THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Determination of Human Research

This form should be used when it is unclear whether the proposed activities require review by an Institutional Review Board (IRB). **If the proposed study clearly is Human Research, do not complete this form! Instead, please submit the appropriate application for review and approval by the IRB.**

Title (If funded, provide exact title of funded project)

Effects of Stress, Sleep Hygiene, and Exercise on Academic Engagement in Undergraduate Students

Contact Information

Principal Investigator Name	Audrey Nelson
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College/Division	College of Education
Department/ Unit	Department of Disability & Psychoeducational Studies

Status ☐ Undergraduate Student ☒ Graduate Student ☐ Resident ☐ Faculty ☐ Staff

Additional Contact (These individuals will receive copies of this correspondence):

Add Line / Delete Line	Name	UA Net ID	Research Role	Institution	Email Address

Funding Information

Will the project be using/receiving any of the following funding types to support the research:

- ☒ No funding supporting the proposed research
- ☐ Federal funding (e.g., NIH, NSF, DoE, DoD)
- ☐ Foundation Funding
- ☐ Departmental Funds
- ☐ Gift Funds
- ☐ Industry Funded

Determination of "Research"

45 CFR 46.102(l): ***Research*** - a ***systematic investigation***, including research development, testing and evaluation, ***designed to develop or contribute to generalizable knowledge.***

A ***systematic*** approach involves a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or qualitative.

Activities ***designed to develop or contribute to generalizable knowledge*** are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).

1. Does the proposed activity involve a ***systematic*** *approach*?

☒Yes

☐No

2. Is the intent of the proposed activity to ***develop or contribute to generalizable knowledge?***

☒Yes

☐No

If Yes to BOTH questions the study is Research. Proceed to Section: Determination of "Human Subject."

If the answers to one or both questions are NO, proceed to Section: Determination of "Human Subject" per FDA Regulation.

Determination of "Human Subject"

45 CFR 46.102(e): ***Human subject*** - a *living individual* about whom an investigator (whether faculty, student, or staff) conducting research obtains: **(1)** data through ***intervention*** *or* ***interaction*** with the individual; or **(2)** ***identifiable private information.***

Intervention includes both physical procedures by which information is gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable.

Identifiable is where the identity of the subject is or may be ascertained by the researcher, or will be associated with the information. The research could involve the use of ***coded*** data/specimens.

1. Does the activity involve obtaining information about *living individuals* through ***intervention*** or ***interaction*** with the individuals?

☐Yes

☒No

2. Does the activity involve obtaining ***identifiable*** and ***private information*** about living individuals?

☐Yes

☒No

If YES to either question, the research activity is *research* that involves *human subjects*. STOP and submit an IRB application for approval of human research.

If the answers to one or both questions are NO, proceed to Section Determination of "Human Subject" per FDA Regulation.

Determination of "Human Subject" per FDA Regulations

21 CFR 50.3(g): ***Human subject*** - *an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.*

**Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation.

***In vitro diagnostic products* are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae.*

1. This is a clinical investigation involving a test article including in vitro diagnostics with a human subject(s) or their biospecimens?

☐Yes

☒No

Note: The FDA regulations (21 CFR Parts 50 and 56) apply to all clinical investigations regulated by FDA, as well as other clinical investigations that support applications for research or marketing permits. Therefore, all studies of investigational IVDs that will support applications to FDA are subject to 21 CFR Parts 50 and 56, even if they are not subject to most requirements of 21 CFR Part 812. For more information see the FDA Guidance on In Vitro Diagnostic Device Studies - FAQs.

Coded private information and/or human biological specimens per OHRP

Coded means a living individual's identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof ***and*** there is a key to link the code to the identifiable information of that individual. *Coded data are considered identifiable under the Common Rule.*

1. Does the activity involve the use of ***coded*** private information/specimens?

☐Yes

☒No

2. Were the information/specimens previously collected (or yet to be collected), specifically for the currently proposed project?

☐Yes

☒No

Other Activities
(Please pick the most appropriate check boxes below)

☐ Program Evaluation/Quality Improvement/Quality Assurance: The proposed activity will assess, analyze, critique, and improve current processes of program or health care delivery in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements in a program or health care delivery?

☐ **Course-Related Activities**: The proposed activity is limited to course-related activities designed specifically for educational or teaching purposes?
☐ **Case Report:** The proposed activity is a case report or case series of no more than three (3) cases describing an interesting treatment, presentation, or outcomes?
☐ **Oral History:** The activity is limited to oral history activities, such as open ended interviews that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.
☐ **Public Use Datasets:** The activity is limited to analyzing information contained within a publically available dataset (Meaning, any person can find and use the data). *NOTE: This does not include reviewing or analyzing information from social media.*
☐ **Journalism/Documentary Activities:** The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis?
☐ **Purchased cell lines:** The activity involves commercially available, de-identified non-human embryonic cell lines.
☒ **Limited Data Set**: A limited data set is a data set that is stripped of certain direct identifiers specified in the Privacy Rule. A limited data set may be disclosed to an outside party without a patient's authorization only if certain conditions are met. Please go to the following link to review the Use Agreement (DUA) from the HIPAA Privacy Program
☐ **dbGap**: Receipt of data from dbGap that requires IRB approval, but the data you will receive. Investigators must also submit an Institutional Certification form to be completed and signed by the Investigator and IRB.
☐ **Preparatory to Research:** The activities are limited review of protected health information (PHI). No PHI is to be removed from the covered entity by the researcher in the course of the review.
☐ **PHI of Decedents:** The use or disclosure is solely for research on the PHI of decedent, the PHI is necessary for research purposes and if requested the Principle Investigator will be required to provide documentation of the death of the individual(s).
☐ **Native American/Alaskan Native:** The activity involves access to tribal resources (e.g. cultural artifacts, environmental samples, or people), but the activity is not intended to produce generalizable knowledge. Please attach a copy of completed Appendix for Vulnerable Populations.

Section 2: Summary

1. Provide a concise description of the purpose or objectives of the project.

To evaluate the effects of stress, sleep hygiene, and exercise on academic engagement in undergraduate students. Including the moderating/mediating effects that the self-care practices of exercise and sleep hygiene may have on the relationship between stress and academic engagement, and the hierarchical influence of the effects of stressful life events, sleep hygiene, and exercise on academic engagement.

2. Describe the proposed methods and study procedures.

The included questionnaires were meant to determine the following: student's demographics including age, ethnicity, class standing, and gender; the Undergraduate Stress Questionnaire (USQ) to measure recent stressful life events, the Sleep Hygiene Index (SHI) to measure positive sleep practices, the Leisure Time Exercise Questionnaire (LTEQ) to evaluate exercise habits; and the Student Course Engagement Questionnaire (SCEQ) to determine self-reported levels of academic engagement.

3. Describe the subject population, or the type of information/specimens to be studied.

The current research will be based on previously collected data. The proposed data set of participants included 203 undergraduate students who were part of the educational psychology research pool at a large southeastern university. An university IRB approved all study procedures. The data was obtained by consent of the PIs of the

original project.

4. Explain where the information/specimens were collected/obtained (i.e. identify source of data/specimens).

☐ NA- Activity does not involve the use of data/specimens
☐ Banner University Medical Center- Medical Records
☐ Clinical Research Data Warehouse (CRDW)
☒ Other

Are they a Business Associate or Collaborator?
Business Associate means a person or entity that performs certain activities or functions that involve the use or disclosure of PHI on behalf of, or provide services to, a Covered Entity.

☐ Yes
☒ No

Explain how the information/specimens will be provided to the investigator (e.g. the investigator will be provided an already existing, de-identified data set, etc.).

The investigator will be provided an already existing, de-identified data set that was collected at the University of Florida.

Section 3: Location of Research

☐ Banner - University Medical Center
☐ University of Arizona Cancer Center
☒ University of Arizona Campus

The current study using the pre-existing data set will take place at the University of Arizona.

☐ Outside the US
☐ Online
☐ Other

You have now completed this form. Next steps:

1) Please save a copy of this document for your records.

2) Email the form to the appropriate individuals for their approval.

3) Once it is ready email the application and attach all additional documents to vpr-irb@email.arizona.edu. Please review HSPP Guidance for any additional documents that are needed.

Principal Investigator

I certify that the information I provide in this application is correct and complete.

☒ Attestation of Principal Investigator

Audrey Nelson
Typed Name of Principal Investigator

04/18/2018
Date

NOTE: A research proposal by a graduate or undergraduate student must have the following attestation statement signed by an Advisor or Mentor.

Advisor/ Mentor

By signing below, I, the Advisor/ Mentor, certify that I have accurately reviewed and mentored the student/resident regarding completion of the items listed above.

Signature of Faculty Supervisor

4/20/18
Date

Dr. Michael Sulkowski,
Print Name and Title of Faculty Supervisor

NOTE: Actual signature is not required. The HSPP Office will accept either email confirmation or an actual signature. This means that all signatures might not be on the same document. Attach email confirmations with your submission.