

West Virginia University - Office of Research Integrity and Compliance
Protocol Number: 1911790841
Principal Investigator: Sera Janson Zegre

Protocol Questionnaire

Human Subject Research

Does the protocol meet the federal definition of research? For help determining the type of research you are conducting, see the DHHR Human Subject Regulations Decision Charts at <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>.

Yes

Does the research involve living person(s)?

Yes

Will information from individual person(s) be collected as part of this research?

Yes

Is this project being done by a student, resident or fellow to fulfill degree, program, or rotation requirements?

No

Please review the following four questions to determine if this study meets the NIH definition of a clinical trial.

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Does this study meet All FOUR of the above criteria?

No

Funding Source

Is there a secured funding source?

Yes

Select the type of funding.

Department/Personal

Locations of Research

Select the location(s) where the research will be conducted. At least one location must be selected.

WVU Campus

Select the location(s) where the research will be conducted. At least one location must be selected.

Off WVU Campus

Will the research take place at an off campus location?

Yes

Is the research site domestic or international?

Domestic

Is this a private residence?

No

Provide the name and contact information for all domestic locations of research and attach letters of permissions on the Notes & Attachments page (Permission Letter found here: <https://human.research.wvu.edu/forms>).

universities, various, including: Ohio University, Oklahoma State, Baylor University

Is this a multi-center trial?

No

Will this study require an Inter-Institutional Authorization Agreement (IAA)?

Yes

Will WVU be the IRB with oversight responsibility? If yes, attach an IAA WVU IRB of Record Form on the Notes & Attachments page.

Yes

Please describe the nature of the collaboration (e.g., sharing of data, information, duties, etc.).

Collaborators (non-WVU institutions) roles: 1.Access swipe card data from student recreation center(s) Note: institution may need to work with their recreation management software system Custom report (in Excel) for Facility Usage (sum) by Membership Type (student membership users only) to include ID# as an optional selectable criterion from entry card reader(s) For one (1) academic fall semester (i.e., August 1, 2016-December 31, 2016) Each excel file should have the following columns: Name 1, Name 2, Student ID, (facility use data to include:)Aug sum, Sept sum, Oct sum, Nov sum, Dec sum 2.Data request to IR (for non-users, covariates for which to control in multi-variate model) Census data for full-time, first-time freshman for a fall academic semester oNote: exclude high school taking college courses and online students Data request to Institutional Research; essential variables include (data dictionary provided): oStudent ID, Gender, Race Ethnicity, High School GPA, Sat Combined Scores, Act Composite Scores, Fall Cumulative GPA, Federal Pell Grant, Retention 3.Pair & de-identify data (i.e., remove student ID after pairing data sets of facility use data and IR data) Study coordinator (West Virginia University) 1.Facilitation & guidance through detailed data requests 2.Data dictionary 3.Data repository to de-identify institutional names 4.Data management & statistical analysis 5.Reports & publication of multi-institutional research in peer-reviewed journal

Design

Please provide a lay summary (written at 6th grade level) that includes a statement about the purpose and the general aims of the research.

Research Objective This research seeks to assess the relationship between academic success and campus recreation participation controlling for differences across students across multiple institutions. Rationale Previous campus recreation studies lack consistency and robustness, including variable use and statistical design. Also, retention analysis is often either focused on the institutional or student levels. This study examines the relationship between campus recreation facility access and first-year retention and cumulative GPA of full-time, first-time freshmen (FTF) students across multiple universities. Authors examine differences between facility users and non-users by pairing facility swipe card data with student records. Statistical analysis includes logistic regression and matching approaches, controlling for student demographics, academic preparedness, academic goals, family characteristics, and various environmental factors. Research can also demonstrate methods to calculate additional revenue from 1-year increase retention. Benefits To increase comparability and reliability of findings, this research focuses on student-level analysis across multiple institutions. Findings will quantify relevance of campus recreation in academic success. Implications include recognizing the role of campus recreation in academic outcomes.

Fully describe all procedures to be performed, from start to finish, numbering your procedures 1,2,3 or A, B, C (e.g., 1. Recruiting, 2. Consent, 3. Collecting data, 4.

How findings will be shared, etc.).

Research coordinator will use retrospective secondary data analysis on data previously collected by the university and held by each university's institutional research. Additional data to be integrated includes student recreation facility use (i.e., card swipe data). All data downloads occur using secure university databases, and all data used for analysis are stored on secure university drives. Data transfers (i.e., from institutions) will use secure university file locker server. Data collection and analysis steps include: Part I: All institutions (WVU and Collaborators/non-WVU): 1. Access swipe card data from student recreation facility(ies) for one academic fall semester (i.e., August 1, 2018-December 31, 2018) 2. Data request to IR for census data for full-time, first-time freshmen (FTF) students for a fall academic semester (Note: exclude high school taking college courses and online students); variables include: Student ID, Gender, Race/Ethnicity (person of color or white), Residency, High school GPA, Sat combined scores, Act composite scores, Major description, First-generation student, Pell grant recipient, Unmet need, Living on campus, Intercollegiate athletics, Fall Cumulative GPA, Retention) 3. Pair & de-identify data (i.e., remove student ID after pairing data sets) 4. Upload de-identified data to secure server. Note: WVU data will not be de-identified by IR; it will be de-identified by research coordinator prior to combining institutional data into one multi-institutional dataset. Part II: Study coordinator (West Virginia University): 1. Provide facilitation & guidance through detailed data requests (part I above) 2. Provide and troubleshoot data dictionary (part I above) 3. Provide data repository to de-identify institutional names to combine institutional data into one multi-institutional dataset. 4. Provide data management & statistical analysis, including summary statistics and significance tests to characterize the sample 5. Statistical analysis, including ordinary least squares and logistical regressions 6. Facilitate writing and publishing reports and presentations.

Please describe the investigational procedures that will be performed throughout the duration of the study.

Data will be organized and analyzed using SPSS and Stata statistical software. Analysis will include creating summary statistics, including significance tests to characterize the different samples. Given the large amount of data, missing data will likely be excluded from the analysis. Statistical analysis, including ordinary least squares and logistical regressions, will be used to explain relationships between key regression variable (i.e., campus recreation facility use) and outcome variables (i.e., retention, GPA), holding constant demographic and income/financial aid variables.

Please describe the standard of care procedures that will be performed throughout the duration of the study.

To protect research subject's confidentiality and privacy, the following steps will be taken: 1. All data downloads occur using secure university databases. During data analysis, all data used for analysis are stored on secure university drives. 2. Each institution will recode student ID to remove identifying link --and keep key to code stored in a secured location-- with random identifier before data transfer for multi-institutional analysis. 3. Data transfers (i.e., between institutions) will use a secure university file locker server. 4. Additionally, individual student data is analyzed only by research coordinator and not anticipated to be shared with project support team. 5. Also, if individual student data is necessary to be shared during analysis phase, research coordinator will recode student ID to remove identifying link with random identifier and keep key to code stored in a secured location. 6. Finally, to protect privacy, all findings will be shared with the team and reported in aggregate (i.e., not at the student nor institutional levels).

Will you be assigning or randomizing participants to groups or conditions (e.g., control, placebo)?

No

Does the research involve surveys/interviews/questionnaires? If so, attach a copy of the interview/survey questions on the Notes & Attachments page.

No

Describe what is known about this topic and why this study is needed. Please include at least two reference citations to support your rationale.

The retention rate for first-year students at colleges and universities in the United States increased only 3.6 percentage points between 2009 and 2017, from 69.9 to 73.5, according to recent evidence from the National Student Clearinghouse (NSC Research Center, 2019). At the same time, colleges and universities have begun to feel pressure from declining enrollments, given projections of national demographic changes to reduce the size of incoming first-year classes between 2014 and 2032, and with incoming classes smaller in 2032 than in 2013 (Bransberger & Michelau, 2016; Grawe, 2018). In the face of lost tuition revenue and stiffer competition in recruiting students, retention of students has become even more important for colleges and universities (Seidman, 2012; Tinto, 2006). Past studies suggest both academic and social engagement are key determinants of student retention (Tinto, 1975, 1993, 2006; Soria & Stebleton, 2012; Swail, 2004). While campus resources outside the classroom may be underfunded on some campuses or seen as ancillary to students' experiences (Danbert, et al., 2014), many students spend time engaging with these resources. For example, a national benchmark survey found that 75 percent of students use on-campus recreation center facilities, programs, and services at their colleges or universities (Forrester, 2014). A growing body of literature in campus recreation includes evidence linking use of recreation facilities and participation in club and intramural athletics with higher retention, higher grade point average (GPA), and higher likelihood of degree completion (Danbert et al., 2014; Mayers, et al., 2017; McElveen & Ibele, 2019; Roddy, et al., 2017; Vasold, Deere, & Pivarnik, 2019; Vasold, Kosowski, & Pivarnik, 2019). Although the body of literature on the benefits of campus recreation for student success is growing, studies lack consistency and are primarily shared within the campus recreation field. As examples, studies may employ inconsistent definitions of recreation participants or facility users, and studies may not have access to a range of data or employ appropriate methods to minimize the salience of plausible alternative explanations for student outcomes. The authors of the present study seek to extend the existing and growing literature connecting recreation participation with student outcomes by taking a systematic approach to defining users, assembling campus-wide, multi-institutional data on student characteristics, and considering the potential for selection bias in recreation participation, while also connecting study findings around retention to next steps and implications for professionals and campus leaders across colleges and universities. (see attached paper for complete references)

What method are you going to use to analyze the data?

Research coordinator will use retrospective secondary data analysis on data previously collected by the university and held by each university's institutional research. Additional data to be integrated includes student recreation facility use (i.e., card swipe data). All data downloads occur using secure university databases, and all data used for analysis are stored on secure university drives. Data transfers (i.e., from institutions) will use secure university file locker server. Data collection and analysis steps include: Part I: All institutions (WVU and Collaborators/non-WVU): 1. Access swipe card data from student recreation facility(ies) for one academic fall semester (i.e., August 1, 2018-December 31, 2018) 2. Data request to IR for census data for full-time, first-time freshman for a fall academic semester (Note: exclude high school taking college courses and online students); essential variables include: Student ID, Gender, Race Ethnicity, High School GPA, Sat Combined Scores, Act Composite Scores, Fall Cumulative GPA, Federal Pell Grant, Retention) 3. Pair & de-identify data (i.e., remove student ID after pairing data sets) 4. Upload de-identified data to secure server. Note: WVU data will not be de-identified by IR; it will be de-identified by research coordinator prior to combining institutional data into one multi-institutional dataset. Part II: Study coordinator (West Virginia University): 1. Provide facilitation & guidance through detailed data requests (part I above) 2. Provide and troubleshoot data dictionary (part I above) 3. Provide data repository, de-identify institutional names, combine institutional data into one multi-institutional dataset. 4. Provide data management & statistical analysis, including summary statistics and significance tests to characterize the sample 5. Statistical analysis, including ordinary least squares and logistical regressions 6. Facilitate writing and publishing reports and presentations.

Expedited Review

Is this study only minimal risk?

Yes

Does the research qualify for Expedited Review Category 1 - clinical studies of FDA-approved drugs or medical devices? (See More Information)

No

Does the research qualify for Expedited Review Category 2 - blood sample collection? (See More Information)

No

Does the research qualify for Expedited Review Category 3 - noninvasive collection of biological specimens? (See More Information)

No

Does the research qualify for Expedited Review Category 4 - noninvasive standard of care procedures? (See More Information)

No

Does the research qualify for Expedited Review Category 5 - evaluation of data (e.g., medical records review)? (See More Information)

Yes

Does the research qualify for Expedited Review Category 6 - voice, video, digital, or image recordings? (See More Information)

No

Does the research qualify for Expedited Review Category 7 - behavior, surveys, interviews, etc.? (See More Information)

No

Briefly describe how the research meets the requirements of the expedited category(ies) selected.

The study uses retrospective secondary data analysis to determine to what extent is there a relationship between participation in Campus recreation and GPA and retention for college first-time freshmen, using non-users as a control group. Student-level data, collected and housed at the university, including all students, will be paired with Campus recreation participation data, including only participants. WVU Campus recreation data includes usage of the campus recreation facility, which is swipe card data. There is no more than minimal risk in participation in the study.

Does the study involve intervention and/or manipulation of the subjects or the subjects' environment (e.g., educational intervention or training, experimental or quasi-experimental design)?

No

Is the research categorized as interventional medical research?

No

Will subjects intentionally be deceived as to the purpose of the study?

No

HIPAA

Does the research involve [protected health information](#) (PHI) or personally identifiable information (PII)?

No

Subjects

Indicate the maximum number of subjects to be enrolled or medical records to be reviewed at all sites by the WVU or VAMC research team.

25,000

Provide a rationale for choosing your sample size.

Census data provides accurate comparison between users and non users and/or participants and non participants of campus recreation. The participant population includes all first-time, full-time undergraduate students from one academic fall semester (i.e., August 1, 2018-December 31, 2018) at WVU, as well as each collaborating institution, including participants and non-participants of campus recreation. The sample does not include vulnerable or special populations. Recruitment is not applicable to this research design as it uses retrospective secondary data analysis to examine all first-time, full-time freshmen (FTF) students to be able to compare participants and non-participants of campus recreation. The number of participants to be enrolled in the study equals the full-time FTF enrollment of the university at that year. That includes about 5 thousand students per institution, or around 25,000 in total. Specifically, full-time FTF used in the sample only include those who are enrolled on the main campus (i.e., at the location of the campus recreation opportunities), and does not include students such as high school students taking college courses. This includes only students who were first-time freshman entering in the fall semester, following institutional protocol for retention calculations for first-time freshman. Analysis only focuses only on students who are enrolled full-time.

State the requirement(s) to become a participant in the study (e.g., age range, sex, language spoken, class enrollment/ranking).

First-time full time undergraduate student for one fall semester (i.e., August 1, 2018-December 31, 2018) paying campus fees - see previous

Explain why selection of participants will be equitable addressing gender, ethnicity, and/or race of subjects.

Reflects actual full time FTF student population - see previous

In outline format and chronological order, describe what will be done to identify and recruit participants (e.g., A, B, C or 1, 2, 3).

Student-level data, collected and housed at each university will be paired with Campus recreation facility use data, including only participants, for one fall semester (i.e., August 1, 2018-December 31, 2018). Data collection and analysis steps include, for all institutions (WVU and Collaborators/non-WVU): 1. Access swipe card /facility use data from student recreation facility(ies) for one academic fall semester (i.e., August 1, 2016-December 31, 2016) by month, if possible. 2. Data request to IR for census data for full-time, first-time freshman for a fall academic semester (Note: exclude high school taking college courses and online students); essential variables include: Student ID, Gender, Race Ethnicity, High School GPA, Sat Combined Scores, Act Composite Scores, Fall Cumulative GPA, Federal Pell Grant, Retention) 3. Pair & de-identify data (i.e., remove student ID after pairing data sets of facility use and student level IR data) 4. Upload de-identified data to secure server.

Will any of the subjects be less than 18 years old?

Yes

Will the subjects include the population classified as neonates (0-28 days of age)?

No

Will the subjects include the population classified as children (29 days to 6 years of age)?

No

Will the subjects include the population classified as minors (7-17 years of age)?

Yes

Will assent be obtained from all minors?

No

Will parental/guardian consent be obtained for the subjects less than 18 years old to participate in the study?

No

Justify the waiver of parental consent.

Utilizing secondary retrospective data and not directly interacting with participants specifically under the age of 18.

Will your study target populations such as pregnant women, fetuses, neonates, or any groups likely to be vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capability or economically or educationally disadvantaged persons?

No

Does this research involve participants who could be coerced or unduly influenced, such as current students/employees of research team members?

No

Does the protocol deal with cancer prevention, treatment, or diagnosis (including surveys)?

No

Has this protocol been reviewed by Clinical Trials Working Group (CTWG)? If yes, please attach the CTWG's correspondence on the Notes & Attachments page.

No

Consent Procedures

Will SIGNED informed consent be obtained from subjects (paper-based and/or electronic)?

No

Is a waiver of informed consent being requested (i.e., there will be no consent process at all)?

Yes

Explain how waiving the requirements for informed consent will not adversely affect the rights and welfare of study subjects.

A waiver will not adversely affect the rights and welfare of the subjects. Data is reported in summarized form, no individual student data is released, and data in analysis phase is stored securely and coded (if necessary). Study coordinator from each institution already has access to this data as a part of their regular jobs.

Explain how waiving the requirements for informed consent presents no more than minimal risk to study subjects.

This study uses retrospective secondary data analysis, and the research involves no more than minimal risk to subjects. Study coordinator from each institution already has access to this data as a part of their regular job. Student level data is de-identified at each institution prior to multi-institutional pairing. The research meets the definition of minimal risk given, given that data is reported in summarized form, no individual student data is released, and data in analysis phase is stored securely and coded (if necessary). Risks to participation may include a breach of confidentiality of any identifiers remain on the data and the data is breached, including: financial aid information, income information, and GPA.

Explain why the research could not be carried out practicably without the waiver.

Given the type of analysis, retrospective secondary data analysis, the research involved no procedures for which written consent is not wholly possible at the scale and scope of the analysis. It would not be practical to carry out a waiver to over 25,000 students across multiple institutions, many of whom are no longer at the institution.

Will subjects be provided with additional pertinent information after participation?

No

Is a waiver of the requirement to obtain written documentation of the consent process being requested (if yes, attach the information to be provided to the participants)?

No

Are you requesting an alteration of consent (e.g., short form, braille consent or witnessed verbal consent)?

No

For remote or in-person electronic consent, complete an e-IC worksheet from the [OHRP Forms page](#) and attach it to the submission.

If only paper-based in-person consent will be used, describe the consent process. Address the following separately:

1. When will prospective participants be approached for consent?
2. Where will the consent occur?
3. How will the research and the consent materials be explained, and how and when will questions be answered?

n/a

Indicate who will be consenting subjects and describe the process of training all personnel who will be obtaining consent.

n/a

Potential Benefits

Is there any known benefit to the individual subject as a result of participating in the research? Payments to subjects should not be included in this section, but addressed in the Payments/Reimbursements section.

The benefit to the participant(s) from participating in the research is the same as the contribution to the scientific field or general population, which includes supporting programming that encourages academic success (i.e., retention, attrition, GPA) at colleges and universities.

Describe the potential benefit(s) to society and/or scientific / medical knowledge of the planned work.

The benefit to the participant(s) from participating in the research is the same as the contribution to the scientific field or general population, which includes supporting programming that encourages academic success (i.e., retention, attrition, GPA) at colleges and universities.

Confidentiality

At any point during this study, will identifiable data be viewed or recorded?

Yes

Data will be kept for a minimum of three (3) years after study completion, or in accordance with the approved Data Protection Form (Yes/No). If No, explain.

Recreational use data will be stored at each institution for the foreseeable future to be able to use for historical purposes. Study coordinator from each institution already has access to this data as a part of their regular job. Student level data is de-identified at each institution prior to multi-institutional pairing and stored securely.

Data will be securely located in accordance with the approved Data Protection Form (Yes/No). If No, explain.

To protect research subject's confidentiality and privacy, the following steps will be taken. First, all data downloads occur using secure university databases. Before combining data, student-level data is de-identified at each institution; identification data will be stored securely with study coordinator from that institution. During data analysis, all data used are stored on secure university drives. Data transfers (i.e., from institutions) would use secure university file locker server. Additionally, de-identified student data across institutions is analyzed only by research coordinator and not anticipated to be shared with project support team. If needed to be shared during analysis phase, institutions will be de-identified (in addition to the already de-identified student data). Finally, to protect privacy, all findings will be shared with the team and reported in aggregate (i.e., across institutions).

Data will be destroyed in accordance with the approved Data Protection Form (Yes/No). If No, explain.

Recreational use data will be stored at each institution for the foreseeable future to be able to use for historical purposes. Study coordinator from each institution already has access to this data as a part of their regular job, so will not specifically seek to destroy data. PI can delete combined multi-institutional data after the required timeframe, if deemed necessary.

Will anyone other than the PI, research team members, or IRB have access to the identifiable data (e.g., sponsor/funding source, other collaborators)?

No

Describe the steps that will be taken to maintain the privacy of subjects (e.g., where interaction takes place) and the confidentiality of data (e.g., master code).
 To protect research subject's confidentiality and privacy, the following steps will be taken. First, all data downloads occur using secure university databases. During data analysis, all data used for analysis are stored on secure university drives. Although not anticipated, any potential data transfers (i.e., between IR and Campus Rec) would use secure university file locker server. Additionally, individual student data is analyzed only by research coordinator and not anticipated to be shared with project support team. Also, if individual student data is necessary to be shared during analysis phase, research coordinator will recode student ID to remove identifying link with random identifier and keep key to code stored in a secured location. Finally, to protect privacy, all findings will be shared with the team and reported in aggregate.

Does this study have a Federal Certificate of Confidentiality? If yes, attach the certificate on the Notes & Attachments page.
 No

Financial Considerations

Will the subjects incur any costs to participate in this project (e.g., travel, physician fees, study procedures, study drugs)?
 No

Will the subject be paid (money, gift certificates, coupons, etc.) to participate in this research project?
 No

Will WVU students receive extra credit for participating in this research project?
 No

Advertisements

Will there be advertisements for this study?
 No

Sample Collection

Will sample(s) be used?
 No

Biological Safety

Does the study involve the handling of any infectious and/or non-infectious agents or recombinant DNA?
 No

Data Protection for IRB

Have you requested and received your data protection certificate?
 No

Protocol Notes

DATE	AUTHOR	TOPIC	NOTE
02/05/2020 02:49 PM	Sera Zegre	Specific minor revisions	Hello, Thank you for the opportunity to edit the protocol. I have responded to the specific minor revisions requested in the 2/5/2020 letter in the following steps: (1) Although the study involved de-identified student records from the participating institutions, WVU data will not be de-identified by IR; it will be de-identified by the Research Coordinator prior to combining institutional data into one multi-institutional dataset. That said, notes were made in both the methods and procedures sections and the study was not reclassified. (2) Lay summary was re-written for clarity. Specifically, the word persistence was removed and replaced with "first-year retention". (3) Made note of correct signatories for IAA, and will proceed with correct signatory at WVU and participating institutions once IRB protocol is finalized. Thank you for your continued review.
01/30/2020 02:04 PM	Sera Zegre	IAA	I've attached three unsigned IAA for each of the three collaborating institutions. I had hoped to get an approved IRB and DUA before sending the IAAs to each school for signatory. I can provide the signed documents once obtained.
01/30/2020 02:02 PM	Sera Zegre	DUA	I've attached the DUA intake form to demonstrate efforts in that realm. I can provide the final document once developed and signed.
02/21/2020 11:09 AM	Sera Zegre	re-submission	Hello. I submitted the revision on 2/5 and received a confirmation email as such. Not sure if there was a glitch in the system or not, but I'm resubmitting again today. I have made edits to the questionnaire to reduce the amount of student-level variables to be collected to streamline the research. No other changes have been made.
01/04/2022 01:20 PM	Sera Zegre	Specific minor revisions	Hello! I've changed the year from 2016 to 2018 as per our amendment throughout the questionnaire design and subject sections. Thank you!