**NURS 5001 Mock IRB Template**

**SECTION A: Authors and Title**

|  |
| --- |
| **1. Investigators:** |
| Tonya Buchanan, Lisa Kruger, Rachelle Lindholm, Courtney Wright |
| **3. Title of Research Project** |
| Suicide Intervention Tools and the Reduction of Female Veteran Suicide |
|  |

**SECTION B: PURPOSE OF PROPOSED RESEARCH (Author: Tonya Buchanan )**

**Study Overview:** *Give an overview of your project. Each of the following* ***MUST BE*** *addressed within this section (leave no question blank).* ***Enter your response below each question, using as much space as needed.* References** are **expected and required** for this section.

1. **What is your research question, purpose and/or aim in conducting this research and why is this topic worth studying?**

 Will screening for depression and suicidal thoughts at each office medical encounter create a reduction in suicidal ideation and completed suicides in female veterans (Kotzias et al., 2018).

1. **Describe the theoretical framework selected for your study and explain how the theory will be incorporated into the study design.**

 Identifying female veterans with suicidal ideation and intervening prior to possible completion. It is easily incorporated into office visits with use of forms to complete prior to office encounter when patients are completing other required forms for visit (Falkenstein et al., 2017).

1. **Include information regarding where and when the research would be conducted, what research instruments or equipment will be used, etc. if this were a real study.**

 Veterans Administration Facilities (VA) would be primary but should be incorporated into primary care offices as veterans are able to seek care outside a VA facility (Kotzias et al., 2018).

1. **Please provide an estimated timeline for your mock research study. If the study has more than one phase, please clearly map out the different phases (illustrations or diagrams may be included).**

 Timeline should be 1 year, 5 years, and 10-year study of use of assessment tools compared to suicide attempts and completions previous years that assessment tools were not in place consistently

**SECTION C: RESEARCH PROCEDURES AND METHODS (Author: Courtney Wright )**

**Procedural Overview:**  *Give an overview of your procedures and methods for this research project. Each of the following* ***MUST BE*** *addressed (leave no question blank).* ***Enter your response below each question****,* ***using as much space as needed.* References** are **expected and required** for this section.

1. **Please describe the specific research design (quantitative, qualitative – include additional specifics such as descriptive, correlational, phenomenological, etc.) and describe why this method is appropriate for your research question.**

 Quantitative, quasi-experimental with a historical comparison group would be best suited (Polit & Beck, p. 189-190, 2021). This would allow comparison of suicide rates pre and post assessment implementation (Polit & Beck, 2021).

1. **Clearly demonstrate how the data gathered will address the proposed question.**

 Identifying veterans that identify as depressed or suicidal with assessments such as PQH-2, PHQ-9, and CSSRS will allow their concerns to be handled and not overlooked. Patients may be more likely to answer assessment questions and discuss when asked rather than seem to be complaining. This will show concern, care, and interest in them as a person.

1. **What data collection tools will be used (survey, interviews, focus groups, physiological measurements, response time, etc.)?**

 Patient Health Questionnaire (PQH)-2, PHQ-9, and Columbia Suicide Severe Rating Scale (CSSRS) would become part of routine paperwork for veterans visiting VA facilities and this would be reviewed by the nurse and the provider prior to each examination.

1. **How will you ensure reliability of the data collection tools?**

 Polit and Beck (2021) define reliability as “the extent to which scores for people who have not changed are the same for repeated measurements, under several situations: repetition on different occasions, by different persons, on different versions of a measure, or in the form of different items on a multi-item instrument (internal consistency)” (p. 316). The four approaches to reliability testing are test-retest reliability, interrater reliability, intrarater liability, and parallel test reliability can be met with the proposed research tools (Polit & Beck, p. 316, 2021).

**SECTION D: HUMAN RISK AND MINIMIZATION OF RISKS (Author: Lisa Kruger )**

**Participant Recruitment: Please provide the demographics of the recruitment population(s).** Describe the participants in terms that are most pertinent to the proposal. The IRB Committee members must understand how working with the target population(s) will address the research objectives, what measures are appropriate to minimize their risk, and how these measures will be implemented throughout the research study. **References** are **expected and required** for this section.

Please fill in the following information below. If you are working with more than one distinct population, information will need to be provided for each group.

1. Estimated demographic information of participants and number of participants (age, gender, etc.) if this were a real study.
2. **Describe how participants would be identified, selected, and recruited to participate in the study. Are there any exclusion criteria? If so, why are the exclusions needed?**

 ALL veterans should be included in the study as females are not the only ones to identify as suicidal. The study should be inclusive for male, female, and transgender veterans that are receiving any type of medical care.

1. **Would the population as a whole, or are individuals within the recruited population, considered “risk-sensitive” or “vulnerable”?**

 The population this research would be after are the risk-sensitive and vulnerable persons. It is to identify those at risk for suicide and/or depression. They may not be able to identify or put into words their concerns and resort to risky behavior to deal with their problems instead of talking to someone.

**Anonymity and Data Collection/Storage:** For most human subject research, one major risk to participants relates to the personal nature of the data collected from them. Thus, it is imperative to consider how the data are collected, stored, and reported. If identifying information must be collected, provide justification for this collection.

1. What would you do to protect the confidentiality of your participants? Include details related to the **type** of information you will gather, and the **material forms** (paper, audio, electronic, etc.) it will take.

**SECTION E: INFORMED CONSENT DOCUMENT (Author: Rachelle Lindholm )**

Consent is an **on-going process** that **starts** when you first inform the participant about the study and **ends** when the data collected are destroyed. Federal regulations **require** that a **formal consent** **process** takes place where you provide participants with specific information about the study, usually provided in the consent form. Participants are generally required to sign the consent form and are allowed to keep of copy of it for their records. **In general, the IRB Committee needs to understand how participants will be recruited and consented to participate in the study**. **References** are **expected and required** for this section.

1. **How will you document consent? In writing or does participation imply consent? Are your participants able to sign a form and, if not, how will you document consent? Will you use more than one form (if you use more than one version of the consent form, each form needs to have a unique title in order for our staff to keep track of the different forms)?**

 Consent could be added to the top of the form prior to completing it. It can identify that the military will utilize their information in comparison to previous veterans to develop better programs for suicide prevention but no names or identifying factors will ever be used per patient privacy guidelines. This would be informed consent (Polit & Beck, p. 139, 2021).

1. **Will you pay participants?**

 N/A

1. **If participants are unable to consent because they are members of vulnerable populations (minors, prisoners, participants with diminished mental capacity, etc.), what provisions would be in place to obtain consent from a parent or surrogate?**

PHQ-9 identifies if it is the patient or someone else completing the form (PHQ-9, n.d.)

 4**. Will there be any benefits to the participants in your study?**

 Yes, there will be intangible benefits for the participants. Benefits would be recognizing fear and depression that are being felt by the veteran and addressing without condemnation. Normalizing their feelings and identifying possible plans of suicide or self-harm can allow them to attend therapy or receive medication to empower them and provide them with hope.

References

Falkenstein, M. J., C’de Baca, J., Belon, K., & Castillo, D. T. (2017). Predictors of PTSD improvement with cognitive/exposure group interventions in Operation Enduring Freedom/Operation Iraqi Freedom Female veterans. *Journal of Loss and Trauma*, *22*(4), 297–306.

Kotzias, V., Engel, C. C., Ramchand, R., Ayer, L., Predmore, Z., Ebener, P., Haas, G. L., Kemp, J. E., & Karras, E. (2018). Mental health service preferences and Utilization among Women veterans in Crisis: Perspectives of Veterans Crisis Line Responders. *The journal of behavioral health services & research*, *46*(1), 29–42.

*PHQ-9\* questionnaire for depression scoring and ...* (n.d.). Retrieved October 30, 2021, from http://www.med.umich.edu/1info/FHP/practiceguides/depress/score.pdf.

Polit, D. F., & Beck, C. T. (2021). *Resource manual for nursing research: generating and assessing evidence for nursing practice*. Wolters Kluwer.