Official Study Title: Examining the Most Effective Method to Reduce Ground Contact Time

NCT Number: NCT06988709

Protocol Number: 24KACH008

Document Date: 5 May 2026

EIRB Protocol Template (Version 1.13)

1.0 General Information

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

Examining the Most Effective Method to Reduce Ground Contact Time

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

24KACH008
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

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

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add sites

2.1 List sites associated with this study:

Is Primary?	Site Name
◆	**P and R** - Keller Army Community Hospital (KACH)

3.0 ▪ Assign project personnel access to the project

3.1 * Please add a Principal Investigator for the study:

Name	Role	Training Record
Stoute, Shawn M, DPT, DSc MAJ	**Principal Investigator**	**View Training Record**

Responsibility

- ☐ Student
- ☐ Resident
- ☑ Site Chair
- ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Name	Role	Training Record
Bulen, Jennah R	**Associate Investigator**	View Training Record
Florkiewicz, Erin Marie, PhD, LAT, ATC	**Associate Investigator**	View Training Record
Freisinger, Gregory Martin, PhD MAJ	**Associate Investigator**	View Training Record
Morris, Jamie Bush, DPT, DSc LTC	**Associate Investigator**	View Training Record

B) Research Support Staff

Name	Role	Training Record
No Research Support Staff have been added		

3.3 *Please add a Protocol Contact:

Name	Role	Training Record
Bulen, Jennah R	**Study Contact**	View Training Record
Stoute, Shawn M, DPT, DSc MAJ	**Study Contact**	View Training Record

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):

Name	Role	Training Record
No Designated Department Approval have been added		

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 * Is this protocol in support of a Graduate Health Science or other Allied Health Education Program?

(•) Yes ( ) No

If yes, check all that apply.

- [ ] Graduate Medical Education (GME)
- [ ] Graduate Dental Education (GDE)
- [ ] Graduate Nurse Education (GNE)
- [x] Graduate Allied Health Science
- [x] Fellowship
- [ ] Other Allied Health Education Program

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

	Physical Therapy

4.3 * 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

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

◉ Yes ○ No

4.5 * What type of protocol is this?

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

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

◉ Yes ○ No

4.8 * 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

4.9 * 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

Principal Investigator

Jennah R Bulen

07/31/2028

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

No results found

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:
Miller, Erin M. Role on Protocol: Associate Investigator	845-938-3067	erin.m.miller45.ctr@health.mil	The Geneva Foundation / KACH

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
No results found		

Total amount of funding:

0

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
DHA	Keller Army Community Hospital	Lead site	FWA00029527	08/19/2029	: IAIR	: NMCP IRB
Army	United States Military Academy	Data analysis	A21405	01/29/2029	: IAIR	: 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 results found					

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

9.0 Study Details

9.1 Key Words:

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

Ground contact time, running retraining, spatiotemporal parameters, running injuries

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

The incidence of running-related injury is high, with reported lower extremity running-related injuries ranging from 19.4% to 79.3% (van Gent et al., 2007). This poses a significant threat to those in career fields that require high levels of physical fitness, such as the military, police, firefighters, and other physically demanding jobs. Running is the primary mode of endurance physical fitness training in the military and is a leading contributor to musculoskeletal injuries (Molloy et al., 2020; Roy et al., 2022). Running-related injuries (RRIs) in the military are cited as the most frequent cause of injury, accounting for approximately 45% of all exercise induced injuries (Hauret et al., 2015). Therefore, risk factors, prevention, and treatment strategies associated with RRIs should be investigated to improve military readiness and decrease RRIs throughout the running community.

RRIs are multifactorial (Meeuwisse, 1994; Weart et al., 2023), consisting of nonmodifiable and modifiable risk factors. These risk factors can be specific to population and to specific injury site (Anderson et al., 2022; Brindle et al., 2020; Ceyssens et al., 2019; Doyle et al., 2022). Nonmodifiable risk factors for RRIs have been reported to include previous injury (Van Der Worp et al., 2015), age (van Gent et al., 2007), and sex (Messier et al., 2018; Van Der Worp et al., 2015). In contrast, modifiable risk factors such as training (Van Der Worp et al., 2015) and running biomechanics (Ceyssens et al., 2019) can be manipulated and may affect RRI risk. Changing running biomechanics, such as increasing step rate or adopting a non-rearfoot strike pattern, have been utilized to reduce injury risk and assist in the treatment of injured runners (Miller et al., 2021; Morris et al., 2020; Roper et al., 2016). Therefore, understanding how changing specific running biomechanics and their influence on injury risk is critical.

There are limited prospective studies on the influence of spatiotemporal variables on RRI development (Brindle et al., 2020). In a meta-analysis by Brindle et al., no differences were noted for pooled averages of spatiotemporal variables, including step rate, step length, and contact time between runners with or without a history of a RRI (Brindle et al., 2020). However, these studies were mainly retrospective. Prospective biomechanical studies on RRIs are limited, and findings are often population and/or injury specific (Brindle et al., 2020; Ceyssens et al., 2019). In prospective studies looking at high school cross-country runners low step rate was identified as a risk factor for shin injury and in collegiate cross-country runners as a risk factor for bone stress injury (Kliethermes et al., 2021; Luedke et al., 2016). Understanding the relationship between specific running biomechanics, specific populations, and RRI development is crucial in the success of future injury prevention and treatment strategies.

Reducing forces associated with ground contact time is believed to be important to prevent injury. Heiderscheit et al, reported that with as little as a 5% increase in step rate there was a 20% decrease in load to the hip and knee (Heiderscheit et al., 2011). Step rate has proven to be modifiable in runners through verbal cues or an audible metronome (Adams et al., 2018; Allen et al., 2016). Although, step rate alone has not been directly linked to decreasing running-related injuries in an Active Duty Military population (Szymanek et al., 2020). However, a recent study by Weart et al., observing Active Duty Soldiers over 12 months, found that runners with the longest ground contact time, greater than 315 ms, had a 2.25 times greater risk of a running-related injury (Weart et al., 2023).

Ground contact time has been found to be associated with running-related injuries (DeJong Lemke et al., 2021; Koldenhoven et al., 2020; Weart et al., 2023). A study by Miller et al. observed that transitioning runners to a non-rear foot strike led to decreased ground contact time, increased step rate, and clinically meaningful improvements in self-reported function (Miller et

al., 2021). Studies by Dejong Lempke et al. found runners with exercise-related lower leg pain had longer ground contact time and in reducing contact time this decreased loading impulse and improved patient outcomes (DeJong Lempke et al., 2021, 2022, 2024).

This evidence highlights that ground contact time is an important variable that warrants further study. However, to examine the effect of decreasing ground contact time on running injuries we must first investigate the most effective way to change it. Running retraining techniques have util ized real-time feedback methods of metronomes, verbal cues, or visual cues to retrain running techniques (Shen et al., 2024). Although, no one specific method has proven to be superior (Agre sta & Brown, 2015). These feedback techniques have focused mainly on ground reaction forces or step rate, with few, if any focusing on decreasing ground contact time, and none have looked at the best way to retrain ground contact time (Brindle et al., 2020).

Therefore, the purpose of our study is to establish the most effective running retraining technique to decrease ground contact time. This will be investigated by applying three running retraining conditions and assessing the change in ground contact time and other biomechanical variables between the runner's baseline running and each retraining technique. As well as questions from the participants on their perceived exertion and difficulty applying the techniques. We hypothesize that each cue will reduce ground contact time, but continuous visual cues will result in the most consistent and easily performed technique. This study will provide clinicians with a running retraining intervention that has been objectively shown to decrease ground contact time and provide researchers with a method to further investigate its effect on running injuries.

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 our study is to establish the most effective running retraining technique to decrease ground contact time utilizing three common running retraining methods in healthy runners.

The first aim will be to apply three running retraining conditions and assess the change in ground contact time and other spatiotemporal and biomechanical variables between the runner's baseline running and each retraining condition.

The three running conditions will be at the participant's self-selected speed corresponding to "run at a comfortable pace that you would choose for a 30 minute run". After the baseline run the participant will be asked their Rate of Perceived Exertion (RPE) on the Omni Pate of Perceived Exertion Scale. The conditions will be, condition 1: a verbal cue to "pull your foot off the ground as quickly as you can, pull, pull, pull," condition 2: a metronome set to 10% above their preferred cadence found during the baseline run, and condition 3: visual feedback to reduce their ground contact time through observing that number in real time provided by a commercial IMU. The participant will attempt to lower that to 5% below their baseline run ground contact time by being given that target number on a sheet of paper.

The second aim will be to examine the effect of the 3 running conditions on the runner's level of exertion and difficulty using the Omni Rate of Perceived Exertional Scale, the Rate of Perceived Difficulty, and ranking the techniques from 1 to 3 on which they felt was most natural feeling.

The third aim will be to examine the correlation between the IMU, the instrumented treadmill, and the Theia markerless camera system.

We hypothesize that each method will reduce ground contact time, but condition 3 providing continuous visual feedback will result in the most consistent decrease to ground contact time across the runners and will be perceived as the easiest to perform.

Overall, this study will provide clinicians with a running retraining intervention that has been objectively shown to decrease ground contact time and provide researchers with a method to further investigate its effect on running injuries.

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

Within-subjects repeated measures experimental design completed in a single session.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

The findings will be generalizable to military Service Members, age 18 to 60 years (and emancipated 17-year-olds) who are healthy runners.

9.6 Benefit to the DoD:

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

Running is the primary mode of endurance physical fitness training in the military and is a leading contributor to musculoskeletal injuries (Molloy et al., 2020; Roy et al., 2022). Running-related injuries (RRIs) in the military are cited as the most frequent cause of injury, accounting for approximately 45% of all exercise induced injuries (Hauret et al., 2015). Therefore, risk factors, prevention, and treatment strategies associated with RRIs should be investigated to improve military readiness and decrease RRIs.

RRIs are multifactorial (Meeuwisse, 1994; Weart et al., 2023), consisting of nonmodifiable and modifiable risk factors. Modifiable risk factors such as running biomechanics (Ceyssens et al., 2019) can be manipulated and may affect RRI risk. Changing running biomechanics, such as increasing step rate or adopting a non-rearfoot strike pattern, have been utilized in the military population to reduce injury risk and assist in the treatment of injured runners (Miller et al., 2021; Morris et al., 2020). Therefore, understanding how changing specific running biomechanics and their influence on injury risk is critical.

Understanding the relationship between specific running biomechanics, specific populations, and RRI development is crucial in the success of future injury prevention and treatment strategies. Reducing forces associated with ground contact time is believed to be important to prevent injury. Heiderscheit et al, reported that with as little as a 5% increase in step rate there was a 20% decrease in load to the hip and knee (Heiderscheit et al., 2011). Step rate has proven to be modifiable in runners through verbal cues or an audible metronome (Adams et al., 2018; Allen et al., 2016). Although, step rate alone has not been directly linked to decreasing running-related injuries in an Active Duty Military population (Szymanek et al., 2020). However, a recent study by Weart et al., observing Active Duty Soldiers over 12 months, found that runners with the longest ground contact time, greater than .315 ms, had a 2.25 times greater risk of a running related injury (Weart et al., 2023).

The purpose of our study is to establish the most effective running retraining technique to decrease ground contact time. These techniques are easy, convenient, cost-effective methods to investigate this variable. The experiment will be comparing the runner's baseline to three running retraining conditions and assessing the change in ground contact time and other biomechanical variables. As well as questionnaires from the participants on their perceived exertion and difficulty applying the techniques. This study will provide MHS Clinicians with a running retraining intervention that has been objectively shown to decrease ground contact time and provide researchers with a method to further investigate its effect on running injuries. Understanding how to manipulate a running variable that has shown to increase Active Duty Service Members risk of running injury will be a valuable tool.

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

Recruitment and Consent Procedures:
Participants will be recruited from a convenience sample of healthy runners that are active-duty military members or cadets. Individuals will be recruited from the Arvin Cadet Physical Development Center and Keller Army Community Hospital using the attached flyer that includes inclusion and exclusion criteria. The recruitment flyer will be posted in both the Arvin Cadet Physical Development Center and at Keller Army Community Hospital as well as electronically on Keller and USMA social media platforms to include both Facebook and Instagram and Keller's intranet page. PAO approval will be obtained where required. Participants will contact the study using the information on the flyer by phone or email, and the study point of contact will respond to the potential participant using the same method of communication that the participant utilized to initiate contact. The study point of contact will respond to the potential participant with the script attached by phone or email. Potential study recruits during that initial contact will be screened by the Principal Investigator (PI) or Associate Investigator (AI) and will briefly go over the study. Individuals who wish to participate in the study will complete a pre-screen checklist and then potential participants will be informed of what procedures the study will entail, including the participant's rights through the study and their ability to withdraw from the study at any time. Participants who agree to participate in the study will be asked to sign an informed consent form. Only the informed consent will have the subject's name all other data will be recorded and stored by the subject identification number.

Data Collection Visit: Participants will be scheduled for one data collection visit of 45 minutes duration at the West Point Advanced Return to Run and Orthopedics Research (WARRIOR) Lab located in Arvin Cadet Physical Development Center. The study visit will occur on any weekday from 0630-1800 to best match the participant's schedule. Participants will be asked to wear physical training attire in addition to their normal running shoes. The participant will complete the pre-screening checklist for participation, read the informed consent document, ask any questions they may have, and then sign the informed consent. The participant will complete the a ttached participant intake form. The participant will be shown and read the instructions on using the Omni Rate of Perceived Exertion Scale and Rate of Perceived Difficulty Scale to answer questions about the running conditions. Participants will have their height and weight measured on a weight scale with an attached height scale. Participant's leg length will be measured from the ground to their greater trochanter while standing and wearing shoes using a telescopic measuring rod. Participants will have a commercial inertial measurement unit (IMU) used to monitor running measurements attached to their shoelaces.

The participant will be randomized by their subject ID to a pre-randomized order for the three running conditions. These running conditions are verbal instructions of "pull your foot off the ground as quickly as you can, pull, pull, pull", "match your step rate to the metronome", and "make this number lower than the number on this paper". Next the participant will be asked to "run at a comfortable pace that you would choose for a 30 minute run". Participants will perform a 4-minute warm up on the instrumented treadmill and their speed will be recorded for use in all other running conditions and 10 seconds of baseline running data will be collected. After the warm-up the participant will be shown the OMNI Rate of Perceived Exertion (RPE) Scale and asked what their RPE was during the baseline run. During that time the preferred step rate and ground contact time will be calculated for each runner from their baseline run using the instrumented treadmill and confirmed with the IMU. The preferred step rate will be used to calculate 10% above their preferred step rate to set the metronome for the condition, "match your step rate to the metronome". The participant's preferred ground contact time will be used to calculate 5% below their preferred ground contact time to set the IMU application for the condition, "make this number lower than the number on this paper".

The participant will then walk for 2 minutes and then gradually be returned to their pre-selected speed. The runner will then be given one of the three running conditions depending on their randomization order. The runner will be given 1 minute 50 seconds to practice this cue then 10 seconds of data will be collected. Between each running task the runner will walk for 2 minutes and answer two questions on the running cue, the amount of exertion they felt was required using the Omni Rate of Perceived Exertion and the amount of difficulty they felt performing the running condition using the Rate of Perceived Difficulty Scale. The participant will then be gradually returned to their pre-selected running speed, given the second running cue, practice for 1 minute 50 seconds then 10 seconds of data will be collected. The participant will walk for two minutes and answer the questions on perceived exertion and difficulty. The participant will then be gradually returned to their pre-selected running speed, given the third running cue, practice for 1 minute 50 seconds then 10 seconds of data will be collected. The participant will walk for two minutes and answer the questions on perceived exertion and difficulty. After the

completion of the three running conditions the participants will be given the opportunity to cool down walking for 2 minutes and asked to rank the conditions from most natural feeling (1) to least natural feeling (3).

Summary:

- Warm-up (4 minutes) "run at a comfortable pace that you would choose for a 30 minute run". 10 seconds of baseline data collected during this time.
- Break (2 minute walk)
- Gradual Return to self-selected speed
- First Running Condition (1 minute 50 second practice)
- First Running Condition (10 second data collection)
- Break (2 minute walk)
- Gradual Return to self-selected speed
- Second Running Condition (1 minute 50 second practice)
- Second Running Condition (10 second data collection)
- Break (2 minute walk)
- Gradual Return to self-selected speed
- Third Running Condition (1 minute 50 second practice)
- Third Running Condition (10 second data collection)
- Cool-down (2 minute walk)

After data collection the participant will be able to receive a running analysis by viewing the runni ng biomechanical variables collected by the IMU including ground contact time, step rate, and step length. Once that is complete the participant will then be thanked for their time and participation.

Primary outcome measures will be assessed in the following order from the baseline running and three running conditions: Ground contact time, spatiotemporal measures, ground reaction forces, and other running biomechanics and Omni Rate of Perceived Exertion Scale and Rate of Perceived Difficulty Scale.

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.

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

Demographic Information
Once participants have gone through the informed consent process, they will be asked to provide demographic information (age, biologic sex, military affiliation, height, weight, running experience, previous running retraining experience, and running shoe information). Contact information (email and/or phone number) will be used to schedule the data collection visit if time does not allow data collection to happen following the informed consent, otherwise no contact information will be collected. PII will be kept separate from data measures on a password locked spreadsheet on a CAC locked computer. Any physical copies of PII will be kept in a separate, locked cabinet from outcome measure files.

Primary Outcome Measures
Participants will have their height and weight measured using a weighing scale with attached height scale. Participant's leg length will be measured from the ground to greater trochanter while standing and wearing shoes using a telescopic measuring rod. Running biomechanics will be collected at a self-selected speed using an instrumented treadmill (AMTI, Watertown, MA) and three-dimensional (3D) motion analysis. Prior to getting on the treadmill participants will have their weight and height measured using a weighing scale with attached height scale. Participant's leg length will be measured from the ground to greater trochanter while standing and wearing shoes using a telescopic measuring rod. Primary measures will include spatiotemporal variables (ground contact time, step rate, step length, vertical oscillation), kinetic variables (peak vertical ground reaction force, braking impulse, and average vertical loading rate). Biomechanical variables and lower-extremity hip and knee kinematics will be computed using motion capture software and the instrumented treadmill (AMTI, Watertown, MA) which will record ground reaction forces at 1200 Hz. Lower extremity hip and knee kinematics to include peak hip adduction angle, peak knee flexion angle, and heel to center of mass distance at initial contact

will be extracted for statistical analysis. Participants will be asked to perform 4 intervals of running at a self-selected pace while the AMTI system, motion capture system, and IMU application system record data simultaneously.

The participants will be asked to rate their perceived exertion and rate of difficulty at each running interval using the Omni Rate of Perceived Exertional Scale and the Rate of Perceived Difficulty Scale. After the running intervals are complete the participant will be asked to rank the running conditions on a scale from 1 to 3, with 1 being the most natural feeling and 3 being the least natural feeling.

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
- [ ] 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
No results found	

PII-Only Systems:

MHS Information System	Requesting Data
No results found	

De-Identified Data & Other Systems:

Information System	Requesting Data
List other system here: Verbal health information obtained from the participant.	

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, sex, 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 sex, 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

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.)

All data collected as part of this study will be handled in a manner compliant with the intent and letter of the regulatory processes. This includes ensuring data security, confidentiality of participant information, use of de-identified data to the maximum extent possible and IRB approval for all activities. All necessary agreements to include cooperative research and development agreements, data sharing agreements, memorandum of understanding or other such documents will be generated and approved, as required, prior to any data sharing.

All paper copies of study files will be stored in a locked cabinet, in a locked room only accessible by investigators on this study. Consent forms that identify the participant by name will be stored in a locked cabinet separately from the remainder of the outcome forms. All research materials will be coded with unique participant identifiers to protect subject identity, and participants will be instructed not to identify themselves by name on any outcome form. No personally identifiable information such as name, date of birth, DoD ID, or other protected identifier will be listed on these documents. Data collected electronically on computers will be collected using the participant ID and will not include any identifiable or patient information. Data collected

electronically therefore would be untraceable to the participant's identity to anyone who does not have access to the master subject list. The data file linking the names and participant ID will be accessible only to the Principal Investigator, and data from each individual will be entered into a computer file by this ID number. A master spreadsheet document linking subject names and their identification numbers will be kept secure on a government computer assigned to the PI. The computer is password and Common Access Card (CAC)-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. After completion of data collection, the coded study data will be entered into an Excel spreadsheet for analysis using the statistical program SPSS 24. The coded spreadsheet data will be password- and firewall protected. Each participant will be assigned a number upon entrance into the study and subsequently given data collection forms with the corresponding number. Each number assigned will only be used once. With the exception of the Informed Consent Document and electronic Master List, all research data (both paper and electronic) will be identified using a unique subject identification number only, and not by the participant's name, date of birth, DoD ID, or other protected identifier.

There are no planned linkages with external databases, nor is transmission of the data for collaborative use anticipated while the study is open. The future use de-identified repository plans after the study is closed are described in Section 10.15. The West Point Sports Medicine Physical Therapy Program may add additional de-identified data to the repository over time with additional planned research. Any data submitted to an approved agency for review will be linked only to the subject identification number and not the personal identity of the participant (i.e., personally identifiable information, such as name, social security number, address, phone number, etc.). If the data are used in scholarly presentations or 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.

Paper research forms and consent documents will be maintained for a period of three years following study closure and then securely shredded. The master list connecting unique study ID to participant identifiers will be destroyed upon study closure. De-identified research data will be maintained indefinitely.

Is this a data repository?

(•) Yes ( ) No

If Yes, provide name of the Repository.

Running Ground Contact Time Repository

Who will have access to the Repository?

The study investigators

What data type will be stored in the Repository?

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

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. Paper research forms and consent documents will be maintained for a period of three years following study closure and then securely shredded. All research data (both paper and electronic) will be coded using a

unique subject identification number only, and not by the participant's name, date of birth, DoD ID, or other protected identifier.

The master list connecting unique study ID to participant identifiers will be destroyed upon study closure. De-identified research data will be maintained indefinitely or as long it is practical to maintain. Once information is de-identified, it cannot be traced back to the participant in any way. The research team may use the participant's de-identified research collected as part of this research for future research studies. At the bottom of the consent form the participant may choose to allow (or not allow) the storage and future use of their de-identifiable research data. Whatever option they choose will not affect their participation in this research study. If the researchers want to use the information or give the information to another investigator for future research, a review board will decide whether this is allowed. This future research may be in the same area as the original study, or it may be for a different kind of study or distributed to another investigator for future research studies.

The specifics of these research studies are unknown at this time, but these studies may be in the area of device testing, running retraining, running biomechanics, surface EMG, and /or outcomes after running related injury or rehabilitation. The West Point Sports Medicine Physical Therapy Program may add additional de-identified data to the repository over time with additional planned research. Any information utilized will be done in a way to protect the participant's privacy and confidentiality.

Is this a data repository?

(•) Yes ( ) No

If Yes, provide the name of the Repository

Running Ground Contact Time Repository

Who will have access to the Repository?

PI will grant access contingent upon IRB/EDO approval for the proposed project.

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., sex or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis.

All data will be input into Microsoft Excel spreadsheets and data analysis will be conducted using SPSS. Descriptive statistics will be performed to describe the sociodemographic characteristics (age, height, weight, etc.). Means and standard deviations will be computed for continuous data and frequency distributions will be analyzed for categorical data. Parametric statistics will be used for continuous data and non-parametric comparisons will be used for ordinal or interval data.

The statistical methods for all continuous variables will be compared across all running conditions using a one way repeated measure analysis of variance (ANOVA) and linear mixed effects model to assess the running biomechanics change, specifically ground contact time, for each participant from their baseline running to each of the running conditions. Significant main effects will be further analyzed using post-analysis tests (Heiderschidt et al., 2011).

To analyze the amount of effort and difficulty each runner perceived across all running conditions a second one way repeated ANOVA will be assessed unless the data is not normally distributed and then a Mann-Whitney U test will be used.

10-second running trials will be collected during the baseline condition and three running conditions. Data from 15 to 20 strides per limb from each of the 10-second running trials will be used to determine GRF and temporospatial data for analyses (Miller et al., 2021). Force data will be low-pass filtered a Butterworth filter using custom code (National Instruments, Austin, TX, USA) (Miller et al., 2021). The filtered data will then be processed using custom code to extract AVLR, step rate, step length, ground contact time, and peak vertical GRF for both the left and right lower extremity (Miller et al., 2021).

To analyze correlation between the IMU, instrumented treadmill, and Theia markerless camera system an Intraclass Correlation Coefficient will be performed for the biomechanical variables we are assessing.

Missing data or missing measurements will be completely excluded from the analysis for that subject. Outliers will be identified via box plot analysis (Huber et al., 2024).

11.2 Sample Size:

36 healthy runners

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

36

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

N/A

11.5 Please provide a justification for your sample size

Studies of interventions targeting running injuries and running retraining have shown small to medium effect sizes (Heiderscheidt et al., 2011 and Adams et al., 2018). Therefore, we will need 36 participants to have 80% power for our two aims that will utilize a one-way ANOVA to be able to detect a small to medium effect size on ground contact time from the baseline running condition to the 3 running tasks at participant's self-selected speed, accounting for up to a 20% error rate.

12.0 Participant Information

12.1 Subject Population:

The target population will be military Service Members aged 17 to 60 years old that are healthy runners.

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.

- [x] 0-17
- [x] 18-24

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

17-60

12.3 Sex:

- [x] Male
- [x] Female
- [ ] Unknown

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [x] 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, paragraphs 7.e. and 12.

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

12.5 Inclusion Criteria:

Order Number	Criteria
1	Military Service Member or USMA cadet between the ages of 17-60
2	Run at least 2 miles three times per week for the past 3 months
3	Able to run for at least 15 continuous minutes at a self-selected speed
4	Fluent in the English language to read and provide informed consent and follow study instructions

12.6 Exclusion Criteria:

Order Number	Criteria
1	Lower extremity or low back pain in the previous 3 months
2	Lower extremity or low back surgery in the previous 6 months
4	Self-reported pregnancy or given birth within the last 6 months.
5	Currently on a profile that restricts or limits running

13.0 Recruitment and Consent

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

All healthy runners that are cadets and active-duty military Service Members will be potential participants. It will be a convenience sample from participants that see the recruitment flyer located at Keller Army Community Hospital or at Arvin Physical Therapy Clinic and reach out to the research study for more information. Once a potential participant reaches out, the PI or AIs will screen the participant and provide a brief summary of the study from the attached script. If the participant meets the inclusion criteria and wants to be part of the study. The PI, AIs, and/or civilian study coordinators will explain the study in more detail to the potential participant and be available for questions. The potential participant will then be setup with an appointment slot to go over the pre-screen checklist and undergo the informed consent process, including the participant's rights through the study, and their ability to withdraw from the study at any time.

13.2 Compensation for Participation:

Participants will not receive compensation

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

The pre-screening process will begin when an Active Duty Servicemember or Cadet reaches out to the research team by phone or email from the information on the recruitment flyer. The PI or AI will then respond through the same communication method using the attached script giving a brief summary of the study and screening the potential participant. If the participant meets the inclusion criteria and decides to participate, they will then be setup with an appointment slot to come in and meet with the PI or AI to go over the prescreen checklist with the inclusion and exclusion criteria and undergo the informed consent process. The PI or AI will answer any questions the potential participant may have and make sure the participant understands their rights through the study, and their ability to withdraw from the study at any time.

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:

All volunteers will read and sign an informed consent form approved by the Institutional Review Board (IRB) prior to participation. Participants will be consented by the PI or other study staff designated by the PI on an individual basis in the Physical Therapy clinic. Participants will be consented by personnel in civilian clothes with no military rank. The PI (or other authorized study staff) will provide copies of the IRB approved consent form to each participant and provide a verbal outline of the study as described in the consent form. Participants will then be encouraged to read the consent form and will be allowed up to 24 hours if requested before signing to appropriately weigh the risks and benefits to them. Throughout the consent process, participants will be instructed that participation is voluntary and that their decision to participate or withdraw will have no bearing on their career, educational status, or overall medical care. The consent form will be written in layman's terms at an eighth-grade reading level. Participants will be given up to 24 hours if requested to read the consent form and ask questions prior to all screening and treatment. If participants do not wish to take the whole 24 hours, they may consent immediately. In this case, the PI will allow the participant to ask any questions they may have prior to participant signature.

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

Throughout the consent process, participants will be instructed that participation is voluntary and that their decision to participate or withdraw will have no bearing on their career, educational status, or overall medical care. At any time, subjects can withdraw from this study without detriment to the healthcare that they are otherwise entitled to, and it will not affect their military position. If a participant withdraws from the study, we may retain and analyze all coded and/or deidentified data collected up to the time of withdrawal if the data is necessary to maintain the integrity of the study. However, no further data will be collected after the date of withdrawal.

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 participation in this study are minimal. There is a slight risk of muscular soreness during the running conditions. Additionally, there is a risk of falling during treadmill running.

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 samples 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. There are multiple safeguards to help prevent the risk of falling off of the treadmills to include two emergency stop buttons (one in front of the runner and one in front of the treadmill operator). Additionally, the treadmill has safety guardrails that a participant can grab onto if they lose their balance. The participant will be encouraged to warm-up and stretch prior to the running conditions to decrease the risk of muscular soreness. Any adverse events which are not serious will be reported on the Annual Progress Report (APR) during the continuing review of 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 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. A master spreadsheet 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 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 coded 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 server 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., personally identifiable information such as name, address, phone number, etc.).

If the data are used in scholarly presentations or 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. Paper research forms will be maintained for a period of 6 years following study closure and then securely shredded. The master list connecting unique study ID to participant identifiers will be destroyed upon study closure. De-identified research data that the participant has given permission to use will be maintained indefinitely. Informed Consent Forms will be maintained for a period of 6 years following study closure and then securely shredded.

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

Information gained from this study may provide valuable data for future running-related injury research. Participants in the research study will receive a running analysis from a commercial accelerometer in an inertial motion unit (IMU). The IMU will collect running biomechanical variables on each participant including ground contact time, step rate, step length, speed, distance, vertical oscillation, and participants will be able to view and have the opportunity to learn about this data. The participants will also be able to practice and become aware of some different running techniques.

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 identification 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 other similar identifier.

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 this study, results will be shared with subject. The researcher will contact the subject and arrange for follow-up care.

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 PI is the individual who is primarily responsible for the actual execution of the clinical investigation. The PI 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 KACH's 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 IRB. KACH Reporting Requirements: As soon as possible, but no later than 5 calendar days, events are to be reported to the HPA and IRB. The PI or designee will report to the HPA by email, phone or face-to-face; the HPA will communicate this to the IO and AIO. The PI will upload the report and notice into EIRB for IRB; the HPA will facilitate that information through EIRB.

Minor Deviations must be reported to the IRB at the time of continuing review or project closure. Major Deviations should be promptly reported to the HPA and IRB and in NLT 5 days. Serious Adverse Events (SAEs): All serious adverse events (SAE) occurring in participants enrolled at KACH will be reported to the IRB immediately upon discovery and an EIRB Reportable Event Form will be submitted to NMCP IRB within 3 business days. Additionally, the KACH HPA Sarah Wilder Hussain will be notified immediately of any adverse events. Unexpected (but not serious) adverse events (AEs) occurring in participants enrolled at KACH which, in the opinion of the PI, are possibly related to participation in the protocol will be reported by the PI within 10 (ten) working days to the IRB using the same procedures. 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 and RM (if applicable). These adverse events will be reported to the 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 or via email to the IRB Office. A complete report will follow the initial notification within three (3) 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

Please describe:

Inertial Measurement Unit (IMU) is a wearable device that clips onto your shoe, and communicates with your running watch, tablet, or phone. The IMU provides the following measures in real time: pace, ground contact time (GCT) and step rate. The IMU will be connected to the research team's iPad and data will be stored for each participant using the participant's subject identifier only. Zeng et al., found IMUs provide valid measures of ground contact time and spatiotemporal measures.

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
- [x] N/A

18.5 Sponsor (organization/institution/company):

- [x] 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

19.2 Defense Technical Information Center Registration (Optional):

- (•) Registration is not required
- ( ) Registration pending
- ( ) Registration complete

20.0 References and Glossary

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20.2 Abbreviations and Acronyms:

IVLR: Instantaneous Vertical Loading Rate (IVLR)
AVLR: Average Vertical Loading Rate (AVLR)
GCT: Ground Contact Time (GCT)
ST: Stance time
FT: flight time (FT)
SL: step length (SL)
SF: step frequency (SF)
ADSM: Active Duty Service Members (ADSM)
BRF: Biomechanical Risk Factors (BRFs)
ROI: Running Overuse Injuries (ROIs)
RRI: Running Related Injuries (RRIs)
PO: Power output (PO)
LSS: leg spring stiffness (LSS)
TA: Tibial Acceleration (TA)
GRF: Ground Reaction Forces (GRF)
vGRF: Vertical Ground Reaction Forces (vGRF)
LR: Loading Rate (LR)
IP: Impact Peak (IP)
m/s: meters per second (m/s)
MPH: miles per hour (MPH)
RPD: Ratings of perceived difficulty (RPD)
RPE-OMNI: OMNI-Run Scale ratings of perceived exertion (RPE-OMNI)
RPE-BORG: Rate of Perceived Exertion from the Borg (6 –20) Scale (RPE-BORG)
TSF: Tibial Stress Fracture (TSF)
BSI: Bony Stress Injury (BSI)
PFPS: Patellofemoral Pain Syndrome (PFPS)
VB: Visual Biofeedback (VB)
ABF: Auditory Biofeedback (ABF)

RED-S: relative energy deficiency in sport
ERLLP: Exercise related lower leg pain (ERLLP)
TM: Treadmill (TM)
LE: Lower Extremity (LE)
PBF: Peak Braking Force (PBF)
IG: Intervention Group (IG)
aF: Augmented Feedback (aF)
TOG: Time on Ground (TOG)
HEP: Home Exercise Plan (HEP)
NRFS: Non-Rearfoot Strike (NRFS)
VO: Vertical Oscillations (VO)
km/h: kilometer per hour (km/h)
VO2: oxygen uptake (VO2)
%VO2max: relative maximal oxygen uptake (%VO2max)
RR: respiratory rate (RR)
RER: respiratory exchange ratio (RER)
HR: heart rate (HR)
IMU: Inertial Measurement Units