Sample IRB Protocol for Exempt, Category 2 Review: Comparing perceived stress levels of college athletes and non-athlete college students.

Protocol ID	004-0823
PI	Shannon Lupien Signed 08/15/2023 2:08 PM EDT
PI Type	Staff
Department	
PI Institution	
External Co-Investigators	
Review Type	Exempt Review - Limited IRB Review
Approval Status	Exempt Review - Limited IRB Review Requested
	(2) Tests, Surveys, Interviews
Submitted By	Shannon Lupien
Date Received	08/15/2023
Date of Completion	
Date Approved	
Final Approval Date	
Proposed Start Date	08/16/2023
Proposed End Date	
Date Closed	
Risk Level	Minimal Risk
Data Types Collected (Select all that apply)	Surveys/Questionnaire/Psychometric Testing
Will subjects be provided with informed consent information?	Yes - Consent information will be provided to subjects
Funding Source	
Grant Number	
Consent Waived	Not Requested
Waiver of Documentation of Informed Consent	Requested
Vulnerable Subjects	
Searchable Keywords	

(2) Tests, Surveys, Interviews Questions **Date Last Updated: 08/15/2023 12:47 PM EDT**

Exemption Category 2: The questions below will confirm that the proposed research meets the specified category of review.

Research that *only* includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- **The information obtained is recorded by the investigator in such a manner that the identity of the human subjects *cannot* readily be ascertained, directly or through identifiers linked to the subjects.**
- **Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation**
- **The information obtained is recorded by the investigator in such a manner that the identity of the human subjects *can* readily be ascertained, directly or through identifiers linked to the subjects, but the researcher can document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data (the IRB will conduct a limited IRB review to make the determination required by §46.111(a)(7)).**

Which of the following methodologies below will be included in the research? (check all that apply)

Answer:

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- ✔Surveys or questionnaires
  If this is the case, this exemption category cannot apply to research subjects under 18 years of age.
- Interviews
- Observation of public behavior in which the researcher does not participate in the activities observed (may include audio or video recording)
- Observation of public behavior in which the researcher does participate in the activities observed (may include audio or video recording)

Will your subjects include anyone under the age of 18 years old?

Answer:

1. Yes
2. ✔No

In order for research to be considered exempt under Exemption Category 2, one of the following additional criteria must be met. Please indicate which one best fits the proposed research.

Answer:

1. The information obtained is recorded in such a manner that the identity of the human subjects CANNOT readily be ascertained, directly or indirectly through identifiers linked to the subjects.
2. The information obtained CAN be identified directly or indirectly, BUT any disclosure of the human subjects' responses outside of the research WOULD NOT reasonably place subjects at risk of harm (i.e., risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, education advancement or reputation).
3. ✔ The information obtained CAN be identified directly or indirectly AND disclosure could put the subjects at risk of harm, BUT the researcher can thoroughly document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
4. None of the above criteria meet the proposed study

Pre-Protocol Questionnaire	08/15/2023 Pre-Protocol Questionnaire.pdf
Consent Form	08/15/2023 Informed Consent (Sample).docx
Recruitment Materials	08/15/2023 Email Recruitment Script (Sample).docx
Study Instruments (e.g., Surveys, Tests)	08/15/2023 Study Materials (Sample).docx

Personnel

PI

Shannon Lupien (08/15/2023)

CITI ✔

Purpose & Procedures

Is this a resubmission of a previously IRB approved study that has been terminated or has expired?

Answer:

Yes

✔ No

Approximately how many subjects you anticipate enrolling in this study (at all research locations/sites)?

Note: it is best to include an approximate range (expected min and max), rather than a specific number of subjects.

Answer: 50-100

Inclusion Criteria - What characteristics (e.g., age, conditions, diagnosis, etc.) must individuals have in order to be included as a research subject? Answer for each subject group, if there are multiple groups.

If not applicable, write N/A; however a common inclusion criterion is that subjects are over the age of 18.

Answer:

College students between the ages of 18 and 25 and who are enrolled in at least 12 credit hours.

Exclusion Criteria - What characteristics would exclude subjects who are otherwise eligible from this research? Answer for each subject group, if there are multiple groups.

If not applicable, write N/A.

Answer:

N/A

Please explain how inclusion/exclusion criteria are verified:

If not applicable, write N/A.

Answer:

Following consent information, the first question in an online survey will ask the participant's age and the second question will ask the number of credit hours the participant is enrolled in. Participants who fall outside either of the specified ranges will be taken to a disqualification page and thanked. Participants who meet the criteria will be taken to the study materials.

Please provide a brief description of the research background and study design:

Answer:

Background

Throughout the years, research has shown that mental health disorders have a significant impact on the quality of life worldwide. According to a survey conducted by the American Psychological Association, 40% of adults report that they lay awake at night because of stress. Though there are many types of mental disorders such as depression, anxiety, or schizophrenia, this study will specifically be exploring perceived psychological stress, which as the research reveals, can be perceived and measured in many different ways. Research is clear that certain types of stress have a

severe impact on one's physical and emotional well-being and has been linked to illnesses such as high blood pressure, myocardial infarction, and many others. When looking at one study conducted by the Center for Collegiate Mental Health at Penn State University, researchers highlighted that out of the 139 colleges and universities that were surveyed, 45% of the students who were seeking support from counseling centers, reported that they were stressed. Also included in this study is the fact that there was a 30% rise in students requesting counseling center appointments in the 2014-15 academic year despite student enrollment only growing by five percent. Common stressors that are often reported by these students consist of financial stress, relationship stress, and academic stress. Thus, with a heightened concern for the mental well being of students and a short supply of available counselors, alternative methods to managing stress should be explored. Apart from counseling and therapy based services, individuals have also used techniques such as meditation, exercise, and participation in sports as methods to help reduce stress levels.

Much attention and research has been dedicated to the idea of determining effective stress intervention techniques. From meditation and mindfulness to exercise and sport, many different methods to combat stress have been utilized. Specifically focusing in on sports participation it's important to note that these activities have been found to increase not only one's physical health, but mental health as well. Because athletes, particularly collegiate athletes, are typically involved in regular physical activity, they are recipients of these positive benefits such as decreased stress levels and decreased risk of developing cardiovascular disease. Other than the physical activity benefits, student athletes are said to possess excellent time management skills which are positively correlated with lower levels of academic stress. Research has also linked sports participation to a number of psychological and social benefits such as increased levels of self esteem and confidence. Taking that one step further, research has shown an increased level of social skills in those who do participate in sports when compared to those who do not participate in sports. Therefore, since we know that relationships can be a major source of stress, participation in sports could serve as a vital tool to decrease stress since social skills are critically important to maintaining healthy relationships.

Design
This study will be a cross-sectional survey comparing the differences in perceived stress levels between college athletes (in season and out of season) and non-athlete college students during the Fall 2022 semester on a division II campus.

Provide a brief, non-technical description of the *purpose* of the research study, including the research questions you hope to answer:

Answer:

The purpose of this research study is to explore the relationship between stress levels and participation in college sports. It is expected that in season athletes will report higher stress levels compared to out of season athletes but that stress levels will be reduced overall for athletes compared to non-athletes.

08/15/2023 12:59 PM EDT

Describe, in detail, the procedures subjects will be asked to complete or undergo using non-technical language. In other words, explain step-by-step what subjects will be asked to do:

If your study includes multiple variations of the procedures, please make clear the procedures that are included in each variation.

Answer:

As potential participants first enter the survey, they will be presented with an online informed consent sheet, written in clear and simple language, and will be asked to read the document fully and carefully. This will inform the participants that participation is voluntary and will provide them with important details regarding the purpose of the study, a description of the tasks they will be asked to complete, risks/benefits, the time commitment and compensation. The principal investigator's email address will be listed indicating that participants may email with any questions they may have prior to deciding whether or not to give consent. At the bottom of the online consent sheet, the participants will have the ability to click "I agree to participate" if they wish to provide their consent. If they click "I do not agree to participate" they will be thanked for their time and exited from the survey.

If they provide their consent, they will be presented with the inclusion criteria questions. If they meet the inclusion criteria, participants will be presented with a 57-question survey located on Survey Monkey, which asks a number of demographic questions and includes scales assessing stress, grit, self-esteem, and physical activity. Once finished with the survey participants will be thanked for their time and will have the opportunity to click on a link that brings them to a separate survey where they can enter their email address to receive a $5 Amazon gift card as compensation for their time. At any point in time, participants are free to exit out of the survey or skip questions and continue to the email survey.

Will subjects undergo any face-to-face or in-person research procedures?

Answer: Yes
✔No

Data and consent are:

Answer: ✔Only being collected electronically (Survey Monkey, Qualtrics, etc.).
Only being collected by paper, handwritten methods.
Being collected by a combination of electronic and nonelectronic methods.

Explain, where the research activities will take place (including recruitment, consenting, data collection, etc.) - be as specific as possible:

Answer:

Recruitment, consenting, and data collection will all take place online. Recruitment will take place over email (using the Daemen University Research Request Listserv: student_research@daemen.edu). The consent process and data collection will be completed via Survey Monkey (a standard data collection platform).

Will any of your research procedures occur outside of the United States?

Answer: Yes

✔No

Will you be collaborating with any researchers at other institutions to carry out this study?

Answer: Yes
✔No

Is this project funded?

Answer: ✔Yes
No

Is the funding:

Answer: ✔Internal
External (outside agency or organization)
Other (please explain)

Please indicate the grant number (if applicable) and/or funding source.

Answer: Daemen University Faculty Research Grant - Awarded Fall 2022

Recruitment

Who will be recruiting potential subjects?

(Select all that apply)

Answer: ✔The study PI
✔Other members of the institution research team
Collaborating researchers from other institutions (listed on this protocol)
Collaborating researchers from other institutions (not listed on this protocol)
Another third party (please describe)
Other (please describe)

How many times will subjects be contacted for recruitment purposes?

(*For subjects who are members of the Daemen community, the maximum allowed is 3 per semester.*)

Answer:
Emails will be sent 3 times during the semester.

Please explain your recruitment methods and procedures in detail. Be sure to include the names of any specific publications/websites/locations in which you will post recruitment information:

(Note: You will subsequently be asked to upload any recruitment-related materials)

Answer:
Participants will be recruited for this study via the Daemen University Research Request Listserv, sent to student_research@daemen.edu (Emails will be sent no more than 3 times during the semester). Inclusion criteria include male and female college students between the ages of 18 and 25 and who are enrolled in at least 12 credit hours. The first question in the survey will ask the participant's age and the second question will ask the number of credit hours the participant is enrolled in. Participants who fall outside these ranges will be taken to a disqualification page and thanked.

Explain how you have permission to access the subject populations, or indicate why permission is not needed:

Answer:
The Daemen University IRB allows the use of the research listservs for research with human subjects conducted by Daemen-affiliated researchers. Emails are sent out and listed as pending approval from the IRB staff. Once approved, the emails are then sent to the prospective participants.

Will you be working with an outside group, agency, or institution (i.e., outside of Daemen University) to recruit subjects?

Answer: 1. Yes
✔2. No

Select each item used in the recruitment of subjects:

(Select all that apply)

Answer: 1. Advertisements (e.g., newspaper, television, radio, etc.)
2. Flyers

✔3. Email scripts
4. Letters (i.e., through the mail)
5. Telephone scripts
6. Website posts or descriptions (including SONA announcements, social media posts, etc.)
7. Daemen University approved research email listservs (e.g., employee_research@daemen.edu, faculty_research@daemen.edu, student_research@daemen.edu)
8. In-person scripts
9. Other recruitment materials (please specify)

Please upload any recruitment materials (e.g., email scripts, flyers, website posts, etc.)

(Please upload in MS Word format if possible. If submitting revised documents, please submit a version showing tracked changes in MS Word (if possible) AND a clean copy with all changes accepted)

Answer:

Email Recruitment Script (Sample).docx 08/15/2023 (Recruitment Materials)

Consent

Who will be providing consent information to study subjects?

(Select all that apply)

Answer:
✔The study PI
Co-Investigators who are affiliated with Daemen University
Co-Investigators who are otherwise affiliated
✔Other

Please explain:
Consent will be conducted online via SurveyMonkey and the contact information of the PI will be provided and participants are encouraged to contact them with any questions or concerns.

Please explain the following:

- **The process of how and when consent information (and assent when relevant) is provided to subjects**
- **How subjects will respond to consent information (and assent when relevant) to indicate their agreement (or non-agreement)**
- **How you will ensure that subjects fully understand the information before deciding whether or not to participate**

Answer:

As potential participants first enter the survey, they will be presented with an online informed consent sheet, written in clear and simple language, and will be asked to read the document fully and carefully. This will inform the participants that participation is voluntary and will provide them with important details regarding the purpose of the study, a description of the tasks they will be asked to complete, risks/benefits, the time commitment and compensation. The principal investigator's email address will be listed indicating that participants may email with any questions they may have prior to deciding whether or not to give consent.

At the bottom of the online consent sheet, the participants will have the ability to click "I agree to participate" if they wish to provide their consent, after which they will be provided with the study materials. If they click "I do not agree to participate" they will be thanked for their time and exited from the survey.

Language used in consent information to ensure subject understanding:

- You may contact the researchers to ask questions about the purpose of the research, what you would be asked to do, any possible risks and benefits, your rights if you were to participate, and anything else about the research before deciding whether or not to participate.
- By clicking 'I agree' you are attesting that you have read the above information, that you understand the tasks and risks associated with the study, and that you have had the chance to ask any questions that you may have and that you are aware that you can contact the researchers now or in the future if concerns arise.

Will the study involve any deception, such that subjects are unaware of or misled regarding the nature and the purpose of the research or any of the study procedures?

Answer:
Yes
✔No

Please select the type(s) of subjects involved in the study:

(Select all that apply)

Answer:
✔Adult subjects (over the age of 18) without impaired decision-making ability
Minors (under the age of 18)
Subjects with impaired decision-making ability

Other

How will consent be documented?

Answer:
- Subjects will provide written, signed consent on paper
- Subjects will provide written, signed consent virtually (e.g., subjects type their full name or use an electronic signature program on a virtual consent document)
- Subjects will provide verbal consent in person, which will be documented by the researcher
- Subjects will provide verbal consent virtually, which will be documented by the researcher
- ✔ Subjects will provide consent through action (e.g., they will place a check mark or click an option that indicates, "I agree to participate", etc.)
- Other

Please upload consent documents here:

(Please upload in MS Word format ONLY. If submitting revised documents, please submit a version showing tracked changes in MS Word AND a clean copy with all changes accepted. Please use the Informed Consent Template when possible.)

Answer:

Informed Consent (Sample).docx 08/15/2023 (Consent Form)

Data Collection, Protection, and Records Retention

Will subject identifiers be recorded?

(names; addresses; phone numbers; email addresses; birth dates, locator information; patient, hospital, laboratory or claim numbers; Social Security numbers; IP addresses; etc.)

Answer:
- Yes - direct identifiers will be recorded (identifiers are recorded along with the data)
- ✔ Yes - indirect identifiers will be recorded (identifiers or potential identifiers are recorded in such a way that they can be linked to subject data - e.g., coding documents, contact information collected separately, time stamps that link data together, etc.)
- No - neither direct nor indirect identifiers will be recorded (i.e., the data will be collected anonymously)

Which types of potentially identifiable information will be collected?

(Select all that apply)

Answer:
- Names
- Addresses
- Phone numbers
- ✔ Email addresses
- Birth dates
- IP addresses
- Social Security Numbers
- Names of employers, types of employers, job titles
- Locator information (e.g., town, city, state, etc.)
- Patient, hospital, laboratory, or claim numbers
- Other

Why is it necessary to collect identifiable information?

Answer:

Email address are collected in a separate survey so they are not directly linked to participant responses. It is necessary to collect emails in order to provide participants with compensation.

Will you use a coding system to store the research data separately from the identification data?

Answer:
- Yes
- ✔ No

Please describe the coding system you will use and how it is designed to protect the confidentiality of the research data OR please explain why a coding system is not needed/not applicable:

Coding system is not needed as we have no reason to link multiple study components or link participant identity to the data.

Will a link between subject ID/code numbers and direct identifiers be retained *after* the data collection is complete?

Answer: Yes

No

✔N/A - no link between subject ID/code numbers and identifiers will exist

Do you plan to collect any data that is considered Protected Health Information (PHI) under the HIPAA law (e.g., data held by a hospital, healthcare provider, or health insurer)?

Answer:

1. Yes

✔2. No

Do you plan to collect any data that is considered protected under the FERPA Law (i.e., identifiable information related to student education records held by elementary, secondary, or higher ed institutions or their educators?

Answer:

1. Yes

✔2. No

Select all subject privacy procedures you will have in place:

Answer:

✔Subjects will be participating from a location of their choosing

Subjects will be participating individually

Subjects will be participating along with other subjects, but there are measures in place so that each subject's data will remain private (e.g., subjects are seated with dividers or adequate space between them, subjects enter their data on individual devices, subjects sign a non-disclosure statement (e.g., if in a focus group setting), etc.)

Subjects will be participating from a location that is private (e.g., a researcher's private office, a research space with doors closed, etc.)

Subjects will be participating remotely (e.g., via phone or online platform, such as Zoom or Skype) and there are steps in place so that their responses cannot be overheard (e.g., the researcher wears headphones, Zoom waiting rooms, individual links with passwords, and meeting locks are utilized, etc.)

Other

Select all confidentiality/anonymity procedures you will have in place:

Answer:

Data are collected anonymously, without (direct or indirect) subject identifiers

✔Use of pseudonyms or subject ID numbers that do not link subjects to data (i.e., subjects are given a random number as their ID and this number is not linked to subject identifiers in a coding document)

Use of pseudonyms or subject ID numbers that can link subject to data, but a separate coding document is used and is stored separately from subject data and will be destroyed as soon as it is no longer needed (e.g., once multi-part data are linked, once subjects are contacted, etc.)

✔Institution at which research is conducted will not be named

✔Data will be de-identified whenever possible (i.e., any identifiers associated with raw data will be removed and deleted)

✔Data will be reported in aggregate/summary only

✔No one other than the researchers will have access to any (either directly or indirectly) identifiable data

✔No one other than the researchers will have access to subject sign-up information

No one other than the researchers will have access to identifying consent documents

✔For any data collected using online data collection software, the recording of IP address will be turned off.

✔Any email or other related correspondence with subjects will be deleted after data collection is complete.

✔Any data that are transferred between members of the study team will be done so securely (e.g., through password protected files, drives, or devices)

✔Any data that are transferred from one storage location to another will be deleted or removed from previous storage locations (e.g., deleted from SurveyMonkey or Qualtrics after downloaded, deleted from recording device after transferred to storage device/cloud, etc.)

Consent is documented by subject signature (written or electronic) but will be collected and stored separately from data so that subject name is not linked to subject data

✔Consent is documented by subject action rather than a signature (e.g., verbally indicating consent, clicking or checking a box that states, “I agree to participate”, etc.)

Other

What electronic storage procedures are you utilizing?

(Select all that apply)

Answer:

Electronic data will be stored on a password protected computer

Electronic data will be stored in a password protected file on a computer

Electronic data will be stored on a password protected disk/flash drive

✔ Electronic data will be stored in a secure and password protected online storage platform (e.g., Google Drive, Dropbox, etc.)

✔ Electronic data will be collected through a secure, password protected online data collection platform (e.g. Qualtrics, SurveyMonkey, etc.) and subsequently downloaded and deleted from the platform after data collection is complete

Electronic consents will be stored on a password protected computer

Electronic consents will be stored in a password protected file on a computer

Electronic consents will be stored on a password protected disk/flash drive

✔ Electronic consents will be stored in a secure and password protected online storage platform (e.g., Google Drive, Dropbox, etc.)

✔ Electronic consents are collected through a secure, password protected online data collection platform (e.g. Qualtrics, SurveyMonkey, etc.) and subsequently downloaded and deleted from the platform after data collection is complete

Electronic data will be stored in a student researcher's office

Electronic data will be stored in a faculty researcher's office

Electronic data will be stored in a student researcher's home

Electronic data will be stored in a faculty researcher's home

Electronic consents will be stored in a student researcher's office

Electronic consents will be stored in a faculty researcher's office

Electronic consents will be stored in a student researcher's home

Electronic consents will be stored in a faculty researcher's home

Other

Please describe, in thorough detail, how the data will be protected against accidental disclosure to the public, other researchers, or non-researchers:

(In your response, please make specific references to the privacy, confidentiality/anonymity, and storage options that you indicated as being part of the study.)

Answer:

Survey Monkey will be set to not record participant IP address. Participant data may be able to be identified indirectly. However, the data itself is collected anonymously, and email addresses (the only identifying information) are collected in a separate survey so that the data cannot be directly linked to participants' identity. No attempts will be made to link the data and the emails collected for the gift card. The survey that contains the emails will only be accessed by the PI and will not be accessed until data collection is complete. Upon completion the emails will be downloaded and subsequently deleted from SurveyMonkey. The downloaded file will be shuffled and any timestamps deleted so it will not be possible to link participants' data to their emails. That shuffled file will used to send participants their gift cards, after which it will be deleted. Only once the emails have been shuffled and time stamps deleted, will the anonymous survey data be downloaded from SurveyMonkey and subsequently deleted. This de-identified file will be kept on the PI's password-protected Google Drive indefinitely. The file will only be shared with the Co-Investigator through the password-protected Google Drive.

Risks & Benefits

On the list below, select the potential risks to subjects (even if minimal) that could result either from participating in the proposed study or from the inadvertent release of (directly or indirectly) identifiable data:

Answer:

Criminal/legal (e.g., admitted law violations, past illegal behaviors or actions, threats to others)

✔ Social status (e.g., public embarrassment, loss of reputation, or threat to social respect)

Physical well-being (e.g., bodily injury, pain, sickness, physical discomfort, or trauma)

✔ Psychological/emotional (e.g., stress, anxiety, depression, anger, emotional reactions, painful memories, etc.)

Economic/employment/education (e.g., impact on conditions of employment or education, work assignments, job opportunities, perceptions of competence)

Privacy/dignity/self-respect (e.g., loss of control of confidential information, control of public access, privacy)

Other

There are no anticipated risks

Please explain:

The researchers do not anticipate any risks beyond what could occur in daily life (including the recall of thoughts and behaviors that could trigger negative emotions such as stress or anxiety, elicited either internally or by external stimuli that are a part of ordinary daily experience). Although breach of confidentiality (e.g., due to public embarassment) could be a risk given the potentially sensitive nature of some of the questions, there are protections in place that make this possibility unlikely. Specifically, the survey data cannot be directly linked to participants' identities, and the potentially identifying email addresses will be collected separately and shuffled with time stamps deleted before survey data is accessed so they cannot be indirectly linked. Additionally, all data is stored under password protection, only accessible by the researchers.

Is it possible that you will discover a subject's previously unknown condition (e.g., disease, suicidal intentions, genetic predisposition, etc.) as a result of the research procedures?

Answer: Yes
✔No

Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare:

Answer:

Survey Monkey will be set to not record participant IP address. Participant data may be able to be identified indirectly. However, the data itself is collected anonymously, and email addresses (the only identifying information) are collected in a separate survey so that the data cannot be directly linked to participants' identity. No attempts will be made to link the data and the emails collected for the gift card. The survey that contains the emails will only be accessed by the PI and will not be accessed until data collection is complete. Upon completion the emails will be downloaded and subsequently deleted from SurveyMonkey. The downloaded file will be shuffled and any timestamps deleted so it will not be possible to link participants' data to their emails. That shuffled file will used to send participants their gift cards, after which it will be deleted. Only once the emails have been shuffled and time stamps deleted, will the anonymous survey data be downloaded from SurveyMonkey and subsequently deleted. This de-identified file will be kept on the PI's password-protected Google Drive indefinitely. The file will only be shared with the Co-Investigator through the password-protected Google Drive.

Are there any anticipated *direct* benefits of the research (i.e., direct benefits for individual subjects)?

(Do not include compensation or incentives offered to subjects as a benefit).

Answer: Yes
✔No

Are there any anticipated *indirect* benefits of the research (e.g., for society or others who are not research subjects)?

Answer: Yes
✔No

Costs, Reimbursement, Compensation and Recruitment Incentives

Are there any costs that subjects may incur as a result of participation?

Answer: Yes
✔No

Will you be providing monetary compensation to subjects for the time or burden associated with research?

Answer: ✔Yes
No

Please explain:
Participants will receive a $5 Amazon Gift Card if they choose to enter their email address at the end of the survey.

Will you still provide the compensation or will you provide partial compensation for subjects who withdraw or do not complete all of the research procedures?

Answer: ✔Yes
No

If "Yes", please explain the what will determine compensation amount. If "No", please explain why not.

Participants will receive the full $5 as long as they enter their email at the end of the survey. However, they may skip any questions they wish to proceed to the end of the survey.

Will you be offering any recruitment incentives?

Answer: Yes
✔No

Surveys/Questionnaires/Psychometric Testing

Please list the names AND provide a brief description of all surveys/questionnaires/psychometric tests to be used in this study. Include both established (i.e. instruments used in previous, published research/methodologies) and study-specific instruments (i.e. instruments created for this specific study).

Answer:

Demographics: The survey consists of basic demographic questions such as age, gender, ethnicity, year in college, as well as questions in regard to their current participation or lack of participation in collegiate athletics.

Perceived Stress Scale: The perceived stress scale is a 10-item validated scale that assesses the degree to which their life feels unpredictable, uncontrollable and overloading. Each question uses a 5-point likert scale with 0 being “never” and 4 being “very often”.

Grit Scale: The Grit scale is an 8-item validated measure that reflects how passionate and persevering a person rates himself or herself to be. Answers are on a 5-point likert scale that ranges from “very much like me” to “not at all like me”.

Rosenberg Self-Esteem Scale: The Rosenberg Self-Esteem Scale is a ten-item scale that measures both positive and negative feelings about oneself. All items are answered using a 4-point likert scale which ranges from “strongly agree” to “strongly disagree”.

Physical Activity: The World Health Organization’s Global Health Physical Activity Questionnaire asks questions related to the amount of time participants are engaging in physical activity at work, during their daily commutes, during recreational activities, and asks questions related to amount of sedentary behavior as well.

How often will subjects be asked to complete the surveys/questionnaires/psychometric tests?

Answer:

Once

Approximately how long will it take to complete the surveys/questionnaires/psychometric tests?

Answer:

10 minutes

Will you be using any data collection software such as Qualtrics or SurveyMonkey?

Answer: ✔Yes
No

Which software will you be using?

Please include the link(s) to the completed survey(s):

(Note, during the IRB review and testing process, it is important to set the surveys to be able to be completed multiple times from the same device.)

SurveyMonkey:

https://www.surveymonkey.com/r/XXXXXXXX

Please upload a copy of each survey/questionnaire/psychometric test you intend to use:

(Be sure to include all directions to subjects, each survey item, and any response scales. Please upload in MS Word format if possible. If submitting revised documents, please submit a version showing tracked changes in MS Word (if possible) AND a clean copy with all changes accepted)

Answer:

Study Materials (Sample).docx 08/15/2023 (Study Instruments (e.g., Surveys, Tests))

Waiver of Documentation of Informed Consent

Select the option that applies to your request for waiver of *signed* documentation of informed consent:

Answer:

(i) The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern.

✔(ii) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Please explain how consent will be otherwise documented:

Answer:

Participants will have the option to click "I agree" or "I do not agree" before being presented with the study materials. This response (but not their name) will be stored along with the data.

Debriefing

Even if a research study does not involve the use of deception, debriefing can be used as an educational tool.

Do you plan to provide debriefing information to study subjects?

Answer: 1. Yes

✔2. No

Correspondences

Publicationss

Continuing Reviews

Modifications

Adverse Events

Event / Date	Status / Comments / Files	Submitted By
No Adverse Events Found.		

Protocol Deviations

Status	Protocol Deviations File/Comments	Submitted By
No Protocol Deviations Found		

EMAIL RECRUITMENT SCRIPT

Email Subject Line: Research Opportunity about Stress in Athletes and Non-Athletes in Exchange for $5 Amazon Gift Card

Hello,

You are invited to participate in a research study being conducted by Dr. XXX and XXX.
The aim of the study is to examine the differences in perceived stress levels between college athletes and their non-athlete peers.

All participants must be between 18 and 25 years old and enrolled in at least 12 credit hours to participate in this study. If you are interested in participating, you would be asked to complete a survey online via Survey Monkey. This survey would first ask some basic information about yourself, such as your age, year in school, major, etc. Next a number of questions would ask about stress levels (e.g., "how often have you been upset about something that happened unexpectedly"), self-esteem (e.g., "I feel I do not have much to be proud of"), and grit (e.g., "setbacks don't discourage me"), followed by a questionnaire about physical activity levels, such as exercise frequency.

There are no anticipated risks beyond what could occur in daily life (including the recall of thoughts and behaviors that could trigger negative emotions, elicited either internally or by external stimuli that are a part of ordinary daily experience), and participants will not benefit directly from taking part in the study.

Participation in this study is voluntary. You are under no obligation to participate, and no one will know if you decide not to participate. Participation is expected to take approximately 10 minutes.

If you are interested in participating, please click on the link below.

https://www.surveymonkey.com/r/XXXXXXXX

This study has been approved by the Daemen University IRB: Protocol# …

Informed Consent

Title of Research Project:

Comparing Perceived Stress Levels of College Athletes and Non-Athlete College Students

Faculty Research Advisor:

Dr. XXX XXXX
Daemen University
Psychology Department
DS XXX
XXX@daemen.edu
716 XXX-XXXX

Student Researchers:

XXX XXXX
Daemen University
Psychology Department
XXX@daemen.edu

You are invited to participate in a research study. The purpose of this information is to help you to make an informed decision about whether or not you would like to participate. Please read the information in this document carefully. You may contact the researchers to ask questions about the purpose of the research, what you would be asked to do, any possible risks and benefits, your rights if you were to participate, and anything else about the research before deciding whether or not to participate.

Participation in this study is voluntary and confidential. If you do not wish to participate or if you decide to participate and then withdraw or skip any part of the research process, there are no penalties or loss of benefits or services that you are otherwise entitled. Whether or not you choose to participate in this project will have no effect on your relationship with the researchers or Daemen University.

Purpose of the Research Project:

The purpose of this research study is to explore the relationship between stress levels and participation in college sports.

Description of the Research Project and Procedures:

If you agree to participant, you will be asked a number of questionnaires online, on SurveyMonkey. These questionnaires will first ask some basic information about yourself, such as your age, year in school, major, etc. Next a number of questions would ask about stress levels (e.g., "how often have you been upset about something that happened unexpectedly"), self-esteem (e.g., "I feel I do not have much to be proud of"), and grit (e.g., "setbacks don't discourage me"), followed by a questionnaire about physical activity levels, such as exercise frequency.

To be included in this study, participants should be between 18 and 25 years old and enrolled in at least 12 credit hours.

Study Duration:

Participation in this study is expected to take approximately 10 minutes.

Risks:

The researchers do not anticipate any risks beyond what could occur in daily life (including the recall of thoughts and behaviors that could trigger negative emotions, elicited either internally or by external stimuli that are part of ordinary daily experience). Although breech of confidentially could be a risk given the potentially sensitive nature of some of the questions, there are protections in place that make this possibility unlikely.

Benefits:

Participants will not directly benefit from taking part in this study.

Compensation:

As compensation for their time, participants will have the opportunity to enter their email address at the end of the survey to receive a $5 Amazon eGift Card.

Confidentiality and Anonymity:

Survey data will be collected anonymously. Participants' names will not be connected to any responses provided, and responses cannot be directly identified. Potentially identifying email addresses will be collected separately and shuffled before participant data is accessed so that they cannot be used to indirectly link participant responses to their identities. All data collected from participants will be kept confidential. Only the researchers mentioned above will have access to participant responses. Any results that will be presented or published will be in group form and will not contain any identifying information or link any individual participant with the data.

Contact Information for Questions or Concerns:

You have the right to ask any questions you may have about this research. If you have any question or concerns, please contact XXX at XXX@damen.edu, 716 XXX XXXX or XXX at XXX@daemen.edu. If you have other concerns about this study or would like to speak with someone not directly involved in the research, or if you have questions regarding your rights as a human subject or would like to make a complaint, please contact the Daemen University Institutional Review Board (IRB) Chair at irb@daemen.edu.

Voluntary Consent:

Please review all the information on this form before deciding whether or not you would like to participate. Taking part in this research study is strictly voluntary. If you choose to take part, you have the right to stop at any time or skip any part of the research that you may wish. If you do not wish to participate, you may exit this site.

If you wish to participate, please click the 'I agree' button below. By clicking 'I agree' below, you are attesting that you have read the above information, that you understand the tasks and risks associated with the study, and that you have had the chance to ask any questions that you may have and that you are aware that you can contact the researchers now or in the future if concerns arise. By clicking 'I agree' below, you are attesting that you understand that your participation is entirely voluntary and that you can choose to

discontinue your participation at any time. By clicking ‘I agree’ below, you are attesting that you are at least 18 years of age. Lastly, by clicking ‘I agree’ below, you are providing your consent to participate in this study.

- I agree
- I do not agree

Please print a copy of this document for your records.

STUDY MATERIALS

(Demographics)

Please answer the following questions about yourself.

2. What is your current age?
<18
18
19
20
21
22
23
24
25
>25

3. How many credits are you currently taking?
1-5
6-11
12-16
>16

4. What is your gender?
Male
Female
Other

5. What is your current year in school?
Freshman
Sophomore
Junior
Senior
Graduate Student

6. What is your Ethnicity?
Hispanic or Latino
Not Hispanic or Latino
Other

7. Please identify your race. Check all that apply:
American Indian or Alaska Native
Asian or Asian American
African or African American
Middle Eastern
Caucasian (White)
Bi-Racial/Mixed Race
Other _____

8. What is your current major?

9. Do you play a collegiate sport?

Yes
No

10. If yes, are you currently in season?
Yes
No

11. Which sport do you participate in?

12. Are you on an athletic scholarship?
Yes
No

13. How many hours per week do you practice?
N/A
0
1-5
6-10
11-15
16-20
20+

14. In the past month, have you experienced any of the following? Check all that apply:
Death of a loved one
Divorce/break up
Major illness/injury
Job loss
Pregnancy
Became engaged/got married
Parents separated or divorced
Major health issues or a family member or close friend
Change is residence
Change in school
Major change in financial state
N/A

(Stress)

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

15. In the last month, how often have you been upset because of something that happened unexpectedly?
Never
Almost Never
Sometimes
Fairly Often
Very Often

16. In the last month, how often have you felt that you were unable to control the important things in your life?
Never
Almost Never
Sometimes
Fairly Often

Very Often

17. In the last month, how often have you felt nervous and “stressed”?
Never
Almost Never
Sometimes
Fairly Often
Very Often

18. In the last month, how often have you felt confident about your ability to handle your personal problems?
Never
Almost Never
Sometimes
Fairly Often
Very Often

19. In the last month, how often have you felt that things were going your way?
Never
Almost Never
Sometimes
Fairly Often
Very Often

20. In the last month, how often have you found that you could not cope with all the things that you had to do?
Never
Almost Never
Sometimes
Fairly Often
Very Often

21. In the last month, how often have you been able to control irritations in your life?
Never
Almost Never
Sometimes
Fairly Often
Very Often

22. In the last month, how often have you felt that you were on top of things?
Never
Almost Never
Sometimes
Fairly Often
Very Often

23. In the last month, how often have you been angered because of things that were outside of your control?
Never
Almost Never
Sometimes
Fairly Often
Very Often

24. In the last month, how often have you felt difficulties were piling up so high that you could not overcome

them?
Never
Almost Never
Sometimes
Fairly Often
Very Often

25. If you are not a computer, skip this question
Never
Almost never
Sometimes
Fairly often
Very often

(Grit)

Please respond to the following 8 items. Be honest – there are no right or wrong answers!

26. New ideas and projects sometimes distract me from previous ones.
Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

27. Setbacks don't discourage me.
Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

28. I have been obsessed with a certain idea or project for a short time but later lost interest.
Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

29. I am a hard worker.
Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

30. I often set a goal but later choose to pursue a different one.
Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

31. I have difficulty maintaining my focus on projects that take more than a few months to complete.

Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

32. I finish whatever I begin.
Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

33. I am diligent.
Very much like me
Mostly like me
Somewhat like me
Not much like me
Not like me at all

(Self-Esteem)

Directions: Indicate the extent to which you agree or disagree with the following items using the scale provided.

34. I feel that I am a person of worth, at least on an equal basis with others.
Strongly Agree
Agree
Disagree
Strongly Disagree

35. I feel that I have a number of good qualities.
Strongly Agree
Agree
Disagree
Strongly Disagree

36. All in all, I am inclined to feel that I am a failure.
Strongly Agree
Agree
Disagree
Strongly Disagree

37. I am able to do things as well as most other people.
Strongly Agree
Agree
Disagree
Strongly Disagree

38. I feel I do not have much to be proud of.
Strongly Agree
Agree
Disagree

Strongly Disagree

39. I take a positive attitude toward myself.
Strongly Agree
Agree
Disagree
Strongly Disagree

40. On the whole, I am satisfied with myself.
Strongly Agree
Agree
Disagree
Strongly Disagree

41. I wish I could have more respect for myself.
Strongly Agree
Agree
Disagree
Strongly Disagree

42. I certainly feel useless at times.
Strongly Agree
Agree
Disagree
Strongly Disagree

43. At times I think I am no good at all.
Strongly Agree
Agree
Disagree
Strongly Disagree

(Physical Activity)

The following questions ask about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. First think about the time you spend doing work. Think of work as things you have to do such as paid or unpaid work, studying/training, or household chores. In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause a large increase in breathing or heart rate, 'moderate-intensity activities' are actives that require moderate physical effort and cause small increases in breathing or heart rate.

44. Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate
(carrying or lifting heavy load, digging or construction work) for at least 10 minutes continuously?
Yes
No

45. In a typical week, on how many days do you do vigorous intensity activities as part of your work?

_____
days
1-2
3-4
5-6

7

46. How much time do you spend doing vigorous intensity activities at work on a typical day?
_____hours
_____minutes

47. Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate
such as brisk walking (or carrying light loads) or at least 10 minutes continuously?
Yes
No

48. In a typical week, on how many days do you do moderate intensity activities as part of your work?
_____ days
1-2
3-4
5-6
7

49. How much time do you spend doing moderate intensity activities at work on a typical day?
_____hours
_____minutes

50. Travel to and from places. The next questions exclude the physical activities that you have already mentioned.
Do you walk or use a bicycle for at least 10 minutes continuously to get to and from places?
Yes
No

51. In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to
and from places? _____ days
1-2
3-4
5-6
7

52. How much time do you spend waking or bicycling for travel on a typical day? _____hours
_____minutes

The next questions exclude the work and transport activities that you have already mentioned. Now think about sports, fitness and recreational activities (leisure).

53. Do you do any vigorous-intensity sports, fitness or recreational activities that cause large increases in breathing or heart rate like running or football for at least 10 minutes continuously?
Yes
No

54. In a typical week, on how many days do you do vigorous intensity sports, fitness or recreational activities?
_____ days
1-2

3-4
5-6
7

55. How much time do you spend doing vigorous intensity sports, fitness or recreational activities on typical
days? _____hours _____minutes

56. Do you do any moderate-intensity sports, fitness, or recreational activities that cause a small increase in
breathing or heart rate such as brisk walking, cycling, or volleyball for at least 10 minutes continuously?
Yes
No

57. In a typical week, on how many days do you do moderate intensity sports, fitness or recreational activities? _____ days
1-2 days
3-4 days
5-6 days
7 days

58. How much time do you spend doing moderate intensity sports, fitness or recreational activities on typical
days? _____hours _____minutes

59. The following question is about sitting or reclining at work, home, getting to and from places, or with friends including time spent sitting at a desk, sitting with friends, traveling in a car, bus, train, reading, studying,
playing cards or watching television, but does not include time spent sleeping. How much time do you usually
spend sitting or reclining on a typical day? _____hours _____minutes