical device, there is an accurate quantification of specific knee biomechanical markers during gait in a clinical setting. There will be two 45-second trials to electronically capture the data which is immediately accessible through automatic reports. Biomechanical markers captured include but are not limited to varus/valgus alignment at stance, varus/valgus alignment at heel strike, knee flexion angle at heel strike, total knee excursion in sagittal plane, tibial rotation at heel strike and throughout gait cycle. The entire procedure will take approximately 15-20 minutes. This procedure will occur at baseline and also again at 4 and 12 weeks.

Randomization:

Participants will be randomized using an electronic random generator in RedCap.

The sequence will be stratified by sex and by acuity (≤ 1 months vs 2 or more months) to ensure equal allocation between groups.

Blinding:

Due to the nature of the intervention, it will not be possible to blind the therapists delivering the intervention. However, therapists delivering usual care will not be provided the KneeKG data. The participants will be blinded to their assigned treatment group.

Treatment 1: Care informed by use of the KneeKG device.

Participants in this group will receive care guided by the impairments identified with the KneeKG. The KneeKG exam results in recommended exercises that target the specific biomechanical impairments identified. The exercises and dose given to the participant will be based on what the KneeKG device recommends after the exam. The participant will be seen twice a week for 4 weeks.

Treatment 2: Usual Care.

Participants in this arm will have their KneeKG data captured, but this information will not be provided to the physical therapist to inform their care. Instead, physical therapists will deliver care as they normally do in routine clinical practice. Recommended treatment will be for 8 sessions, twice a week.

Questionnaires:

Participants will complete questionnaires at baseline, 4 weeks, and 12 weeks. All questionnaires will be administered using REDCap. All REDCap data will be labeled using a unique participant identification number. Please see the next section for a detailed description of the data collection measures utilized in this study.

Treatment Log:

Participants will complete a treatment adherence log to turn in at the end of the study. The log will be provided as a physical copy and will be labeled using a unique participant identification number after it has been returned to the study team.

Participant Withdrawal:

Participants may withdraw their consent at any time. Participants can also be withdrawn by the PI if they fail to adhere to the protocol and/or treatment plan. If a participant "no-shows" two consecutive appointments, or a total of three "no-shows" during the 4wk treatment plan, the PI will withdraw the participant from the study. The participant will be contacted to let them know that they are no longer eligible for the study.

10.2 Data Collection:

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

	W0	W4	W12
Knee Kinesiography exam	X	X	X
Patient-reported outcome measures (PROMS)	X	X	X
Global Rating of change scale		X	X
Self-reported Readiness to RTD questionnaire	X	X	X
Treatment Adherence Activity Log		X	X
Provider Satisfaction Questionnaire			X
Total lost duty days (Self-reported Readiness to RTD questionnaire 5a)			X

- PROMIS
    1. Pain interference domain
    2. Physical function domain
- Anterior knee pain scale

- The KneeKG exam will produce two reports, Biomechanical Markers and Kinematic Profile.
    - The Biomechanical Markers report will contain the following variables:
        - Medial compartment and femoparatellar compartment: varus thrust during loading, varus static functional lower limb alignment, varus alignment at initial contact, varus alignment during stance, and valgus thrust during loading.
        - Lateral compartment and femoropatellar compartment: valgus thrust during loading, valgus functional lower limb alignment, valgus alignment at initial contact, and valgus alignment during stance.
        - Femoropatellar compartment: dynamic knee contracture in flexion at heel strike and external tibial rotation at initial contact.
        - General: knee in extension at initial contact, limited flexion excursion during loading, limited extension movement during stance, internal tibial rotation movement during loading, tibia internally rotated in relation to the femur during loading.
    - The Kinematic Profile report will contain the following movement graphs:
        - flexion/extension during loading, stance, push off, and swing phases of movement.
        - adduction (varus)/abduction (valgus) during loading, stance, push off, and swing phases of movement.

    - external/internal tibial rotation during loading, stance, push off, and swing phases of movement.
    - anterior/posterior tibial translation during loading, stance, push off, and swing phases of movement.
- The Patient-Reported Outcomes Measurement Information System (PROMIS) asks participants about their pain, functional ability, and symptoms. PROMIS is designed as a health-focused rather than a disease-focused measurement system (Evans et al., 2018). We will focus on the Pain Interference and the Physical function domains since PFPS is known to limit function during daily and sports & recreation activities. PROMIS is an efficient and reliable tool for patients with patellofemoral malalignment (Carender C.N. et al., 2019) and it will be the primary outcome.
- Anterior knee pain scale is a 13-item more specific questionnaire related to PF pain which will allow to assess pain and symptoms during specific loading-activities. (Kujala et al., 1993).
- Self-reported Readiness to RTD questionnaire consists of three questions to assess perceived readiness to RTD.
- Service members will complete an activity log to document treatment recommendations received and the actual list of followed treatments to monitor adherence. If home exercises are prescribed, the member will be required to document the nature and frequency of the exercises performed.
- Provider Satisfaction Survey will be used to measure patient satisfaction with quality of physical therapy care.
- Lost duty days will be tracked in e-Profile by research physical therapists and with Self-reported Readiness to RTD questionnaire 5a.
- Demographic data will be collected verbally by the person obtaining consent. The researcher will collect Name, Date of Birth, DOD ID#, Email Address, Phone Number, Sex, Ethnicity, Height, Weight, and Side of Knee Pain. This information will be stored in the Master Log.

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

(•) Yes ( ) No

10.4 Review the definitions below and respond to the following two questions. If you are not sure of the answers, email DHA.PrivacyBoard@mail.mil for assistance. The *Military Health System (MHS)* is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force *MHS workforce members* are employees, volunteers, trainees, and other persons whose conduct, in the performance of work for the MHS, is under the direct control of the MHS, whether or not they are paid by the MHS. *MHS business associates* are persons or entities that provide a service to the MHS and require protected health information (PHI) to provide the service.

Are you an MHS workforce member?

(•) Yes, I am an MHS workforce member
( ) No, I am not an MHS workforce member

10.5 Have you consulted with an MHS data expert to determine the data elements required for your study?

Consulting with a data expert often saves time later in the compliance process because the data expert can advise on the data available in the numerous MHS information systems, the quality of that data and the methods for encrypting and collapsing data. To schedule a consult with an MHS data expert, send an email to: (**DHA.PrivacyBoard@mail.mil**)

( ) Yes, then complete the questions below according to the data consult
(•) No, then complete the questions below according to the best of your knowledge

10.6 Indicate how you will request data from the MHS. Select all that apply.

- [ ] Talking with MHS health care providers or MHS health plans about specific research participants
- [ ] Obtaining MHS hard copy records specific to research participants
- [x] Obtaining data from an MHS information system(s)

10.7 If you are obtaining data from an MHS information system(s), indicate whether you plan to receive a data extract or whether you plan to access an MHS information system directly to create a data set.

A data extract is when the MHS or a contractor provides the data set directly to the researcher. When receiving a data set through data extract, the researcher may indicate whether the data elements should be provided as is, encrypted or collapsed. In contrast to a data extract, access to an information system means that the researcher may directly access an MHS information system and create a data set for the research study

- [ ] Data Extract
- [x] Access

10.8 Do you intend to request de-identified data from the MHS in your research study?

There are different two methods for de-identifying data pursuant to HIPAA:
1) Safe Harbor Method: Removing all of the identifiers listed in Table 1 below, provided that the researcher does not have actual knowledge that the remaining data can be used alone or in combination with other information to identify the individual who is the subject of the information
2) Statistical Method: An expert, with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, determines that the data is not individually identifiable

- ○ Yes
- ◉ No

10.9 Indicate the MHS information system(s) from which you will seek to obtain data

If you do not know which system(s) contains the data elements you need, refer to the Guide for DoD Researchers on Using MHS Data or request guidance from an MHS data expert at: **DHA.PrivacyBoard@mail.mil**.

Below is a list of commonly used MHS systems. If the system from which you seek to obtain data is not listed below, list the name of the system in the "Other MHS Systems" category below
PHI Systems:

MHS Information System	Requesting Data
: MHS Genesis	: No

PII-Only Systems:

MHS Information System	Requesting Data
No records have been added	

De-Identified Data & Other Systems:

Information System	Requesting Data
No records have been added	

10.10 Do you intend to merge or otherwise associate the requested data with data from any sources outside of the MHS, including other DoD systems that are not part of the MHS?

- ○ Yes, will merge data
- ◉ No, will not merge data

10.11 Indicate the data elements about research participants or relatives, employers, or household members of the research participants that you will request from MHS hard copies or from MHS information systems.
If you will merge data, also indicate non-MHS data elements about research participants or relatives, employers, or household members of the research participants that you will have access to in any form or medium.

Direct and Indirect Identifiable Data Elements	DHA Hard Copies	DHA Data Elements to be Accessed	DHA Data Elements Verbal	Extracted DHA Digital Data	Downloaded DHA Digital Data	Non-DHA Hard Copies or Digital
1. Names	☐	☑	☑	☐	☐	☐
2. Postal address with only town, city, state, and zip code	☐	☐	☐	☐	☐	☐
3. Postal address with all geographic subdivisions smaller than state, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census: 1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 2) the initial three digits of a zip code from all such geographic units containing 20,000 or	☐	☐	☐	☐	☐	☐

fewer people is changed to 000						
4. Dates including all elements (except year) directly related to an individual, including birthdate, admission date, discharge date, and date of death	☐	☑	☑	☐	☐	☐
5. Ages over 89 and all elements of dates (including year) indicative of such age, unless you will only request a single category of "age 90 or older"	☐	☐	☐	☐	☐	☐
6. Telephone Numbers	☐	☑	☑	☐	☐	☐
7. Fax Numbers	☐	☐	☐	☐	☐	☐
8. Email Addresses	☐	☑	☑	☐	☐	☐
9. Social Security Numbers	☐	☐	☐	☐	☐	☐
10. Medical Record Numbers (MRN) (including record ID)	☐	☐	☐	☐	☐	☐
11. Health Plan Beneficiary Numbers (including						

DEERS ID, Electronic Data Interchange Personal Identifier (EDIPI) or Number (EDIPN))	☐	☑	☑	☐	☐	☐
12. Account Numbers	☐	☐	☐	☐	☐	☐
13. Certificate /License Numbers	☐	☐	☐	☐	☐	☐
14. Vehicle identifiers and serial numbers, including license plate numbers	☐	☐	☐	☐	☐	☐
15. Device identifiers and serial numbers	☐	☐	☐	☐	☐	☐
16. Web Universal Resource Locators (URLs)	☐	☐	☐	☐	☐	☐
17. Internet Protocol (IP) address numbers	☐	☐	☐	☐	☐	☐
18. Biometric identifiers, including finger and voice prints	☐	☐	☐	☐	☐	☐
19. Full-face photographic images and any comparable images	☐	☐	☐	☐	☐	☐
20. Any other unique identifying number,						

characteristic, or code (including non-military provider IDs)	☐	☐	☐	☐	☐	☐
21. Free Text Fields	☐	☐	☐	☐	☐	☐

If you are obtaining SSNs, provide a justification as to why and explain why a substitute cannot be used.

Due to guidelines stated within DoDI 1000.30, Reduction of SSN Use within DoD, the reduction or elimination of SSN usage must occur wherever possible. If SSNs are required to complete the project, the PI must provide a justification and explanation as to why a substitution cannot be used.
For example:

- If alternatives to SSN (e.g., EDIPNs or pseudo person IDs) are sufficient in other instances, will those alternatives to SSN usage be sufficient to respond to Congressional inquiries and /or Senior DoD stakeholders inquiries?
- Are alternatives to SSN used first?
- Are those alternatives to SSN insufficient to combine data from multiple data sources? Is the issue that some individuals do not possess alternatives ID numbers and SSN is the only way to identify them?

a. Will you receive or obtain health information?

> ***Note:*** *If you indicate you are not receiving health information, the answer must be consistent with the DHA data source. For a non-health information data request, if you are a non-MHS employee or non-MHS business associate, you may not access an information system that has PHI or LDS. For both MHS and Non-MHS employees and MHS business associates, you may* ***NOT*** *include data elements in the above table on: 1) lines 10 or 11, 2) line 21 if the free text field comes from a PHI or LDS system, and 3) lines 12, 13, or 18 if the account numbers, certificate and license numbers, biometric data, or any other data elements are health information created or received by an MHS health care provider, health plan, or business associate in relation to the physical or mental health or condition of an individual or payment for health care.*

◉ Yes, I will receive or obtain health information
○ No, I will not receive or obtain health information

b. If no data elements were checked in the above table, is it possible that the requested DHA data is or will be identifiable because of any unique data elements, triangulation, or small cell size?

☑ Data elements were checked in the above table, STOP HERE.

NOTE: *A unique data element includes any unique features that alone are not identifiable but that could be used to identify an individual within the context of other information, such as any type of code (such as diagnosis or procedural), rank of general or admiral, gender, or race. Triangulation means using different data elements that when combined can be used to identify an individual, such as including the above lists of unique data elements in a data set. Determining whether an individual is identifiable through triangulation requires consideration of all data elements in combination. Within the military, the use of rank and/or diagnosis code, procedural codes, or any other code that changes on a predictable basis, increases the possibility of identification. Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Department of Defense Manual 6025.13, Medical Quality Assurance and Clinical Quality Management in the Military Health System MHS, provides that the threshold for de-identifying data within the MHS requires a cell size of three, but also states that the de-identification standards must meet the DoD implementation of the HIPAA Privacy Rule.*

Centers for Medicare and Medicaid also gives guidance on small cell size stating that no data cell less than 11 may be published or displayed. However, the Office for Civil Rights' OCR, which is the official regulatory office for the HIPAA Privacy Rule, provides that OCR does not designate a universal value for small cell size in accordance with the de-identification standard; instead, the cell size should be set at a level that is appropriate to mitigate risk of identification by the anticipated recipient of the data set. This means that a cell size of 3 or 11 may not meet the HIPAA Privacy Rule requirements if the cell size level does not appropriately mitigate risk of identification by the anticipated recipient of the data set.

Note: If dates are altered as a means of de-identifying the data, diagnosis and procedural codes need to be rolled-up or collapsed. If dates are provided "as time between events," the roll-up is not necessary.

- [ ] Yes, the DHA data will become identifiable
- [ ] No, the DHA data will not become identifiable

10.12 Do you believe it is possible for the MHS data to become identifiable because of triangulation, a small cell size, or any unique data element(s)?

Triangulation means using different data elements that are not themselves identifiable but that when combined can be used to identify an individual. For example, triangulation would use rank and race together to determine the identity of an individual with a particular health condition.

Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Guidance for acceptable cell size is available from the Centers for Medicare and Medicaid Services. For example, the rank category of four star generals with a particular diagnosis may be less than 30, so the rank category may need to be expanded to include lower ranks.

A unique data element includes any unique features that are not explicitly enumerated in the categories of data in rows 1 – 20 of the table above (in Section 10.10), but that could be used to identify an individual. Unique data elements include characteristics that are not themselves identifying, such as the rank of general or admiral, or a race or gender, but within the context of other information could be identifiable.

- ○ Yes, I believe there is a reasonable possibility the MHS data will become identifiable
- ◉ No, I believe there is no reasonable possibility the MHS data will become identifiable

10.13 Have you completed and uploaded an appropriate HIPAA document (i.e. HIPAA Authorization will be obtained or Waiver/alteration of HIPAA Authorization is being requested)?

- ◉ Yes
- ○ No
- ○ N/A

If yes, please check which one.

- [x] HIPAA Authorization
- [x] HIPAA Waiver (Full or Partial)
- [ ] Other (please provide copies when uploading Other Study Documents)

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

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

Data Capture Methods:
The local study team will collect study data directly from the study participant (in person, over the phone, or directly into REDCap), for from the participant's medical record (i.e., relevant

medical and treatment history and relevant clinical notes).

REDCap is an encrypted, access controlled, password-protected electronic data capture and management system maintained by the Geneva Foundation. No PII will be entered into REDCap.

Participants may also enter study data directly into REDCap using a coded survey link or via a tablet provided by the research team. Motion capture data will be recorded directly on the Emovi KneeKG system. All information collected through the Emovi KneeKG system will be housed in the KneeKG system. All other research data collected on paper, if applicable, will be entered into REDCap by the research team. Other source documents include relevant Kinematic and Biomechanical Reports, personalized exercises, and clinical notes which will be printed, redacted, and stored in the participant's research file. Once verified, the paper documentation will be securely destroyed. All paper documentation will be kept in a locked, secure cabinet within a locked, secure office accessible only by the authorized site research team.

Data Storage & Access:
With the exception of the Informed Consent Document and HIPAA Authorization, and electronic master list, all research data (both paper and electronic) will be identified using a unique study ID only and not by the participant's identifiers such as name, date of birth, DoD ID, or other any protected identifier.
Paper research forms and source documents will be stored in a locked cabinet inside within a locked room, accessible only by local approved research staff designated and authorized by the site PI. The coded electronic research data for this study will be stored in REDCap and will only be accessible by local research staff designated and authorized by the PI.
Access to the electronic coded research data will be governed strictly on an individual basis within REDCap. Data access and privileges will be clearly delegated, audited, and monitored by the core PI. Appropriate data sharing agreements will be in place between the data owner(s) (e. g. DHA for AHLTA, Genesis) and the Geneva Foundation.

During data collection, all files containing coded research data will be encrypted, password-protected, and stored on a secure, HIPAA-compliant computer and file system. This ensures that participant confidentiality is protected throughout the study. Such secure file systems are often created on department-designated shared drives (intranet) for PII and PHI by the Information Management Division (IMD). The electronic master list will be stored separately from the coded electronic research data in a secure, password protected Excel spreadsheet on a computer and network requiring CAC access. Only approved, local, research staff will have access to the master list.

All research data and forms (paper and electronic) will only be accessible by authorized study staff, the local IRB, and applicable governmental agencies, in accordance with federal law. These duties include ensuring the protection of research participants. The electronic coded research data will be maintained indefinitely as described in protocol section 10.15.

After the study closes, de-identified data will continue to be stored in an encrypted, password-protected format on a secure, HIPAA-compliant system. At the end of the study, the master list and any other paper documentation kept throughout the study will be permanently destroyed. At this point, the data will be fully de-identified, and there will be no way to re-link the data back to individual participants. The de-identified dataset will be securely stored indefinitely for potential secondary analyses.

Data Transfer and Security:
At all sites, a site-specific master list will be kept that links the participant (name, DoD ID and coded subject identification number). That list will be kept secure and under the purview of the site-specific PI, stored on an encrypted computer and in an encrypted and password-protected file. If any de-identified study data needs to be transferred to the Core Site, the data will be transferred using a DoD-approved Safe File Exchange (SAFE) to the core site's PI to merge files from all sites. DoD-approved SAFE is considered as an encrypted, secure, and preferred for sensitive information exchanges. The master list will be destroyed after the study closes, and there will be no way to identify individuals in the cohort.

Any de-identified data sharing with organizations outside the DoD (MTEC, MOMRP) will occur after appropriate Data Sharing/Use Agreements are approved, ensuring that only coded, non-identifiable information is exchanged securely.

Managing Data Access:
The study team will access data within the designated MHS systems in a secure, de-identified format. The research team will view relevant information directly within the MHS platform to maintain confidentiality and comply with data protection protocols. No identifiers (PII/PHI) will be recorded, collected, or stored as part of this study, and all access will remain strictly within the system.

If follow-up is required for any data clarification, the research team may refer to the master list. Prior to analysis, only files containing coded identifiers will be used to ensure that no PHI is included in the final dataset. The research staff will strictly maintain the confidentiality of all participant information, adhering to established privacy and security protocols.

Nature of Identifying Data:
Timeframes will be requested in reference to the baseline enrollment date, not actual dates. For example, the date of appointment will be required initially to determine when the healthcare visit is associated with the Knee Kinesiography exam that occurred. However, this data will be coded differently in the working spreadsheet. Follow-up appointments will be recorded in days from the baseline examination (e.g. +35 or +135, etc.). The exact appointment date will not be included in the master list. Analysis of the data will only occur in the coded spreadsheet.

Is this a data repository?

○ Yes ◉ No

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

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

No human specimens will be collected, banked or stored in this study.

The electronic master list will be destroyed following the completion of the study; it will be stored separately from the coded electronic research data in a secure, password protected Excel spreadsheet on a computer and network that requires CAC access and will only be accessible by local research staff. The de-identified electronic dataset will be maintained indefinitely (or as long as it is practicable to maintain) for possible use in future research.

Long Term Data Storage & Access:
The coded electronic research data will be securely transmitted from local study teams to the Geneva Foundation via REDCap or the DoD SAFE application (or other comparable safe data sharing system implemented by the local site and/or the US Army/DHA). REDCap utilizes Secure Sockets Layer (SSL) in addition to other safeguards on its web server to maintain secure communication with end-users (see Appendix G). DoD SAFE uses a TLS (Transport Layer Security) protocol when files are uploaded and downloaded. Once received, the electronic coded research data will be stored within REDCap, an encrypted, access controlled, password protected electronic data capture and management system maintained by the Geneva Foundation. Access to the de-identified research data will be governed strictly on an individual-by-individual basis within the secure electronic data capture and management system. Individual data access as well as privileges will be clearly delegated, audited, and monitored by the core PI. Any future research using the deidentified data collected in this study will be approved by an Institutional Review Board (IRB). Access to the de-identified Emovi KneeKG research data will be governed strictly on an individual- by-individual basis by the core PI.

Consent for Future Use:
The Informed Consent Form for this research study will state that de-identified research data will be maintained indefinitely for possible use in future research. By consenting to participate in this research study, participants agree to allow us to maintain their deidentified research data indefinitely for possible use in future research.

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Is this a data repository?

◉ Yes ○ No

If Yes, provide the name of the Repository

The Geneva Foundation REDCap

Who will have access to the Repository?

Authorized study personnel

What data type will be stored in the Repository?

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

11.0 Statistical/Data Analysis Plan

11.1 Data Analysis Plan and Statistical Considerations:

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

The primary outcome is the between-group difference in PROMIS Physical Function T-score at 3 months. A linear mixed effects model will be used to analyze the between-group differences across the various time points (repeated measures). These models are robust for handling unbalanced data and can be flexible in accounting for missing data. This will be our primary plan for handling missing data, but plan to run sensitivity analysis using multiple imputation (Markov chain Monte Carlo with 20 iterations), assuming data is missing completely at random (Little's MCAR Test is not significant). We will report estimated marginal mean T-Scores (e.g. least squares mean) with 95% confidence intervals and set statistical significance at P value of <0.05. Age, sex and baseline PROMIS Physical Function scores will be added to the model as covariates.

Secondary outcomes that are continuous variables will be analyzed in the same manner. All other data collection tools besides PROMIS Physical Function scores are secondary outcomes. Non-parametric tests will be used to analyze dichotomous and categorical variables.

Descriptive statistics will be used to examine the distributions of demographic and clinical characteristics of the intervention and usual care control group before participant treatment has started (pre-treatment data). Means and standard deviations will be calculated for continuous variables that are normally distributed. The median and interquartile range will be calculated for those showing an asymmetric distribution. For categorical variables, we will use frequency tables and proportions. Statistically significant differences between groups will be identified and adjustments will be made in all subsequent analyzes to take into account the potentially confounding effects of these variables ("potential confounders"). Demographic and clinical pre-treatment data for participants who completed all follow-up measures and those who dropped out during the study will also be compared to assess the possible presence of an attrition bias.

11.2 Sample Size:

A power sample size calculation has been performed to observe a 20-point difference on the PROMIS questionnaire with an 80% statistical power (effect size 0.3, SD=10). A total of 149 patients will be needed, with an equal number of participants allocated to each intervention group (i.e., 75). Accounting for a 20% attrition, our goal is to recruit 180 participants for this study (both sites included).

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

180

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

This will be a two armed randomized clinical trial with 75 participants with knee pain in each arm.

11.5 Please provide a justification for your sample size

A sample size calculation has been performed to observe a 20-point difference on the PROMIS questionnaire with an 80% statistical power (effect size 0.3, SD=10). The statistical method for this power sample size calculation was a linear mixed effects model. **A total of 149 participants** will be needed, with an equal number of participants allocated to each intervention group (i.e., 75). Accounting for a 20% attrition, our goal is to recruit 180 participants for this study (both sites included).

12.0 Participant Information

12.1 Subject Population:

The subject population is active duty service members who have been diagnosed with patellofemoral pain syndrome (PFPS) at Womack Army Medical Center (WAMC) and Tripler Army Medical Center (TAMC).

12.2 Age Range:

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

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

18-50

12.3 Gender:

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

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen
- [x] Active Duty Military Personnel

- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons
- [ ] Educationally Disadvantaged Persons
- [ ] Physically Challenged (Physical challenges include visual and/or auditory impairment)
- [ ] Persons with Impaired Decisional Capacity
- [ ] Prisoners
- [ ] Pregnant Women, Fetuses, and Neonates
- [ ] Non-English Speakers
- [ ] International Research involving Foreign Nationals - Headquarters Review is necessary

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

12.5 Inclusion Criteria:

Order Number	Criteria
1	Age 18-50
2	Active Duty Service Member stationed at Fort Liberty and Schofield Barracks
3	Diagnosis of patellofemoral pain (ICD-10 codes: M25.2 (pain in unspecified knee), M25.561 (pain in right knee), and M25.562 (pain in left knee)

12.6 Exclusion Criteria:

Order Number	Criteria
1	Pregnancy
2	Known to be leaving that duty station within next 3 months
3	Concurrent lower limb injuries (examples include but are not limited to ankle sprain or HS strain)
4	Previous knee surgery
5	History of traumatic knee injury, such as ligament tear or meniscal tear
6	Presence of rheumatoid or neurological diseases

13.0 Recruitment and Consent

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

Participants will be screened by the research team from those seen in physical therapy and primary care clinics. A record review in Genesis will be completed searching for knee pain diagnoses in primary care and physical therapy documentation. We will also accept direct referrals from PTs.

13.2 Compensation for Participation:

No

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

Genesis screening knee referrals and visits to physical therapy clinics at Fort Liberty and Schofield Barracks. Participants will be contacted via a phone call and asked if they would like to come in and meet with the research team in order to read the consent form and decide if they would like to volunteer to participate in the study. This is when the Emovi Sample Interview Script will be used. If they choose not to participate, they will receive their normal standard of care physical therapy for their knee pain.

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

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

The research team will consent participants in a private area. Potential participants will be invited into the research office or conference room to meet the research team. We have a planned script (Emovi Sample Interview Script) that will be used for recruitment. The research team members will explain the study to the subject and offer them a chance to read the consent form. The research team will offer to answer any questions the participant has prior to signing the consent form. After consent, the baseline data collection will occur. During the consent process, it will be made clear to them that they can continue with their standard of care physical therapy treatment for their knee pain and choose not to participate in the study.

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

◉ N/A
○ Propose ombudsman

13.6 Withdrawal from Study Participation:

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

Participants may withdraw their consent at any time and stop participating in this research study without affecting their eligibility for care or any other benefits to which they are entitled. They have the right to withdraw from this study at any time. If they decide to stop taking part in this study, they will contact the principal investigator as soon as possible. If this happens, the research team will use the Emovi Master Log to identify the data that is associated with the participant. Then the team will remove the participant's data from the existing study data.

Participants can be withdrawn by the PI if they fail to adhere to the protocol and/or treatment plan.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

The main risk of this study is a potential loss of privacy. The physical risks associated with participating in this study are minimal. There is minimal risk of muscle soreness as participants complete the walking. However, soreness can be expected during standard rehabilitative care, and typically resolves within 2-3 days. There is a small risk that participants may fall during treadmill walking.

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

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

We will protect subjects' privacy by labeling exercise programs and information only with a unique study ID number, and by keeping the link to these ID numbers in a password-protected database on a secure military server which is only accessible by the principal investigator and designated research staff using CAC authentication.

The physical risks associated with participation in this study are minimal. To minimize the risk of stress fracture the participants' response to running will be assessed weekly for the first 4 weeks and bi-weekly thereafter through individual video follow-ups to minimize this harm.

There are multiple safeguards to help prevent the risk of falling off of the treadmill. On the treadmill, participants will wear a safety clip to trigger the emergency stop if needed. Additionally, the treadmill has safety guardrails that a participant can grab onto if they lose their balance.

Adverse events which are not serious are reported on the Annual Progress Report (APR) during the continuing review of the protocol. APR is due in a 12-month cycle, the anniversary month of the protocol's initial approval or due in less than 12-month cycle as determined by the IRB for continuing review and approval.

Serious Adverse Events: The PI, within two working days, will report all serious adverse events (SAE) occurring in participants. This is accomplished by submitting an adverse event report memorandum to the IRB. Additionally, the WAMC HPA will be notified immediately of any adverse events. Serious adverse events will be reported even if the PI believes that the adverse events are unrelated to the protocol.

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

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

Like many biomedical research protocols considered by IRBs, the protection of confidentiality among subjects is a significant concern. In order to protect the confidentiality of all subjects, all subjects will be assigned a unique participant identification number upon enrollment. Each number assigned will only be used once. All research-related data (both paper and electronic) will be labeled using this unique identification number and not by participant name, date of birth, DoD ID, or other similar identifier. Consent forms and data collection forms will be stored in separate locked filing cabinets in a locked room.

The master log document linking participant names and their participant numbers will be kept secure on a government computer assigned to the PI. The computer is password and CAC-card protected, and the system is firewall protected. This document will not be shown to anyone except for the investigators in this study or governmental agencies only in accordance with federal law. The de-identified spreadsheet data will be password and firewall protected.

All electronic data will be stored on password secured computers, behind locked doors. Data files for this study will be stored on a secure sever with DoD firewalls. Data from this study will be transmitted encrypted to only the associate investigators as needed.

Any data submitted to an approved agency for review will be linked only to the participant's study number and not the personal identity of the participant (i.e. protected health information such as name, address, phone number, etc.) If the data are used in scholarly presentations of journal articles, the investigators will protect the anonymity of individual patients and will report only aggregate data (e.g. group means) where appropriate. Participants will not be specifically identified in any publication or presentation of research results.

14.4 Potential Benefits:

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

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

Prospective case study participants have experienced positive results. If improvements are observed, these results will be shared with other rehabilitation professionals across the DoD to potentially benefit hundreds of thousands of active-duty service members with knee pain.

14.5 Privacy for Subjects:

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

Recruitment and consent conversations will take place in a private setting (e.g. closed clinic room, investigator's office, etc.) to minimize the potential opportunity to be overheard or inadvertently witnessed. Information being collected will be limited to only the minimum amount of data necessary to accomplish the proposed research. Additionally, all subjects will be assigned a unique participant identifier number upon enrollment in order to protect their privacy. All

research-related data (both paper and electronic) will be labeled using this unique participant identification number and not by participant name, date of birth, DoD ID, or similar identifier. Consent forms will be locked in a locked cabinet in a locked office.

All questionnaires and the Provider Satisfaction survey will be delivered electronically through REDCap. Electronic data will be stored in a password protected file on a CAC enabled secure drive protected intranet with CAC enabled computers.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

Based on the type of data being collected in this study, the researchers do not anticipate any incidental or unexpected findings. No biological specimens are being collected and no genetic testing is being completed. In cases where the subject could possibly benefit medically or otherwise gain from the study, results will be shared with the subject. The researcher will contact the subject and arrange for follow-up care. Unexpected findings or adverse events will be reported by the PI within 10 (ten) working days to the Institutional Official through the Human Protection Administrator (HPA) and to the IRB through the HPA and directly through EIRB.

15.0 Study Monitoring

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

- ○ DSMP
- ○ DSMB
- ○ Both
- ◉ Not Applicable

16.0 Reportable Events

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

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

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

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or

consent form are needed and the scale that will be used to grade the severity of the adverse event

The principal investigator is the individual who is primarily responsible for the actual execution of the clinical investigation. He is responsible for the conduct of the study, obtaining participants' consent, providing necessary reports, and maintaining study documents. The Associate Investigators will assist the Principal Investigator in these responsibilities.

The PI will be familiar with all applicable regulations governing research and will adhere to all of the requirements outlined in the DOD Assurance and Federal-Wide Assurance granted by the Office for Human Research Protections, Department of Health and Human Services.

The PI will be familiar with all applicable regulations set forth by the NMCP IRB.

As soon and possible, but no longer than three calendar days, events are to be reported to the site specific HRPP and NMCP IRB. The PI or designee will report to the site specific HRPP and NMCP IRB by email, phone or face-to-face; the HPD will communicate this to the IO and the AIO. The PI will upload the report and notice into IRB for the site specific HRPP and NMCP IRB; the HPD will facilitate that information through EIRB.

Minor Deviations will be reported to the site specific HRPP and NMCP IRB at the time of continuing review or project closure.

Major Deviations will be promptly reported to the site specific HRPP and NMCP IRB no later than 5 days.

Serious Adverse Events: The PI, within three working days, must report all serious adverse events (SAE) occuring in participants enrolled at WAMC or TAMC. This is accomplished by submitting an adverse event report memorandum to the site specific HRPP and the NMCP IRB.

Adverse events that are expected and therefore are not UPIRTSOs (to include IND safety reports) will be tracked on a log and monitored by the PI. These adverse events will be reported to the stie specific HRPP and the NMCP IRB at the annual Continuing Review.

All UPIRTSOs, UADEs, and SAEs that are unexpected and determined to be at least possibly related or definitely related to research participation will be promptly reported by telephone 757.953.5939 or via email to the group email box: **usn.hampton-roads.navhospporsva.list.nmcp-usarmy.liberty.medcom-wamc.mbx.hrpp@health.mil** A complete report will follow the initial notification withing five (5) business days.

17.0 Equipment/non-FDA Regulated Devices

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

○ Yes ◉ No

18.0 FDA-Regulated Products

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

- ☐ Drugs
- ☐ Dietary Supplements
- ☐ Biologics
- ☑ Devices
- ☐ N/A

18.3 Device Details:

☑ Are device(s) in this research being used in accordance to the approved labeling?
☐ Are device(s) in this research being used in a manner other than its approved labeling?

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

View Details	Device Name
⊟	Emovi Knee KG

Manufacturer/Supplier of Device	Emovi
Where will the Devices Be Stored	In physical therapy sections locked up
Will Devices be supplied at no Cost	No
Is this a HUD (HDE)	No
HDE Number	
Who holds the IDE	N/A
IDE details	

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

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

Research team must report to the manufacturer each adverse experience,as soon as possible but no later than 15 calendar days from initial receipt of the information by the Research team.

18.5 Sponsor (organization/institution/company):

☑ N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

○ Registration is not required
○ Registration pending
◉ Registration complete

"NCT" number:

NCT06517056

19.2 Defense Technical Information Center Registration (Optional):

◉ Registration is not required
○ Registration pending
○ Registration complete

20.0 References and Glossary

20.1 References:

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20.2 Abbreviations and Acronyms:

ADSM: Active Duty Service Member
AKPS: Anterior Knee Pain Scale
GROC: Global Rating of Change
HCPs: Health Care Providers
MCAR: Missing Completely at Random
MTFs: Military Treatment Facilities
KneeKG: Knee Kinesiography
PF: Patellofemoral
PFP: Patellofemoral Pain
PFPS: Patellofemoral Pain Syndrome
PROMIS: Patient Reported Outcomes Measurement Information System
RTD: Return to Duty
UPIRTSO: unanticipated problems involving risk to subjects or others