Title: Gait Retraining Enhances Athletes' Technique: GREAT after Anterior Cruciate Ligament Reconstruction

NCT Number: 03918681

Date: 30 Nov 2020

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

Keller Army Community Hospital (KACH)
CONSENT TO PARTICIPATE IN RESEARCH
Research Title: *Gait Retraining Enhances Athletes' Technique: (GREAT) after Anterior Cruciate Ligament Reconstruction*
Principal Investigator: *CTR Erin M. Miller, MS ATC, ACSM-CPT*

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions that you have. You may also wish to talk to others (for example, your friends, family, or your personal doctor) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without any consequence.

Please tell the researchers if you are taking part in another research study.

NOTE: If you are providing consent as a legally authorized representative (LAR), "you" or "your" refers to the research participant.

You do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty.

Your decision will not affect your future care at KACH or your military career.

1. **KEY INFORMATION:** *This section provides a one-page summary of the information outlined in this consent form. More information will be provided to you on the pages that follow.*

Voluntary Participation	You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study. Your decision will not affect your current or future care at *KACH*. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.
Purpose	The purpose of this research study is to learn about the effectiveness of different ways to return to run after ACL surgery.
Duration	You will be in this study for about 3-4 months depending on your individual progress.

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

Procedures	While you are in the study, you will: • Fill out forms that ask you about personal and medical information to include your current knee pain and function. • Complete a strength and balance screening process to confirm that you are ready to start a return to run program. • Be randomly assigned to one of 2 return to run programs; a standard return to run program or a personalized return to run program that will include specific technology assisted, clinician-guided feedback to change your foot strike pattern while you run. • Complete a 4-week lower leg strength and flexibility program, and an activity log to track your running and exercise progress. • **Provide blood samples at 3 different times throughout your return to run program. To draw the blood samples a needle will be inserted in your arm near the bend in your elbow.** • Wear a Milestone pod on each foot for the duration of the study to monitor run program adherence. • Complete 3 runs on an instrumented treadmill, at your self-selected pace while we collect information about your running form. • **Meet with a physical therapist, in-clinic, at weeks 1-4, 6, 8 and every other week thereafter until the run program is complete.**
Why might you want to participate in this research (benefits)?	You may have the opportunity to learn about your running form and possibly retrain your running pattern. You will learn mobility and strengthening exercises for your core and legs. You will receive 2 free Milestone Pods to use after the study to track and monitor your personal running information.
Why might you choose not to participate in this research (risk)?	The **main** risks from being in this study are: • There is a small risk of discomfort from having your blood drawn to include swelling or bruising at the site of the needle stick. • There is a small risk of muscle soreness as you complete the return to run progression. There is a small risk of loss of privacy.

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

What are the alternatives to participating?	Your alternative is not to participate in this research and continue seeing your medical provider (physical therapist or athletic trainer).

2. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to learn about the effectiveness of different ways to return to run after ACL surgery. Re-injury rates and return to full activity following ACL injury and surgery can be complicated by alterations in movement patterns. Researchers have shown this to be because people return to sport after surgery with muscle weakness and different movement, landing and running patterns than before surgery. Return to run programs that include individual clinician-guided feedback to alter foot strike pattern may improve strength, running-related pain, loading and landing patterns during running after ACL surgery. If you chose to participate in this study, you will be asked to provide blood samples at three time points. From these samples we will be measuring levels of certain substances, known as biomarkers in your blood that are related to the condition of the cartilage and bone inside your joints. A previous study has shown that biomarker levels in cadets who tear their ACL while at West Point, are significantly different both before injury and at graduation, from those that have not had any significant joint injury. This study will allow us to more closely examine and compare these biomarker levels at different time points during return to run and may help us predict who may benefit from running a specific way after surgery. The levels of biomarkers in these samples will be compared and analyzed to look for any changes following your return to running in these biomarkers that are related to joint health status and they will be compared between return to run groups. In addition, we will evaluate your running pattern, balance, landing patterns, running comfort, and running function to help find the most effective and safe way to return people to run after ACL surgery. Return to run programs have not been well studied in people returning to run after ACL surgery. This means that return to run programs are considered experimental.

There will be about 40 people taking part in the study at the Keller Army Community Hospital, over a period of 18 months. During the study, you will participate in between 8-12 visits with the study investigators over a 4-month period depending on your individual progress. This is no more time than you would already be spending with your physical therapist at this point in your rehabilitation process. The average duration of participation per visit is 20 minutes.

3. WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you recently had surgery to reconstruct the anterior cruciate ligament (ACL) in your knee.

4. HOW LONG IS THE RESEARCH STUDY?

You will participate in between 8-12 visits with the study investigators over a 4-month period depending on your individual progress. This is no more time than you would already be spending

with your physical therapist at this point in your rehabilitation process. The average duration of participation per visit is 20 minutes.

There will be about 40 people taking part in the study at the Keller Army Community Hospital, over a period of 18 months.

At the end of this research study the clinical results, including research results about you will be shared with you.

5. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". This information is collected as a part of your regular medical care and will include 20 single leg heel raises, 10 single leg squats and 20 single leg hops on each leg to screen your lower body strength.

6. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will:

1. Read and sign this informed consent document and fill out the questionnaire included with this form at this time. The questionnaire includes questions about your age, gender, weight, height, most recent APFT score, shoe make, shoe model, past injuries/medical history, running comfort, running confidence and running function.
2. Complete a screening process that will include testing the strength of your lower body muscles to confirm that you are ready to start a return to run program.
3. Complete initial surveys that will ask you about your knee function and knee pain.
4. Complete initial tests, that are standard of care, that will assess your lower body strength, lower body balance and hopping ability.
5. Be randomly assigned to one of 2 return to run groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either of the groups. Group 1 is a standard physical therapy return to run program. Group 2 is a physical therapy return to run program that will include specific technology assisted, clinician-guided feedback to change your foot strike pattern while you run during your in-clinic follow-ups.
6. Receive two Milestone Sport Pods to wear throughout the duration of the study that you will be allowed to keep upon completion of the study and receive instruction on personal usage after the study.
7. Be asked to provide an initial blood sample. The amount of blood to be drawn at each time point is approximately 20ml. These procedures will take approximately 15 minutes and can be performed by qualified medical staff. To draw the blood samples a needle will be inserted in your arm near the bend in your elbow.
8. Receive a graduated return-to-run program, a 4-week lower leg strength and flexibility program, and an activity log to track run progression and exercise progress.
9. Complete a five-minute run on an instrumented treadmill at your self-selected pace. Information about your running and movement patterns will be collected. You will be videotaped from the shoulders down.

10. Return at weeks 1-4, 6, 8 and every other week thereafter until the return to run program is complete for in-clinic running sessions and follow-up with a study provider.
11. Return at the completion of return to run program and 1 month after the completion of return to run program to complete a five-minute run on an instrumented treadmill at your self-selected pace. Information about your running and movement patterns will be collected.
12. Allow the study team to review your electronic medical records in AHLTA, the Surgery Scheduling System, CIITS, and AMS to classify your previous injuries appropriately and to determine if you sustain any type of new or repeat injury from running during the duration of the study. We may also use these electronic databases to determine if you develop medical conditions or subsequent joint injuries, such as osteoarthritis or cartilage tears in your knee, or if you have surgeries over the course of the study period.
13. Allow us to monitor your Milestone pod online account for the duration of the study to monitor usage of the devices to correlate with your running pattern at the completion of the study.

Testing for the concentration of the biomarkers in your blood samples will be performed in the biochemistry laboratory in the Department of Chemistry & Life Sciences at the USMA under the direction of Dr. J. Kenneth Wickiser. After these blood samples have been analyzed, any remaining samples will be securely stored in the Traumatic Joint Injury Tissue Repository in the Department of Chemistry & Life Sciences indefinitely, or until the PI and research team have determined that no further scientific benefit can be achieved from the stored samples. The samples collected and stored as part of this study will be used to address the specific goals of the current study and potentially in future studies.

This research study is a single blind study, which means that you will know whether you are in the standard return to run program or return to run group with individual technology-guided clinician-assisted feedback. Only the investigators who are recording your results and analyzing your results will not know what group you are in.

If you agree to participate in this study, samples we collect from you may be used for future research. The specifics of these research studies are unknown at this time, but these studies will frequently be in the area of ACL and other traumatic joint injury and osteoarthritis. For example, in future studies we may want to merge the outcomes of this study with other biomarkers studies at the Keller Army Community Hospital you may have consented to previously that have longer term follow-up (1 and 2 years post-ACL surgery). Another example would be we may want to evaluate changes in the levels of blood substances related to the condition of the cartilage inside your joints (biomarkers) at other time points following your ACL injury (e.g., 10 years), if existing samples are available. If you are in the control group and do not sustain any future major joint injury, we may want to compare your future samples to samples of those in the intervention group who also do not sustain any future major joint injury. You may also be contacted for participation in future studies using these samples if the aims of the future studies differ significantly from the purposes of this original study or the related purposes described here.

Your blood samples will primarily be used by researchers at Keller Army Hospital and the USMA; however, there may also be collaborative efforts with other universities, the government, private

companies, and other organizations within the Military Health System. Any collaborative efforts that use your blood or fluid samples will be governed by the Institutional Review Board (IRB).

7. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

The physical risks associated with participating in this study are minimal. There may be some discomfort from having your blood drawn, and you may have swelling or bruising at the site of the needle stick. There is also a slight risk of infection at the site where blood will be drawn. Some people may feel dizzy or light-headed for a few minutes after their blood is drawn. This procedure will take place at the Cadet Health Clinic or the Keller Army Hospital Laboratory using all standard of care precautions to minimize these risks. Samples will be drawn by the qualified laboratory staff.

If you choose to take part in this study, there is also a minimal risk of muscle soreness as you complete the return to run progression. This soreness typically resolves within 2-3 days. Additionally, you may also develop symptoms (to include pain, soreness, discomfort, etc.) at the location of your previous injury, or in a new location. If you experience symptoms at your previous injury location, or in a new location, that persists for longer than 72 hours, please follow-up with the medical provider (primary care provider, physical therapist, orthopaedic surgeon, etc.) who referred you to this study.

While every effort will be made to protect your identity and health information, there is a small risk of loss of privacy. Confidentiality of your health information is discussed below. In the unlikely event that there is a breach in confidentiality, there is a risk you could learn information about the inheritance of disease genes within families or regarding possible paternity determinations and this risk potentially extends to other members of your family.

While all possible risks that we know about have been listed above, other risks about which we do not know may occur or be discovered during future studies. If we find that there was a major risk to you that was not known at the time of your participation in the study, and the risk might have some effect on your health, you will be informed based on the following criteria: 1) findings emerge that pose a significant threat to the future health of the subject, 2) there is a high degree of accuracy in the data and methods used to predict that the threat will be realized, and 3) there is the possibility to take action that can avoid, ameliorate, or mitigate the potential injury or illness.

There may also be other risks of taking part in this study that we do not yet know about.

Overall, the investigators expect minimal risks.

8. ARE THERE BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

There is no guarantee that you will directly benefit from taking part in this study, but the information we gain may help us learn about early biological changes that may occur after ACL injury that are related to joint health and better ways to return individuals to run after ACLR. A possible benefit to you as a research participant in this research study is you may have the

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

opportunity to learn about your running form and possibly retrain your running pattern. Additional potential benefits include learning mobility and strengthening exercises for your core and lower extremities and receiving a Milestone Pod to use after the study to track and monitor your personal running information.

However, there is no guarantee that you will benefit from being in this research.

9. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research. If you choose not to participate in this research you will continue care with your medical provider (physical therapist or athletic trainer).

10. WILL YOU GET PAID FOR TAKING PART IN THIS RESEARCH STUDY?

You will be eligible for compensation for completing your study related blood draws at the pre-intervention timepoint, post-intervention timepoint and follow-up timepoint. You will be eligible to receive $25.00 for each blood draw. The total potential compensation for participants in this study is $75.00 for the three blood draws. There are no plans to pay you additional money if research done with your samples and information results in the development or sale of any product or technology.

You will not receive any compensation (payment) if you are injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the study investigator before you enroll in this study.

11. ARE THERE COSTS FOR TAKING PART IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

12. WHO IS THE STUDY SPONSOR? (

The study sponsor is the organization or people who oversee the study. They may also be responsible for analyzing any research study information. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoD Instruction 3216.02.

13. IS THERE A SOURCE OF FUNDING?

The Army Advanced Medical Technology Initiative (AAMTI)

14. WHAT IS THE LOCATION OF THE RESEARCH?

All research activities will take place at West Point, NY. Locations will include the Keller Army Community Hospital, Arvin Cadet Physical Development Center, Mologne Health Clinic Laboratory and Mahan Hall Treadmill Lab.

15. ARE THERE ANY DISCLOSURES OF FINANCIAL INTERESTS OR OTHER COMMERCIAL RELATIONSHIPS?

The research study team has no financial interests or commercial relationships related to this research study.

16. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The principal investigator will keep your research records. These records may be looked at by staff from the Keller Army Community Hospital, the Institutional Review Board (IRB; (a committee responsible for protecting research participants)), the DoD Higher Level Review, Human Research protections Office (HRPO) and other government agencies as part of their duties.

These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your research records may be disclosed outside of the hospital, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to authorized research study personnel.

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss. Procedures to protect the confidentiality of the data in this study include but are not limited to: coded data, removal of personal information, computer password protection and locking of drawers and offices.

There is a description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

17. WHAT KIND OF SPECIMENS WILL YOU PROVIDE AND HOW WILL THEY BE USED?

You will not receive any compensation (payment) should you be injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Injuries sometimes happen in research even when no one is at fault. Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you. There are no plans to pay you or give you other compensation for an injury, should one occur. Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations. If at any time you believe you have suffered an injury or illness as a result of participating in this research project, you should contact the Principal Investigator immediately at (845) 938 – 3067.

Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the principal investigator, Erin Miller at KACH at (845) 938-3067, erin.m.miller45.ctr@mail.mil or Ms. Lori Cartwright at (845-938, lori.d.cartwright.civ@mail.mil. For questions about your rights as a research subject, contact the privacy officer Kim Wiley at KACH at (845) 938-5033.

18. WILL YOUR INFORMATION OR SPECIMENS BE USED IN THE FUTURE?

During this research study, you will be asked to provide the following types of samples (biological specimens): Blood. De-identified information or biospecimens may or may not be used or shared for future research.

While this study is on-going, your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory: biochemistry laboratory in the Department of Chemistry & Life Sciences at the USMA under the direction of Dr. J. Kenneth Wickiser.

Future Use of Biologic Specimens: The investigators have requested to save selected data collected from your participation in this research study for possible use in future research. You will have a choice to allow us to use your specimens for future research at the end of this form.

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 will frequently be in the area of ACL and other traumatic joint injury and osteoarthritis. For example, in future studies we may want to merge the outcomes of this study with other biomarkers studies at the Keller Army Community Hospital you may have consented to previously that have longer term follow-up (1 and 2 years post-ACL surgery).

Your blood samples will primarily be used by researchers at Keller Army Hospital and the USMA; however, there may also be collaborative efforts with other universities, the government, private companies, and other organizations within the Military Health System. Any collaborative efforts that use your blood or fluid samples will be governed by the Institutional Review Board (IRB).

Your samples would be stored with the following information: a unique study identifier. This is considered not identifying information and cannot be traced back to you as the donor. The current and future research will not include whole genome sequencing.

You may request that your specimen be withdrawn from storage at any time if you decide you no longer want to participate. This can be done by notifying the PI who's information is included throughout this consent form.

HIPAA AUTHORIZATION

I. Purpose

An Authorization is your signed permission to use or reveal your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or reveal your health information with a valid Authorization. The 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.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

The purpose of this study is to determine if military service members recovering from Anterior Cruciate Ligament Reconstruction or revision benefit from running gait retraining when compared to a traditional walk to run program. Our military service members are at greater risk of ACL injury, greater risk of early onset knee osteoarthritis and are required to maintain high levels of fitness to remain in the military. It is therefore clinically important to identify interventions to decrease loads and forces at the knee in military service members returning to run after ACLR or revision.

A. What health information will be used or disclosed?

If you choose to participate in this study the following health information will be collected;

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

previous injury history, lower-body injuries sustained over the period of the study, blood biomarkers representative of joint changes, and information about your pain and function with running. This information will be protected. If you decide to participate in this study, you will be assigned a number from 1-40 upon entrance into the study and subsequently given consent forms and data collection forms with the corresponding number. A master spreadsheet document linking subject names and their subject numbers will be kept secure on a government computer assigned to the PI. The computer is password and CAC-card protected, and the system is firewall protected. This document will not be shown to anyone except for the investigators in this study or governmental agencies only in accordance with federal law.

Any data submitted to an approved agency for review will be linked only to your study number and not your personal identity (i.e., protected health information such as name, DOD ID, 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. Subjects will not be specifically identified in any publication or presentation of research results.

No identifiable information will be obtained during this study such as home address, or phone number.

B. Who will be authorized to use or disclose (release) your health information?

The Military Health System (MHS) will use or disclose the participant's health information, including the Armed Forces Health Longitudinal Technology Application (AHLTA) and Cadet Injury and Illness Tracking system (CIITS). Information will be obtained at Keller Army Community Hospital (KACH) Physical Therapy department, Arvin Gym Physical Therapy Clinic, and/or Mahan Hall.

C. Who may receive your health information

Only researchers involved in this specific study will have access to your health information.

D. What if you decide not to sign this Authorization?

The MHS **will not** refuse treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

Yes, your health information *is* requested for future research studies.

F. Can you access your health information during the study?

You may have access to your health information at any time unless your identifiers are permanently removed from the data.

To maintain the integrity of this research study, you will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you will have access to your health information that the MHS maintains in a designated record set. A designated record set means a set of data that includes health information or billing records used in whole or in part by your health care providers at the MHS to make decisions about you. If it is necessary for your care, your health information

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

will be provided to you or your health care providers.

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you take back this authorization?

- You may change your mind and take back your Authorization at any time. However, if you take back this Authorization, any person listed above may still use or share any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you take back this Authorization, you may no longer be allowed to take part in this research study.
- If you want to take back your Authorization, you must write to: Erin Miller at erin.m.miller45.ctr@mail.mil

H. Does this Authorization expire?

Yes, it expires at the end of the research study.

I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you
- If all the information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or shared for other purposes
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

19. WHAT HAPPENS IF THE RESEARCHERS SEE AN INCINDENTAL FINDING?

Based on the outcomes collected in this study the researchers see no feasible possibility that while reviewing your test results we may see an abnormality that we did not expect. This is what is called an "incidental finding."

They will let you know if they see such an incidental finding. Depending on the type of incidental finding, they may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

20. WHAT HAPPENS IF YOU WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should contact the principal investigator Erin Miller as soon as possible (845-987-0029). By leaving this study at any time, you in no way risk losing your right to medical care and there will

be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your referring physical therapist to discuss medical treatment for your condition. Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

21. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

You will not receive any compensation (payment) should you be injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Injuries sometimes happen in research even when no one is at fault. Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you. There are no plans to pay you or give you other compensation for an injury, should one occur. Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations. If at any time you believe you have suffered an injury or illness as a result of participating in this research project, you should contact the Principal Investigator immediately at (845) 938 – 3067.

Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the principal investigator, Erin Miller at KACH at (845) 938-3067, erin.m.miller45.ctr@mail.mil or Ms. Lori Cartwright at (845-938, lori.d.cartwright.civ@mail.mil. For questions about your rights as a research subject, contact the privacy officer Kim Wiley at KACH at (845) 938-5033.

22. WHO DO YOU CONTACT IF YOU HAVE QUESTIONS?

Principal Investigator (PI)
The Principal Investigator or a member of the research study team will be available to answer any questions throughout this study.

Principal Investigator: Mrs. Erin Miller
Phone: (845) 938-3067
Mailing Address: 900 Washington Rd., West Point, NY 10996
Department: Baylor University - KACH D1 Sports PT Fellowship

Clinical Research Coordinator: Mrs. Erin Miller (the PI is the Clinical Research Coordinator)
Phone: (845) 938-3067Mailing Address: 900 Washington Rd., West Point, NY 10996
Department: Baylor University - KACH D1 Sports PT Fellowship

Keller Army Community Hospital Human Research Protection Program (HRPP) Office
The Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator: Lori Cartwright
Phone: 845-938-2680
Email: lori.d.cartwright.civ@mail.mil

KACH Privacy Officer: Ms. Khim Wiley
Phone: 845-938-5033
Email: khim.m.wiley.civ@mail.mil
Mailing Address: 900 Washington Rd., West Point, NY 10996

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, you can contact the office of the committee responsible for ensuring research participant protection, the Institutional Review Board (IRB).

Naval Medical Center Portsmouth
620 John Paul Jones Circle
ATTN: CID
Portsmouth, VA 23708
(757) 953-5939
usn.hampton-roads.navhospporsva.list.nmcp-irboffice@mail.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE RESEARCHER BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL DOCTOR OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

23. FUTURE USE OF INFORMATION AND/OR SPECIMENS:

Please initial the sentences that reflect your choices:

Your health information will not be used for future research studies unless you give your permission by initialing your choice below:

_____I *do not* give permission to use my health information for future research studies.

_____I give permission to use my health information for future research studies.

_____I *do not* authorize the storage of data collected as a part of this study for future use in research studies.

_____I authorize the storage of data collected as a part of this study for future use in research studies.

With regard to future research studies done on stored data that has a link to my personal identity.

_____I *do not* wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that my current principal investigator may use any appropriate identifier to locate me in the future.

Please initial the sentences that reflect your choices:

_____I *do not* authorize the storage of my biological specimens for future use in research studies.

_____I authorize the storage of my biological specimens for future use in research studies.

With regard to future research studies done on my biological specimens kept at the storage bank:

_____I *do not* wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that the investigators conducting this study may use my DOD ID number to locate me in the future.

DoD
IRB NUMBER: RHC-A-19-029
IRB APPROVAL DATE: 11/30/2020
IRB EXPIRATION DATE: 11/01/2021

24. SIGNATURES

SIGNATURE OF PARTICIPANT

Your signature below indicates that:

- You authorize the Military Health System to use and reveal your health information for the research purposes stated above;
- You have read (or someone has read to you) the information in this consent including the HIPAA Authorization;
- You agree that you have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to you. You have been provided with the opportunity to ask questions
- You voluntarily consent to take part in this research study.

By signing this form, I have not given up any of my legal rights as a research participant.

Printed Name of Participant

Signature of Participant | Date (DDMMMYYYY)

SIGNATURE OF INDIVIDUAL ADMINSTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

Printed Name of Administering Individual

Signature of Administering Individual | Date (DDMMMYYYY)