Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Protocol Information

Reference #	107085		
Protocol #	IRB-18-0346		
Protocol Type:	Original		
PI:	Strickland, Ora Lea	**Approval Date:**	9/27/2018
Submittal Date:	10/3/2018	**Effective Date:**	10/9/2018
Author:	FRAY, BEVERLY	**Renewal Date:**	9/27/2019
Status:	Approved	**Next Review Date:**	9/27/2019
Inactive Date:		**Expiration Date:**	9/27/2019

INSTRUCTIONS 1

Completing this IRB Approval Form 1.1

This IRB Approval Form is used for obtaining approval for non-exempt human subject research.
While filling out this form, some questions may have additional information in blue "?" help icon located on the right of the question.
For additional assistance with completing this form, visit the Office of Research Integrity Topaz website located at: http://research.fiu.edu/irb/pages/topaz.html
Save often by selecting the "Save" icon at the top of this form since the system does not automatically save your progress.

****
IMPORTANT UPDATE
****
The U.S. Department of Health and Human Services (HHS) announced on June 18, 2018 that the revisions to the "Federal Policy for the Protection of Human Subjects" (also known as the Common Rule) will be delayed until January 21, 2019.
Please visit the following website for more information: http://research.fiu.edu/irb/revised-common-rule

ADMINISTRATIVE 2

Reference Number 2.1

This number is system generated.
107085

Protocol Number 2.2

This number will be assigned after the protocol has been processed.

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Relation to Another FIU IRB Approved Study

2.3

Is this study related to another FIU IRB approved study under one of the following scenarios?
This is a sub-study, which is based off of a larger study (e.g., this study utilizes the data or participants from a larger study); or
The former study had a lapse in IRB approval, so the study is being resubmitted as a new original submission submission in order to resume the research.

- ☐ Yes
- ☑ No

2.3.1

Yes

2.3.2

No

Title

2.4

Provide the title of the project.
Factors Predicting High Risk Sex Practices and Incidence of STIs among Female Veterans

Department

2.5

Select the FIU Principal Investigator's department.
CNHS Nursing PhD Program

Principal Investigator

2.6

Provide the name of the FIU Principal Investigator (PI).
Students cannot serve as the PI. Courtesy and voluntary faculty members cannot serve as the PI.
Please Note: Undergraduate/Graduate student research projects are required to have an FIU faculty member with Graduate Faculty Status or Dissertation Advisor Status (DAS) serving as the Principal Investigator. Student researchers need to be listed separately in the "Protocol Associates" section below. Exceptions to this policy may be judged appropriate under particular circumstances and those exceptions shall be determined by the Division of Research.

Strickland, Ora Lea		olstrick@fiu.edu

Author

2.7

The Author is the person that is completing this application form. This is typically the same person as the Principal Investigator unless another individual is assisting with the completion of the application form (e.g., Project Coordinator). The Author will be able to access and edit the initial submission as well as all future amendments, renewals, and interim submissions that are associated with this project.

FRAY, BEVERLY		bfray001@fiu.edu

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Protocol Associates

2.8

Add all FIU Co-Investigators and FIU Key Associates that will be engaged in this project. Individuals are considered "engaged" if they will be intervening or interacting with human subjects (e.g., consenting subjects, collecting data, etc) and/or accessing coded or identifiable human subject data (e.g., data analysis). See the OHRP Engagement Guidance or contact the FIU IRB Office (ORI) for more information on whether someone is considered engaged.
Individuals that are designated as Co-Investigators can view and edit this application and will also receive email alerts.
Individuals that are designated as Key Associates cannot view and edit this application, but will receive certain email alerts.
Select the green "+" icon to the right to add the individual(s). Select only one role per person. List the responsibilities for each individual.

FRAY, BEVERLY

Responsibilities	Beverly is the PhD candidate/student who will be coordinating the entire study. She will be sccreening prospective participants, enrolling participants, consenting participants, collecting data, obtaining all the necessary permsissions, analyzing and disseminating the results of the study.
Comments	Beverly will be the main point of contact for this study.

☑ **Co-Investigator** ☐ **Key Associate**

Protocol Associates (Not Requiring TOPAZ Access)

2.9

Add all FIU Co-Investigators and FIU Key Associates that will be engaged in this project, but do not need the ability to view/edit the protocol or receive TOPAZ system email notices regarding this protocol. For the "Role" column, designate if the individual is a Co-PI or Key Associate on the project. See the OHRP Engagement Guidance or contact the FIU IRB Office (ORI) for more information on whether someone is considered engaged.
For the "Position" column, designate if the individual is a Faculty Member, Staff Member, Undergrad Student, Grad Student, or Post-Doc. "Responsibilities" might include data entry, recruiting subjects, consenting subjects, etc. Click "Add Row" to add each individual.

First Name	Last Name	Role	Position	Department	Email	Panther ID	Responsibilities

External Protocol Associates

2.10

Indicate if there will be any external (non-FIU) Co-Investigators or Key Personnel engaged in this project. Individuals are considered "engaged" if they will be intervening or interacting with human subjects (e.g., consenting subjects, collecting data, etc) and/or accessing coded or identifiable human subject data (e.g., data analysis). See the OHRP Engagement Guidance or contact the FIU IRB Office (ORI) for more information on whether someone is considered engaged.

☐ Yes
☑ No

2.10.1

Yes

2.10.2

No

IRB Educational Training (Attachment)

2.11

All investigators and key personnel that are engaged in conducting research with human subjects are required to complete the web-based Collaborative Institutional Training Initiative Program (CITI) training in the protection of human research subjects. Indicate below if all of the individuals on this project have completed the required CITI IRB training. See the IRB Training web page for more information. Click the blue "?" icon to the right for further instructions. Attach the CITI IRB Training Completion Reports. Click the paper clip icon to the right to upload the documents.

- [x] Yes - CITI IRB Training has been completed by all project personnel.
- [ ] No - CITI IRB Training has not yet been completed by all project personnel.

  Note: All project personnel must complete the online training prior to the conclusion of the IRB review and approval process. Failure to complete the training will delay the approval process.

2.11.1

Yes - CITI IRB Training has been completed by all project personnel.

2.11.2

No - CITI IRB Training has not yet been completed by all project personnel.

Good Clinical Program (GCP) Training (Attachment)

2.12

All researchers that are engaged in conducting one of the following types of research studies are also required to complete online GCP training:
NIH funded clinical trial (one or more human subjects are prospectively assigned to one or more interventions, which may include placebo or other control, to evaluate the effects of those interventions on health related biomedical or behavioral outcomes); or
FDA regulated clinical trial (involving drugs, devices, or biologics)
Indicate the type of project that you are conducting below. See the IRB Training web page for more information.
Attach the GCP Training Completion Reports if this study is an NIH or FDA Clinical Trial. Click the paper clip icon to the right to upload the documents.

- [ ] Clinical Trial (NIH Funding)
  GCP Training is required
- [ ] Clinical Trial (FDA Regulated - Drugs, Devices, or Biologics)
  GCP Training is required
- [ ] Clinical Trial (No NIH Funding and not FDA Regulated)
- [x] Not Applicable (Not a Clinical Trial)

2.12.1

Clinical Trial (NIH Funding)

2.12.2

Clinical Trial (FDA Regulated - Drugs, Devices, or Biologics)

2.12.3

Clinical Trial (No NIH Funding and not FDA Regulated)

2.12.4

Not Applicable (Not a Clinical Trial)

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Conflict of Interest

2.13

Does anyone on this study team, their spouses, or dependent children have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?

- ☐ Yes

  FIU employee(s) are required to complete the applicable Faculty Outside Activities and Financial Interest Report available at http://academic.fiu.edu/AcademicBudget/www/downloadforms.htm or the A&P/USPS Report of Outside Activities form, available at http://hr.fiu.edu/index.php?name=forms_library
- ☑ No

2.13.1

Yes

2.13.2

No

REVIEW TYPE

3

Institutional Review Board

3.1

Select the Board that you feel will be most appropriate to review this type of research. Click the blue "?" help icon to the right to assist you with making your selection. You can leave this field blank if you are uncertain of the appropriate Board to review your research. Final Board assignment will be determined by the Office of Research Integrity.

- ☑ Health Sciences IRB (HS-IRB)
- ☐ Social and Behavioral IRB (SB-IRB)

3.1.1

Health Sciences IRB (HS-IRB)

3.1.2

Social and Behavioral IRB (SB-IRB)

Type of Review Being Requested

3.2

Indicate if you are seeking Expedited Review or Full Board Review. Click the blue "?" help icon to the right to assist you with making your selection. You can leave this field blank if you are uncertain of the type of review to request. Final determination will be made by the IRB.

- ☑ Expedited Review
- ☐ Full Board Review

3.2.1

Expedited Review

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Expedited Category Number

3.2.1.1

Select the Expedited Category Number(s) that your protocol falls under. The most commonly used categories are Categories #2, #3, #4, #5, and #7. Final determination will be made by the IRB.
Please review the full detailed Expedited Category Listing online.

- ☐ Expedited Category #1 (Clinical studies of drugs and medical devices - If an IND or IDE is not required)
- ☐ Expedited Category #2 (Collection of blood samples)
- ☐ Expedited Category #3 (Prospective collection of biological specimens)
- ☐ Expedited Category #4 (Collection of data through noninvasive procedures - Physical sensors, moderate exercise, MRI, ultrasound, etc.)
- ☐ Expedited Category #5 (Research involving data, documents, records, or specimens that have been collected, or will be collected solely for nonresearch purposes)
- ☐ Expedited Category #6 (Collection of data from voice, video, digital, or image recordings made for research purposes)
- ☑ Expedited Category #7 (Research on individual or group characteristics/behavior including surveys, interviews, oral history, focus groups, program evaluation, etc.)
- ☐ Expedited Category #8 (Continuing review of research previously approved by the convened Full IRB - Under certain conditions)
- ☐ Expedited Category #9 (Continuing review of research, where categories 2-8 do not apply, but the Full IRB determines that the study is eligible for Expedited review)

3.2.1.1.1

Expedited Category #1 (Clinical studies of drugs and medical devices - If an IND or IDE is not required)

3.2.1.1.2

Expedited Category #2 (Collection of blood samples)

3.2.1.1.3

Expedited Category #3 (Prospective collection of biological specimens)

3.2.1.1.4

Expedited Category #4 (Collection of data through noninvasive procedures - Physical sensors, moderate exercise, MRI, ultrasound, etc.)

3.2.1.1.5

Expedited Category #5 (Research involving data, documents, records, or specimens that have been collected, or will be collected solely for nonresearch purposes)

3.2.1.1.6

Expedited Category #6 (Collection of data from voice, video, digital, or image recordings made for research purposes)

3.2.1.1.7

Expedited Category #7 (Research on individual or group characteristics/behavior including surveys, interviews, oral history, focus groups, program evaluation, etc.)

3.2.1.1.8

Expedited Category #8 (Continuing review of research previously approved by the convened Full IRB - Under certain conditions)

3.2.1.1.9

Expedited Category #9 (Continuing review of research, where categories 2-8 do not apply, but the Full IRB determines that the study is eligible for Expedited review)

3.2.2

Full Board Review

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

PROJECT OVERVIEW

4

Project Starting Date

4.1

Provide the date that you are planning to begin the research with human subjects (e.g., date to begin recruitment or access a database). Click the calendar icon below to select your starting date.
Please use a future starting date. When selecting your starting date, please allow at least 3 weeks for an Expedited Review and at least 4-6 weeks for a Full Board Review.
9/30/2018

Project Completion Date

4.2

Provide the date that you are planning to finish the research with human subjects (e.g., date that you will be finished with all data analysis). Click the calendar icon below to select your completion date.
12/3/2018

Funding

4.3

Indicate if funding is (or will be) associated with this project.

- ☐ Yes
- ☑ No

4.3.1

Yes

4.3.2

No

Student Research Project

4.4

Is this study being conducted by an FIU student as part of an undergraduate or graduate research project?

- ☑ Yes
- ☐ No

4.4.1

Yes

Type of Student Project (Attachment)

4.4.1.1

Attachments: Fray Research Proposal for UGS 2018.docx

Select the type of student project that this study falls under.
Attach a copy of the five page UGS proposal if the study is part of a Thesis or Dissertation. Click the paper clip icon to the right to upload your document.

Dissertation Research

Student Investigator Details

4.4.1.2

Provide the following details about the primary student investigator conducting this project.

First Name	Last Name	Email Address	Phone Number	Panther ID
BEVERLY	FRAY	Bfray001@fiu.edu	3055866753	1144248

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

4.4.2

No

Other Institutional Committees

4.5

Does this project involve components other than human subjects that will require review by other FIU committees (e.g., animals, rDNA, radiation)?

- ☐ Yes
- ☑ No

4.5.1

Yes

4.5.2

No

Type of Project

4.6

Indicate the type of project you will be conducting by selecting the green "+" icon on the right. Select all that apply for this project.
Note: Select "Clinical Trial Study" if one or more human subjects are prospectively assigned to one or more interventions, which may include placebo or other control, to evaluate the effects of those interventions on health related biomedical or behavioral outcomes.

Data Collection Study

4.6.1

Data Collection Study

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Summary of the Research

4.7

Summarize the proposed research using non-technical language that can be readily understood by someone outside the discipline.
Your summary needs to briefly explain the following information in paragraph format using complete sentences (limit to 300 words):
Research design;
Procedures to be used;
Risks and anticipated benefits; and
The importance of the knowledge that may reasonably be expected to result

The study is designed in a manner that will allow me to interact with the participants at one point in time (cross-sectional). It is a correlational study because all data collected will be compared and contrasted to see if any significant trends are present using low and high level statistical procedures (such as descriptive, and regression analyses to see which ones are most correlational and/or predictive of high risk sexual behavior (outcome behavior). Procedures: The PI will recruit female Veterans from the community via flyers, social media post, and radio public service announcements. The PI will screen any female Veteran willing to participate (see attached Screening Form and Flyer). Informed Consent, including risks and benefits to participants will be explained and obtained by the PI. A copy of the Informed Consent will be given to each consenting participant. Participants and PI will agree on the place and time for survey instruments completion confidentially (instruments are attached). Participants will be cautioned not to include any identifying information such as name, date of birth or address. A blank, nondescript envelope will be given to each participant to secure the completed surveys. After sealing the envelope, the participant will give it to the PI. The PI will then place the envelope in a code-locked container accessible by the PI only. The participant will then be given a $10 gift certificate for taking the time to participate. Risks to participants are no more than minimal. Findings from this study will have implications for practice, policy and theory testing. In terms of practice, findings will contribute to the understanding of female Veterans' sexual behaviors, STD knowledge, the impact (SDO effects) of the military environment on post military sexual behaviors and assist in shaping care interventions to mitigate unhealthy behaviors elucidated, while encouraging healthy ones. In terms of policy and health care, study findings may lead to the development of policy changes/development to address issues emanating from the study and begin a trajectory of research focused solely on female Veterans. Because this is the first time that the Social Dominance Theory is being used to guide a nurse-driven study in this population, it may broaden the understanding of sexual behaviors in this population from a new perspective.

Scientific Background & Literature Review

4.8

Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. Use complete sentences (limit to 300 words).

The study will use a descriptive, correlational, cross-sectional, non-experimental design to describe the sexual behaviors and factors that predict high risk sex as well as the incidence of STIs among a sample of female military Veterans in Florida. Sexually transmitted infections (STIs), also known as sexually transmitted diseases (STDs), remain a significant public health problem in the United States and the world. HIV, the most serious, is most prevalent in the Southern United States, especially Florida. They refer to more than 25 diseases that are transmitted sexually, primarily through unprotected sex with an infected partner (CDC, 2016). STI prevention is, therefore, an essential primary care strategy for improving reproductive health and safer sexual practices. Despite their burdens, costs, and major negative health consequences, they remain a major public health issue, especially when diagnosed late. Stahlman (2014) conducted an inquiry on a large sample of active duty personnel (10,250) of which 3,248 were female. The study revealed that in the previous 12 months, STI prevalence for men was 4.2% and 6.9% for women and 9.3% of the women reported five or more sexual partners in this period. Binge drinking, illicit substance use, and unwanted sexual contact were associated with increased report of sexual partners among both genders. Notably, risk factors were different for women and were enumerated as family/personal-life stress and psychological distress influenced the number of partnerships more strong;y for women than for men. The researcher concluded that, based on these findings, gender-specific interventions are necessary. This study will begin to address this need and to further determine to see if such behaviors remain prevalent after active duty (as female Veterans).

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Research Objectives

4.9

List the specific scientific or scholarly aims of the research study. Use complete sentences (limit to 300 words).

Specific Aims:
1. Examine how female Veterans' individual and demographic characteristics (such as age, racial/ethnic background, military experience, an dprior experinece with abuse); cognitive and behavioral factors (such as safer sex behvaiors and STD knowledge); socioeconomic factors; and, social dominance orientation are associated with each other.
2. Explore the degree to which female Veterans' individual and demographic characteristics (such as age, racial/ethnic bacground, military experience, and prior experience with abuse); and socioeconomic factors predict safer sex behaviors, STD knowledge and social dominance orientation.

Location of Research

4.10

Indicate if the location(s) of the research is domestic or international. Select all that apply.

- [x] Domestic Site (United States)
- [ ] International Site (Foreign)

4.10.1

Domestic Site (United States)

Domestic Site Information

4.10.1.1

Select the sites/locations where you will be conducting this research project. Click the green "+" symbol to the right to make your selection(s). Select all that apply.
Note: If your site is not listed in the available options, then please select the "Other Location" option. You will have an opportunity to provide the specific details of the location in the next question below.

Florida International University

4.10.1.1.1

Florida International University

Domestic Site Details (Attachment)

4.10.1.2

Provide the details below for each site/location that will be used in the research study. Examples of tasks done at a site might include activities such as recruitment, consenting, data collection, etc. External (Non-FIU) sites will normally require a letter of support and may also require another IRB's approval if the personnel at that site are engaged in conducting the research.
Note: Researchers are required to comply with all applicable IRB policies and procedures of external sites when conducting research off-campus.
Note: If the research will only take place at FIU, then you should just write "FIU" as the Location Name and then list the Task(s) Done at Site (you do not need to provide FIU's address, city, state and phone number).
Click "add row" for each additional site that you need to add.
If using an external (non-FIU) site, attach your letter(s) of support and/or external IRB approval letter(s) by clicking the paper clip icon to the right.
Requirement for Nicklaus Children's Hospital (NCH): If conducting research at NCH, you will need to attach an NCH support letter from Mr. Jose Perdomo (VP of Ethics & Compliance) or a copy of the NCH Western IRB approval letter.

Location Name	Address	City	State	Phone Number	Task(s) Done at Site
Florida International University	11200 SW 8th Street	Sweetwater	Florida	305 348-7718	Coordination site; Storage and data management

4.10.2

International Site (Foreign)

SUBJECT POPULATION

5

Duration of Participation

5.1

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

It is estimated that each participant will spend no more than 2 hours in this study, from screening to survey completion. There will be no follow-up contact and no participant's contact information will be collected as part of ths study. All interactions between participants and PI willl take place at one point in time.

Number of Participants

5.2

The number of participants is defined as the number of individuals who agree to participate even if all do not prove eligible to complete the study. If you are planning to screen out participants, then you will need to differentiate between the proposed number of subjects that will be recruited for screening and the proposed number of subjects that are expected to be consented into the study. If datasets are being used, then provide the number of datasets that will be accessed.

The sample size will be at 116 female Veterans.

Justification for Number of Participants

5.3

Provide a brief rationale on how you came up with your proposed number of participants.

This number was determined by G*Power 3.1 software as the least number of participants needed to render an anticipated effect size of .30 or higher in order to achieve statistically significant results at the alpha level of of .05, and a minimum power of .80. Effect size is a set of statistics that indicates the relative magnitude of relationship among variables or the strength of the differences among groups (Tabachnick & Fiddell, 2007 in Pallant, 2010).

Multi-Site or Collaborative Study

5.4

A multi-site study involves multiple institutions and/or organizations that are collaboratively working together on administering a research study and/or enrolling subjects across multiple sites.

- ☐ Yes
- ☑ No

5.4.1

Yes

5.4.2

No

Gender of Subjects

5.5

Indicate the gender of the subjects.

Female

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Age of Subjects

5.6

Select the age range(s) of the subjects. Click the green "+" symbol to the right of the screen to make your selection(s). Select all that apply.

18-24 Years

25-59 Years

60+ Years

5.6.1

18-24 Years

5.6.2

25-59 Years

5.6.3

60+ Years

Participant Populations

5.7

Specify the participant population(s) to be included. Click the green "+" symbol to the right of the screen to select the populations. Select all that apply.

Adults

5.7.1

Adults

Characteristics of Populations

5.8

Describe the characteristics of the population(s) and explain how the nature of the research requires/justifies inclusion of the proposed population(s).

The target population for this study is US female military Veterans of any age who are residents in the State of Florida. Participants who meet the screening criteria will be deemed appropriate to participate in the study (please refer to screening form). Anyone who does not meet these criteria will be excluded from participating. Participants must be able to speak, write and understand English. According to US Public Law, Code 38, 101, "the term "Veteran" refers to any person who served in the active military, navy, or air service, and who was discharged or released therefrom under conditions other than dishonorable." This includes those who participated or did not participate in war, or were in the reserves. Hence, female Veterans will be any woman who meets these criteria. This will also include men who identify as women or who underwent gender change surgery and now identify as female.

Inclusion & Exclusion Criteria

5.9

Indicate if you will be including and/or excluding individuals based on a specific set of criteria for this project. Provide a justification for the inclusion and/or exclusion criteria.

Inclusion criteria are: adult female (born as a woman and still a woman; born a man and now identifies as a woman after sex change; born as a man and now identifies as a woman without a sex change); 18 years or older; was enrolled at one point or another in a branch of the United States military; residing in Florida; speaks, writes and understands English (please refer to the screening form). Anyone woman who meets these criteria and is willing to participate will be included, and anyone who does not meet the criteria will be excluded as these are the characteristics of concern in the study. The justification for these inclusion criteria is that these are the characteristics that would provide the best data for the study and minimize chance of attrition.

Coercion or Undue Influence

5.10

Indicate if any of the participants are likely to be vulnerable to coercion or undue influence.

- ☐ Yes
- ☑ No

5.10.1

Yes

5.10.2

No

Vulnerable Populations

5.11

Additional requirements are needed if your study includes vulnerable populations (this includes secondary data analysis studies). Please select all that apply. Additional questions will be populated on the form based on your selections.

- ☐ Children
- ☐ Decisionally Impaired Adults
- ☐ Neonates
- ☐ Pregnant Women
- ☐ Prisoners
- ☑ Not Applicable

5.11.1

Children

5.11.2

Decisionally Impaired Adults

5.11.3

Neonates

5.11.4

Pregnant Women

5.11.5

Prisoners

5.11.6

Not Applicable

Foreign Language Participants

5.12

Indicate below if this project will involve recruiting and/or interacting with non-English speaking/reading participants.

- ☐ Yes
- ☑ No

5.12.1

Yes

5.12.2

No

SUBJECT RECRUITMENT

6

Identification of Subjects

6.1

Describe how potential participants will be identified (e.g., individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

The PI will gain access to potential participants through personal contacts, Veterans groups in the community, and through references from participants (snowballing). Individuals who are also Veterans known to investigator will be recruited to participate. Investigator will also recruit participants via social media such as Face Book, Instagram and Twitter (see attached message to be used.

Individuals Recruiting Subjects

6.2

List the names of the investigators and/or key personnel who will be recruiting subjects.

Beverly Fray, PhD Candidate, FIU Student

Recruitment/Advertising Process (Attachment)

6.3

Attachments: APPENDIX G - Flyer for Inviting Research Participants.doc APPENDIX A - Study Participant Screening Form.pdf APPENDIX M - Script for Face Book, Twitter and Instagram for the Study.pdf

Describe the recruitment process; including the setting in which recruitment will take place. Explain how the process respects potential participants' privacy. Describe the types of advertisements that will be used (e.g., ads, flyers, website postings, email messages, recruitment letters, and/or oral written scripts). If you will not be using any types of advertisements, then you will need to indicate this below.
Attach copies of the proposed recruitment materials. Click the paper clip icon to the right to upload your document(s).

Participants responding to the call to participate will be screened (see attached Screening Form) to ensure they meet criteria to participate. Those who meet study criteria will make arrangements with the PI for instrument completion. Once the PI and the participant agree on a date, place, and time, the PI will explain the study, answer any participant questions, address any concerns, obtain informed consent and provide participant with the instruments for completion. Once completed, participant will be given a blank envelope to secure the surveys. Participant will seal the envelope and return it to PI who will secure it in a locked receptacle for safekeeping until all data are collected from at least 116 participants. Safety of both PI and participant will be taken into consideration. Each participant will be given a $10 gift certificate at the end of their participation. If participants wish to complete surveys online, that choice will be provided via SurveyMonkey account (see attached). All Surveys will be sent to any participants who wishes to complete the surveys online. For online participants, the PI will screen for eligibility prior to sending the links to the survey. No participant will be able to access the survey again after completion online. The surveys will be designed so that once they have been completed, the participant will not be able to reopen the link. They will be given a chance to review the answers but once submitted, further access will be denied. The PI will monitor the site to see the number of participants to ensure adequacy in numbers. After submitting the survey, they will be taken to a site to claim the gift certificate of $10.

Protocol Detail Report

Printed By: Melendez-Vargas, Maria
10/12/2018 3:01:01 PM

Participant Compensation or Incentives

6.4

Indicate if participants will receive compensation or other incentives to participate in the research study.

- [x] Yes
- [ ] No

6.4.1

Yes

Type of Compensation or Incentives

6.4.1.1

Select the type of compensation or incentive(s) that will be offered to the subjects. Click the green "+" symbol to the right of the screen to make your selection(s). Select all that apply.
Note: Raffles, lotteries, drawings, or mechanisms where there is a pre-determined winner (e.g., every nth person enrolled or the first N participants) are not permitted as an incentive.

Gift Cards

6.4.1.1.1

Gift Cards

Description of Compensation or Incentives

6.4.1.2

Describe the compensation or incentive(s) to be given, including the amount and timing of all payments for the tasks to be completed. If extra credit is to be given to students in a classroom, there must be an alternative extra credit opportunity for those students that do not wish to participate in the research (i.e., students should be given an option to complete a special assignment in lieu of participating in the research).
Compensation needs to be pro-rated for subjects who withdraw before completion (based on the study procedures he/she has completed), not contingent upon study completion.

$10 Gift Card for food items at Publix Supermarket.

Breakdown of Compensation or Incentives

6.4.1.3

Provide a breakdown of the compensation or incentive(s) that will be provided to each participant for each task they complete. In the "Population" column, you should indicate the type of population (e.g., child, father, mother, etc.) that will be receiving the compensation. In the "Reason for Payment" column, you should indicate why the individual is receiving the compensation (e.g., interview, survey, referral, follow-up, etc). For the Incentive Type, you should put the type of incentive that will be received (e.g., cash, gift card, etc.).
Important: The Office of the Controller and the Post Award Office have specific requirements on the administration and tracking of payments to human subjects. In addition, if any subject will be receiving more than $600 in financial incentives over a calendar year, you may have additional IRS requirements to adhere to, which could impact the confidentiality requirements of your study. Please see the Participant Payment web page for further information on making payments to human subjects.
Click "Add Row" to separately list each compensation/incentive scenario that will be utilized.

Population	Reason for Payment	Incentive Amount	Interval/Frequency	Incentive Type	Total Amount
Female Veterans in the Study	Survey completion	$10.00	Once	Gift Cards	$10.00

6.4.2

No

Participant Costs

6.5

Indicate if subjects (or their insurers) will incur costs as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

- ☐ Yes
- ☑ No

6.5.1

Yes

6.5.2

No

Alternatives to Study Participation

6.6

Other than choosing not to participate, list any specific alternatives, including available procedures or treatments that may be advantageous to the subject. If extra credit is being provided to students, an alternative assignment needs to be made available, which offers the same time committment and amount of extra credit for those students that do not wish to participate in the research.

If a female Veteran chooses not to participate in the study, there will be no alternative assignment or offer. That person will not be coerced to participate.

METHODS & ACTIVITIES

7

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Explanation of Methods & Activities (Attachment)

7.1

Attachments: APPENDIX K - Revised Aug. 12 2018 Infomed Consent Adult for the Study.pdf APPENDIX A - Study Participant Screening Form.docx APPENDIX B - Demographic Questionnaire.docx APPENDIX D - SDO Scale July - with Scores.docx APPENDIX F - Abuse Assessment Tool Short Form - modified with scoring.docx APPENDIX C - Safer Sex Behavior Questionnaire with scoring for IRB.pdf APPENDIX E - STD Knowledge Questionnaire -Short Form with scoring.docx APPENDIX M - Script for Face Book, Twitter and Instagram for the Study.pdf Study Distress Protocol APENDIX N.pdf AGREEMENT WITH PROVIDER - ELLIS.pdf

The following items need to be addressed in the textbox below:
Identify and describe in detail all interventions and interactions that are to be performed solely for the research study.
Distinguish research (i.e., experimental) activities from non-research activities (if applicable).
Explain any tests, procedures, or exams that the subjects will be involved with.
Describe data to be collected and data analysis procedures.
List the names of the different data collection forms that you will be using if conducting surveys, interviews, and/or focus groups (if applicable).
Attach the surveys, interview questions, and focus group questions (if applicable) by clicking on the paper clip icon to the right.

The study will be advertised using the attached flyer and Script for Face Book, Twitter and Instagram. Interested participants will be contacted by the PI and screened using the Study Participant Screening Form (Attachment A). If participant meets criteria, the PI will make arrangements to meet with participant to complete the Informed Consent (Appendix H). A copy of the consent will be given to the participant. Consent forms will be stored separately from completed surveys to maintain anonymity. Participant will be given privacy to complete the surveys anonymously. Where possible, a private room will be used. If not, the place selected for data collection will be safe and convenient for both the PI and participant. Once the participant completes the surveys, they will be placed in a blank nondescript envelope. Participants will be cautioned to ensure that no identifying information is entered into the surveys. The envelope will be the sealed by the participant and dropped in a locked receptacle before leaving the room. The PI will then give the participant the gift certificate of $10 for having participated. The PI will have no more contact with the participants once the surveys have been completed and submitted. There is no randomization involved in this study.
Using the latest version of SPSS, descriptive statistics will be computed for all data collected to reduce, summarize and describe data obtained from participants. This includes frequency distribution, measures of central tendency such as mode, median and mean. Variability will also be analyzed to determine the spread or dispersion of the data. This includes the comparison of range and standard deviation, where appropriate. Below are listed the overall two (2) broad aims, related hypotheses, and data analyses for each hypothesis:

Aim 1, Hypothesis 1: Female Veterans that report a history of intimate partner violence or abuse will have higher SDO scores, and lower Safer Sex Behavior scores than those who do not report a history of intimate partner violence or abuse.
Data Analysis: a) SDO scores of female Veterans with and without a history of abuse will be compared using Student's Independent t-tests. Further analyses will be conducted to compare the scores of these two groups in terms of their SSBQ scores to determine if there are any differences in their mean behavior scores. the test statistic will be the t-statistic with a p -value of .05 with a moderate or higher effect size (.06 to .14 or higher based on Cohen's d). A priori power analysis revealed that a sample of size of 116 could yield significant results.
b) To determine the best predictor of safer sex practices among female Veterans, stepwise hierarchical multiple logistic regression analyses will be conducted among these variables. The variables with the highest R-squared will be deemed the most predictive of the behavior. The overall strength of the relationships will be determined by the R-squared value and whether or not the individual variables make significant contribution to the predicted relationships. Assumptions of size, multicollinearity and singularity, normality, linearity, homoscedasticity, and independence of residuals need to be met in order to carry out these statistical functions.
Hypothesis 2: There will be an inverse relationship between socioeconomic factors (education, income, number of years living in the United States, minority/racial ethnic status, immigration status), female Veterans' level of religious commitment, and social obligations/responsibilities with Safer Sex Behavior scores (SSBQ), and STD knowledge scores.
Data Analysis: To determine the strength of the relationships among these variables, correlation coefficient analyses will be conducted. Either Pearson's correlation, Kendall's Tau and/or Spearman's Rho will be used, based on the level of measurement for variable pairs.
Hypothesis #3: There will be an inverse relationship between Social Dominance Orientation scores with Safer Sex Behavior scores, STD Knowledge scores, age at sexual debut and female Veterans' current age.

Data Analysis: The same statistical approach described in #3 will be used to analyze data for this hypothesis.
Hypothesis #4: There will be an inverse relationship between the following variables and Safer Sex Behavior (SSBQ) scores: married or in a committed relationship; perceived economic dependence; and perceived religious commitment.
Data Analysis: Using the latest version of SPSS, bivariate correlations will be conducted between these variables to determine the strength of the relationships that exist among each pair. Basically, the same correlational statistical analyses described above for 2 and 3 will be conducted.
Hypothesis #5: There will be a positive relationship between female Veterans' years of active duty and rank at the time of discharge from service with Safer Sex Behavior (SSBQ) scores; and, a negative relationship with Social Dominance Orientation scores.
Data Analysis: Again, bivariate correlations will be conducted to determine the strength and direction of the relationships that exist among each pair of variables, as described above.

AIM 2 RESEARCH QUESTIONS and DATA ANALYSES:
1. To what extent do female Veterans' individual and demographic characteristics (such as age, number of years of age discordance in the relationship, being in an age discordant relationship, racial/ethnic background, military rank, history of intimate partner violence of abuse, perceived religious commitment, and social obligations/responsibilities) predict Safer Sex Behaviors, STD Knowledge and SDO? Data analysis will similar to that to be conducted for Aim 1, Hypothesis 1b. The same assumptions for sample size, multicollinearity, singularity, normality, linearity, homoscedasticity and independence of residuals will be carried out to ensure appropriateness of these statistical procedures.

2. To what extent do female Veteran's socioeconomic factors (education, income, number of years living in the United States, minority racial/ethnic status, immigration status) predict Safer Sex Behaviors among female Veterans, STD knowledge and Social Dominance Orientation scores? Data Analysis: Stepwise hierarchical multiple logistic regression will be conducted among these variables to determine if socioeconomic factors predict, STD knowledge, and Social Dominance orientation predict safe sex behaviors among female Veterans. The variables with the highest R-squared will deemed most predictive of the behavior. The overall strength of the relationship will be determined by the R-Squared. The same a priori assumptions of sample size, normality, and so forth, must be met to carry out these statistical functions.

Missing Data: Because this study involves human participants, it is highly likely that not all the instruments will be completed, resulting in missing data. The PI will inspect the data collected carefully and run descriptive analyses to find out what percentage of values is missing for each of the variables being studied. The PI will also check to see if the missing data happen randomly, or whether there is a systematic problem such as a large number of participants failing to answer certain questions, such as age or HIV status. SPSS will be used to find any such patterns. If a variable is missing at least 10% of its data, the cases will be excluded pairwise. This option allows for exclusion of cases (persons) only if they are missing the data required for the specific analyses (Mertler & Vannatta, 2010; Pallant, 2010).

Surveys to be Used (see attached):
1. Study Participant Screening Form - PI Developed for study eligibility, no reliability or validity scores available.
2. Demographic Questionnaire - PI Developed, no validity and reliability scores available.
3. Safer Sex Behavior Questionnaire (DiIorio, Parsons, Lehr, Adame & Carlone, 1992). Cronbach's alpha range between .52 to .85. Stability for females (r=.63-.82; Validity for females = -.21 and .27.
4. Social Dominance Orientation Scale (Pratt, Sidanius, Stallworth & Malle, 1994). Internal reliability =.83 with a range from .31 to.63; Stability = .81; validity = .72.
5. STD Knowledge Scale (Jaworski & Carey, 2007). Alpha = .86; test-retest reliability r=.88.
6. The Abuse Assessment Tool - Short Form (McWhinney-Dehaney, 2006). Alpha = .97; reliability ranges between .56 - .66.
7. Script for Face Book, Twitter and Instagram

Types of Activities

7.2

Carefully identify all of the activities that will be involved in the research. Click the green "+" symbol to the right of the screen to make your selection(s).
Please be sure to identify ALL that apply to the research.

Surveys or Questionnaires

7.2.1

Surveys or Questionnaires

Activities Requiring Additional Details

7.3

Additional information is needed for certain types of research activies. Please select ALL that apply from the options below. Additional questions will be populated on the form based on your selections.

- ☐ Biohazardous Materials
- ☐ Biospecimen Repositories
  This is for future unspecified use
- ☐ Blood Drawing
- ☐ Data Repositories
  This is for future unspecified use
- ☐ Deception
- ☐ Drugs or Biologics
  The FIU IRB only reviews studies involving drugs or biologics that present no more than minimal risk. Most drug/biologic studies (and all studies requiring an IND) will need to be submitted to Western IRB (WIRB). Contact the FIU IRB Office to determine if your study is eligble for FIU IRB review before proceeding any further.
- ☐ Genetic Testing
- ☐ Internet (Social Media, Online Surveys, MTurk, etc.)
- ☐ Medical Devices
  The FIU IRB will only review studies with medical devices that present no more than minimal risk. Studies involving medical devices that present more than minimal risk will to be submitted to Western IRB (WIRB). Contact the FIU IRB Office to determine if your study is eligble for FIU IRB review before proceeding any further.
- ☐ Magnetic Resonance Imaging
- ☐ Neuroimaging
- ☐ Nutritional or Dietary Supplements
- ☐ Radiation (CT Scans, X-Rays, etc.)
- ☐ Secondary Data Analysis
  You will need to request a waiver of informed consent in the Informed Consent section of this application.
- ☐ Surgical Procedures
- ☐ Ultrasounds
- ☑ Not Applicable

7.3.1

Biohazardous Materials

7.3.2

Biospecimen Repositories

7.3.3

Blood Drawing

7.3.4

Data Repositories

7.3.5

Deception

7.3.6

Drugs or Biologics

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7.3.7

Genetic Testing

7.3.8

Internet (Social Media, Online Surveys, MTurk, etc.)

7.3.9

Medical Devices

7.3.10

Magnetic Resonance Imaging

7.3.11

Neuroimaging

7.3.12

Nutritional or Dietary Supplements

7.3.13

Radiation (CT Scans, X-Rays, etc.)

7.3.14

Secondary Data Analysis

7.3.15

Surgical Procedures

7.3.16

Ultrasounds

7.3.17

Not Applicable

Miscellaneous or Additional Information

7.4

Attachments: Rev6. Feb. 15, 2018 Social Dominance Orientation and Sexual Practices of Female.pptx

This area can be used to incorporate any additional information or attachments that pertain to this study (i.e., information or attachments that do not pertain to any of the other questions above).

1. Attached is the depiction of theoretical framework that will guide the study.
2. Please note that I have removed the VA as an additional site and will be recruiting from the community. Should it become necessary to partner with them, I will notify the FIU IRB.
3. I have addressed the online issues raised and attached a script to be used. I have a SurveyMonkey account, should anyone desire using that method to complete the surveys. In order to keep the identifiable information separate from the data, I will create a separate online survey to collect information needed to ensure that participants receive their incentive for participating. This will mean that 2 different web servers will be used to ensure any breach of anonymity (https://help.surveygizmo.com).
4. I have the agreement of a highly qualified mental health nurse practitioner in the community, should any participant need this service.
5. A reviewer raised concern that cross-sectional data cannot be used to make predictions about behavior. Please note that the date collected will not be used ascertain causation. The statistical analyses that will be conducted are to demonstrate correlation and make some higher level predictions through regression analyses.
6. I apologize for the many typos in the previous submission. I was not sure how to maneuver the application but the more I use it, the better it gets, making each rendition better. Thanks for pointing them out as it should not be tolerated. I appreciate the attention to detail.

Thanks for taking the time to review this application.

BENEFITS & RISKS

8

Benefits to Subjects

8.1

List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants.
Compensation is not to be considered a benefit.

There are no direct benefits to participants. Despite this, participants will be contributing to the body of investigative literature, specifically related to improving the sexual health of female Veterans in the United States. Any significant findings could contribute to practice, theory and policy improvement/development. These possibilities may evoke feelings of pride and wellbeing among participants who may feel they are making a positive contribution to their peers, and society at large.

Benefits to Society and/or Others

8.2

List the potential benefits that society and/or others may expect as a result of this research study.

This study is significant for the following reasons: The VA spends millions of dollars yearly treating STIs and its complications as well as disbursing disability benefits related to specific STIs, such as syphilis and the incurable HIV/AIDS. Veterans with HIV/AIDS tend to be older than the general population and have many more medical conditions that complicate STI /HIV treatment. Many STIs, such as gonorrhea and syphilis, have developed resistant strains to antibiotics that had been effective for decades. Second, the Department of Defense (DoD, 2009, 2014) expects that the rate of female enrollment in the armed forces will continue to rise,. Therefore the rate of STIs is expected to rise among them. It is reasonable to conclude that the rate among those ho leave the military will continue to rise also. The VA admits that they are behind the curve when it comes to women Veterans' health (. Third, there are no rigorous, theory-based studies that have been solely focused on female Veterans to explore the factors related to high risk sex choices and STIs among them. The rate of STIs among Veterans and military personnel range between two and seven times that of the general population (Lehavot, et al., 2012, 2014; Turchik, et al., 2014). The CDC (2016) and WHO (2016) advocate the need for gender and culture-specific research to understand such factors and develop interventions to mitigate them through practice changes, theory development and policy changes/development. The military is a specific culture, male-oriented, and testing the Social Dominance Theory, and the SDO variable in particular among this population may yield significant information to improve the health of female Veterans and change behavior.

Reasonably Expected Risks, Harms, and/or Discomforts

8.3

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research.
Consider the range of risks, including physical, psychological, social, legal, and economic.
Characterize the nature and probability of a potential risk for illness or injury due to this research.
As applicable, discuss severity and likelihood of occurrence with the risks.
Answering "none" or "no risks" is not an acceptable response for this question.

The immediate potential risk to participants in the proposed study is minimal. The only potential risk, at this time, is the possibility of emotional distress as participants recall traumatic events while completing survey instruments. Should this become untenable for participants, they will have the option to withdraw and/or seek, or be referred for the appropriate medical care. If participants are able to read but have some difficulty, the PI will assist participants if they choose or are comfortable. If this creates a situation that will insert bias into the study, participants will be asked to suspend participation. No long range risks, discomfort, and/or inconvenience are anticipated from having participated in the proposed study. No direct/indirect economic burdens are foreseen at this time and will be placed on participants. No legal ramifications are foreseen at this time as participation will be voluntary and records will be totally anonymous, and data will be collected in privacy and kept confidential according to Florida statutes.

Minimizing Risks, Harms, and/or Discomforts

8.4

Describe how risks, harms, and/or discomforts will be minimized.

Risks, harms and discomfort will be minimized through the Informed Consent process. Participants will be informed that participations is voluntary and there will be no repercussions to not having participated or having withdrawn from the study. All their questions and concerns will be addressed. Copy of the Informed Consent document, including contact information (see Consent Form) for study investigators and the FIU IRB will be provided to all participants. They will be assured that no blood or other body fluids, tissue will be taken from them, and that all surveys will be anonymous, with no identifying information traceable back to them. They will be afforded privacy to complete the surveys. No names other identifying information will be collected. The PI will also inform them that contact with the researcher is one time only.

Assessment of Risks & Benefits

8.5

Discuss how the risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

As outlined earlier in this application, the benefits to be gained from the proposed study outweigh the minimal risks that are anticipated. This is in no way meant to minimize any potential risks to participants. Despite this, each participant will be treated as an individual with her own set of physical, and emotional characteristics which must be respected and weighed against participation or not. No participant will be forced to participate in the name of social good to be derived from the study.

Monitoring Safety

8.6

Select "Yes" below if one or more of the following items apply to your research project:
The research involves greater than minimal risk (i.e., harms or discomforts are beyond what is normally encountered in daily life or during the performance of routine physical or psychological tests);
The research involves a clinical intervention or a clinical trial;
The funding agency requires a Data Safety Monitoring Plan (DSMP) and/or a Data Safety Monitoring Board (DSMB); or
The IRB has specifically requested for a DSMP or DSMB to be included for this research project

- ☐ Yes
- ☑ No

8.6.1

Yes

8.6.2

No

INFORMED CONSENT

9

Protocol Detail Report

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Informed Consent Process

9.1

Select the consent document(s) to be used in the study (select all that apply from the options below). Informed Consent is required (unless waived) for all Expedited and Full Board review research.
Investigators are required to use FIU's Informed Consent templates when developing their documents. In some cases another institution's IRB-approved consent documents can be accepted for projects that involve collaborative off-site research, but you should first check with the FIU IRB Office. See Consent for Research for guidelines and to access the FIU Informed Consent templates.
Deception Studies: Studies that involve the use of deception will also be required to select the "Other" box below to request an alteration of the Informed Consent Process. This is in addition to checking off the applicable consent form boxes below.
Electronic Signatures / Online Consent: If participants will be providing their signature in an electronic format (e.g., writing their signature on a tablet device), then please select one of the "Written" consent boxes below. If participants will not be providing a signature, but will instead be clicking a checkbox on a web page, then please select one of the "Online" consent boxes below.

- [x] Adult Written Informed Consent Form (18 years +)
- [ ] Adult Verbal Informed Consent Form (18 years +)
- [x] Adult Online Informed Consent Form (18 years +)
- [ ] Child Written Assent Form (7-17 years old)
- [ ] Child Verbal Assent Form (7-17 years old)
- [ ] Child Online Assent Form (7-17 years old)
- [ ] Parental Written Consent Form (for research w/ children)
- [ ] Parental Verbal Consent Form (for research w/ children)
- [ ] Parental Online Consent Form (for research w/ children)
- [ ] Other (Requesting a Waiver or Alteration of the Informed Consent Process)

  This box is for requesting to waive the Informed Consent Process (i.e., not obtaining any type of consent from the subjects) or if you will be altering the required language within your Informed Consent Form. This box should not be selected for requesting a waiver of written consent (i.e., waiving the signature).

9.1.1

Adult Written Informed Consent Form (18 years +)

Adult Written Informed Consent Form (Attachment)

9.1.1.1

Attachments: APPENDIX K - Revised Aug. 11, 2018 Infomed Consent Adult for the Study.doc

If using a language other than English, you will need to attach both the English version and the Translated version(s). If the translation was not done by a professional translation service, then you will also need to attach a Back-Translated version. Each attachment needs to be clearly labeled to differentiate between the English version, the Translated version, and the Back-Translated version.
Attach a clean copy of the Written Adult Informed Consent Form(s) in Microsoft Word format. Click the paper clip icon to the right to upload your document(s).

Description of Written Adult Consent Process

9.1.1.2

Explain when, where, and how consent will be obtained. Explain how subjects will be provided sufficient opportunity (i.e., waiting period, if any) to consider participation. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

Informed consent will be obtained after screening and at the time when the participant agrees to participate in the study. For in-person surveys, once participants have been screened, found eligible and are willing to participate, they will be escorted to a private area where the researcher will explain the elements of the Informed Consent, answer any questions/concerns and obtain participant's signature indicating that they understand what is going to happen. Participants will be asked again if they wish to proceed or reconsider participation and explained that they have the chance to withdraw or stop the surveys at any time without any repercussions. Their incomplete surveys will be shredded/destroyed in their presence to assure confidence that their information will not be used without their permission. For those opting to do online surveys, they will be guided to the Informed Consent first where they will electronically sign the form using a checkbox, and be able to print, and/or download it after completing it. The website settings will be configured to prevent the storage of any type of identifying information such as IP addresses. This feature also enhances the anonymity of the participant data. Once the consent has been completed, the participant will then be guided to a website for survey completion. At the end of the surveys, participants will then click on a link to claim their gift certificate. Since the Informed Consent and survey data will be stored on separate servers, it will be impossible for the PI to tell who completed which survey. It The literature on online confidentiality and anonymity suggest that this relies heavily on the researcher's ingenuity in setting up survey limits (Regmi, et al., 2016; Saunders, Kitzinger & Kitzinger, 2015). These steps to maintain online anonymity and confidentiality represent the best evidence available, highlighting the importance of the need for more research in this area.

Individuals Obtaining Written Adult Consent

9.1.1.3

List the names of investigator(s) and/or key personnel who will obtain consent from the participants.

Beverly Fray, PhD Candidate

Location of Signed Consent Forms

9.1.1.4

Provide the physical location(s) where the signed Consent Forms will be stored (e.g., provide the campus, building, and office room number). Also specify how the signed Consent Forms will be securely stored (e.g., in a locked filing cabinet).

All signed consents will be stored in a safe place, a locked filing cabinet in the School of Nursing, PhD Coordinator's office located in AHC3, 5th Floor at the School of Nursing, accessible to the research team and/or other University authorities for audit purposes, when necessary.

Tools to Assist During Written Adult Consent Process (Attachment)

9.1.1.5

Indicate below if any other tools (e.g., quizzes, visual aids, information sheets) will be used during the consent process to assist participant comprehension.
Attach a copy of the tool(s) if applicable. Click the paper clip icon to the right to upload your document(s).

N/A

9.1.2

Adult Verbal Informed Consent Form (18 years +)

9.1.3

Adult Online Informed Consent Form (18 years +)

Adult Online Informed Consent Form (Attachment)

9.1.3.1

Attachments: APPENDIX K-1 Adult Online Informed Consent Form.doc

If using a language other than English, you will need to attach both the English version and the Translated version(s). If the translation was not done by a professional translation service, then you will also need to attach a Back-Translated version. Each attachment needs to be clearly labeled to differentiate between the English version, the Translated version, and the Back-Translated version.
Attach a clean copy of the Online Adult Informed Consent Form(s) in Microsoft Word format. Click the paper clip icon to the right to upload your document(s).

Waiver of Adult Consent Documentation

9.1.3.2

You have requested to use an Online Adult Consent Form, which does not include the signature of the participant. Therefore, additional justification will be required for the IRB to approve the waiver of consent documentation.
DHHS regulations permit waivers of documenation of the consent process if the research meets certain conditions. However, please note that DHHS and FDA regulations differ regarding when an IRB may waive the requirement to document the informed consent process. Additional guidance on the requirements for waiving consent documentation can be found at 45 CFR 46.117 and 21 CFR 56.109.
Is your research subject to FDA regulations (e.g., involves use of a food, drug, biologic, device)?

- ☐ Yes, this research is subject to FDA regulations
- ☑ No, this research is not subject to FDA regulations

9.1.3.2.1

Yes, this research is subject to FDA regulations

9.1.3.2.2

No, this research is not subject to FDA regulations

Options for Waiving Signed Consent

9.1.3.2.2.1

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the study falls under one of the following two options:

- ☑ Option #1: 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.
- ☐ Option #2: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

9.1.3.2.2.1.1

Option #1: 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.

Minimal Risk

9.1.3.2.2.1.1.1

Does the research present more than minimal risk?

- ☐ Yes
- ☑ No

9.1.3.2.2.1.1.1.1

Yes

9.1.3.2.2.1.1.1.2

No

Justification of Response

9.1.3.2.2.1.1.1.2.1

Explain why the project does not present more than minimal risk.

This project presents no more than minimal risk because the probablity and magnitude of harm or discomfort anticipated in its execution are not greater in, nor are of themselves greater than those ordinarily encountered in their daily lives or during the performance of routine physical or psychological tests or examinations.

Requirement for Written Consent

9.1.3.2.2.1.1.2

Does the research involve procedures for which written consent is normally required outside of the research context?

- [x] Yes
- [ ] No

9.1.3.2.2.1.1.2.1

Yes

9.1.3.2.2.1.1.2.2

No

9.1.3.2.2.1.2

Option #2: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Description of Online Adult Consent Process

9.1.3.3

Explain when, where, and how consent will be obtained. Explain how subjects will be provided sufficient opportunity (i.e., waiting period, if any) to consider participation. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

Before the survey begins, all relevant information regarding the research study and its voluntary nature will be given to all eligible participants. Eligible participants who express a willingness to participate will be sent a link via email to complete the Informed Consent. A statement informing participants that, though all efforts will be made to maintain confidentiality and anonymity, there is always the possibility of hacking and compromise to data collected via the Internet. They will be informed that they are free to decide not to answer any of the surveys. The Informed Consent will be set up so that participants will click a button to indicate that they have read, and understood the consent information and are willing to participate in the study. Once they click the button, they will be redirected to the surveys. In other words, they will not see any of the research questionnaires until they have indicated their voluntary participation. To assure anonymity of participants, if any IP addresses or other digital identification information are collected, they will be deleted before being downloaded from the server. All responses and any identifying data will be deleted from the servers before analysis and will be stored on a password protected computer, accessible by the PI. Once they have completed the surveys, they will be redirected to a link where they can claim the gift certificate.

Tools to Assist During Online Adult Consent Process (Attachment)

9.1.3.4

Indicate below if any other tools (e.g., quizzes, visual aids, information sheets) will be used during the consent process to assist participant comprehension.
Attach a copy of the tool(s) if applicable. Click the paper clip icon to the right to upload your document(s).

The tools are the same as described and attached earlier.

9.1.4

Child Written Assent Form (7-17 years old)

9.1.5

Child Verbal Assent Form (7-17 years old)

9.1.6

Child Online Assent Form (7-17 years old)

9.1.7

Parental Written Consent Form (for research w/ children)

9.1.8

Parental Verbal Consent Form (for research w/ children)

9.1.9

Parental Online Consent Form (for research w/ children)

9.1.10

Other (Requesting a Waiver or Alteration of the Informed Consent Process)

Informed Consent Languages

9.2

Indicate below if this project will involve consenting non-English speaking/reading participants.

- ☐ Yes
- ☑ No

9.2.1

Yes

9.2.2

No

CONFIDENTIALITY & PRIVACY

10

Information on Confidentiality and Privacy

10.1

Please review the IRB Data Management Security Tips for a listing of the best practices for securing data. Click the blue "?" icon to the right to learn about the differences between confidentiality and privacy.

Provisions to Protect Privacy

10.2

Describe the provisions to protect the privacy interests of the participants.

No information that can identify participants will be collected. All quantitative data collected will be maintained in a password -protected computer, and computerized surveys are not expected to be used in this study. Combination to computer files, and access to keys, where possible, will only be given to the research team. Full disclosure will be given about how the data collected will be used. That is, no data will be sold or traded and, will be used for the sole purpose of closing the gap in knowledge on which the study is founded. POarticiants will be assured in writing and verbally that the Informed Consent includes elements of an agreement between researcher and participant that private information will be managed, handled and disseminated in ways that will protect their anonymity and that is why no identifying information about them will be collected.

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10/12/2018 3:01:01 PM

Associating a Participant to a Study

10.3

Will the researchers know the identity of the enrolled subjects and therefore be able to associate them as being participants in this study?

You should select "Yes" to this question if it will be possible for you to associate a participant to your study (e.g., via a name on a signed consent form, via a name in the Sona System, etc.).
You should select "No" to this question if it will not be possible for you to associate a participant to your study (e.g., the names of subjects are never collected or provided to the researchers).

- ☐ Yes - It will be possible for me to associate a participant to my study
- ☑ No - It will not be possible for me to associate a participant to my study

10.3.1

Yes - It will be possible for me to associate a participant to my study

10.3.2

No - It will not be possible for me to associate a participant to my study

Associating Data to an Individual

10.4

Does the research require the access or collection of personally identifiable data about human subjects? Sources for identifiable data include, but are not limited to surveys, interviews, focus groups, medical records, datasets, etc.
Note: Personally identifiable data are considered data about a human that can be linked to the subject directly (i.e., name, birthdate, social security number, medical record number, phone/fax number, email address, mailing address, full face video/photo, etc.) or indirectly through an identifier linked back to the subject (i.e., a unique code that links the data back to the subject via a master key).
Note: Anonymous data are considered data that are impossible to link back to a subject in any manner. Data that are coded and linked to a master key are not considered as anonymous.

- ☐ Yes - I will be accessing or collecting personally identifiable data (or coded data)
- ☑ No - I will only be accessing or collecting anonymous data

10.4.1

Yes - I will be accessing or collecting personally identifiable data (or coded data)

10.4.2

No - I will only be accessing or collecting anonymous data

Explanation of Anonymous Data

10.4.2.1

Describe the variables that will be collected for your study. Provide an explanation as to how the study will be conducted such that it will not be possible to link the data back to the subjects at any point during or after the study.

Demographic data - age, gender, educational level, ethnicity, country of origin, religious affiliation, SES, length of residence in the uNited States, STI/HIV status (See Demographic Questionnaire)
Safe Sex Practices - See Safer Sex Behavior Questionnaire (SSBQ)
Social Dominance Orientation - See SDO Scale

STD Knowledge - see STD Knowledge Questionnaire (STD-KQ)
Abuse in Relationships - see The Abuse Assessment Tool - Short Form
All surveys will be numbered but no identifying information such as name, date of birth, address, telephone numbers, etc. will be collected from participants. Hence, the research team will not be able to say who completed the survey when and where. Results will be presented in aggregate, not individual analysis, another method to protect the provacy and cofidentilaity of participants.

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10/12/2018 3:01:01 PM

Confidentiality of Data

10.5

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Be sure to address both the electronic and hard copy versions of your records in your explanation.

As discussed earlier, only the research team will have access to the data. The IRB and any other University authorities will be granted access for audit purposes, if necessary. Hard copies of the data will be stored in a locked cabinet in the PhD Department at the School of Nursing at FIU, AHC3, 5th Floor. Electronic databases of results will be maintained in a password-protected computer, accessible only to the research team or the IRB/University authorities, if needed.

Data Storage Methods

10.6

Select the different methods that will be used for storing your data. Please select the green "+" icon to the right to make your selections. Select all that apply.

Filing Cabinet

USB Jump Drive

Desktop Computer

Survey Website Database

10.6.1

Filing Cabinet

10.6.2

USB Jump Drive

10.6.3

Desktop Computer

10.6.4

Survey Website Database

Data Protection Methods

10.7

Select the different security methods that will be used for protecting your stored data. Please select the green "+" icon to the right to make your selections. Select all that apply.

Password Protection

Locked File Cabinet

10.7.1

Password Protection

10.7.2

Locked File Cabinet

Location of Data

10.8

Provide the physical location(s) where the data will be stored (e.g., provide the campus, building, and office room number). If data will not be physically stored anywhere (e.g., it will only be stored on a network, website, SharePoint, etc), then please indicate this below.

Nicole Wertheim College of Nursing & Health Sciences
11200 SW 8th Street
AHC3, 5th Floor, Room #534
Miami, Florida 33199

Transportation of Data

10.9

Indicate if data will need to be physically transported.

- [x] Yes, data will need to be physically transported
- [ ] No, data will not need to be physically transported

10.9.1

Yes, data will need to be physically transported

Procedures for Securing the Data

10.9.1.1

Indicate how you will secure the data during transport to minimize the risks of data loss. Indicate the steps that will be taken to minimize the duration of the transit.

Data will be transported on a USB memory stick, when needed, or a password-protected laptop computer accessible only to the principal investigator.

10.9.2

No, data will not need to be physically transported

Breaking Confidentiality

10.10

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.

Proper procedures will be established so that no member of the research team will be able to breach confidentiality before contacting the IRB. An example of a good reason to breach participant confidentiality would be any threat of harm to physical, emotional, economic or social wellbeing while participating in the study. Otherwise, the research team has a duty to protect study participants' confidentiality ethically and legally.

FERPA Student Education Records

10.11

Researchers are required to follow the Family Educational Rights and Privacy Act (FERPA) requirements when accessing, using or disclosing FIU student education records for research purposes.
For more information, visit the FIU Student Education Records (FERPA) web page. In addition, you can view the regulatory requirements at 34 CFR Part 99.
Will individually identifiable FIU student education records be accessed, used, or disclosed in this research study?

- [ ] Yes
- [x] No

10.11.1

Yes

10.11.2

No

HIPAA Protected Health Information

10.12

Protected Health Information (PHI) is health information (e.g., medical records) maintained by a Health Insurance Portability Accountability Act (HIPAA) covered entity (e.g., hospital, clinic, FIU CCF, FIU HWCOM) that contains one or more of the 18 patient identifiers.
For more information, visit the FIU Privacy Practices and HIPAA web page or the HIPAA and Research web page.
Will individually identifiable PHI be accessed, used, or disclosed in this research study?

- ☐ Yes
- ☑ No

10.12.1

Yes

10.12.2

No

AFFIRMATION OF COMPLIANCE

11

Affirmation of Compliance and Acceptance of Responsibility

11.1

As the Principal Investigator, I recognize that I am responsible for the conduct of this study, including the conduct of my co-investigators and research staff. I certify that:
I will follow the procedures outlined in this application form and any attachments
I understand that no contact may be initiated with subjects until I have received approval of these procedures from the IRB and have complied with any modifications required in connection with that approval.
I or my designee will obtain informed consent from each subject on the approved consent form for all non-exempt research unless the consent process has been waived by the IRB.
I will do everything in my power to protect the rights and welfare of human subjects in my research project.
I will immediately notify in writing to the FIU Office of Research Integrity of:
Any additions to or changes in the procedures involving human subjects.
Every serious or unusual or unanticipated adverse event as well as problems with the rights or welfare of the human subjects.
I understand and will follow all of FIU's policies and procedures concerning research with human subjects. I verify that the information in this application is accurate and complete.

E-Signature for the Affirmation and Acceptance of Responsibility

11.2

Important: Only the Principal Investigator is permitted to provide the affirmation below, since an e-signature is required. Therefore, if you are completing this application on behalf of the Principal Investigator, you will need to log out of the system and then ask the Principal Investigator to login and complete this affirmation.
Additional instructions are available for the Principal Investigator by clicking the blue "?" help icon to the right.

- ☑ As the Principal Investigator, I agree with the affirmation and accept these responsibilities.

11.2.1

As the Principal Investigator, I agree with the affirmation and accept these responsibilities.

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10/12/2018 3:01:01 PM

End of Application Form

11.3

Please ensure that all of the questions have been fully addressed before submitting your application. Incomplete applications will delay the process. You should then complete the following steps to submit your protocol:
Save your application.
Click the "Submit" button at the top of this page.
Click the "Set Status" button in the bottom corner of the the popup window.
You will immediately receive an email notice, which confirms that you have successfully submitted your application for review.
College of Medicine: College of Medicine investigators are required to pre-submit their applications to the COM IRB Administrator prior to submitting the application to the IRB for review. Please review the question mark icon to the right for special instructions if you are an investigator from the College of Medicine.

OFFICE USE ONLY

12

Office Use Only

12.1

The FIU Office of Research Integrity will use this remaining "Office Use Only" section for administrative purposes. The investigator does not need to complete anything within this section.

IRB Approval Memorandum

12.2

Attachments: Initial Approval

The FIU Office of Research Integrity will use this area to attach copies of the most recent IRB approval letter.

IRB Approved Consent Forms

12.3

Attachments: Strickland 18-0346_Adult_Written_ICF_092718.pdf Strickland 18-0346_Adult_Online_ICF_092718.pdf

The FIU Office of Research Integrity will use this area to attach copies of the most recent stamped consent forms (when applicable).

IRB Approval Type

12.4

The FIU Office of Research Integrity will use this area to display the approval type that was used for the initial review (e.g., Exempt, Expedited, or Full Board).
Note: This approval type designation will remain the same for all subsequent amendments and renewals (unless the protocol needs to be "permanently" upgraded/downgraded to another approval category). "Admin" approvals and/or "temporary" review category upgrades/downgrades will not be listed here.

Expedited Approval

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10/12/2018 3:01:01 PM

Additional IRB Approval Details

12.5

The FIU Office of Research Integrity will use this area to reference any additional details that pertain to this approved project.

- [x] Expedited Approval Category Number(s)
  This box should be selected for any protocol that underwent an Expedited review.
- [ ] IRB Approved Informed Consent Waivers (Waiver of Informed Consent or Waiver of Documentation of Informed Consent)
  This box should be selected if the IRB approved a Waiver of Informed Consent or Waiver of Documenation of Informed Consent.
- [ ] IRB Approved HIPAA Authorization Waiver - Requires a special IRB Approval Letter from the IRB Chair
  This box should be selected if the IRB approved a Waiver or Alteration of HIPAA Authorization. IMPORTANT: A special IRB Approval Template for HIPAA Waiver-Alteration needs to be signed by the IRB Chair.
- [ ] IRB Approval Satisifies Subpart B (Pregnant Women, Human Fetuses, and Neonates)
  This box should be selected if the research satisfies 45 CFR part 46, subpart B and 21 CFR part 50, subpart B
- [ ] IRB Approval Satisifies Subpart C (Prisoners)
  This box should be selected if the research satisfies 45 CFR part 46, subpart C and 21 CFR part 50, subpart C
- [ ] IRB Approval Satisifies Subpart D (Children)
  This box should be selected if the research satisfies 45 CFR part 46, subpart D and 21 CFR part 50, subpart D
- [ ] IRB FDA Determinations
  This box should be selected if the IRB made an FDA Determination (e.g., IDE Exempt, Non-Significant Risk, or Significant Risk).
- [ ] IRB Authorization Agreement (IAA)
  This box should be selected if another institution has entered into an agreement to use FIU's IRB as their IRB of record.
- [ ] Individual Investigator Agreement (IIA)
  This box should be selected if there is an external person that needs to be covered by FIU's IRB as a result of not being from an FWA assured institution.
- [ ] Exempt Review Category Number(s)
  This box should be selected for any protocol that underwent an Exempt review.

12.5.1

Expedited Approval Category Number(s)

IRB Expedited Approval Category Number(s)

12.5.1.1

The FIU Office of Research Integrity will use this area to display the final IRB determined Expedited Approval category number(s).

Category 7

12.5.1.1.1

Category 7

12.5.2

IRB Approved Informed Consent Waivers (Waiver of Informed Consent or Waiver of Documentation of Informed Consent)

12.5.3

IRB Approved HIPAA Authorization Waiver - Requires a special IRB Approval Letter from the IRB Chair

12.5.4

IRB Approval Satisifies Subpart B (Pregnant Women, Human Fetuses, and Neonates)

Protocol Detail Report

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10/12/2018 3:01:01 PM

12.5.5

IRB Approval Satisifies Subpart C (Prisoners)

12.5.6

IRB Approval Satisifies Subpart D (Children)

12.5.7

IRB FDA Determinations

12.5.8

IRB Authorization Agreement (IAA)

12.5.9

Individual Investigator Agreement (IIA)

12.5.10

Exempt Review Category Number(s)

Other Notes

12.6

The FIU Office of Research Integrity will use this area to record any additional notes regarding the approved project.