Issue Two: Summer 2022

NCAA•DOD Grand Alliance CARE Consortium

The CARE Consortium Newsletter

Thank you for participating in the CARE Consortium Studies

As a student-athlete or military service academy cadet/midshipman, you played a vitally important role in the CARE Consortium research study – the largest of its kind to examine the short- and long-term effects of concussion.

Over the coming months and during the five-year study cycle (2021-2026), you may receive an email, text message or telephone call from our research team inviting you to participate in the next phase of the study, the CARE- SALTOS Integrated (CSI) Study. Your participation is vital in this continued effort to study the long-term effects of concussion and repetitive head impact exposures.

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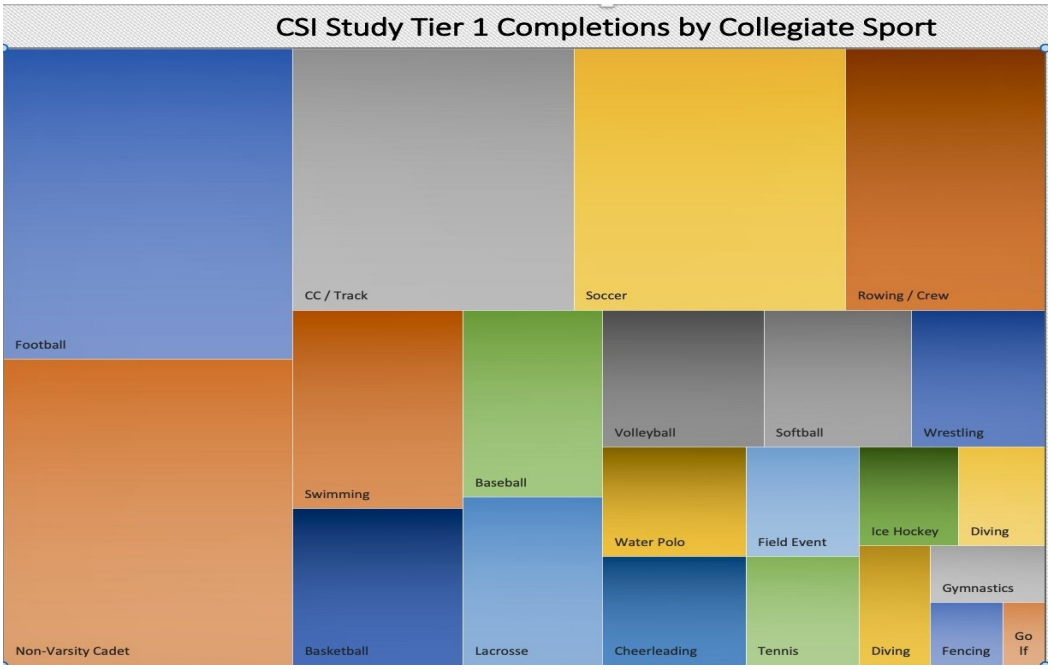
CSI Biennial Online Assessments Underway



In the Fall of 2021, the CARE Consortium was selected as the recipient of a $25M award from the Medical Technology Enterprise Consortium (MTEC) to be used in combination with a $10M award from the NCAA and $7.65M from the Defense Health Agency to support research following up with former civilian and military participants from the initial CARE Consortium Study. This new five- year project, entitled the CARE-SALTOS Integrated (CSI) Study, involves both fully remote biennial study questionnaires, as well as comprehensive in-person study visits for a select subset of eligible participants.

For the remote portion of CSI, also referred to as Tier 1, you may be contacted by email, text message, or by a University of Michigan survey research operations (SRO) specialist, inviting you to complete the study questionnaires either online or over the telephone. If you choose to complete the study online, you will be able to access the secure CSI study portal 24/7 at your convenience. We would like you to complete the online study questionnaires twice in the five-year study period and will be compensated for each of the two Tier 1, CSI completions.

Recruitment calls, emails, and text messages began in March, 2022 and we have had an overwhelming response to the invitations to participate. At the time of print for this newsletter we already have over 2000 former CARE study civilian and military participants enroll in the CSI Study and we hope you will join your friends, colleagues, and peers by participating!

Study related questions? Email us: carealumni@umich.edu

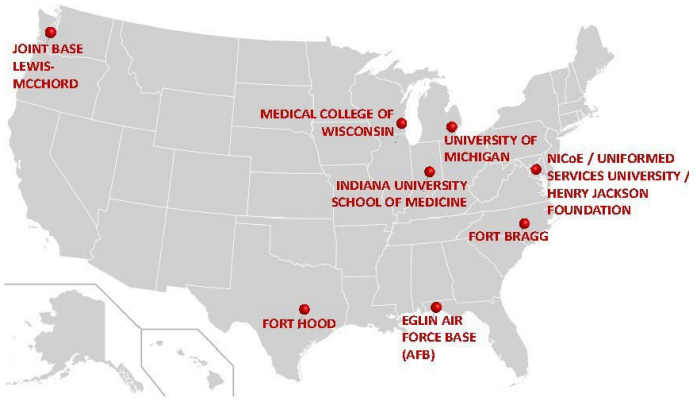
CARE Website, Publications, and Resources

Please visit our newly designed CARE Consortium website (www.CAREConsortium.net) for more information about the CARE Consortium studies and links to beneficial physical and mental health resources for participants and families.

For those interested in reading further, the CARE Consortium website offers active links to many of the over 80 scientific publications authored by CARE Consortium investigators. *www.CAREConsortium.net >> Resources >> Publications*

CSI In-Person Study Visits Begin

Exciting work has been going on behind the scenes in preparation for the launch of the in-person portion of CSI, also referred to as Tier 2! Over the next 5 years, Tier 2 will target 2,000 former undergraduate civilian and military participants from CARE to travel to in-person sites around the country.



Former civilian NCAA athletes will be recruited to participate in Tier 2 visits at either the Medical College of Wisconsin (MCW; Milwaukee, WI) or Indiana University School of Medicine (IU; Indianapolis, IN). The Medical College of Wisconsin served as the coordinating center of the ARC (Advanced Research Core) arm of CARE, while Indiana University acted as the Administrative Operations Core (AOC).

Former military cadets and active duty service members will be recruited by one of four military sites: National Intrepid Center of Excellence (NICoE; Bethesda, MD), or one of the Intrepid Spirit Centers (ISC) at Ft. Hood (Ft. Hood, TX), Ft. Bragg (Fort Bragg, NC), or Joint Base Lewis-McChord (JBLM; Tacoma, WA). These 2,000 individuals will consist of two groups of former participants – one group that sustained a concussion and were exposed to a lot of additional head impacts, and one group with no history of a concussion and low head impact exposure during their participation in CARE.

In-person visits involve a full day of surveys, neuropsychological testing, a blood draw, and an MRI scan in order to determine whether there are any long-term effects of concussion and repetitive head impact exposure. Recruitment calls began in late May to establish eligibility, with a targeted date of early June for the first in-person visits. Participants will be reimbursed for travel expenses and will also receive a stipend for completing the in-person visit.

Naval School Explosive Ordnance Disposal (EOD) Joins CSI

As part of the CSI project, we will be enrolling a new cohort of military service members at Naval School Explosive Ordnance Disposal (NAVSCOLEOD), located at Eglin Air Force Base, Florida.

Participants in the CSI EOD cohort will undergo an in-person, baseline research evaluation, including surveys, neuropsychological testing, and a blood draw. Participants will then become eligible to participate in additional CSI studies in the future, including the biennial online assessments (Tier 1) and the in-person comprehensive assessments (Tier 2).

The EOD Cohort study is designed to offer the same opportunity to NAVSCOLEOD affiliates that has been previously offered to cadets/midshipmen at the military service academies, with the purpose of allowing further exploration regarding the differences between blast versus blunt brain injury/exposure. The addition of this cohort will also allow comparisons among enlisted personnel, officers, and civilian athletes.

We expect to start enrolling the EOD Cohort in summer of 2022.

Tier 3: An Integrated Data Repository

A larger goal of the CSI effort is to characterize and understand the relationship between concussion/repetitive head impact exposure, military performance, and long-range health outcomes. The military health record integration project, also known as Tier 3, will address this goal by linking information from electronic health records and existing CARE datasets to create an integrated data repository.

Military participants who elect to join the Tier 3 portion of the study will share their military medical record information for the purpose of assessing the intermediate and long-term effects of concussion/repetitive head impact exposure on health, performance, and quality of life related outcomes.

These data will allow for integrated, multivariate analyses and more detailed characterization of the effects of head impact exposure.

Uniformed Services University (USU) is partnering with Enterprise Intelligence and Data Solutions (EIDS) at the Defense Health Agency (DHA) to construct the data repository for Tier 3. This project is currently in development.

Military participants from any of the CSI Tiers (Tier 1, Tier 2, Eglin EOD) will be invited to participate in Tier 3.

Data Protections and Security

Data security and maintaining your confidentiality are of utmost importance to our study team. The CARE/CSI study data application is HIPAA compliant and complies with Federal (HIPAA), State, and JCAHO health information standards for data integrity, confidentiality, auditing, and availability. All CARE/CSI study data is encrypted in transit and the systems are secured by software firewalls on the specific servers. Only select study team members, on an as-needed basis, have permissions to access identifiable study data.

CARE/CSI study data is further protected by a Certificate of Confidentiality (CoC) which provides formal protection for sensitive research data permanently, even after death. Sensitive data includes information that may cause perceivable damage to someone if revealed to persons not entitled to it. Sensitive information includes, but is not limited to, information related to sexual preferences, attitudes, and experiences; use of alcohol, drugs and other substances; information about an individual's emotional and psychological health; and genetic information, including biological samples. For more information on CoC FAQs, please visit: https://www.cdc.gov/os/integrity/confidentiality/faq_confidentiality.htm

Participants who complete the online (Tier 1) CSI surveys while located in the European Union (EU) are also protected by the General Data Protection Regulation (GDPR) that went into effect May 25, 2018. GDPR is a European Law that requires organizations to safeguard the personal data and privacy rights of anyone in EU territory. The CSI study is responsible for controlling and securing personal data following consent, and is in compliance with these regulations. For more information on GDPR, please visit: www.gdpr.eu.

Thank you!

On behalf of the CARE Consortium Principal Investigators and study teams, we would like to thank you for your continued participation in this very important study. Your contribution will inform policy aimed at improving the health and safety of athletes and military service members.

If you have study specific questions, you may email us at carealumni@umich.edu and we will respond to you within 48 hours.

Meet the Survey Research Operations (SRO) Data Collection Team

Survey Research Operations (SRO) is the data collection unit within the Survey Research Center at the Institute for Social Research, University of Michigan. SRO provides a wide range of survey design, data collection and data processing services to both internal and external research clients. SRO conducts cross-national, national, regional, and methodological surveys. SRO also provides consultation and project management for international and multi-national research projects. SRO has the infrastructure, capability, and experience to conduct surveys in multiple, mixed, and sequential modes. These modes include in-person, telephone, mail, web, Interactive Voice Response (IVR), text messaging, and video-mediated surveys.

SRO maintains an experienced field management team made up of production managers and team leaders. They are responsible for hiring, training and supervising interviewers, implementing a wide variety of survey designs, quality control activities in the field, as well as for validation activities and monitoring interviewers' weekly progress and cost reports. SRO maintains an active national field staff that has numbered as many as 1000 interviewers – with the capability to expand to meet project demands. SRO interviewers are well-educated, experienced, and represent the diversity of over 140 areas in which they work. SRO also retains a bilingual interviewing staff in areas of high concentrations of non-English speaking households, and is able to hire specialized interviewers to meet specific project needs.

SRO operates a state-of-the-art telephone facility which has been conducting Computer-Assisted Telephone Interview (CATI) surveys since 1975. The computer-assisted interviewing (CAI) software and physical facilities are regularly updated to ensure the highest possible quality for all national, regional and local projects. Samples of interviews are monitored, and interviewers are evaluated on interviewing technique (question reading, probing, data recording, etc.) as well as on qualitative factors (pace, clarity, and tone, etc.). The CARE Consortium is proud to partner with University of Michigan SRO data collection team for the CSI Study.