INSTITUTIONAL REVIEW BOARD GUIDE FOR THE NCAA STUDENT-ATHLETE HEALTH AND WELLNESS STUDY

Dear Faculty Athletics Representative:

The purpose of an institutional review board (IRB) is to ensure that the rights and welfare of human participants involved in proposed research are adequately protected. IRBs have the right to approve, disapprove or require modification of all research involving students on their campus. While the NCAA has received approval from its own Research Review Board (RRB), a national external board consisting of faculty and community representatives, it is important that you consult with your campus IRB to determine whether additional approval is required to carry out this research on your campus.

The NCAA's full RRB materials and approval letter are included in an accompanying document. However, in order to make the IRB process at your school as simple as possible as you administer this study on behalf of the NCAA, we have also included summary information below that may be of use in answering questions posed to you directly by your campus IRB.

Please contact Kelsey Gurganus-Wright at kgurganus@ncaa.org or 317-917-6566 if you have any questions or would like assistance in completing your IRB application.

Note that it is possible your local IRB will require changes to the standard study administration procedures as a condition for conducting the study on your campus. If this is the case, please contact Michael Miranda, NCAA Research Review Board administrator, at michael.miranda@zoho.com or 317-917-6409 who will work with you in implementing such changes. In most instances, study procedures can be modified in ways that will meet the requirements of a particular IRB while maintaining the integrity of the study's research methodology.

Project Information

Project Title:

2022-23 NCAA Student-Athlete Health and Wellness Study.

Project Dates:

Start Date (7-1-2022); End Date (6-30-2023).

Number of Participants:

Previous large-scale NCAA student-athlete studies have included data from approximately 20,000 student-athletes surveyed at over 600 NCAA member institutions. We anticipate a similar number of respondents in the 2022-23 study.

Project Description/Purpose:

The 2022-23 NCAA Student-Athlete Health and Wellness Study will provide NCAA policymakers and member institutions with detailed information on the health and wellness of student-athletes. The survey consists of eight brief sections. Student-athletes will be asked about their mental health

concerns and peer support, sleep behaviors, attitudes toward their weight and body image, nutrition, competition and injury history, and substance use experiences. This information will be used to assess trends and design appropriate educational initiatives for student-athlete well-being.

Project History:

This is a new comprehensive health and wellness study that subsumes many of the survey items from the NCAA Substance Use Study and incorporates a range of well-being items previously used in other NCAA RRB-approved survey instruments (e.g., NCAA GOALS, Social Environments, Well-Being).

Prior NCAA RRB Approval:

The study commenced July 1, 2022, after it was approved by the RRB. The RRB is an external body composed of seven non-staff members who represent individual colleges/universities or the community and follows policies and procedures similar to a campus IRB. The RRB is assisted by an independent consultant who works with RRB members to communicate their decisions and concerns back to relevant NCAA staff and member institution representatives.

Federal-wide Assurance:

The NCAA is registered with the U. S. Health and Human Services Department, Office of Human Research Protections (IORG #0007717). The NCAA RRB is a registered IRB (IRB #00009263). The Federal-wide Assurance number is 00020028. Institutions interested in pursuing IRB Authorization Agreements are encouraged to contact Michael Miranda, NCAA Research Review Board administrator, at 317-917-6409 or michael.miranda@zoho.com.

Scientific or Academic Merit of Current Study:

Considerable care has gone into designing a study, survey instrument and sampling protocol that will lead to unbiased, generalizable results. From a sampling perspective, we attempt to minimize bias via strict stratified random sampling of teams, comparison of obtained demographic profiles of the sample versus known demographics of the student-athlete population and subsequent (as necessary) weighting of individual responses to create aggregate estimates that are likely to best represent the behavior of the national student-athlete population.

Instruments:

The only instrument in this study will be a survey taken by the participating student-athletes. The paper survey consists of eight sections: (1) demographics, (2) mental health and peer support, (3) sleep, (4) weight, body image and nutrition, (5) competition and injury, (6) alcohol, tobacco and other drug use, (7) supplements, and (8) support. Most survey items have been used in previous studies and were either derived from standard scales or specifically designed for this study by subject matter experts.

Testing of the survey indicates that it typically takes about 30 minutes to complete.

The survey will be administered anonymously. No attempt will be made by the researchers to tie individual responses to particular individuals or institutions.

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Study Administration:

After the sample for the current study was determined by NCAA staff, an email was sent to the faculty athletics representative (FAR) at each NCAA member institution. The email solicited the FAR's participation in conducting the study and identified the athletics teams that the institution is being asked to survey. Detailed study materials are provided to each FAR that highlight appropriate study protocols for producing scientifically useful data and protecting the well-being of student-athlete participants.

Survey Administration:

To best ensure that student-athlete and institution anonymity are maintained, the survey will be administered in paper form only. Detailed instructions for administration of the survey will be provided to the FAR, this includes a script that the FAR will read aloud to the student-athlete participants about the study, their voluntary participation, and how materials will be handled. These instructions, and the instructions that are printed on the survey form, will make it clear to the student-athletes that their participation in this study is completely voluntary and that their responses will be totally anonymous. The FAR will be instructed to give the survey to all members of a particular team on the same occasion in a classroom-type proctored setting. All staff from the athletics department (e.g., coaches, trainers, etc.) will be asked to leave the room before the survey is distributed. The FAR will be provided with a pre-addressed, pre-paid envelope into which student-athletes are to deposit surveys on completion. The last student-athlete to complete the survey will be asked to seal the envelope in the FAR's presence and see that it is ready to send to the third-party vendor that will scan the survey forms and create a national database for analysis. After verification of the data entry, the paper surveys and any survey images will be destroyed. The resulting database will have no student or school identifying information.

Other Frequently Asked Questions

Describe the setting in which the research will be conducted.

It is suggested that the research take place in a classroom setting. The FAR on each campus is asked to administer the survey to the student-athletes. All staff from the athletics department (e.g., coaches, trainers, etc.) will leave the room before the survey is distributed. The FAR will read the attached scripted statement to the student-athletes detailing the purpose of the study and the directions for completion of the survey. All student-athletes who are not yet 18 years of age (or the age of consent in the state the institution is located) will be excused from further participation and asked to leave the room.

Is this a collaborative project?

Yes. All 1,100+ schools participating in NCAA athletics are asked to participate. In studies conducted previously using similar methods, institutional response rates have tended to be 50-70 percent. The NCAA takes the lead in IRB review, but each FAR must submit to their campus IRB as required.

Please explain how you intend to manage information obtained in multi-site research that could be relevant to the protection of research participants, such as reporting unanticipated problems involving risks to participants or others

In addition to reporting any unanticipated problems to their own campus IRBs, the survey administrators are instructed to also report any such incidents to the NCAA RRB. This will allow the NCAA RRB to track and correct unanticipated problems should they occur.

Sampling

Explain your recruitment process and enrollment procedures.

All active member institutions of the NCAA will be asked to participate and a sample of the student-athletes at each institution will be surveyed. This sampling plan was devised to achieve an appropriate representation of all NCAA student-athletes while minimizing the burden to institutions by asking that all student-athletes on not more than three teams be surveyed on any campus. The teams surveyed will be determined by a computer-generated random draw that is stratified by sport and NCAA competitive division. Schools may opt to replace teams only with the assistance of NCAA research staff. The NCAA does its best to ensure that teams that have been recently sampled in other FAR-administered studies are not sampled again in this study.

The FAR will contact the coach and/or athletics department to arrange a time and place to administer the survey to all student-athletes on the sampled teams.

Participants

Will the subject's identity remain anonymous, confidential or other?

The identity of specific schools, teams and student participants will be anonymous. That is, no identifying information is collected that could identify a school or an individual student-athlete participant. All results from this study will be reported in aggregate and in terms of national and subgroup (for example, sport, division, race/ethnicity, etc.) averages and trends. The identity of a particular school, team or student will not be known at any point by the researchers.

Does your research involve an investigation into legal matters, illegal activities, admissions of guilt, breaches of duties or noncompliant matters?

Possibly, as some questions deal with various activities (e.g., illicit drug use) that may be illegal in some jurisdictions. Additionally, some of the questions relate to behaviors that may violate NCAA regulations.

Describe the informed consent process in detail.

The participants will be read instructions that will make clear that they are consenting to participate by filling out the survey. The instructions on the survey also state that, by filling out the survey they are consenting to be a participant. A waiver of documentation of consent has been approved by the NCAA RRB.

Do you intend to obtain a Certificate of Confidentiality? No.

Please explain how you intend to protect the privacy interests of participants during the research.

We have attempted to be sensitive to these issues in designing the suggested procedures for administering and collecting the survey forms. Only the participant will handle their own completed survey form until it is deposited and sealed in the return envelope that goes to the third-party data entry vendor.

Please explain how you intend to protect the privacy interests of participants after their involvement in the research.

Once the data are entered and checked, survey forms and any resulting images will be destroyed. Only NCAA researchers will have access to the database, but even that file will contain no identifying information. Any data shared with researchers outside of the NCAA will be completely unidentifiable at the individual or school level. Only aggregate information will be published.

Describe the procedure(s) in place for research participants to ask questions and voice concerns or complaints to the research investigator(s).

Participants can report concerns or ask questions to the on-campus survey administrator, to NCAA researchers or to the NCAA RRB administrator. Contact information is provided on the first page of the paper survey and on the informational handout sheet.

How do you intend to minimize the risks to the subjects?

In the event that any questions asked are disturbing to the student-athlete, they may stop responding to the survey at any time. Student-athletes who experience discomfort will be encouraged to contact their college student-health offices or one of the national hotlines listed on a contact sheet distributed at each site. The survey administrator is being instructed to provide information on local mental health resources at the beginning of the survey administration.

The questions contained in this survey are generally not expected to cause psychological discomfort or pose more than minimal risk. The primary risk in this study relates to possible violation of student-athlete anonymity if survey administration procedures are not followed as designed. This risk is minimized if on-campus survey administrators adhere to study protocols.

What benefits to society may result from this research?

The 2022-23 NCAA Student-Athlete Health and Wellness Study will provide NCAA policymakers and member institutions with detailed information on several health and wellness topics of interest within the college athletics community. Issues around mental health, bystander intervention, sleep behaviors, weight management, nutrition, injuries, and substance use are important to understand because prior research has shown that student-athletes are prone to certain attitudes and behaviors that could impact their well-being, their eligibility for athletics competition and the integrity of the sports they play. Currently, there are open questions about how to best design education/intervention programs that are optimal for student-athletes. It is hoped that the results

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of this study will provide much-needed insight for coaches, athletics administrators and other campus officials into some infrequently studied issues that can strongly impact student-athletes and others involved in athletics.

About the NCAA.

The NCAA is a membership-led nonprofit association of colleges and universities committed to supporting academics and athletics opportunities for nearly 500,000 student-athletes at more than 1,100 member colleges and universities. Each year, more than 52,500 student-athletes compete in NCAA championships in Division I, II and III sports.