

CONSENTING SCRIPT:

Firstly, I want to thank you for volunteering to be a part of this study. Today we're going to go through the consent process and form. Your participation is completely voluntary and not command directed. If at any time you decide not to participate, you can withdraw without any consequences for your medical care or duty responsibilities. This form talks about our responsibilities as researchers and your rights as a participant and is required for any research study. If you decide to take part, we will both sign this document, but I want to be sure you understand all sections of the form. I'll give you a copy of the form to take with you.

We are will have 2 groups of service members in this study, half of which who've had a concussion, like yourself, and the other half which are considered "healthy controls", for a total of 50 participants. We are studying the use of heart rate variability during exercise and recovery in the time period immediately following a concussion. Our hope is to use the heart rate measures and self-report of symptoms measures during exercise tasks to make return to duty decisions.

During your session you will answer a short survey with questions about your military, deployment, and medical history, and about your current symptoms. You will participate in two short exercise tasks, a stepping task and a push-up task. We will be recording your heart rate using a Polar H10 strap monitor around your chest. The total length of time of this study will be ~45 minutes at the Intrepid Spirit Center.

During the exercise tasks your symptoms could increase, but we have safety guidelines to stop if this occurs, or you may make your own decision to stop at any time. As stated on page 3 of the consent form, there is a risk of possibly tripping or falling during the stepping task, or experiencing discomfort, shortness of breath, dizziness, or a faint feeling. Additionally, you could experience anxiety or frustration if you have difficulty completing or performing the task. We will be monitoring your symptoms and exertion to ensure your safety, and you are free to stop at any time if you choose to. While efforts are made to protect your research study records, there is always a small risk that someone could access information in your medical records, but we safeguard against this by using password protected files and storage of forms in a locked area. Once we record your data, we assign you with a specific study ID and your data is stored with that study ID number, without any way to identify you personally. Research results are only shared in a de-identified way, so we report on how all those with concussion responded together, making it impossible for your individual information to be known.

While there are not any direct benefits for participating in this study, the information learned could help improve the way we take care of service members in the future after concussion.

Have you heard of HIPAA? (federal law that requires the creation of national standards to protect patient health info) We follow the same standard HIPAA guidelines as providers related to your health information. Your HIPAA authorization will allow us to access your medical history for the purpose of collecting details about your concussion. No other health information will be accessed. No one outside of the Military Health System or research regulatory bodies will have access to your health information. You may change your mind and take back your authorization at any time, you would just need to let us know in writing if that is the case. If you revoke authorization we may still use or disclose any already obtained health information to maintain the integrity of the research. The authorization will expire at the end of this research study and no publication or presentation about this research would reveal your identity without another signed authorization from you.

If we see anything unusual when reviewing your test results, we may contact you by phone and give this information to your primary doctor or refer you to an appropriate doctor for further evaluation.

As mentioned earlier, you can withdraw your participation in this study at any time. If you decide to discontinue with this study, you can tell any study team member. If you have already completed the session protocol and you decide not to continue with the study, you need to notify the principal investigator in writing that you want to completely withdraw your data.

In the event that a research-related injury occurs you won't incur additional medical costs since you are a DoD healthcare beneficiary.

Do you have any questions? You can take as much time as you'd like to review this form. Please feel free to ask any questions at any point throughout the study. In section 22 we have included contact information for members of the research staff.

On the 2nd to last page of the consent form there is a place where we'd like you to initial about the future use of your information and specimens. You will not be asked to provide any biological specimens, only recordings of your heart rate. If this data is used in future research studies, it will be de-identified and only linked to your study ID.

On the last page you will sign your name here. But before you do so, do you have any questions? If you don't have questions at the moment but any come up later, you can always ask!

Testing will not occur today since you have symptoms, but we'll be in touch about your symptoms (show them the symptoms scale) with daily check ins and once they have improved, we will schedule a time for the exercise testing to make sure we are safe. For now, you should follow the guidance you got from the provider you saw this morning.