Injuries in an Extreme Conditioning Program: A Prospective Surveillance Study

**Sponsor:** The American Sports Medicine Institute  
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**Investigator:** Kyle Aune, MPH  
**Sub-Investigator:** Brett Ivey, CS, CSCS

You are being asked to take part in a research study. Your participation is voluntary.

**Why is the study being done and what does it involve?**  
Extreme conditioning programs (ECPs) such as Iron Tribe Fitness™ (ITF) and CrossFit® have become increasingly popular in the last few years. As with all physical activities, some people do get injured while taking part in ECPs. However, the type of injuries and rate of injuries have not been adequately studied. The researchers at the American Sports Medicine Institute (ASMI) would like to follow up to 500 ECP participants for one year to determine the rate and type of injuries that occur.

If you choose to take part in this study, you will be asked to complete a baseline survey on SurveyMonkey, an online survey company. The survey will ask questions about your training, medical, and injury history. It will take approximately 10 minutes to complete the survey. You will then be asked to complete a monthly survey on SurveyMonkey for the next twelve (12) months. You will receive an email on the 15th of each month from the researchers with a link to the online survey. Each survey will ask you if you have developed an injury during the prior month. If you don't respond within 7 days, you will receive a reminder email. If you have not had an injury in the past month it will take less than five minutes to complete the survey. If you have experienced an injury it may take up to 15-20 minutes to complete the survey. Each survey will allow you the option to choose not to answer a question. You will also have the option to not submit a survey. However, once you submit your answers to the survey, you will not be able to withdraw your responses.

The researchers will also collect information from ITF each month regarding the frequency and intensity of your fitness regimen.

**Are there any costs related to this study and will I be paid to take part in this study?**  
There is no cost to you for taking part in this study. You will not be paid to participate in this study.

**Are there any benefits or risks to participating in this study?**  
You will not receive any direct benefits from taking part in this study. However, the knowledge gained from this study may help ECP athletes, trainers, and healthcare providers develop ways to identify, treat, and prevent injuries.
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

How will my privacy be protected and my information kept confidential?
The American Sports Medicine Institute (ASMI) is a part of St. Vincent’s Health System which has mechanisms in place to protect your privacy and confidentiality. Identifiable health information is called Protected Health Information (PHI) which is protected by the Privacy Rule (HIPAA). By agreeing to participate in this study, you also are authorizing the use and disclosure of this information as described below.

The researchers will collect the following PHI through the online surveys: your date of birth, your health history, your current medications and information about any injuries resulting from taking part in an ECP. The researchers will use this information to identify risks factors for injury such as age, general physical condition and length of time taking part in an ECP.

The answers you provide to the surveys will be stored on secure servers at SurveyMonkey using security safeguards that are compliant with HIPAA law. The information will be sent to the ASMI through an electronically secure, encrypted connection (the same security used for online banking). The information will be stored in an electronic, secure database on a password-protected computer at ASMI. Once the results of the study have been analyzed, all individual participant identifiers will be destroyed.

Iron Tribe will know which of their members are taking part in this research study so they may provide researchers with your workout history. However, Iron Tribe Fitness will not have access to or be provided the results of your individual survey responses. Your information will be combined with that of other participants to provide an overview of the types of injuries and the pattern of injuries in extreme conditioning programs. This combined information may be shared with Iron Tribe or be published in medical or professional journals about sports medicine.

The individual health information you provide will not be shared outside of the research team. It is possible that your information may be reviewed by the STVHS Institutional Review Board and its staff or outside regulatory agencies as a part of their routine audit procedures. However, if your PHI is shared with someone outside of ASMI/St. Vincent’s Health System or if you choose to share this information with others outside of this study, your health information may no longer be protected by HIPAA.

You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Your authorization for the uses and disclosures described above does not have an expiration date. You may cancel this Authorization at any time by notifying Kyle Aune in writing, referencing the Research Protocol. If you cancel this Authorization, the research staff will not use any new health information for
research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

**Can I stop participating in this study?**
You may choose to stop your participation in this study at any time by contacting the researchers using the contact information listed in this document, or clicking the “opt out” link in the emails you receive. Your decision to stop your participation will have no effect on your training with Iron Tribe Fitness, your relationship with the coaches, trainers, and management at Iron Tribe Fitness, or your standing with Andrews Sports Medicine, the American Sports Medicine Institute, or our medical partners.

**Who should you call with question(s) about this study?**
Kyle Aune, MPH or Brett Ivey, BS, CSCS will answer any questions you have about this study. These individuals are available to answer your questions before, during, and after the study. They can be contacted at:

Kyle Aune, MPH  
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Brett Ivey, BS, CSCS  
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If you have any questions about your rights as a research participant, contact:

Melissa Holloway  
St. Vincent’s East Institutional Review Board  
50 Medical Park East Drive  
Birmingham, Alabama 35235  
(205) 838-3170

**Consent to Participate and Authorization to Use and Disclose Protected Health Information**

I have read this consent document before accessing and completing any surveys or questionnaires. I have had the opportunity to contact the researchers to ask questions. I authorize the use and disclosure of my protected health information as outlined in this form. My consent to participate in this research study has been given freely and willingly. I confirm that I am 19 years of age or older.

By choosing to proceed with the survey provided to you by the researchers, you state your agreement with the above statement.