Does Self-efficacy Predict Outcomes Among U.S. Military Academy Cadets During Initial Entry Training?

NCT05453110

May 19, 2022

EIRB Protocol Template (Version 1.1)

1.0 General Information

*Please enter the full title of your study:

Does self-efficacy predict injury and training outcomes among U.S. Military Academy cadets during initial entry training?

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

22KACH007

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

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

No

Does this protocol involve the use of animals?

Yes • No

2.0 Add Site(s)

2.1 List sites associated with this study:

mm mn Department 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:

Kreisel, Brian Robert, Doctorate of Science MAJ

Select if applicable

D Student

D Resident

D Site Chair

Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Benedict, Timothy **M,** PhD, DPT LTC

Associate Investigator

Casper, Preston C, Doctorate in Physical Therapy LT

Associate Investigator
Crowell, Michael SCOTT, DPT, DSc LTC
Associate Investigator
Dummar, Max Ken
Associate Investigator
Francis, Matthew W, DPT MAJ
Associate Investigator
Kuwik, Paul ANDREW, DPT
Associate Investigator
Scott, Kelly Maureen
Associate Investigator

B) Research Support Staff

Miller, Erin Marie, PhD
Research Coordinator

3.3 *Please add a Protocol Contact:

Benedict, Timothy **M,** PhD, DPT LTC
Kreisel, Brian Robert, Doctorate of Science MAJ
Scott, Kelly Maureen

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):

Haley, Chad Allen
Department Chair

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?

Physi I Thernpyl

4.2 * Has another IRB/HRPP reviewed this study or will another IRB/HRPP be reviewing this study? If Yes, answer the questions according to the IRB/HRPP Determination.

0 Yes G No

IRB Name	Review Date	Determination
No records have been added		

4.3 * Is this a research study or a Compassionate Use/Emergency Use/HUD project?

@ Yes O No

4.4 What type of research is this?

I? Biomedical Research
r Clinical trial (FDA regulated)
r Behavioral Research
0 Educational Research
C Psychosocial Research
D Oral History
D Other

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

@ Yes O No

4.7 * Is this human subjects research? (As defined by 32 CFR219} 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 O No

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

0 Yes @ No

5.0 Personnel Details

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

Norecords have been added

5.2 Will you have a Research Monitor for this study?

0 Yes
@ No
0 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}?

0 Yes @ No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
No records have been added		

Total amount of funding:

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?

0 Yes 0 No

If Yes, complete and attach Conflict of Interest forms for all key personnel

8.0 Study Locations

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

0 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	Keller Army Community Hospital	Performance site	000029527	10/28 /2025		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

0 Yes *Gi* No

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

0 Yes @ No

Select the area of responsibility:

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

0 Yes O No

9.0 Study Details

9.1 Key Words:

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

self-efficacy; musculoskeletal injury; tactical performance; initial-entry training

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

Since World War I, U.S. Army leaders have faced a challenging conundrum: conduct training tough enough to prepare Soldier for warfare's physical and mental demands without causing so many injuries that units become non-deployable (East, 2013). The steady decline in physical activity levels and increases in overweight and obese adolescents (Center for Disease Control and Prevention /Division of Adolescent, 2020) has continued to widen the physical readiness gap between the general population and military physical demands (Alemany et al., 2021). This disparity increases the difficulty to train physically capable recruits without injuring those who are less fit.

Despite efforts to improve Soldier readiness, as many as 58,400 Soldiers were not capable to deploy in April 2020, which is equivalent to 13 Brigade Combat Teams (Department of the Army, 2020). More than half (31,500) were due to either temporary or long-term physical limitations, including musculoskeletal injuries (MSKIs). MSKIs are the leading cause of nondeployability, lost duty days (LDD), medical encounters, military discharge, and disability (Molloy, Pendergrass, Lee, Chervak, et al., 2020; Roy et al., 2021). In 2018 the U.S. Army spent $434 million in direct medical costs alone to treat MSKIs (Molloy, Pendergrass, Lee, Chervak, et al., 2020).

Ironically, the leading causes of MSKIs are same activities that leaders deliberately conduct to develop physical resilience: running, foot marching, other physical fitness training activities (besides running) and work-related tasks (Roy et al., 2021). Although physical training results in the highest number of total injuries, obstacle courses and ruck marching have greater injuries per exposure (Lovalekar et al., 2021). Other common causes of MSKIs include overexertion, falls/slips, and accidental injury (Army Public Health Center, 2021).

Lower back injuries are a common occurrence in athletes and sports programs. They are especially common in sports in which athletes train strength and power movements, such as powerlifting and weight lifting (Bengtsson, 2018; Reichel, 2019; Stromback, 2018). Tactical athletes- referring to firefighters, police officers, and military servicemembers- report similar prevalence of low back pain (LBP), often due to heavy equipment worn or carried for their jobs (Roy, 2021). In the US military, musculoskeletal (MSK) injuries are highly prevalent and costly in lost duty days, depleted readiness to deploy, and medical expenses(Grimm, 2019; Teyhen, 2018).

Researchers have identified multiple physical and behavioral MSKI risk factors including prior injury, female gender (Hearn et al., 2021; Kucera et al., 2016), high or low BMI (Lovalekar et al., 2021; Rappole et al., 2017), history of smoking, low aerobic endurance (Molloy, 2016; Rappole et al., 2017),

and (to a lesser extent) muscular strength and endurance (Jones et al., 2017). Unit leaders and military trainers have used these study outcomes to develop injury prevention and training program including physical fitness programs, MSKI risk screening and leader education with mixed results (Canham-Chervak et al., 2015; Lovalekar et al., 2021; Molloy, Pendergrass, Lee, Hauret, el al., 2020; Terry et al., 2018).

These epidemiological and correlational studies summarize the dilemma: Soldiers with prior injury and lower fitness levels tend to get injured (again) while training to improve their physical fitness. It is possible that other modifiable risk factors exist that, if trained, do not carry such high injury risk.

The Army's new mandatory fitness test- Army Combat Fitness Test (ACFT)- is a comprehensive assessment of strength, power, speed, and endurance, and represents a dramatic shift from the previous fitness lest that primarily evaluated soldiers' endurance. One event of the ACFT is a three-repetition maximum deadlifl. The addition of a required deadlifl strength test has raised concern amongst servicemembersand healthcare workers about the risk of injury (Hauschild, 2019; Kind, 2019). The Army doctrine specifies the purpose of testing this event is to evaluate a soldier's lower body and core strength to safely lift heavy equipment, and the graders are instructed to not permit any lumbar flexion during the deadlift. (Army Field Manual 7-22).

Many coaches and physical therapists agree that lumbar flexion should not be permitted during a deadlifl (Nolan, 2019; Sjoberg, 2020; Spencer, 2015) however the majority of the research supporting this is based on empirical data derived from biomechanical or cadaver studies (Arjmand, 2005; Cholewicki, 1991; Dolan, 1994; Faber, 2009; Gallagher, 2012; Potvin, 1991; von Arx, 2021; Wade, 2014). There is some debate amongst researchers regarding the importance of avoiding lumbar flexion for injury back injuries during a deadlift (Adams, 1986, 1994; Beach, 2018; Spencer, 2015).

Alberto Bandura (1977) introduced self-efficacy as one's confidence to perform a specific task. In behavioral psychology, this concept helps patients and clinicians establish a therapeutic path by accomplishing individualized, increasingly difficult tasks (Bandura, 1977). Multiple subsequent publications have proposed positive relationships between self-efficacy and self-regulation (Bandura, 1982), performance (Bandura, 1982; Feltz et al., 2008), goal-setting (Brinkman et al., 2020) and motor learning (Beattie et al., 2014).

Performance effects resulting from the messages provided to athletes shouldn't be ignored, and this is referred to as placebo (has a perceived positive effect) or nocebo (has a perceived negative effect (Horvath, 2021). Theconcept of performance decline after negatively-perceived stimulus has a less robust presence in the literature than placebo effects, though this is evolving. Numerous recent studies have now documented the significant detriments to physical performance when subjects are exposed to negative or potentially threatening information (Cook, 2012; Corsi, 2019; Emadi Andani, 2015; Horcajo, 2019; Jackson, 2005; Pollo, 2012; Zech, 2019).

To our knowledge, there are no longitudinal studies evaluating the risk of injury from deadlifting with a flexed lumbar spine resulting in no clear evidence that a flexed spine is a risk factor for injury. However, it is well documented that information related to potential threat (nocebo) can adversely affect physical performance. Our research aim is to determine if cautionary information about the risk of spine injury harms performance on a maximum strength test compared to a message of spine resiliency. The cautionary education is similar to standard information provided to many servicemembers before the start of an ACFT or a maximum deadlifl.

9.3 Objectives/Specific Aims/Research Questions:

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

1. Determine if general self-efficacy is a predictor of injury during Cadet Basic Training(CBT) by performing a Kaplan-Meier Survival Curve of a single self-efficacy assessment (Cadet General Self-Efficacy Assessment) and injury occurrence using the Defense Medical Surveillance System (DMSS), Cadet Illness and Injury Tracking System (CIITS), Armed Forces Health Longitudinal Technology Application (AHLTA) and a follow-up self-reported injury assessment.

1. Independent Variable: Cadet General Self-Efficacy score

2. Dependent Variables: Injury report according to CIITS, AHLTA, DMSS, sick call report or self-reported

2. Determine if task-specific self-efficacy is a predictor of injury during specific CBT events by performing a Kaplan-Meier Survival Curve, a single assessment of cadet task-specific self-efficacy and injury occurrence using DMSS, CIITS, AHLTA and a follow-up self-reported injury assessment.

1. Independent Variable: Cadet Task-Specific Self-Efficacy score
2. Dependent Variables: Injury report according to DMSS or self-reported

3. Determine if general self-efficacy is a predictor of performance during CBT by performing a multivariate regression between a single self-efficacy assessment and multiple measures of performance during CBT including 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) raw or calculated score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.

1. Independent Variable: Cadet General Self-Efficacy score
2. Dependent Variables: performance outcome by event- 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.

4. Determine if task-specific self-efficacy is a predictor of performance during CBT by performing a multivariate regression between a single (or multiple) assessments of cadet task-specific self-efficacy, and multiple measures of performance during CBT including 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) raw or calculated score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.

1. Independent Variable: task-specific self-efficacy scores
2. Dependent Variables: performance outcome by event including **1)** successful completion (pass /fail), 2) basic rifle marksmanship qualification score, 3) 12-mile road march outcome (pass/fail), 4) Army Combat Fitness Test (ACFT) score, 5) land navigation score, 6) swimming assessment outcome (pass/fail) and 7) any other individually-graded events.

5. After completing CBT, determine which sources of self-efficacy ((1) enacting mastery experiences, 2) vicarious experiences, 3) verbal persuasion, 4) physiological state, 5) affective state, 6) mental imagery) were the most influential on cadets' self-efficacy throughout CBT specific tasks by conducting a Chi-square test.

1. Independent Variable: reported level of influence of each (6) source of self-efficacy.
2. Dependent Variables: performance outcome by event including 1) successful completion (pass /fail), 2) basic rifle marksmanship qualification score, 3) 12-mile road march outcome (pass/fail), 4) Army Combat Fitness Test (ACFT) score, 5) land navigation score, 6) swimming assessment outcome (pass/fail) and 7) any other individually-graded events.

6. Determine the effect of low back pain education (cautionary vs resiliency) on deadlift performance (weight lifted).
We will analyze this with MDL weight lifted as the dependent variable (one-way ANOVA), with a planned comparison analysis if significant differences are found between groups.

7. Determine the degree of confidence cadets have in their ability to succeed at the MDL both before and after the education and MDL
We will analyze if there is a main effect of time in the pre-to-post self-efficacy scores with a paired t-test. We will use multiple regressions to analyze the impact of self-efficacy scores on MDL performance.

8. Determine the effect of low back pain education (cautionary vs resiliency) on deadlift self-efficacy.
We will analyze change scores with one-way ANOVA with planned comparisons between groups if ANOVA is significant.

9. Determine the effect of low back pain education (cautionary vs resiliency) on perceived spine vulnerability on a deadlift.
We will analyze change scores with one-way ANOVA with planned comparisons between groups if ANOVA is significant.

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, orIV- forFDA-regulated investigational drug research

TI1is study willbe a randomized controlled trial withparallel design and I:I allocationratio. Weplantouse cluster randomization. We willhave three groups- control, cautionary, resiliency (Jackson, 2005).

9.5 Target Population:

Describe the population to whom the study findings will be generalized

U.S. Military Academy Cadets

9.6 Benefit to the DoD:

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

Researchers inside and outside of the military have also found that self-efficacy predicts both performance and is negatively correlated with MSKI (Gruber et al., 2009; Samuels et al., 2010). In a study on Navy SEAL training resilience, researchers found that successful graduation was related to physiological markers of resilience (Ledford et al., 2020). However, few studies have investigated the combined effects of physical, behavioral and psychological factors on predicting MSKIs.

Cadet basic training (CBT) at the United State Military Academy (USMA) is a 7-week initial-entry training event that physically and psychologically prepares cadets to become officers. It includes similar training events and physical demands as other initial-entry military courses such as a 12-mile foot march with 35 lbs., physical training including running multiple days per week, weapons familiarization, and basic tactical training. The injury risk factors for cadets attending CBT are similar to trainees attending U.S. Army Basic Combat Training and regular military training even though injury incidence is lower (Hearn et al., 2021). Identifying self-efficacy as an injury risk factor is the first step to designing and implementing injury prevention measures. The purpose of this study is to investigate relationships between performance, MSKI and self-efficacy alone and in combination with other MSKI risk factors in USMA cadets participating in CBT.

There is currently an emphasis in Army Doctrine (FM 7-22) on form/technique for events on the ACFT, especially the maximum deadlift (MDL) and the prevention of lower back injuries. The rationale behind this is due to the perception that breakdowns in form during the deadlift lead to injuries, however, the research does not support this. Specifically, the research is unclear regarding the position of the spine while deadlifting- neutral vs flexed. Our results could impact future DoD publications regarding technique on the MDL and de-emphasize the role of a rounded spine as a safety concern.

The researchers hypothesize that self-efficacy (general and task-specific) will be positively correlated with successful completion and performance and negatively correlated with MSKI risk during CBT. The researchers will also explore the relationship between self-efficacy and other known injury risk factors. Furthermore, we hypothesize that such beliefs about the vulnerability of the spine to injury might contribute to future disabling beliefs about back pain. This research marks an important step in investigating the role of beliefs about the back and readiness.

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

Phase I: Consent and Self-Efficacy Assessment
All new cadets are eligible to participate in this study and willreceive verbal and written study desc1iption dming the first or second week of cadet basic training. Immediately after consenting to pat1icipate, they will complete the study demographic data information ai1d the Cadet Basic Training Projective Performance

Invent01y, which assesses self-efficacy measured prospectively via questionnaire on a IO-point Likert scale from 1 (no confidence) to 10 (folly confident) for overall perfonnance dming cadet basic training, marksmanship/live fire training, mck marching 12 miles, land navigation, swimming, and the Anny Combat Fitness Test. It will also assess for any recent injuries and whether the injmy is cuffently hinde1ing them.

Phase 2: Injury Smveillance During Cadet Basic Training
TI1e researchers will monitor the Cadet Injury and Illness Tracking System (CIITS), Aimed Forces Health Longitudinal Technology Application (AHLTA) and the Defense Medical Stnveillance System (DMSS) up to weekly to track injmies for the duration and for up to 9 weeks afte1wards. They will classify injuries as by diagnosis, region, and impact on training ("not injured" (1), "injured-not limited" (2), "injured-modified training" (3) and "injured-limited" (4)). Cadets will initially be defaulted as "not injured" (1). They will also complete the Single Assessment Nlllllleric Evaluation (SANE), rating their cuffent ability level on a scale of 0- 100% with regards to their injury.

Phase 3: Maximum Deadlift and Low Back Pain Education
TI1e randomized control element of this study will occur before and during the maximum deadlift (MDL) of the Aimy Combat Fitness Test. At the start of cadet basic training, researchers will randomly allocate each company of cadets into a group receiving a cautionary message regarding risk of spine injmy, a group receiving a reassming me.ssage of spine resiliency, and a group receiving no education prior to the MDL. This education will include infonnation about the lumbar spine as it relates to a deadlift. The researchers will administer this education shortly prior to cadets taking the MDL. Cadets, test graders, and data analysts will all be blinded to group allocation. The researchers will collect MDL scores from each group and explore relationships between group assigmnent and MDL performance.

Because the study is deceptive, all subjects will be provided a handout with best-evidence summary statements on how to maintain a healthy back as a cadet and beyond. All patiicipants will be given this infonnation, debriefed and provided an opportunity to speak with a licensed physical therapist about any concerns they might have about their back or lifting for the deadlift at a later date.

Phase 4: Perfo1mance Outcomes
TI1e researchers will receive cadet perfonnance outcomes from the Department of Militaiy Instmction (DMI) and the Department of Physical Education (DPE). At a minimum, this will include overall outcome (pass/fail) and Aimy Combat Fitness Test (ACFT) raw ai1d calculated scores. If available, this will also include marksmanship score, live fire score, land navigation score, swim test pass/fail outcome, road maid1pass/fail outcome. TI1e reseai·chers will enter this data into the reseai·ch database.

Phase 5: Post-Cadet Basic Training Injmy Questionnaire and Self-Efficacy Sources
After cadet basic training, the cadets will complete an electronical injmy assessment questionnaire. This v.ri.11 ensm·e that any cadets who coped with an injmy or self-modified training (such as pe1fonning at a lower level) ai·e also captured. This questionnaire will also classify the injuries according to the saine classification system as in phase 2. Thecadets will also answer questions related to the sources of confidence dming task-specific CBT events.

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.

Cadet Demographics: Age, gender, height, weight, USMA Preparatory School attendance, intended athletics participation, intended USMA performance

Injury Questionnaire: Recent injury information (within last year), still effecting performance, and Single Assessment Numeric Evaluation (SANE), and after-cadet basic training injury presence, region, and limiting classification

Self-Efficacy: Overall Cadet Basic Training performance, marksmanship, buddy team live fire, swimming 150 yards, ruck marching (load carriage), ACFT, deadlift, land navigation

Maximum Deadlift (MDL) performance: Measured by the amount of weight successfully lifted during the ACFT.

Reported Self-Efficacy Source: Measured on the post-CBT survey using Qualtrics. The cadets will rank-order commonly cites sources of self-efficacy from most to least influential. The options will include commonly-cited self-efficacy sources: physiological state, previous experiences, affective state, mental imagery, vicarious experiences, and verbal persuasion.

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 O 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
0 No, I am not an MHS workforce member

Are you an MHS business associate?

0 Yes, I am an MHS business associate
@ No, I am not an MHS business associate

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)**

0 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
D Obtaining MHS hard copy records specific to research participants
Obtaining data from an MHS information system(s)

10.7 If youare obtaining data from an MHSinformation 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
P' Access

10.8 Doyouintend 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

Statistical Method: An expert, with appropriate knowledge of and experience with generally epted statistical and scientific principles and methods for rendering information not individually identifiable, determines that the data is not individually identifiable

0 Yes ® No

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

Ify oudo 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.**

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

PHI Systems:

HS Information System	Requesting Data
AHLTA	Yes
DMss	Yes
TMoos	Yes

PII -Only Systems:

M	HS Information System	questing Data
No records have been added		

De-Identified Data & Other Systems:

In formation System	Requesting Data
Other MHS System (May include PII and/or PHI) List other system here: Cadet Illness and Injury Tracking System (CITTS)	Yes

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?

0 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 youwill request from MHShard 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 youwill have access to in any form or medium.

a Element(s)	MHS	Non-MHS Systems	MHS Hard Copies
1. Names	☐	☐	Ci

2. Postal address with only town, city, state and zip code	☐	☐	C
3. Postal address with all geographic subdivisions smaller than a 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 for all such geographic units containing 20,000 or fewer people is changed to 000	☐	☐	0
4. Dates including all elements (except year) directly related to an individual, including birth date, admission date, discharge date, and date of death	n	[J	
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"	0	0	Ci
6. Telephone numbers	☐	l']	r
7. Fax numbers			

	n	n	r
8. Electronic mail addresses	n	rJ	r
9. Social Security numbers (SSNs)	☐	n	r
10. Medical record numbers	☐	0	r
11. Health plan beneficiary numbers	n	rJ	n
12. Account numbers	D	D	C
13. Certificate /license numbers	D	D	C
14. Vehicle identifiers and serial numbers, including license plate numbers	r1	r:"J	r
15. Device identifiers and serial numbers	☐	D	C
16. Web Universal Resource Locators (URLs)	☐	☐	D
17. Internet Protocol (IP) address numbers	D	D	C
identifiers, including finger and voice prints	☐	D	C
19. Full-face photographic images and any comparable images	n	D	r
20. Any other unique identifying number, characteristic, or code (Diagnosis,	n	0	r

DEERS ID, EDIPI, Rank)

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

10.12 Doyoubelieve 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.

0 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

0 No

0 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.)

The consent form, baseline questionnaire, CBT outcomes, and pre-ACFT / post-ACFT self-efficacy forms will all be hard copy acquired. The post-ACFT injury case report form will be electronically acquired through Qualtrics, a secure electronic survey application. All of the case report forms (hard copy and electronic) will require the participants name on them. No subject ID will be included on these forms to remain in compliance with human research protections guidelines. Once the hard copy case report forms are collected, the study data will be transcribed into an electronic spreadsheet where the participant will only be identified by their assigned subject ID. Theonly document (electronic or hard copy) linking the subject ID and the participant name will be the electronic master subject list. The hard copy case report forms with participant names on them will all be stored together in a folder with the participant's consent form. Participant folders will be stored together in a locked filing cabinet, behind locked doors, in a CAC card protected building. All electronic files will be stored on DoD-server, CAC card protected computers. Only the PI and AI's will have access to the physical and electronic participant files.

Performance information received from the Department of Military Instruction (DMI) is not considered private health information, but will include personnel identifiers. The information, to include copies of ACFT scorecards, will be collected from the DMI following the ACFT and stored

with the rest of the participants hard copy CRFs containing personnel identifiers. In addition, the researchers will collect outcomes data from the DMI (CBT and task-specific event performance outcomes data) via secure access to department databases and/or via encrypted emails or an encrypted drop box.

When we are ready for data analysis, we will subsequently collect injury information, number of days on profile for each subject for up to 9 weeks following cadet basic training. Subject number of days on profile will be combined with the previously de-identified study data on a spreadsheet for analysis. The spreadsheet data will be password and firewall-protected. There are no planned linkages with external databases, nor is transmission of the data for collaborative use anticipated. The PI will keep a master spreadsheet that links subject names with their unique identification number 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. All research data and forms (both paper and electronic) will only be accessible by authorized study staff, the local IRB, and applicable governmental agencies as part of their duties and in accordance with federal law. These duties include making sure that research participants are protected.

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.

All records containing HIPAA PHI will be maintained for a period of 6 years at which time they will be destroyed by securely shredding. The master list connecting unique study ID to participant identifiers will be destroyed upon study closure. De-identified research data will be maintained indefinitely.

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 (ie, protected health information such as name, SSN, 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. No data sharing/use agreements are necessary or will be utilized.

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

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

To determine the effect of low back pain education (cautionary vs resiliency) on deadlift performance (weight lifted), we will use ANOVA and planned comparison analysis if between-group differences are found between groups.

To determine the effect of low back pain education on deadlift self-efficacy, we will analyze change scores with a one-way ANOVA and planned comparisons if significant.

To determine the effect of low back pain education on perceived spine vulnerability, we will analyze change scores with a one-way ANOVA and planned comparisons if significant.

Our study design accounts for some confounding factors by utilizing randomization. Potentially confounding variables should be balanced between groups. We will test groups at baseline to ensure they are similar among important characteristics. Furthermore, characteristics that are different among groups at baseline or that appear to be influential on load lifted will be included in the ANOVA model as a covariate to control for and test for potential confounding.

11.2 Sample Size:

1200 participants

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

1200

11.4 If youare 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

We have powered this study to determine a between-group difference of 5kg. This is equivalent to an effect size of d=.10 given a standard deviation of 23kg (available from previously collected data in this lab). Weused G*Power 3.0 with power at .80 to calculate a total sample size of 969 subjects (323 per group). We will therefore attempt to recruit 1200 participants, allowing for 20% injury or attrition which might prevent subjects from completing the MDL event during CBT ACFT.

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

1. Determine if general self-efficacy is a predictor of injury during CBT by performing a Kaplan-Meier Survival Curve, a single assessment (Cadet General Self-Efficacy Assessment), analysis of the Defense Medical Surveillance System (DMSS) and a follow-up self-reported injury assessment.
    1. Independent Variable: Cadet General Self-Efficacy score
    2. Dependent Variables: Injury report according to DMSS or self-reported

2. Determine if task-specific self-efficacy is a predictor of injury during specific CBT events by performing a Kaplan-Meier Survival Curve, a single (or multiple) assessments of cadet task-specific self-efficacy, analysis of the Defense Medical Surveillance System (DMSS) and a follow-up self-reported injury assessment.
    1. Independent Variable: Cadet Task-Specific Self-Efficacy score
    2. Dependent Variables: Injury report according to DMSS or self-reported

3. Determine if general self-efficacy is a predictor of performance during CBT by performing a multivariate regression between a single assessment (Cadet General Self-Efficacy Assessment) and multiple measures of performance during CBT including 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) raw or calculated score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.
    1. Independent Variable: Cadet General Self-Efficacy score
    2. Dependent Variables: performance outcome by event- 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.

4. Determine if task-specific self-efficacy is a predictor of performance during CBT by performing a multivariate regression between a single (or multiple) assessments of cadet task-specific self-efficacy, and multiple

measures of performance during CBT including 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) raw or calculated score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.

1. Independent Variable: task-specific self-efficacy scores by event
2. Dependent Variables: performance outcome by event- 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.

5. After completing CBT, determine which sources of self-efficacy (1) enacting mastery experiences, 2) vicarious experiences, 3) verbal persuasion, 4) physiological state, 5) affective state, 6) mental imagery) were the most influential on cadets' self-efficacy throughout CBT specific tasks including 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) raw or calculated score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events by conducting a Chi-square test.

1. Independent Variable: task-specific events 1) successful completion (pass/fail), 2) Army Combat Fitness Test (ACFT) score, 3) Warrior Competition performance, 4) marksmanship score, 5) written exams, 6) swimming assessment and 7) any other individually graded events.
2. Dependent Variables: reported level of influence of each (6) source of self-efficacy.

6. Determine the effect of low back pain education (cautionary vs resiliency) on deadlift performance (weight lifted).
We will analyze this with MDL weight lifted as the dependent variable (one-way ANOVA), with a planned comparison analysis if significant differences are found between groups.

7. Determine the degree of confidence cadets have in their ability to succeed at the MDL both before and after the education and MDL
We will analyze if there is a main effect of time in the pre-to-post self-efficacy scores with a paired I-test. We will use multiple regressions to analyze the impact of self-efficacy scores on MDL performance.

8. Determine the effect of low back pain education (cautionary vs resiliency) on deadlift self-efficacy.
We will analyze change scores withone-way ANOVA with planned comparisons between groups if ANOVA is significant.

9. Determine the effect of low back pain education (cautionary vs resiliency) on perceived spine vulnerability on a deadlift.
We will analyze change scores withone-way ANOVA with planned comparisons between groups if ANOVA is significant.

12.0 Participant Information

12.1 Subject Population:

All incoming US Military Academy cadets, class of '26, attending cadet basic training in the summer of 2022

12.2 AgeRange:

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
- 18-24
- 25-34
- C 35-44
- r 45-54
- r 55-64
- C 65-74
- 0 75+

12.3 Gender:

Male

Female

Cother

12.4 Special categories, check all that apply

C Minors /Children
r Students
r Employees - Civilian
C Employees - Contractor
D Resident/trainee
Cadets /Midshipmen
D Active Duty Military Personnel
C Wounded Warriors
r Economically Disadvantaged Persons
r Educationally Disadvantaged Persons
C Physically Challenged (Physical challenges include visual and/or auditory impairment)
C Persons with Impaired Decisional Capacity
C Prisoners
D Pregnant Women, Fetuses, and Neonates
C Non-English Speakers
r 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.

12.5 Inclusion Criteria:

1 English	Inclusion criteria are cadets age 17-26 (cadets under the age of 18 are legally emancipated therefore able to consent), those paiticipating in the ACFT, and speak and understand

12.6 Exclusion Criteria:

No Criteria has been added to this Protocol

13.0 Recruitment and Consent

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

All 1,200 new Cadets will be recruited all together in an auditorium with a mass verbal explanation and handouts available for written explanation. Researchers will be dressed in professional civilian attire to prevent perceived authoritative influence due to higher military rank. Cadets who do not wish to participate can decline participation. Participation is voluntary with no incentives offered for participating and those who opt out will receive no adverse actions.

13.2 Compensation for Participation:

Participation is voluntary with no incentives offered for participating and those who opt out will receive no adverse actions.

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

Not applicable

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?

0 Yes ® No

Please explain the consent process:

Researchers will obtain written consent from participants all at once.

13.S 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.

0 N/A
® Propose ombudsman

Proposed ombudsman name, if the desired ombudsman is not in the system

Kelly Channell

Please explain the ombudsman's role and responsibilities on this project

In accordance with the KACH Policy for use of an Ombudsman, the Ombudsman will act as an impartial and objective advocate for human subjects participating in research (DODI 3216.02). He/she will ensure that cadets are not coerced in any way and that all of their question and/or concerns are answers. The Ombudsman will be present during the study recruitment and consent process to ensure voluntary involvement and that the research is presented in clear, adequate and accurate means.

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

All participants will receive the researchers email address during the study description and consent briefing. To be removed, they just need to email the primary investigator to be removed from the study.

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 most likely risk of this study is a potential loss of privacy. We will protect subjects' privacy by labeling 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 server which is only accessible by the principal investigator and designated research staff using CAC authentication.

There is an inherent risk of injury during cadet basic training and during the ACFT, however this study does not increase or decrease that risk. Cadets who choose to participate in this study will have identical risk as cadets who choose not to participate.

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

TI1e cautionaiy education provided to one of the groups is similai·to standat·d coaching advice offered to servicemembers before maximum deadlift testing or conducting an ACFT. However, in order to prevent perpetuating any participants' fear of spine vulnerability during deadlifts, we will consolidate best-evidence SIIIIIIIaty statements on how to maintain a healthy back as a cadet and beyond. All pa1ticipants will be given this inf01mation and provided an opportunity to speak with a licensed physical therapist about any concerns they might have about their back or lifting for the deadlift at a later date.

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., useof 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

All physical case report forms of the participants will be stored together in a locked filing cabinet which is secured behind a locked door in the Physical Therapy clinic that is located in a CAC protected building. The case report forms will be stored with the consent form of participants due to them containing personally identifiable information (first and last name).

Following the completion of data collection the study data collected on physical case report forms **will** be transcribed into password protected electronic spreadsheets, that will be stored on CAC protected, firewall secured, DoD server computers only accessible to the PI and AI's. The data spreadsheets will identify participants by subject ID and not by name. The master subject list is the only file that will connect subject ID and participant name.

There are no planned linkages with external databases, nor is transmission of the data for collaborative use anticipated. The PI will keep a master spreadsheet that links subject names with their unique identification number on a government computer assigned to the PI. The computer is password and CAC-card protected, and the system is firewall protected. This electronic spreadsheets will not be shown to anyone except for the investigators in this study or governmental agencies only in accordance with federal law. All research data and forms (both paper and electronic) will only be accessible by authorized study staff, the local IRB, and

applicable governmental agencies as part of their duties and in accordance with federal law. These duties include making sure that research participants are protected.

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

The outcomes of this study could benefit the military community if self-efficacy proves to be an adaptable characteristic that is correlated with injury during cadet basic training. Planning training to include self-efficacy development could therefore help prevent future injury in cadets and U.S. Army Soldiers.

There is currently an emphasis in Army Doctrine {FM 7-22) on form/technique for events on the ACFT, especially the maximum deadlift (MDL) and the prevention of lower back injuries. The rationale behind this is due to the perception that breakdowns in form during the deadlifl lead to injuries, however, the research does not support this. Specifically, the research is unclear regarding the position of the spine while deadlifting- neutral vs flexed. Our results could impact future DoD publications regarding technique on the MDL and de-emphasize the role of a rounded spine as a safety concern.

14.S
Privacy for Subjects:

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

Like many biomedical research protocols considered by IRBs, the protection of confidentiality is a significant concern. In order to protect confidentiality, all participants will be assigned a unique ID at the time of record review. All research related data will only be labeled and stored with each participant's unique ID. Furthermore, for the current study, only the immediate research team will have access to the data associated with this project. The linkage between the unique ID number and master participant list will be maintained electronically on the physical therapy server which is limited to authorized KACH users in the physical therapy department and requires CAC authentication.

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

All participants will be assured that any injury information that they share with us is private and under the same protections as any other medical information. The information will not be shared with USMA administrators, faculty or cadre and will no way change the admission status or training status. We do not anticipate any unexpected findings that could be detrimental to subject. Any medical concerns will be brought up privately between the primary investigator and the cadet directly if needed.

15.0 Study Monitoring

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

0 DSMP
0 DSMB
0 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

Adverse events: Events which are not serious are reported on the Annual Progress Report (APR) or Continuing Review Report (CRR) of the protocol.

Serious Adverse Events: The PI, within one working day, will report all serious adverse events occurring in participants enrolled at KACH. the investigator must contact the HPD within one business day of discovery. HPD will inform the NMCP HPD, who will notify the IRB Chair via email and phone call. The HPD will report the event to the IO as soon as possible after determining the event is an SAE or unanticipated problem. The HPD will notify DHA within 3 days that an event is under investigation and follow up by email. A Reportable Event Form and supporting documentation must be submitted to the HPD within *five* business days and will be forwarded to the IRB for review at the next available meeting.

Unexpected (but not serious) adverse events 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 three working days to the IRB using the same procedure.

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. A complete report will follow the initial notification within three (3) business days.

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 three days.

17.0 Equipment/non-FDA Regulated Devices

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

0 Yes @ No

18.0 FDA-Regulated Products

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

C Drugs
0 Dietary Supplements
0 Biologics
0 Devices
l;i N/A

18.S Sponsor (organization/institution/company):

P° N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

0 Registration is not required
@ Registration pending
0 Registration complete

19.2 Defense Technical Information Center Registration (Optional):

@ Registration is not required
0 Registration pending
0 Registration complete

20.0 References and Glossary

20.1 References:

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20.2 Abbreviations and Acronyms:

USMA: United States Military Academy
CBT: Cadet Basic Training
MSK-I: Musculoskeletal Injury
SANE: Single Assessment Numerical Evaluation
CIITS: Cadet Injury and Illness Tracking System
ACFT: Army Combat Fitness Test
MDL: Maximum Deadlift
AHLTA: Armed Forces Health Longitudinal Technology Application
DMSS: Defense Medical Surveillance System