Study Identification

1. * **Select the Principal Investigator:**
   Heather Fudala

2. * **Study Title:**
   The feasibility and acceptability of using weighted blankets to prevent and/or mitigate delirium in adult critical care patients in urban and rural settings

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - ○ Yes
   - ● **No**

4. * **Please select the primary department or center that this study is being conducted under:**
   MCV Hospitals Employee

5. **Select the VCU IRB numbers assigned to studies that are:**
   1. **Associated with this study**
   2. **Research registries this study will utilize**
   3. **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**

ID	Title	PI

There are no items to display

6. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Fudala	Heather	fudalahm@vcu.edu	8044328944	
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Orr	Shelly	mlorr@vcu.edu	8046284756	

7. * **Select one of the following that applies to the project (selection will branch to new pages):**
   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
   See *https://research.vcu.edu/human_research/guidance.htm*
   - ● **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ○ Exception from Informed Consent (EFIC) for Planned Emergency Research
   - ○ Humanitarian Use of Device for Treatment or Diagnosis
   - ○ Humanitarian Use of Device for Clinical Investigation
   - ○ Emergency Use of Investigational Drug, Biologic or Device
   - ○ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
   - ○ Center or Institute Administrative Grant Review
   - ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

Federal Regulations

1. * **Is this a FDA regulated study?**

   FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future.
   Check Yes if
   the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,
   the study involves a test article being administered or dispensed to subjects NOT according to a clinicians medical judgment but rather, per the study protocol, OR
   the study does not involve a test article but intends to provide safety or efficacy data to the FDA.

   - ● **Yes**
   - ○ No

2. * **Indicate the FDA regulated product(s) this study involves:**
   - [ ] Drug
   - [x] **Medical Device**
   - [ ] Biologic
   - [ ] Dietary Supplement
   - [ ] Food/Food Additive
   - [ ] Color Additive
   - [ ] Electronic Products for Human Use (radiation producing)
   - [ ] Tobacco Product
   - [ ] Other

3. * **Is this study supported by the Department of Defense (DoD):**
   - ( ) Yes
   - (•) **No**

4. * **Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):**
   - [ ] Department of Education
   - [ ] Department of Justice
   - [ ] Environmental Protection Agency
   - [x] **None of the above**

ID: MS12_HM20027241 View: SF2 - IRB Panel Setup

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**
   - (•) **VCU IRB**
   - ( ) WCG IRB
   - ( ) NCI Central IRB
   - ( ) Advarra IRB
   - ( ) Other IRB

2. * **Is this study transitioning to review by another IRB?**
   - ( ) Yes - transitioning from VCU IRB to an external IRB (WCG, CIRB, Other)
   - ( ) Yes - transitioning from an external IRB (WCG, CIRB, Other) to VCU IRB
   - (•) **No or not applicable**

ID: MS12_HM20027241 View: SF2 - Review Setup

Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**
   - (•) **Bio-Medical Research**
   - ( ) Social/Behavioral/Education (SBE) Research

2. * **Which option(s) best describe the way(s) this studys procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   - [x] **In-person interactions / interventions with participants**
   - [x] **Remote interactions / interventions with participants**
   - [ ] Secondary data/specimen analyses with or without contact with study participants

3. * **Would it be possible to convert in-person activities in your study to remote if there is an approved contingency protocol?**
   No, not possible to convert to remote activities

4. * **Does this study involve greater than minimal risk:**
   - ( ) Yes (•) **No**

5. * **Review type requested: (subject to IRB approval):**
   - ( ) Full Board
   - (•) **Expedited**
   - ( ) Exempt

6. * **Is this study initiated by a VCU investigator or a sponsor:**
   - (●) **VCU Investigator initiated**
   - ( ) Sponsor or industry initiated

The IRB has determined that the selected types of anticipated individual and social benefit apply to this study

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study. This information may be used by the IRB in triaging studies during an emergency situation.
Scientific benefit

The following information applies to studies being reviewed by the VCU IRB.

The IRB has determined that the selected Exempt and/or Expedited categories apply to this study.

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study or the study is being reviewed by an external IRB.

7. **For Expedited Studies:**

Category 8c	Continuing Review - Data Analysis	Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis.

ID: MS12_HM20027241 View: SF2 - Initial Setup Complete

Initial Setup Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS12_HM20027241 View: SF2 - Background, Rationale and Goals

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

Background & Significance
ICU Delirium. Delirium is a state of acute brain dysfunction characterized by changes in cognition, attention, and awareness.13 Delirium occurs frequently in the Intensive Care Unit (ICU) patient population, impacting between 60-80% of mechanically ventilated patients and 20-50% of lower acuity ICU patients.2,49 The development of delirium is associated with acute illness, severe/critical illness, mechanical ventilation, disruption of circadian rhythm, the use of medications for pain and sedation, older age, and chronic illnesses.1,8 In particular, opioid analgesics, benzodiazepine medications, sleep disturbances, and circadian rhythm disruptions are associated both with delirium and worse patient outcomes in the ICU patient population.1,8,1012 ICU delirium is independently associated with higher morbidity and mortality, longer mechanical ventilation, increased ICU length of stay, increased length of hospitalization, increased subsequent hospitalizations, and increased health care costs.9,1315 It is estimated that $143 to 152 billion dollars per year are directly attributable to delirium in elderly hospitalized patients alone.16 Long term negative neuropsychological sequelae associated with ICU delirium include post-intensive care syndrome, cognitive deficits (e.g., memory deficits, poor concentration, worse executive function) and functional disability (activities of daily living).3,1720 ICU delirium contributes to long-term mental health challenges, including anxiety, depression, and PTSD, although these relationships are less consistent in the literature.2123
Pharmacological agents have been ineffective in both prevention and treatment of ICU delirium.10 Pharmacological agents such as opioid analgesics and sedatives are frequently used to manage hyperactive delirium behaviors but are paradoxically associated with increased risk of and greater duration of delirium.8,10,24 Current evidence also shows that opioid analgesics and sedating medications (particularly benzodiazepines) are themselves associated with increased morbidity, increased length of mechanical ventilation, increased ICU length of stay, and worse post-ICU outcomes.11 For these reasons, minimization of opioid analgesics and sedating medication is crucial in the ICU patient population. While no pharmacological agents have been identified to prevent or treat delirium, non-pharmacological interventions have been shown to reduce delirium and improve outcomes in ICU patients when combined in a bundled approach.8,11 The Society of Critical Care Medicine recommends evidence-based, non-pharmacological interventions in their clinical practice guideline for the management of delirium. These non-

pharmacological interventions include strategies to improve cognition (e.g., reorientation, cognitive stimulation, use of clocks), improve sleep, improve daytime wakefulness (e.g., reduced sedation), promote early mobility, and increase usage of devices to reduce vision and hearing impairment (e.g., eyeglasses, hearing aids).8,11,25
Growing evidence suggests an association between critical illness, sleep disturbance, circadian rhythm disruption, and delirium.1,11,12,26 Fragmented sleep and abnormal sleep architecture are common in critically ill patient populations, with ICU patients experiencing frequent arousals and disrupted circadian rhythms.1,27,28 These sleep disruptions are associated with an increased incidence of delirium, increased length of stay, and increased short- and long- term cognitive impairment.1,3,11,17,29,30
Weighted Blankets. Weighted blankets are a sensory integration modality which provide deep pressure stimulation, decreased sympathetic arousal, and increased parasympathetic arousal.3135 Multiple studies have demonstrated the safety and feasibility of weighted blankets in diverse inpatient and outpatient populations, including patients with dementia, neurological disorders, psychiatric/mental health diagnoses, oral surgery, cancer, and in healthy participants.32,34,3640
The therapeutic use of weight and compression, including the use of weighted blankets, has been used as an occupational therapy modality and is associated with significant reductions in anxiety, stress, insomnia, and pain as well as significant increases in grounding, orientation to reality, soothing, and quality of life.31,3436,4045 Studies conducted in a variety of populations show associations between the use of weighted blankets and improvements in sleep, agitation, and anxiety.31,3638,40,42,4649 Weighted blankets have been shown to decrease sleep disturbances, nighttime waking, agitation, and fatigue and to improve sleep latency, insomnia severity, and subjective and objective sleep quality.31,38,40,46,48 One study found weighted blankets had an impact on circadian rhythm activity demonstrating significant increases in circadian peak activity as well as delayed timing of circadian peak activity (increased daytime wakefulness/activity) in individuals who were classified as responders to weighted blanket therapy.46 Another noted that increases in salivary melatonin one hour after bedtime were 32% higher with weighted blanket usage49. Significant improvements in symptoms of depression and anxiety were also noted in an inpatient adult psychiatric patient population.46
Only one study to date has examined weighted blankets and delirium. Eull et al. (2021) examined the feasibility of weighted blanket use as an intervention for emergence delirium in postoperative pediatric patients.39 In this study, weighted blankets were applied in the post anesthesia care unit (PACU) immediately postoperative. Study participants used the blankets until they were self-removed, an adverse event occurred, or they left the PACU. Blankets in this study were in place for an average of 21.4 minutes. Only one participant (out of 93) experienced an adverse event (decrease in heart rate >20%) requiring the removal of the blanket. This study concluded that weighted blanket use was feasible and safe in this patient population but did not find a statistically significant difference in emergence delirium. They did note that emergence delirium was significantly associated with suspected pain in this patient population. Notably, this study used weighted blankets for a much shorter time period than other research studies and our proposal.
To date, no research studies have examined the use of weighted blankets in an adult medicine critical care patient population or for the prevention of ICU delirium. However, one quality improvement initiative was conducted in an adult medicine critical care patient population (n=81) at Massachusetts General Hospital.43 This initiative was conducted in a magnet-designated academic medical center similar in size to Virginia Commonwealth University Medical Center (VCUMC), and in an analogous medical patient population. In this initiative, weighted blankets were placed on intubated patients identified as nearing extubation with the intention to facilitate sedation weaning, increased level of consciousness, and earlier extubation (E. Mover, personal communication, February 14, 2023). There were no time limits to how often or long patients used the blankets. They were used for as long as the patient responded to them or wanted to use them (E. Mover, personal communication, February 14, 2023). A pre- post-intervention comparison found that weighted blankets were associated with a decrease in agitation (average RASS score change 1.33), a 22.6% decrease in the use of continuous sedation medications, a 51.6% decrease in the use of PRN medications for agitation, and a 9.4% decrease in the average number of ventilator days resulting in an estimated annual cost savings of nearly $500,000.43
Notably, weighted blankets are a single component, nonpharmacologic strategy which have been shown to improve three of the five categories recommended as targets to reduce ICU delirium in the clinical practice guideline issued by the Society of Critical Care Medicine.11 Specifically, weighted blankets have been shown to improve cognition (increased grounding and orientation to reality), improve sleep, and improve daytime wakefulness (increased circadian peak activity/delayed timing of circadian peak activity).31,3436,38,4046,48 Additionally, weighted blankets have been shown to reduce agitation and the use of sedating medications in an adult medicine ICU patient population43. As such, weighted blankets represent an easy to use, single component, nonpharmacological strategy with the potential to prevent and/or improve delirium in the ICU patient population.
Rural Patient Population/Study Recruitment/Participation. Despite advances in health research, significant disparities persist in rural and minority patient populations50. One contributing factor to these ongoing disparities is limited participation by rural and minority patient populations in clinical research.51 Participation of rural and minority patient populations in health research is an imperative step to improve the generalizability of health research and to address health disparities.52
One fifth of all Americans live in rural areas53. Rural populations participate in health research at lower rates than urban populations.51 Research has elucidated major barriers to research participation for rural and racial and ethnic minority groups. Among the greatest barriers are lack of access to clinical research and trials (often due to geographical and transportation challenges) as well as lack of infrastructure to conduct clinical trials.51,54,55 Almost half of one recent rural population sample indicated that they would be willing to participate in clinical trials if given the opportunity.56 Other significant barriers to research participation for rural and minority populations include lack of engagement of local healthcare providers and a distrust of outsiders, including researchers.51,54,55,57 Increasing rural clinical trial participation is crucial to the advancement of rural health equity. Evidence is also needed to examine methods designed to increase rural population participation in clinical research. Analysis and reporting that includes comparisons between rural and non-rural populations participating in research are needed to inform investigators regarding future strategies for rural research participation58.
The acquisition of Community Memorial Hospital (CMH), located in rural South Hill, Virginia, by VCU Health has the potential to increase research participation opportunities for rural individuals by offering a common electronic health record (EHR) system, research infrastructure support, and expansion of clinical research to rural sites. CMH nurses and nurse leaders are actively engaged in collaboration with VCU Medical Center to increase research and clinical trial participation in their hospital and community. Notably in the literature, rural survey participants deemed nurses as the most trustworthy health care professional to provide accurate information about research participation, making nursing-driven research potentially more acceptable to rural populations.59
The use of digital technology can be used to increase access to and inclusivity in clinical research for rural populations.58,60 This study will engage a rural patient population in this research through collaboration with CMH. A common EHR allows remote screening of potential research participants. Videoconferencing technology is available through VCU Health Zoom at CMH and VCUMC and provides the ability to conduct research activities remotely including collaboration with local health care providers, obtaining informed consent, staff training, and on-demand research staff availability for questions and protocol support. Additionally, data will be collected to enable us to report on the use of digital technology in the facilitation of the conduct of clinical research in a rural population including: VCU Health Zoom, EHR, VCU Health intranet resources (Clinical Research Page, Clinical Research Nursing Guides), and other VCU and VCU Health infrastructure (REDCap database, OnCore, Protocol Oversight and Review Committees). This knowledge will inform future research studies and provide evidence to promote the engagement of rural populations in clinical research.

References

1. Daou M, Telias I, Younes M, Brochard L, Wilcox ME. Abnormal Sleep, Circadian Rhythm Disruption, and Delirium in the ICU: Are They Related? Front Neurol. 2020;11:549908. doi:10.3389/fneur.2020.549908
2. Ely EW, Inouye SK, Bernard GR, et al. Delirium in Mechanically Ventilated Patients: Validity and Reliability of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). JAMA. 2001;286(21):2703.

doi:10.1001/jama.286.21.2703
3. Girard TD, Jackson JC, Pandharipande PP, et al. Delirium as a predictor of long-term cognitive impairment in survivors of critical illness: Crit Care Med. 2010;38(7):1513-1520. doi:10.1097/CCM.0b013e3181e47be1
4. Bergeron N, Dubois MJ, Dumont M, Dial S, Skrobik Y. Intensive Care Delirium Screening Checklist: evaluation of a new screening tool. Intensive Care Med. 2001;27(5):859-864. doi:10.1007/s001340100909
5. Guenther U, Popp J, Koecher L, et al. Validity and Reliability of the CAM-ICU Flowsheet to diagnose delirium in surgical ICU patients. J Crit Care. 2010;25(1):144-151. doi:10.1016/j.jcrc.2009.08.005
6. Pandharipande P, Cotton BA, Shintani A, et al. Prevalence and Risk Factors for Development of Delirium in Surgical and Trauma Intensive Care Unit Patients. J Trauma Inj Infect Crit Care. 2008;65(1):34-41. doi:10.1097/TA.0b013e31814b2c4d
7. Morandi A, Jackson JC, Wesley Ely E. Delirium in the intensive care unit. Int Rev Psychiatry. 2009;21(1):43-58. doi:10.1080/09540260802675296
8. Stollings JL, Kotfis K, Chanques G, Pun BT, Pandharipande PP, Ely EW. Delirium in critical illness: clinical manifestations, outcomes, and management. Intensive Care Med. 2021;47(10):1089-1103. doi:10.1007/s00134-021-06503-1
9. Ely EW, Shintani A, Truman B, et al. Delirium as a Predictor of Mortality in Mechanically Ventilated Patients in the Intensive Care Unit. JAMA. 2004;291(14):1753-1762.
10. van den Boogaard M, Slooter AJC, Brggemann RJM, et al. Effect of Haloperidol on Survival Among Critically Ill Adults With a High Risk of Delirium: The REDUCE Randomized Clinical Trial. JAMA. 2018;319(7):680. doi:10.1001/jama.2018.0160
11. Devlin JW, Skrobik Y, Glinas C, et al. Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU: Crit Care Med. 2018;46(9):e825-e873. doi:10.1097/CCM.0000000000003299
12. Flannery AH, Oyler DR, Weinhouse GL. The Impact of Interventions to Improve Sleep on Delirium in the ICU: A Systematic Review and Research Framework*. Crit Care Med. 2016;44(12):2231-2240. doi:10.1097/CCM.0000000000001952
13. Klein Klouwenberg PMC, Zaal IJ, Spitoni C, et al. The attributable mortality of delirium in critically ill patients: prospective cohort study. BMJ. 2014;349(nov24 16):g6652-g6652. doi:10.1136/bmj.g6652
14. Duprey MS, van den Boogaard M, van der Hoeven JG, et al. Association between incident delirium and 28- and 90-day mortality in critically ill adults: a secondary analysis. Crit Care. 2020;24(1):161. doi:10.1186/s13054-020-02879-6
15. Rood PJT, van de Schoor F, van Tertholen K, Pickkers P, van den Boogaard M. Differences in 90-day mortality of delirium subtypes in the intensive care unit: A retrospective cohort study. J Crit Care. 2019;53:120-124. doi:10.1016/j.jcrc.2019.06.007
16. Leslie DL, Inouye SK. The Importance of Delirium: Economic and Societal Costs. J Am Geriatr Soc. 2011;59:S241-S243. doi:10.1111/j.1532-5415.2011.03671.x
17. van den Boogaard M, Schoonhoven L, Evers AWM, van der Hoeven JG, van Achterberg T, Pickkers P. Delirium in critically ill patients: Impact on long-term health-related quality of life and cognitive functioning*. Crit Care Med. 2012;40(1):112-118. doi:10.1097/CCM.0b013e31822e9fc9
18. Wolters AE, van Dijk D, Pasma W, et al. Long-term outcome of delirium during intensive care unit stay in survivors of critical illness: a prospective cohort study. Crit Care. 2014;18(3):R125. doi:10.1186/cc13929
19. Brummel NE, Girard TD, Ely EW, et al. Feasibility and safety of early combined cognitive and physical therapy for critically ill medical and surgical patients: the Activity and Cognitive Therapy in ICU (ACT-ICU) trial. Intensive Care Med. 2014;40(3):370-379. doi:10.1007/s00134-013-3136-0
20. Pandharipande PP, Girard TD, Jackson JC, et al. Long-Term Cognitive Impairment after Critical Illness. N Engl J Med. 2013;369(14):1306-1316. doi:10.1056/NEJMoa1301372
21. Parker AM, Sricharoenchai T, Raparla S, Schneck KW, Bienvenu OJ, Needham DM. Posttraumatic Stress Disorder in Critical Illness Survivors: A Metaanalysis*. Crit Care Med. 2015;43(5):1121-1129. doi:10.1097/CCM.0000000000000882
22. Davydow DS, Gifford JM, Desai SV, Bienvenu OJ, Needham DM. Depression in general intensive care unit survivors: a systematic review. Intensive Care Med. 2009;35(5):796-809. doi:10.1007/s00134-009-1396-5
23. Bulic D, Bennett M, Georgousopoulou EN, et al. Cognitive and psychosocial outcomes of mechanically ventilated intensive care patients with and without delirium. Ann Intensive Care. 2020;10(1):104. doi:10.1186/s13613-020-00723-2
24. Duprey MS, Dijkstra-Kersten SMA, Zaal IJ, et al. Opioid Use Increases the Risk of Delirium in Critically Ill Adults Independently of Pain. Am J Respir Crit Care Med. 2021;204(5):566-572. doi:10.1164/rccm.202010-3794OC
25. Barr J, Fraser GL, Puntillo K, et al. Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit: Executive summary. Am J Health Syst Pharm. 2013;70(1):53-58. doi:10.1093/ajhp/70.1.53
26. Patel SB, Poston JT, Pohlman A, Hall JB, Kress JP. Rapidly Reversible, Sedation-related Delirium versus Persistent Delirium in the Intensive Care Unit. Am J Respir Crit Care Med. 2014;189(6):658-665. doi:10.1164/rccm.201310-1815OC
27. Pisani MA, Friese RS, Gehlbach BK, Schwab RJ, Weinhouse GL, Jones SF. Sleep in the Intensive Care Unit. Am J Respir Crit Care Med. 2015;191(7):731-738. doi:10.1164/rccm.201411-2099CI
28. Elliott R, McKinley S, Cistulli P, Fien M. Characterisation of sleep in intensive care using 24-hour polysomnography: an observational study. Crit Care. 2013;17(2):R46. doi:10.1186/cc12565
29. Kotfis K, Marra A, Ely EW. ICU delirium ? a diagnostic and therapeutic challenge in the intensive care unit. Anestezjol Intensywna Ter. 2018;50(2):160-167. doi:10.5603/AIT.a2018.0011
30. Drouot X, Roche-Campo F, Thille AW, et al. A new classification for sleep analysis in critically ill patients. Sleep Med. 2012;13(1):7-14. doi:10.1016/j.sleep.2011.07.012
31. Eron K, Kohnert L, Watters A, Logan C, Weisner-Rose M, Mehler PS. Weighted Blanket Use: A Systematic Review. Am J Occup Ther. 2020;74(2):7402205010p1-7402205010p14. doi:10.5014/ajot.2020.037358
32. Harris ML, Titler MG. Feasibility and Acceptability of a Remotely Delivered Weighted Blanket Intervention for People Living With Dementia and Their Family Caregivers. J Appl Gerontol. 2022;41(11):2316-2328. doi:10.1177/07334648221111123
33. Reynolds S, Lane SJ, Mullen B. Effects of Deep Pressure Stimulation on Physiological Arousal. Am J Occup Ther. 2015;69(3):6903350010p1-6903350010p5. doi:10.5014/ajot.2015.015560
34. Chen HY, Yang H, Meng LF, Chan PYS, Yang CY, Chen HM. Effect of deep pressure input on parasympathetic system in patients with wisdom tooth surgery. J Formos Med Assoc. 2016;115(10):853-859. doi:10.1016/j.jfma.2016.07.008
35. Chen HY, Yang H, Chi HJ, Chen HM. Parasympathetic effect of deep pressure input on third molar extraction in adolescents. J Formos Med Assoc. 2019;118(9):1317-1324. doi:10.1016/j.jfma.2019.05.026
36. Mullen B, Champagne T, Krishnamurty S, Dickson D, Gao RX. Exploring the Safety and Therapeutic Effects of Deep Pressure Stimulation Using a Weighted Blanket. Occup Ther Ment Health. 2008;24(1):65-89. doi:10.1300/J004v24n01_05
37. Vinson J, Powers J, Mosesso K. Weighted Blankets: Anxiety Reduction in Adult Patients Receiving Chemotherapy. Clin J Oncol Nurs. 2020;24(4):360-368. doi:10.1188/20.CJON.360-368
38. Hjort Telhede E, Arvidsson S, Karlsson S, Ivarsson A. Weighted Blankets Effect on the Health of Older People Living in Nursing Homes. Geriatrics. 2022;7(4):79. doi:10.3390/geriatrics7040079
39. Eull D, Zachrison B, Nickel A. Feasibility trial of weighted blankets as an intervention for emergence delirium in postoperative pediatric patients. J Pediatr Nurs. 2022;62:30-35. doi:10.1016/j.pedn.2021.11.022
40. Ackerley R, Badre G, Olausson H. Positive Effects of a Weighted Blanket on Insomnia. J Sleep Med Disord. 2015;2(3):1022.
41. Baumgartner JN, Quintana D, Leija L, et al. Widespread Pressure Delivered by a Weighted Blanket Reduces Chronic Pain: A Randomized Controlled Trial. J Pain. 2022;23(1):156-174. doi:10.1016/j.jpain.2021.07.009
42. Champagne T, Mullen B, Dickson D, Krishnamurty S. Evaluating the Safety and Effectiveness of the Weighted

Blanket With Adults During an Inpatient Mental Health Hospitalization. Occup Ther Ment Health. 2015;31(3):211-233. doi:10.1080/0164212X.2015.1066220
43. McCarthy C, Mover E, Shim C. Blanket Bolus. Presented at: Innovation Conference; December 6, 2019; American Association of Critical Care nurses. Accessed February 10, 2023. https://www.aacn.org/clinical-resources/csi-projects/blanket-bolus
44. Champagne T. Expanding the role of sensory approaches in acute psychiatric settings. Ment Health Spec Interest Sect Q. 2005;28(1):1-4.
45. Champagne T, Stromberg N. Sensory Approaches in Inpatient Psychiartric Settings: Innovative Alternatives to Seclusion and Restraint. J Psychosoc Nurs Ment Health Serv. 2004;42(9):34-44.
46. Ekholm B, Spulber S, Adler M. A randomized controlled study of weighted chain blankets for insomnia in psychiatric disorders. J Clin Sleep Med. 2020;16(9):1567-1577. doi:10.5664/jcsm.8636
47. Chen HY. Physiological Effects of Deep Touch Pressure on Anxiety Alleviation: The Weighted Blanket Approach. J Med Biol Eng. 2013;33(5):463. doi:10.5405/jmbe.1043
48. Gee BM, Lloyd K, Sutton J, McOmber T. Weighted Blankets and Sleep Quality in Children with Autism Spectrum Disorders: A Single-Subject Design. Children. 2020;8(1):10. doi:10.3390/children8010010
49. Meth EMS, Brando LEM, van Egmond LT, et al. A weighted blanket increases pre-sleep salivary concentrations of melatonin in young, healthy adults. J Sleep Res. Published online October 3, 2022. doi:10.1111/jsr.13743
50. US Department of Health and Human Services , Office of the Secretary, Office of the Assistant Secretary for Planning and Evaluation, and Office of Minority Health. HHS Action Plan to Reduce Racial and Ethnic Health Disparities Implementation Progress Report. Office of the Assistant Secretary for Planning and Evaluation; 2015.
51. Tanner A, Kim SH, Friedman DB, Foster C, Bergeron CD. Barriers to Medical Research Participation as Perceived by Clinical Trial Investigators: Communicating with Rural and African American Communities. J Health Commun. 2015;20(1):88-96. doi:10.1080/10810730.2014.908985
52. Zarin DA, Tse T, Williams RJ, Carr S. Trial Reporting in ClinicalTrials.gov The Final Rule. N Engl J Med. 2016;375(20):1998-2004. doi:10.1056/NEJMsr1611785
53. United States Census Bureau. One in Five Americans Live in Rural Areas. Published August 9, 2017. Accessed February 10, 2023. https://www.census.gov/library/stories/2017/08/rural-america.html
54. Friedman DB, Foster C, Bergeron CD, Tanner A, Kim SH. A Qualitative Study of Recruitment Barriers, Motivators, and Community-Based Strategies for Increasing Clinical Trials Participation among Rural and Urban Populations. Am J Health Promot. 2015;29(5):332-338. doi:10.4278/ajhp.130514-QUAL-247
55. Pribulick M, Williams I, Fahs P. Strategies to Reduce Barriers to Recruitment and Participation. Online J Rural Nurs Health Care. 2010;10(1):22-33. doi:10.14574/ojrnhc.v10i1.68
56. McElfish PA, Long CR, Selig JP, et al. Health Research Participation, Opportunity, and Willingness Among Minority and Rural Communities of Arkansas: Health Research Participation, Opportunity. Clin Transl Sci. 2018;11(5):487-497. doi:10.1111/cts.12561
57. Dibartolo MC, McCrone S. Recruitment of rural community-dwelling older adults: Barriers, challenges, and strategies. Aging Ment Health. 2003;7(2):75-82. doi:10.1080/1360786031000072295
58. Noonan D, Simmons LA. Navigating Nonessential Research Trials During COVID-19: The Push We Needed for Using Digital Technology to Increase Access for Rural Participants? J Rural Health. 2021;37(1):185-187. doi:10.1111/jrh.12446
59. L. L. Morgan, P. S. Fahs, J. Klesh. Barriers to Research Participation Identified by Rural People. J Agric Saf Health. 2005;11(4):407-414. doi:10.13031/2013.19719
60. Simon CM, Schartz HA, Rosenthal GE, Eisenstein EL, Klein DW. Perspectives on Electronic Informed Consent From Patients Underrepresented in Research in the United States: A Focus Group Study. J Empir Res Hum Res Ethics. 2018;13(4):338-348. doi:10.1177/1556264618773883

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   Is the use of weighted blankets feasible and acceptable to prevent and/or mitigate delirium in adult critical care patients in urban and rural settings?

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   Specific Aims
   Aim 1: To examine the feasibility and acceptability of weighted blankets as a single component, nonpharmacologic strategy to prevent and/or mitigate delirium in an adult medicine critical care patient population.
   Aim 2: To examine the feasibility and acceptability of videoconferencing (VCU Health Zoom), EHR screening, and VCU and VCU Health infrastructure (REDCap, OnCore) for rural participant recruitment and research participation, remote healthcare provider protocol training and research engagement, and remote research monitoring and support for a rural patient population.
   Aim 3: To collect preliminary descriptive data and examine trends related the use of weighted blankets to prevent and/or mitigate delirium to inform future efficacy trials in an adult medicine critical care patient population (e.g., agitation, delirium, ICU length of stay, number ventilator days, sedation/opioid medication usage).

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

   Our goal is to generate descriptive data examining the feasibility and acceptability of weighted blankets and the use of technology to recruit and support clinical research in a rural patient population. Plans are for the results of this study to be used to support a larger, randomized clinical trial to be conducted in similar patient population (adult medicine ICU patients; rural and non-rural participants).

5. * **Describe any potential for direct benefits to participants in this study:**
   Participants are unlikely to benefit from this study as it is intended for feasibility and acceptability assessment only. However, some participants may experience prevention or reduction in their delirium which would be beneficial to their overall health and potentially decrease some of their healthcare needs.

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
   This study will engage participants from both the VCU Health downtown campus (medical respiratory ICU) and participants at VCU's Community Memorial Hospital (general ICU) in rural, South Hill, Virginia. Participants at CMH are being targeting for enrollment given the rural nature of the hospital's location and difficulty in enrolling rural patients into clinical research.

7. **Upload a supporting citation list if applicable:**

Study Population

1. * **Provide the maximum number of individuals that**

   1. **May participate in any study interaction or intervention (Including screening, consenting, and study activities) AND/OR**
   2. **You obtain any data/specimens about (regardless of identifiability)**

at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
500

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
not applicable

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
Our goal is to generate descriptive data examining the feasibility and acceptability of weighted blankets and the use of technology to recruit and support clinical research in a rural patient population.

Sample size is based on the literature regarding targets for pilot studies examining feasibility and acceptability. Our sample will consist of the following:
50 adult medicine ICU patient participants: 25 at VCU Medical Center (VCUMC) and 25 at VCU's Community Memorial Hospital (CMH).
50 legally authorized representatives (upper limit; one for each patient participant)
100 Nurses (upper limit; two for each patient)
100 Medical Providers (upper limit; two for each patient)
Total Enrolled Participants = 300

Approximate number of additional individuals expected with study interaction to account for screening failures and individuals who are approached but elect not to participate:
125 patient participants approach but are then Screening Failures
75 patient participants approached but who Failure to consent/enroll
Total additional individuals with study interaction: 200

Total number of individuals who may participate in any study interaction or screening: 500
Patient participants enrolled = 50
LARs maximum = 50
Nurse maximum = 100
Medical Provider maximum = 100
Screening failures = 125
Failure to enroll = 75

The estimate to account for screening failures and those who are approached, but elect not to participate based on the following data (and rounded up to capture the maximum number):
2019 average screen failure rate in global clinical trials was 36.3% - https://blog.onestudyteam.com/3-ways-reduce-screen-failures-clinical-trials#:~:text=As%20of%202019%2C%20the%20average,at%2036.3%25%20across%20therapeutic%20areas.
2020 study showed 53% of those approached to participate in a clinical trial elect not to participate https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8482053/#:~:text=Findings,of%20those%2C%2047%25%20participated

4. * **List the study inclusion criteria:**
Patient Participant Inclusion:
18 years of age or older
Requiring ICU level of care
Have a primary medical diagnosis
Proficient in English language

LAR Inclusion:
18 year of age or older
LAR of patient enrolled in study
Proficient in English language

Healthcare Provider Inclusion:
18 year of age or older
Nurse, advanced practice provider, or physician of patient enrolled in study
Proficient in English language

5. * **List the study exclusion criteria:**
Patient Participant Exclusion:
-BMI less than 18.5
-Significant deficit in cognitive functioning that is not expected to improve due to an end-stage disease stage or permanent injury (e.g., end-stage encephalopathy, traumatic or anoxic brain injury, dementia)
-Known pregnancy
-Prisoner
-Presence of skin injury (e.g., surgical wound, pressure injury, moisture injury) in an anatomical location where additional weight/pressure of blanket could prevent healing and/or lead to an expansion of the injury. Patients with skin injuries to areas easily left uncovered by the blanket (e.g., hands, feet) can be enrolled with additional communication to clinical team to leave areas uncovered to prevent additional injury.
-Paralysis effecting an area the weighted blanket will cover?
-Current neuromuscular blocking agent
-Presence of recent/unhealed fractures on an area the blanket will cover (e.g., lower limb long bone, rib, pelvis, spine)?
-History of claustrophobia?reported by patient and/or their legally authorized representative (LAR)
-Fever of 37.5C (99.5F) or greater
-Limited English proficiency

LAR Exclusion:
-Not documented in EHR as enrolled participant's LAR

Healthcare Provider Exclusion:
-Not active healthcare provider of enrolled study patient

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
- ◯ Included
- ◯ Excluded - safety concerns if participants are unable to communicate with the study team
- ◯ Excluded - instruments/measures only validated in English
- ◯ Excluded - no prospect of direct benefit to individual participants
- ◯ Excluded - minimal risk study

- **Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]**
- Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
   For Patient Participants:
   Excluding those with BMI less than 18.5 due to risk of skin injury from the blankets.
   Excluding those with deficit in cognitive functioning of significant severity that (not expecting to improve) due to inability to identify and track delirium at baseline.
   Excluding those with known pregnancy due to weight of blanket, including abdominal area.
   Excluding prisoners due to vulnerability and inability to consent for study likely requiring LAR consent.
   Excluding those with presence of skin injuries in a location that weighted blanket may add additional pressure because of risk that weight of blanket will increase injury.
   Excluding those with paralysis effecting an area the weighted blanket will cover due to risk of skin injury and autonomic dysreflexia.
   Excluding those with current neuromuscular blocking agent as standard of care is to eliminate any additional risks of skin pressure for these individuals.
   Excluding those with presence of recent/unhealed fractures on an area the blanket will cover (e.g., lower limb long bone, rib, pelvis, spine) due to risk of weight of blanket.
   Excluding those with a history of claustrophobia reported by patient and/or their legally authorized representative (LAR) due to risk of increased sense of claustrophobia with additional covering on body.
   Excluding those with a fever due to the risk of increasing the fever even greater with placement of the weighted blanket.
   Excluding those with limited English proficiency due to the inability to have translational services directly in Zoom (required when enrolling and engaging with participants at CMH site). May be possible at a later date but the logistics of translation services while using Zoom is beyond the initial abilities of this initial project due to funding limitations.

Background, Rationale & Goals Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   Is the use of weighted blankets feasible and acceptable to prevent and/or mitigate delirium in adult critical care patients in urban and rural settings?

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   Specific Aims
   Aim 1: To examine the feasibility and acceptability of weighted blankets as a single component, nonpharmacologic strategy to prevent and/or mitigate delirium in an adult medicine critical care patient population.
   Aim 2: To examine the feasibility and acceptability of videoconferencing (VCU Health Zoom), EHR screening, and VCU and VCU Health infrastructure (REDCap, OnCore) for rural participant recruitment and research participation, remote healthcare provider protocol training and research engagement, and remote research monitoring and support for a rural patient population.
   Aim 3: To collect preliminary descriptive data and examine trends related the use of weighted blankets to prevent and/or mitigate delirium to inform future efficacy trials in an adult medicine critical care patient population (e.g., agitation, delirium, ICU length of stay, number ventilator days, sedation/opioid medication usage).

3. * **Choose all types of recruitment materials that may be used and upload them below:**
   - [ ] E-mail invitations
   - [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
   - [ ] Flyers, Mailed Letters or Newspaper/TV/Radio Ads
   - [ ] TelegRAM announcements
   - [ ] Website text
   - [ ] Study-specific web sites (provide the design and text)
   - [ ] Social Media
   - [ ] EPIC MyChart Patient Portal research study descriptions
   - [ ] Psychology Research Participant Pool (SONA) study descriptions
   - [ ] Scripts for announcements made to groups
   - [ ] Other recruitment document
   - [x] **No recruitment materials**

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address all of the following three aspects of recruitment in your response.**

1. Identification of potentially eligible participants or secondary data/specimens of interest.
- What database(s) will be queried to identify secondary data/specimens
- How VCU Informatics or VCU IRDS will be used for cohort identification (when applicable, see help text)
- How potential participants' contact information will be obtained

2. Recruitment procedures to invite participation in the study (when applicable):
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact, approach, or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
Daily screening for inclusion/exclusion criteria will be conducted by the research team for patients admitted to VCUMC Medical Respiratory ICU (MRICU) and CMH ICU via EHR bedboards (via Epic) for both sites.
For VCU Medical Center patients meeting inclusion criteria, a member of the study team will approach the patient at the bedside to review the informed consent form and answer any questions the patient may have before signing the consent. If the patient is not alert and oriented (as determined by the most recent physical assessment in the EHR and verified by the study team member bedside when engaging with the patient), the patient's LAR will be approached for consent, either in person in the intensive care unit (in the patient's room or in the dedicated family conference room to provide for privacy), or by phone (via number for LAR in EHR) if not available in person. The informed consent form will be reviewed with the LAR and questions answered by a member of the study team before signing. If the LAR does not answer when called, a message will be left via voicemail indicating that their family member may be eligible for participation in a clinical research study. They will be asked to call the study team member back at their convenience. If the LAR does not call back that day, a member of the study team will reach back out the next day. Failure to return a second message before the end of that day will indicate the desire to not have their family member participate and the LAR will not be contacted any further.
The same procedures will occur for patients at CMH that meet study criteria. However, all in-person interactions planned for the VCU Medical Center site will be transferred to electronic means via Zoom. The designated study team member at CMH will bring the study dedicated iPad to the patient's bedside to engage with patients and/or their LAR. If the LAR desires, there will also be a dedicated private room at CMH where LARs can engage with the study team member reviewing the consent via Zoom.
Although LAR consent will be required for enrollment of patients that are not alert and/or oriented, patient assent will be sought whenever possible.

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**
- ○ Yes
- ● **No**

6. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

1. A statement explaining the study design
2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
3. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)
4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

See the help text for additional guidance
This is a descriptive feasibility and accessibility pilot study that will be conducted in a convenience sample of adult medicine ICU patients at VCU Health (VCUMC and CMH hospitals). Our sample will consist of 50 adult medicine ICU patients: 25 at VCUMC and 25 at CMH. Our goal is to generate descriptive data examining the feasibility and acceptability of weighted blankets and the use of technology to recruit and support clinical research in a rural patient population. Plans are for the results of this study to be used to support a larger, randomized clinical trial to be conducted in similar patient population (adult medicine ICU patients; rural and non-rural participants).
Daily screening for inclusion/exclusion criteria will be conducted by the research team for patients admitted to VCUMC Medical Respiratory ICU (MRICU) and CMH ICU via EHR bedboards. Participants will be enrolled within 72 hours of ICU admission.
Once informed consent is obtained, medical-grade weighted blankets (equal to approximately 10% of the participants body weight up to 20lbs maximum) will be applied to participants by the bedside nurse for a minimum of 6 continuous hours nightly between 7pm-7am and additional hours as desired by the patient, their LAR, or the patient's clinical care team. Weighted blankets of various weights will be readily available on the nursing unit; the study team will communicate with the bedside nurse regarding what weight blanket will be used for each patient enrolled. Hourly rounding by a study champion will be utilized to document blanket use between the hours of 7pm-7am. Participants will remain enrolled in the study until they are withdrawn (either at participant request, administrative due to an adverse event, or at the request of the clinical team), or they are transferred from an ICU level of care. Data will be collected on: (1) feasibility and acceptability of weighted blankets; (2) feasibility and acceptability of technology to promote rural participation; (3) preliminary descriptive data and trends related to delirium, agitation, ventilator days, length of stay; and (4) participant demographics (see Data Collection Spreadsheet supporting document attached). A REDCap database the incorporates all data points needed to answer study aims will be developed with the assistance from the Wright Center Biostatistical Consulting Laboratory. Data analysis will include descriptive statistics and comparison statistics between VCUMC and CMH.
Once the patient's participation ends (withdrawn or transferred from an ICU level of care), the patient (if alert and oriented), the patient's LAR, the patient's nurse, and the patient's physicians and/or advanced practice providers (APPs) will be asked to complete an electronic survey based on their experience with the weighted blanket use. Surveys will only be administered if a patient uses the blanket for at least one night. The survey will be in REDCap; no participant identifiers will be used. The survey will be opened by a member of the study team and brought to the participant on a study dedicated iPad. The study team member will remain in close proximity until the participant indicates they are done. At the time, the study team member will collect the iPad and ensure the survey has been closed. Who the patient's nurse and physicians/APPs are for the day will be determined by the ICU's electronic assignment board and/or care team noted in the EHR via the storyboard.

7. * **The IRB only reviews research activities, so indicate for each of the study activities described in the question above or in the protocol which activities are:**

- Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
- Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location,

amount, etc.) VERSUS.
- Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
See the help text for additional guidance

Placement and monitoring of weighted blanket use is being done exclusively for research purposes. Additionally, survey data collected from healthcare providers, participants, participant LARs is also being done exclusively for research purposes. All other study-related activities include data collection from the EHR - these data are already collected as standard processes.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
Potential patient participants that choose not to participate in this study will continue to receive standard of care (same as those enrolled without nightly use of weighted blanket).

9. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

Project Details

An intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

An interaction includes communication or interpersonal contact between investigator and subject. It may include in-person, online, written, or verbal communications.

Secondary information/biospecimens are information or biospecimens that have been or will be collected for some other primary or initial activity and that will be used secondarily in the research study.

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
- [ ] Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations
- [ ] Deception (misleading participants through false or incomplete information)
- [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
- [ ] IV contrast administration for research-related imaging (will branch to the Drugs page)
- [ ] Placebos
- [x] **Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, software functions, and HUDs used in clinical investigations**
- [ ] Washout Periods
- [ ] Expanded Access Treatment Use of an Investigational Product
- [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
- [ ] Specimen/biological sample collection
- [ ] None of the Above

2. * **Select all of the following types of interactions and methods of data collection that apply to this study (selections will branch):**
- [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
- [x] **Active Internet data collection (i.e. using the internet to collect data, including online surveys, data collection via Zoom, apps, etc.)**
- [ ] Passive Internet data collection (i.e. passively observing online behavior, bots)
- [ ] Interviews / Focus Groups / Verbal responses to questions
- [ ] Audio / Video recording or photographing participants
- [ ] Observations
- [ ] Educational Settings/Assessments/Procedures
- [ ] None of the Above

3. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**
- [x] **Individually Identifiable Health Information (PHI)**
- [ ] Secondary data/specimens NOT from a research registry or repository
- [ ] Information/specimens from a research registry or repository (Usage Protocol)
- [ ] Information/specimens originally collected for a previous research study
- [ ] Publicly available information/specimens
- [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
- [ ] No secondary data/specimens will be used

Bio-Medical Device Details

1. * **Select the type of device :**
   - [ ] Marketed Device (including 510k device) used as indicated
   - [ ] Marketed but new indication or intended use
   - [ ] Mobile application or software function with regulatory discretion
   - [ ] Mobile application or software function without regulatory discretion
   - [x] **Investigational device**
   - [ ] Humanitarian Use Device (HUD)

2. * **List devices this study will involve:**

Device	Manufacturer	Device Risk	IDE	IDE Holder
Weighted Blanket	Sensory Goods	Non-Significant Risk	Abbreviated IDE	Not Required

3. * **Describe how the device will be stored and controlled.**
Weighted blankets will be stored in a centralized clean location on each ICU (VCUMC MRICU and CMH ICU) when not assigned to a study participant. They will be clearly labeled for use only by the Weighted Blanket Study (signage and written on the blanket with permanent marker). When assigned to a study participant, they will be kept in the patient's assigned room. The vinyl weighted blankets can be sanitized according to VCUHS infection control processes (e.g., with appropriate sanitizing wipes). When the participant has completed the study, the blanket will be sanitized and returned to the centralized clean location.

4. A. For each device listed above, **upload documentation of the approved use(s) (operation manual, instructions for use, etc.) or a detailed description of the design, use, and risks of the device.**

B1. If 'Investigational Medical Device' or 'New Use for Marketed Medical Device' was selected above AND the device qualifies for IDE exemption under under 21 CFR 812.2(c), upload one of the following for each applicable device:
- A document explaining how the device's use in this study meets one of the categories for IND exemption under 21 CFR 812.2(c).
- External sponsor's protocol including IDE exemption information
- Communication from the external sponsor verifying the IDE exemption
- Communication from the FDA with verification of IDE exemption

B2. Upload at least one of the following for each Significant Risk medical device:
- External sponsor's protocol including IDE number
- Communication from the external sponsor verifying the IDE number
- VCU sponsor-investigator's FDA IDE protocol including IDE number
- Communication from the FDA with verification of the IDE number

B3. Upload at least one of the following for each Non-Significant Risk medical device:
- External sponsor's protocol including a justification regarding the risk of the device (significant vs. non-significant)
- Communication from the sponsor holding the IDE, which provides a justification regarding the risk of the device (significant vs. non-significant) according to 21 CFR 812.3(m).

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.docx	Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.pdf	0.03	6/7/2024 1:56 PM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx	Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx	0.01	5/22/2024 3:53 PM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Consent Form	Weight Blanket Study Consent Form_10-11- 2023 - Copy - Copy.pdf	0.04	10/11/2023 11:35 AM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Weighted Blanket Device Information	Weighted Blanket Info for IRB_07 27 2023.docx	0.02	7/27/2023 10:29 AM	Shelly Orr	Other	Yes
View	Data Collection Spreadsheet	Weighted Blanket Data Spreadsheet 5 23 2023.xlsx	0.01	5/23/2023 11:02 AM	Heather Fudala	Other	Yes
View	Patient Participant Experience Survey	Weighted Blanket Participant Survey 5 23 2023.pdf	0.01	5/23/2023 11:02 AM	Heather Fudala	Research Measure	Yes
View	Legally Authorized Representative (LAR) Experience Survey	Weighted Blanket Legally Authorized Representative Survey 05 23 2023.pdf	0.01	5/23/2023 11:02 AM	Heather Fudala	Research Measure	Yes
View	Healthcare Provider Perception of Participant Experience Survey	Weighted Blanket Healthcare Provider Perception of Participant Survey	0.01	5/23/2023 11:01 AM	Heather Fudala	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
		05 23 2023.pdf					
View	Healthcare Provider Experience Survey	Weighted Blanket Healthcare Provider Experience Survey 05 23 2023.pdf	0.01	5/23/2023 11:01 AM	Heather Fudala	Research Measure	Yes
View	PROC Approval Letter	VCU ONETRAC Notifier - PROC Request #397 - Approval Without Revision.pdf	0.01	5/21/2023 10:26 PM	Shelly Orr	Other	Not Applicable
View	Fudala Biosketch	Weighted Blanket Fudala Biosketch Wright Center Rural Pilot.docx	0.01	5/21/2023 10:17 PM	Shelly Orr	CV/Biosketch	Not Applicable

Active Internet Data Collection

1. * **Describe the platform/technology chosen for collecting the data and transmitting data securely over the internet. If proposing a non-VCU approved platform, give the rationale for selecting the technology instead of a VCU-approved platform.**
   REDCap (a secure, VCU approved platform) will be used to provide surveys to the healthcare providers, patient participants, and legally authorized representatives (LARs). For the healthcare provider and the LAR, a waiver disclosure will be present at the top of the survey to reinforce the waiver of consent for the survey. A study team member will login, select the correct survey, then give the study specific iPad to the patient, healthcare provider, or LAR as appropriate to complete their respective survey.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   The data will be unlinked to any identifiers (including email addresses, names, and/or IP address or participant numbers). In order to keep track of the number of surveys completed, the study team will solely be informed of whether or not the survey was completed by each survey contender.

3. * **How will you protect your data collection from fraudulent responses:**
   REDCap is a secure platform, therefore false survey contenders will not have access. A study team member will present the iPad to ensure that only the intending survey contender is able to receive access. The study team member will remain close by, without hovering, to ensure only the intending respondent has access to the survey.

4. * **Is there an alternative method for completion of the data collection other than the internet?**
   - ○ Yes
   - ● **No**

5. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
   Individuals have the ability to skip or not answer a question. If there are unanswered survey questions, there will be a warning given before submission. This warning is intended to provide guidance for those that may not be aware that they have an unanswered question. Although a warning is present, individuals will still be able to submit the survey without being mandated to answering a question. None of the survey questions are mandatory.

6. **If not including children, describe any procedures used to verify that research participants are adults.**
   The inclusion criteria for each patient participant will be verified via medical record screening. In the inclusion criteria, it is stated that each participant must be 18 years of age or older. The waiver of consent language at the top of the healthcare provider and LAR survey will enforce the need for the respondent to be 18 years of age or older. By proceeding through the survey, they are self-verifying that they meet the age criteria.

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

   a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
   b. List what types of specimens will be obtained (when applicable); and/or
   c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.
   a. Data will be collected from the participants electronic health record (EHR)

   b. No specimens will be collected during this study.

   c. See attached Data Collection Spreadsheet document which contains all information that will be obtained from the EHR (demographic, delirium/agitation assessments, sedation/pain medications, diagnoses, history, hospital history, ventilator use, etc.)

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
   We will be assigning participants sequential study IDs that will be kept secure and separate from patient identifiers. The study team are clinical providers within VCU Health. Once a patient has been removed from the study and data collection has been completed, we will not attempt to re-identify individuals.

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**
   - ○ Yes
   - ● **No**

ID: MS12_HM20027241 View: SF2 - Costs to Participants

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - ☑ **Participants will have no costs associated with this study**
   - ☐ Study related procedures that would be done under standard of care
   - ☐ Study related procedures not associated with standard of care
   - ☐ Administration of drugs / devices
   - ☐ Study drugs or devices
   - ☐ Other

ID: MS12_HM20027241 View: SF2 - Compensation

Compensation

It is recommended that investigators consult with VCU Procurement Services before proposing a compensation plan (monetary or non-monetary) to the IRB to ensure the plan will comply with VCU policies. Refer to WPP XVII-2 for the IRBs guidelines about compensating research participants.

1. * **Describe any compensation that will be provided including:**
   1. total monetary amount
   2. type (e.g., gift card, research pre-paid card, cash, check, merchandise, drawing, extra class credit)
   3. how it will be disbursed
   4. how you arrived at this amount
   5. What identifiers and tax forms will be required for compensation purposes (i.e. W-9 form, SSN, V#, addresses, etc.)

   No compensation will be provided for participation in this study.
2. **If compensation will be pro-rated, explain the payment schedule.**

ID: MS12_HM20027241 View: SF2 - Contingency Plan

Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

ID: MS12_HM20027241 View: SF2 - Research Plan Complete

Research Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS

? DOCUMENTS

Click Continue below to go to the next section

ID: MS12_HM20027241 View: SF2 - Consent Process

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Patient Participant	Signed Consent by Participant Signed Assent by Child or Decisionally Impaired Adult Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult Signed Parent/Guardian Permission or Legally Authorized Representative Consent	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator		Not using electronic signature platforms	At the VCU Health Medical Center Main Hospital, the informed consent process will occur in an in-patient (bedside or unoccupied family conference room) or telephone setting. If the patient is decisionally competent (alert and oriented), the patient will be approached. If the patient is decisionally impaired in any capacity, the legally authorized representative (LAR) will be approached for consent. In that case, the patient will give a signed, verbal, or other indication of assent, if possible. During the informed consent process, an unbiased review of the trial and consent form will be discussed. It will be stated that the patient will continue to receive standard of care, with or without consenting for the voluntary trial. A physical copy of a consent form will be used. If the LAR is not available in person, the consent discussion may occur via telephone. At the VCU Health Community Memorial Hospital, consent will in the same manner as it	Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion Removing physical symbols of authority like white coats or police badges Sitting down beside the participant instead of standing over them If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to) Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)	The patient and/or their LAR will be given as much time as possible to make a decision, as long as it is within the indicated 72 hour time frame.	Continual assent will be sought for any patient enrolled that is decisionally impaired. This will enable the team to ensure their assent if they become no longer decisionally impaired.

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
							will at the VCU Medical center but all in-person activities will occur using remote technology (i.e., Zoom). A designated study team member at the CMH site will provide the patient and/or their LAR a study-specific iPad so that the study team member conducting the ICF process can speak with them using live communication via Zoom. The CMH team member will provide the patient and/or LAR a physical copy of the ICF to review during the discussion. If the patient and/or LAR agree to enroll the patient, they will sign the form and will give it to the CMH study team member who will place it in a locked cabinet at CMH dedicated for the study until it is transported by the study PI or Co-I to the study office at VCU Medical Center.			
View	Healthcare Provider	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	N/A: Requesting Waiver of Consent		Not using electronic signature platforms	At the end of the patient's participation (withdrawn or removed from ICU level of care), the healthcare provider (nurse, physicians, and/or APPs) will be asked to partake in a study survey with which we are asking for a waiver of consent. The survey will contain directions that specify that the survey is voluntary and that the answers provided will not be identifiable to others in any way. An iPad will be brought to the healthcare provider by a	N/A: Requesting Waiver of Consent	Once the healthcare provider is provided the survey and they have a chance to read the instructions, they will immediately be asked to complete the survey or return the iPad to the study team member without completing the survey.	

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
							member of the study team with the healthcare provider survey opened. After reading the directions, the healthcare provider's decision to complete their survey will indicate their consent to participate. This activity will only be done in person using a study-specific iPad.			
View	Legally Authorized Representative (LAR)	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	N/A: Requesting Waiver of Consent		Not using electronic signature platforms	At the end of the patient's participation (withdrawn or removed from ICU level of care), the LAR will be asked to partake in a study survey with which we are asking for a waiver of consent. The survey will contain directions that specify that the survey is voluntary and that the answers provided will not be identifiable to others in any way. An iPad will be brought to the LAR by a member of the study team with the LAR survey opened. After reading the directions, the LAR's decision to complete their survey will indicate their consent to participate. This activity will only be done in person using a study-specific iPad.	N/A: Requesting Waiver of Consent	Once the LAR is provided the survey and they have a chance to read the instructions, they will immediately be asked to complete the survey or return the iPad to the study team member without completing the survey.	

2. Upload any consent / assent documents:

Waiver of Some or All Elements of Consent

Consent groups that require a waiver of some or all elements of consent:

Group	Types	Waivers	Roles	Roles - Other	Consent	Decision	Status Change
Healthcare Provider	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	N/A: Requesting Waiver of Consent		At the end of the patient's participation (withdrawn or removed from ICU level of care), the healthcare provider (nurse, physicians, and/or APPs) will be asked to partake in a study survey with which we are asking for a waiver of consent. The survey will contain directions that specify that the survey is voluntary and that the	Once the healthcare provider is provided the survey and they have a chance to read the instructions,	

Group	Types	Waivers	Roles	Roles - Other	Consent	Decision	Status Change
					answers provided will not be identifiable to others in any way. An iPad will be brought to the healthcare provider by a member of the study team with the healthcare provider survey opened. After reading the directions, the healthcare provider's decision to complete their survey will indicate their consent to participate. This activity will only be done in person using a study-specific iPad.	they will immediately be asked to complete the survey or return the iPad to the study team member without completing the survey.	
Legally Authorized Representative (LAR)	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	N/A: Requesting Waiver of Consent		At the end of the patient's participation (withdrawn or removed from ICU level of care), the LAR will be asked to partake in a study survey with which we are asking for a waiver of consent. The survey will contain directions that specify that the survey is voluntary and that the answers provided will not be identifiable to others in any way. An iPad will be brought to the LAR by a member of the study team with the LAR survey opened. After reading the directions, the LAR's decision to complete their survey will indicate their consent to participate. This activity will only be done in person using a study-specific iPad.	Once the LAR is provided the survey and they have a chance to read the instructions, they will immediately be asked to complete the survey or return the iPad to the study team member without completing the survey.	

1. * **For each group listed at the top of this page, describe which elements of informed consent you are waiving or altering.**

   - To request a waiver or alteration of SOME elements of informed consent, describe each of the elements that you wish to waive. See the help text for a list of elements, and copy/paste the descriptions of the elements (not just the element numbers) into this response.
   - To waive ALL elements of informed consent, state "All elements of informed consent" in this response.
   We are requesting a waiver of consent for the surveys that LARs and healthcare providers will be asked to complete at the end of the study patient's participation in the study.

2. * **Will you be waiving parental permission for wards of the state (and/or a Legally Authorized Representative's consent) in any of the consent groups at the top of this page:**
   - ○ Yes
   - ● **No**

3. * **Is this study conducted by or subject to the approval of State or Local Government and designed to study, evaluate, or otherwise examine public benefit or service programs:**
   - ○ Yes
   - ● **No**

4. * **Explain how the research involves no more than minimal risk to the participants (Alternative question phrasing: How do the risk(s) of the research activity for which consent is being waived compare to the risks a person might reasonably experience in normal everyday life?)::**
   LARs and healthcare providers will be asked to complete a survey about their experience with use of weighted blankets. Their decision to not participate in survey completion will have no impact on the care of the patient enrolled in the study. Additionally, completion, or lack thereof, will have no impact on the healthcare providers employment at VCU. There will be no identifiers on the survey - they study team is only interested in the feedback given within the surveys and will only maintain a log of number of surveys completed.

5. * **Explain how the research could not practicably be carried out without the waiver or alteration (Alternative question phrasing: Why would obtaining consent from participants make the study not achievable or not viable?):**
   This study aims to examine the acceptability of use of weighted blankets. Data obtained from LARs and healthcare providers regarding blanket use is therefore critical to the aims of this study. It would be time prohibitive for the study team to obtain informed consent from each LAR and healthcare provider completing a survey. Additionally, the study team would then need to link each survey with a participant ID which is not desired given the complete anonymity being sought.

6. * **Explain why this study can only be carried out using identifiable or de-identified information/biospecimens.**
   - Studies with Department of Justice funding may state "Not applicable."
   (Alternative question phrasing: Why would it be impossible to conduct the study using only anonymous information/biospecimens?).
   There will be no identifiers on the survey - they study team is only interested in the feedback given within the surveys and will only maintain a log of number of surveys completed. They study team desires to provide both LARs and healthcare providers completing the surveys complete anonymity.

7. * **Explain how the waiver or alteration will not adversely affect the rights or welfare of the participants (Alternative question phrasing: Will this consent waiver violate any of the participant's rights or adversely affect their welfare - why or why not?):**
   This waiver of consent will not violate the participant's rights or adversely affect their welfare. Their decision to complete the survey, or not complete the survey, changes nothing for the LAR, healthcare provider, or the patient participant.

8. * **Explain how participants will be provided with additional pertinent information after participation. If this will not be provided, explain why not:**
   Participants will not individually be provided with additional information after participation. The goal of the study team is to publish the results of this study - the publication will contain aggregated results which will be available to all participants who read the manuscript.

Consent Plan Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**
   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   Physical risk: The addition of a weighted blanket increases the amount of pressure placed on a patient's skin. Additionally, the weight of the blanket itself increases the risk of injury for the nurse applying the blanket to the patient each night (related to lifting of blanket).
   Research data risk: There is a risk of loss of confidentiality and privacy for data collected from the patient's EHR record.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   The minimize the physical risk for patients, exclusion criteria have been designed to eliminate enrollment of those with skin breakdown, or risk thereof.
   The design of the study includes no additional safeguards for the nurses moving the weighted blankets. However, the weight of the blankets does not exceed lifting requirements of unit nurses. Additionally, proper body mechanics are fundamental to nursing education received by all nurses.
   To minimize the risk of loss of confidentiality and privacy, only study team members will have access to the data collected. Additionally, data collected will be stored in REDCap, a secure system endorsed by VCU. Only aggregated, de-identified data will be used for reporting purposes.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   Not applicable.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   Although unlikely, any skin injury as a result of weighted blanket use would be medically treated as all other developing skin injuries. Additionally, use of the weighted blanket would immediately cease.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   The investigator would withdrawal an individual participant from the study if any skin changes are noted on daily physical examinations, the patient experiences increased agitation with blanket use as reported by the patient's nurse, or the patient displays a lack of assent over blanket use.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
   The investigator will re-examine the study protocol if any adverse events occur. Adverse events are based on the risks identified above (patient skin injury or increased agitation, nurse lifting-related injury, loss of participant confidentiality or privacy).

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the studys data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

   The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
   - Participant safety (physical, psychological, etc.)
   - Data validity
   - Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**

- [ ] DSMB
- [ ] DSMP
- [x] **No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]**

ID: MS12_HM20027241 View: SF2 - Privacy

Privacy

Privacy refers to an individuals right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. The options listed include some of the most common best practices. Not all will be applicable to every study.

****The IRB will expect studies to operationalize all selected checkboxes into the conduct of the research.**

To elaborate on any response, also click the Other Protections checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
   - [x] **Verifying identity before discussing personal information.**
   - [ ] Asking the participant if they are comfortable answering questions in that location
   - [x] **Asking the participant if they are comfortable with having other people present (if any)**
   - [ ] Moving away from other people when conducting activities in public spaces or offering a private space
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [ ] Other protections not listed in this question describe below
   - [ ] N/A study has no in-person interventions or interactions with participants

2. * **Protections when conducting group interventions or interactions:**
   - [ ] Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)
   - [ ] Moving to a more private area to answer questions or to discuss concerns
   - [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session
   - [ ] Allowing participants to use a pseudonym or limiting use of individuals names during the group activity
   - [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
   - [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area
   - [ ] Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)
   - [ ] Allowing people to distance themselves from other participants during group activities
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [ ] Ensuring non-participating individuals are not captured on recordings or in photos
   - [ ] Other protections not listed in this question describe below
   - [x] **N/A study has no group interventions or interactions**

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):**
   - [x] **Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)**

- [x] **Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.**
- [ ] Obtaining permission prior to sending text messages
- [ ] Advising the participant to move to a location where they are comfortable answering questions and will not be overheard - incorporate this instruction into your study materials
- [ ] Advising online participants to complete the activity at a time and location where they will be comfortable answering questions - incorporate this instruction into your study materials
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [ ] Offering a way to save and return later to the online activity if privacy is compromised
- [ ] Other protections not listed in this question describe below
- [ ] N/A study has no remote interventions or interactions with participants

4. * **Protections when mailing study materials to/from participants:**
   - [ ] Obtaining permission to mail study materials
   - [ ] Confirming/verifying the accuracy of addresses before mailing items
   - [ ] Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)
   - [ ] Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.
   - [ ] Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)
   - [ ] Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address
   - [ ] Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer
   - [ ] Offering other options of ways to complete the activity (i.e. by phone or online) if desired
   - [ ] Other protections not listed in this question describe below
   - [x] **N/A not mailing any materials to/from participants**

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies*:
   - [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
   - [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
   - [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
   - [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
   - [x] **Only publishing or presenting aggregate results or findings (i.e. no individual-level information)**
   - [ ] Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images describe below
   - [ ] Other protections not listed in this question describe below

6. **Describe any other way(s) that the research team will protect participants' privacy.** ***See the help text for additional guidance.***

ID: MS12_HM20027241 View: SF2 - Data Confidentiality and Storage

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. It describes how the studys research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the Other Protections checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**
   - [x] **Maintaining control of paper documents at all times, including when at an off-campus location**
   - [x] **Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)**
   - [x] **Storing paper documents in a secure location accessible only to authorized study personnel**
   - [x] **Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy**
   - [x] **Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
   - [ ] Other protection not listed in this question describe below

- [ ] N/A no paper research materials

2. * **Protections for research specimens:**
   - [ ] Maintaining control of specimens at all times, including when at an off-campus location
   - [ ] Storing specimens in a secure location accessible only to authorized study personnel
   - [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers
   - [ ] Final destruction of specimens will be in accordance with VCU policies and specimen containers will be devoid of any identifiable information
   - [ ] Other protection not listed in this question describe below
   - [x] **N/A no research specimens**

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**
   - [x] ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
   - [ ] Remotely accessing VCU network storage to store data when at off-campus locations
   - [x] **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
   - [x] **Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)**
   - [ ] When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps, multi-site data collection platforms): consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/); advising participants about the terms of use and privacy policies of those sites/apps; limiting or avoiding use of identifiers; and removing data promptly from the external location after transferring it to a VCU storage location
   - [x] **De-identifying the research data by replacing subjects names with assigned subject IDs**
   - [x] **Storing the studys linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
   - [ ] When analyzing particularly sensitive information, using computers that are unconnected from the internet.
   - [x] **Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
   - [ ] Other protection not listed in this question describe below

4. * **Protections for computers and research devices/apps that are provided to participants for use in the study and taken out of the lab (i.e., giving participants a phone or iPad to take home, wearable trackers, apps, etc.):**
   - [ ] Transferring data promptly from the device/app given to the participant to a VCU storage location
   - [ ] Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants
   - [ ] Device/app set up by VCU Information Security
   - [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
   - [ ] Other protection not listed in this question describe the device/app and protection below
   - [x] **N/A no computers or devices/apps being provided for participant use outside the lab**

5. * **Protections for email/online communications**
   - [ ] Only using VCU/VCU Health email addresses for study-related communications
   - [x] **Only using VCU/VCU Healthapproved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)**
   - [ ] Other protection not listed in this question describe below
   - [ ] N/A no email/online communications

6. **Specify any other places where this studys paper and electronic research data and/or physical specimens will be stored and any other ways they will be secured from improper use and disclosure.**

   See the help text for additional guidance.
   Not applicable

7. * **If research data/specimens will be sent/released to person(s) or group(s) outside of the VCU study team or the PIs department for the conduct of this protocol (not for future sharing),**
   1) identify the data/specimen recipient(s) along with their VCU department or other institutional or organizational affiliation(s).
   2) give a description of what identifiers and/or codes will accompany the data/specimens.
   If data/specimens are not being sent/released outside of the VCU study team or the PIs department, state that:
   Not applicable - will not be sent/released outside of the VCU study team.

8. * **Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**
   - [x] **Names**
   - [x] **Geographic Locators Below State Level**
   - [ ] Social Security Numbers
   - [x] **Dates (year alone is not an identifier)**
   - [x] **Ages over 89 (age under 89 is not an identifier)**
   - [ ] Phone Numbers
   - [ ] Facsimile Numbers
   - [ ] E-mail Addresses

- [x] **Medical Record Numbers**
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

9. * **If the study will code (i.e. de-identify) the research data by replacing subjects names and/or other identifiers with assigned subject IDs, explain the following aspects of the coding process:**

   - The process for how subject IDs will be generated/assigned (e.g. random, sequential)
   - Whether there will be a key that links the subject ID with direct identifiers. If there will be no linkage key, state that.

   If a key will be created, describe
   - The place where the key will be stored
   - The role(s) of all individuals who will have access to the key
   - When the key will be destroyed

   See the help text for guidance.
   Subject IDs for patient participants will be generated sequentially at each site. There will be a key that will be kept in the locked office of the study coordinator that links the participants name with a study ID. Only study personnel will have access to this key. The key will be destroyed at the end of the study, once the study is closed with the IRB.

ID: MS12_HM20027241 View: SF2 - Data Retention

Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - [ ] N/A - study does not require screening procedures
   - [ ] Immediately destroy the information and identifiers (no data collected)
   - [x] **Immediately destroy the identifiers connected with the data (anonymization)**
   - [ ] Store until the end of study & then destroy
   - [ ] Use as "screening failure" data by members of the study team
   - [ ] Provide to others outside of the research team (with the participant's permission)
   - [ ] Request permission from participant to maintain and use the identifiable information
   - [ ] Other

2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No see help text)**
   - ( ) Yes
   - (•) **No**

3. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - ( ) Stored indefinitely with identifiers removed
   - ( ) Stored indefinitely with identifiers attached
   - (•) **Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements**
   - ( ) Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ( ) Other

ID: MS12_HM20027241 View: SF2 - Sharing Plan

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when

and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   ◯ Yes

   ● **No**

2. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ◯ Yes ● **No**

3. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   ● **No Will not obtain CoC for this study**

   ◯ Yes CoC has been obtained or issued automatically

   ◯ Yes CoC request is pending

4. * **Select the way(s) that information or biospecimens (including DNA) may be used <u>by the VCU PI or VCU study team for other future research projects</u> (i.e. analyses beyond/apart from the aims of this study)?**
   See help text for definitions.

   ☐ Will use directly identifiable information or specimens.

   (Directly identifiable means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

   ☐ Will use de-identified or indirectly identifiable information or specimens.

   (De-identified means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

   ☐ Will use anonymized information or specimens.

   ('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)

   ☑ Will use aggregate results (summary-level results), not individual-level information or specimens.

   (The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)

   ☐ Will contribute to an existing registry or repository

   (VCU IRB studies will be asked more questions about this on a later page.)

   ☐ Will not use information/specimens for purposes beyond this study.

   ☐ Not sure and will submit an amendment when known

   ☐ Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share information or biospecimens (including DNA) <u>with other researchers</u> who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).**
   See help text for definitions.

   ☐ Will share directly identifiable information or specimens with other researchers.

   (Directly identifiable means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipients use of identifiable data would require them to obtain IRB review. VCU IRB studies will be asked more questions about this on a later page.)

Will share de-identified or indirectly identifiable information or specimens with other researchers.

(De-identified means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipients use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. VCU IRB studies will be asked more questions about this on a later page.)

Will share anonymized information or specimens with other researchers.

('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)

Will only share aggregate results (summary-level results), not individual-level information or specimens.

(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)

- [ ] Will contribute to an existing registry or repository (VCU IRB studies will be asked more questions about this on a later page.)
- [ ] Will submit data to an NIH genomic data repository (VCU IRB studies will be asked more questions about this on a later page.)
- [ ] Will not share information/specimens with other researchers.
- [ ] Not sure and will submit an amendment when known
- [ ] Other sharing of individual-level information with other researchers

6. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

- The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
- If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
- The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
- The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

- ○ Yes
- ○ No
- ● **N/A - No sharing will occur**

ID: MS12_HM20027241 View: SF2 - Pertinent Results and Incidental Findings

Pertinent Results and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**
   - ○ Yes
   - ● **No**

ID: MS12_HM20027241 View: SF2 - Risk Benefit Complete

Risk Benefit Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS12_HM20027241 View: SF2 - Populations with Special Considerations

Populations with Special Considerations

1. * **Check all participant groups that will be either**

a) Specifically included in this study or

b) Discernable in the research data/specimens.

(Selections will branch)

- [ ] Children
- [ ] Emancipated minors
- [ ] Wards of the State
- [ ] Pregnant women or fetuses
- [ ] Neonates or Post-delivery Materials
- [ ] Prisoners
- [x] **Decisionally Impaired Adults**
- [ ] VCU / VCUHS students or trainees
- [x] **VCU / VCU Health System employees**
- [ ] Individuals with limited English proficiency
- [ ] Active military personnel
- [ ] Student populations in K-12 educational settings or other learning environments
- [ ] Members of a federally recognized American Indian and Alaska Native tribe
- [ ] None of the Above

2. **Additional considerations for VCU/VCU Health System employees:**

   * **Describe how the study will minimize the possibility of coercion to participate.**
   VCU nurses, physicians, and APPs ("healthcare providers") will be invited to complete a survey at the end of a patient's participation in the study. The survey does not contain any sensitive information. Healthcare providers will be approached and asked if they are willing to complete a survey using the study iPad. Within the survey, information will clearly state the their willingness to complete the survey is completely voluntary. The survey will in no way be linked to the healthcare provider so there is no record of whether individual providers completed the survey or not.

Decisionally Impaired Adults

1. * **Choose the nature of the decisional impairment participants will have:**
   - (●) **Temporarily Incompetent to Give Consent**
   - ( ) Permanently Incompetent to Give Consent
   - ( ) Unknown

2. * **Explain why this population is necessary for the conduct of the study.**
   ICU patients most at risk for development of delirium are crucial to answering the aims of this study. It is common for ICU patients to have limited decisional capacity during their ICU level of care due to their medical conditions and/or sedative medications they are receiving. Decisional impairment for ICU patients may be temporary (i.e., resolves when sedating medication is decreased or removed) or permanent (i.e., the mechanism of their medical conditions is permanent in nature).

3. * **Describe methods for determining whether participants are capable of providing consent or assent.**
   The study team will determine consent capability by utilizing a primary method, followed by a secondary confirmation. To obtain primary determination, the study team will examine the patient's EHR documentation of neurological status. Per the EHR, is the patient alert and orientated? If yes, the study team member obtaining consent will proceed to the patient's bedside. During the informed consent discussion, the study team member will pay close attention to any actions and/or communication from the patient that is not in alignment with the patient's documented mental status. If there are ever any doubts, the LAR will be sought for primary consent with patient assent.

4. * **If a participant is capable of exercising some judgment concerning the nature of the study, describe how assent will be obtained.**
   Three scenarios are possible. If the patient is awake and capable of signing, a signature of assent will be asked from the patient following LAR consent. If the patient is awake but not able to sign, the patient will be asked to give some sign of assent (i.e., head nod yes, thumbs up). However, there is a case where patient assent may not be possible, and therefore, the study team will need to solely rely on LAR consent only. This situation would be related to a patient that has a medical condition or sedation that prevents their alertness.

5. **Describe, if applicable, how the individuals' ability to give consent will be assessed throughout the study and how consent will be obtained when appropriate.**
   Throughout the study, continual assent will be assessed by members of the study team. At any point the patient's assent does not seem clear, the patient will be withdrawn from the study.

6. * **Describe how and when consent will be obtained from participants' legally authorized representative (LAR).**
   Consent will be sought from the patient's LAR when the patient is not able to fully consent for themselves.

Populations with Special Considerations Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS12_HM20027241 View: SF2 - Study Funding

Study Funding

1. * **Have you applied for funding:**
   - (●) **Yes**
   - ( ) No

2. **Is this study already funded:**
   - (●) **Yes**
   - ( ) No

3. * **Select all funding sources for this study (pending or awarded):**
   - [ ] Industry
   - [ ] Direct Federal
   - [ ] Indirect Federal
   - [ ] State/Local Government
   - [ ] Non-Profit - Sponsored Project
   - [ ] Non-Profit - Gift
   - [x] **Internal Grant**
   - [ ] Investigator/Departmental Funds
   - [ ] None
   - [ ] Other

4. * **In addition to providing funding support, what is the funding sources role in this study? Select all that apply:**
   - [x] **Solely providing funding support**
   - [ ] Providing resources (e.g. study drug, device)
   - [ ] Providing guidance to the researcher but does NOT make decisions about study design
   - [ ] Study design/Creation of the study protocol
   - [ ] Collaborator in the research (helps design and/or conduct the study) [list the funder as a site on the Types of Sites page]
   - [ ] Data or sample analysis regardless of identifiability

5. **Select all related funding proposals and contracts that have been submitted through the Division of Sponsored Programs (DSP):**

RAMS-SPOT ID# (FP/PT/PD#)	Direct Sponsor	PI	Title	Status	Start	End

There are no items to display

ID: MS12_HM20027241 View: SF2 - Types of Sites

Types of Sites

VCU Site Information

1. * **Select all VCU sites that will be utilized in this study:**
   - [ ] Children's Hospital of Richmond at VCU
   - [ ] Clinical Research Services Unit (CRSU)
   - [ ] Massey Cancer Center
   - [x] **VCU Health Community Memorial Hospital**
   - [ ] VCU Health Tappahannock Hospital
   - [x] **VCU Medical Center**
   - [ ] Other VCU Health Location
   - [ ] VCU Monroe Park Campus
   - [ ] VCU Qatar

☐ Other VCU Site

Non-VCU Site Information

Non-VCU sites should be selected whenever any of the following situations apply:
a) Non-VCU sites that will be collaborating on a VCU-led study (i.e. involved in conducting the research, including being involved in the study interpretation or analysis of data and/or authorship of presentations or manuscripts related to the research.)
b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
d) Non-VCU sites/locations where VCU investigators will conduct study activities

2. * **Select any of the following non-VCU sites utilized in this study:**
   - ☐ McGuire VAMC
   - ☐ Foreign Sites
   - ☐ Other Non-VCU Sites
   - ☑ **No Non-VCU Sites**

3. * **Is this a multi-center study being led by VCU?**
   ○ Yes ● **No**

4. **For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**

   - Completed Local Context Form for Relying on VCU's IRB
   - Site specific informed consent form(s) and HIPAA authorization(s), if applicable

   For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.docx	Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.pdf	0.03	6/7/2024 1:56 PM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx	Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx	0.01	5/22/2024 3:53 PM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Consent Form	Weight Blanket Study Consent Form_10-11- 2023 - Copy - Copy.pdf	0.04	10/11/2023 11:35 AM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Weighted Blanket Device Information	Weighted Blanket Info for IRB_07 27 2023.docx	0.02	7/27/2023 10:29 AM	Shelly Orr	Other	Yes
View	Data Collection Spreadsheet	Weighted Blanket Data Spreadsheet 5 23 2023.xlsx	0.01	5/23/2023 11:02 AM	Heather Fudala	Other	Yes
View	Patient Participant Experience Survey	Weighted Blanket Participant Survey 5 23 2023.pdf	0.01	5/23/2023 11:02 AM	Heather Fudala	Research Measure	Yes
View	Legally Authorized Representative (LAR) Experience Survey	Weighted Blanket Legally Authorized Representative Survey 05 23 2023.pdf	0.01	5/23/2023 11:02 AM	Heather Fudala	Research Measure	Yes
View	Healthcare Provider Perception of Participant Experience Survey	Weighted Blanket Healthcare Provider Perception of Participant Survey 05 23 2023.pdf	0.01	5/23/2023 11:01 AM	Heather Fudala	Research Measure	Yes
View	Healthcare Provider Experience Survey	Weighted Blanket Healthcare Provider Experience Survey 05 23 2023.pdf	0.01	5/23/2023 11:01 AM	Heather Fudala	Research Measure	Yes
View	PROC Approval Letter	VCU ONETRAC Notifier - PROC Request #397 - Approval Without Revision.pdf	0.01	5/21/2023 10:26 PM	Shelly Orr	Other	Not Applicable
View	Fudala Biosketch	Weighted Blanket Fudala Biosketch Wright Center Rural Pilot.docx	0.01	5/21/2023 10:17 PM	Shelly Orr	CV/Biosketch	Not Applicable

Personnel

1. * **List all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as including:
- **Conflict of interest investigators, including**
- **the PI**
- **the Lead Student/Trainee Investigator,**
- **medically/Psychologically responsible investigator(s)**
- **FDA Form 1572 investigators, and**
- **Other personnel whose roles are essential to the conduct of the research.**

Note: Individuals who are not key personnel are not required to be listed here, but PIs still bear the responsibility to document the delegation of responsibilities in the study records.

PIs may elect to use the Study Roster activity button in RAMS-IRB (available after approval) as an alternative way to document study staff involvement and delegation of responsibilities. Personnel changes made to the non-key personnel listed in the separate Study Roster activity do not require an amendment.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Shelly Orr	Co/Sub-Investigator		Data Analysis Project Coordination Participant Consent Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Intervention Services Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		yes
View	Heather Fudala	Principal Investigator		Data Analysis Project Coordination Participant Consent Data Collection - Lab Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Intervention Services Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		yes
View	Kinker	Research Nurse Co/Sub-Investigator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Collection - Lab		Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Intervention Services Data Collection - Interviews/Surveys				
View	Keila Najera	Research Coordinator		Project Coordination Participant Consent Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research		no
View	Catherine Grossman	Co/Sub-Investigator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Collection - Lab Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Intervention Services Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Kim Harrison	Research Coordinator		Project Coordination Participant Consent Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry		Experience - Research		no

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Coding Participant Recruitment Data Collection - Interviews/Surveys				
View	Yongyun Shin	Statistician		Data Analysis Data Management Data Coding		Experience - Research Education and/or Professional Preparation		no
View	Alexandra Gerveni	Statistician		Data Analysis Data Management Data Coding		Student Trainee		no

2. **Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.**

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

There are no items to display

3. If independent investigators or community engaged investigators are listed above, **describe the human subjects training these individuals will complete and the process that will be used to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions:**
All investigators and the research coordinator have completed CITI and CGP training. Additionally, all study team members are aware of their duties as outlined in this application and will be thoroughly trained on the protocol outlined in this application.

4. * **Upload a CV or Biosketch for the PI, Medically/Psychologically Responsible Investigators and the lead Student/Trainee Investigators. Do not upload CVs or Biosketches for other individuals.**

ID: MS12_HM20027241 View: SF2 - Conflict of Interest

Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**
Financial interest include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project
○ Yes ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**
Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity, and
- equity or business ownership in a company that has yet to make a profit and is related to this project
- conflict of time/effort,
- personal and professional relationships/affiliations,
- intellectual passions or personal beliefs
- other factors that could create bias in the study
○ Yes ● **No**

3. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.

ID: MS12_HM20027241 View: SF2 - Other VCU Requirementsv2

Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. **Cost Coverage Analysis**

Information on coverage analysis requirements and processes can be found through VCUs Clinical Research Compliance Program at https://research.vcu.edu/human-research/clinical-research/vcu-clinical-research-coverage-analysis/

1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**
   - (●) **Yes**
   - ( ) No
   - ( ) Not Applicable

2. **ClinicalTrials.gov Program & OnCore**
   For guidance, see https://cctr.vcu.edu/support/consultation/clinical-trials-gov/ or email CCTRCTGOV@vcu.edu

   1. * **Is this a Clinical Trial?**
      (●) **Yes** ( ) No

   2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

      - Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
      - When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
      - When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless the federal department or agency will post it).
      (●) **Yes** ( ) No

3. **Community Engagement**
   For more information, see https://community.vcu.edu/

   1. * **Is this a community engaged research study? (See help text for definitions)**
      - ( ) Yes
      - (●) **No**

4. **Family Educational Rights and Privacy Act (FERPA) Requirements**
   For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

   1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**
      - ( ) Yes
      - (●) **No**

5. **Research Data Privacy Requirements**
   Contact the VCU Research Data Privacy Office with questions: https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/

   1. * **Does this study involve the VCU site (regardless of the IRB of record), or any sites under the VCU IRB's oversight, obtaining data in, or from, a foreign country?**
      ( ) Yes (●) **No**

6. **Information Security**
   For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

   1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

      Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

      See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan at https://dms.vcu.edu**.**
      - (●) **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
      - ( ) Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

   2. * **I confirm use of the VCU Data Classification Tool at** https://go.vcu.edu/dataclassification **in determining the data classification category selected in Question 1:**
      - (●) **Yes**
      - ( ) No

   3. * **The PI is aware that if the studys data is classified as Category 1, a Data Management Plan must be submitted to and approved by VCU Information Security prior to IRB approval. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/
      (●) **Yes** ( ) No

   4. * **I confirm that any use of external technology has been submitted to Information Security in the studys Data Management Plan. If this study uses any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data, I am required**

to have VCU Information Security conduct a security review of that technology. I may contact infosec@vcu.edu with questions.

I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):

- ○ Yes
- ○ No
- ● **N/A - not using external technology**

7. **Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)**
   For guidance, see https://www.masseycancercenter.org/research/~/link.aspx?_id=ee49e95faa8b44d09b6e89d8e3b48b57&_z=z

   1. * **Does this study involve any of the following?**
      - Research involving patients with cancer, their families or their health care providers
      - Research involving cancer screening, diagnosis or prevention
      - Secondary data collected from cancer patients or their medical records
      - Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the general population
      - ○ Yes
      - ● **No**

8. **VCU ONETRAC Protocol Review Oversight Committees (PROCs) For guidance, see** https://onetrac.vcu.edu/

   1. * **Does this study involve research with any of the following?**

      - VCU Health System patients

      - VCU Health System facilities

      - VCU Health System data
      - ● **Yes**
      - ○ No

      If Yes, upload documentation of approval or review by the PROC or PRMC in this studys topic area. If you do not have PROC or PRMC approval, please visit onetrac.vcu.edu for additional information and to submit your project for review.

9. **VCU Health Department of Patient Centered Services**

   1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**
      - ● **Yes**
      - ○ No
      - ○ Not Applicable

   2. * **Will research participants be offered any form of incentive or payment for study participation (*See Help Text):**
      - ○ Yes
      - ● **No**

10. **VCU Faculty-Held IND or IDE**
    For guidance, see **https://research.vcu.edu/human-research/regulatory-affairs/**.

    Questions related to if you need an IND or IDE for your study should be emailed to: indide@vcu.edu. Please submit a copy of your FDA
    submission prior to submitting to the FDA to https://redcap.vcu.edu/surveys/?s=NR7K7LR4JW.

11. **VCU Health System locations**

    1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, Tappahannock Hospital, VCU Medical Center and Massey Cancer Center)?**
       - ● **Yes**
       - ○ No

    2. * **The PI has reviewed and agreed to comply with the VCU Health System Research in Patient Care Areas policy (https://research.vcu.edu/compliance_program/vcuhs_policies.htm):**
       - ● **Yes**
       - ○ No

12. **VCUHS Department of Pathology**
    Learn more about requesting and establishing an account with Pathology here: See https://pathology.vcu.edu/research-services/

    1. * **I have contacted VCUHS Department of Pathology to determine feasibility if my study involves the following:**
       - Storage of Microbiology isolates
       - New instrumentation provided by clinical trial/study sponsor, or
       - Non-routine specimen processing (examples include but arent limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)
       - ○ Yes
       - ○ No

- ● **N/A - my study does not involve any of the listed processes.**

2. * **If my study involves specimen retrieval from the Pathology laboratory, I have established a process with Pathology to deidentify and retrieve specimens.**
   - ○ Yes
   - ○ No
   - ● **N/A - my study won't involve specimen retrieval from Pathology**

13. VCU Institutional Biosafety Committee (IBC)
To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this project involve any of the following hazardous biological agents (biohazardous agents) that have NOT been FDA approved? These may include, but are not limited to, any of the following. If you are unsure, please contact the Biosafety Office:**

   - Any functional recombinant viruses (especially viruses that may integrate into the patients genome).

   - Expression or administration of biological toxins.

   - Live pathogenic or potentially pathogenic organisms of plants or animals (bacteria, fungi, wild-type viruses, parasites, etc.), that are, or potentially may be, in experimental products.

   - Introduction or expression of rDNA or synthetic nucleic acids

   - Use of a product (e.g., monoclonal antibodies, recombinant cytokines) produced from virally infected mammalian cells.

   - Use of a product (purified growth factors, cytokines) produced from mammals or their cells.

   ○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)
To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**
   - ○ Yes
   - ● **No**

15. VCU Scientific Review Committee (SRC)
For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**
   - ○ Yes
   - ● **No**

16. Upload any documents requested in the questions above:

ID: MS12_HM20027241 View: SF2 - HIPAA

HIPAA

In order for VCUHS to meet HIPAA regulations regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics to obtain any VCUHS data. This does not include obtaining data for which the study team has patient authorization. [VCU Health System Authority and Affiliates Policy COMP-014]

For data requests, including preparatory to research and research with decedents, submit a request for the desired PHI, or for a consultation on alternate methods to obtain the data, at https://informatics.vcu.edu.

HIPAA Privacy Board Requirements
For guidance, see https://www.vcuhealth.org/our-story/who-we-are/compliance-services/compliance-services

1. * **Select the source of the Individually Identifiable Health Information. See help text for definitions.**
   - ☑ **PHI associated with or derived from (i.e. obtained from or entered into) VCU Health medical records or VCU Dental Care records**
   - ☐ Research Health Information (RHI) created or received by a study and kept solely in study records (e.g. self reported or the result of research tests and not entered into health records)
   - ☐ PHI associated with or derived from (i.e. obtained from or entered into) a non-VCU HIPAA covered entitys health records

2. * **Summarize the types of health information that will be obtained or used in this research. Do not describe only the identifiers that you will collect or use during the study.**
   The following demographic information will be obtained from the participant's medical record while enrolled in the

study: Participant name, age, weight/BMI, sex, race and ethnicity, medial history/diagnoses, admission diagnoses, home zip code, admitting hospital (CMH or VCUMC)

The following health information will be collected from the participant's medical record while enrolled in the study: Participant medical history/diagnoses, admission diagnoses, agitation and delirium scores, sedation and pain medications given and amounts given, hospital length of stay, ICU length of stay, and number of days ventilated.

3. * **Describe the source(s) of the protected health information (e.g. Informatics or which clinical databases):**
The source of the PHI will be demographic and clinical data entered into the participant's EHR (Epic)

4. * **Does the PI certify that this study's access to and use of the protected health information is limited to the minimum amount necessary to be able to effectively conduct the research?**
(●) **Yes** ( ) No

5. * **Select all pathways this research will employ to use or access PHI (selections will branch):**
- [ ] De-Identified Data (none of the 18 identifiers are recorded or associated with the research data)
- [ ] Limited Data Set
- [ ] Waiver of Authorization
- [x] **Partial Waiver of Authorization (temporary waiver for recruitment purposes and/or waiver of some elements of Authorization)**
- [x] **Signed Authorization Combined with Consent Form**
- [ ] Signed Authorization as Stand-Alone Form

ID: MS12_HM20027241 View: SF2 - Partial Waiver of Authorization

Partial Waiver of Authorization

1. * **Select the purpose for requesting the partial waiver of authorization:**
- [x] **Identify possible participants to recruit for the study**
- [ ] Waive some elements of authorization (such as signature)

2. * **Explain how the partial waiver of authorization poses no greater than minimal risk to participants' privacy:**
(Alternative question phrasing: How do the risk(s) of this use of identifiable health information compare to the risks to privacy a person might reasonably experience in normal everyday life?).
The request for partial waiver of authorization for the sole purpose of identifying possible participants to recruit for the study will be limited to patient participant inclusion/exclusion criteria. Thus, we will access the minimum amount of information needed to recruit potential participants. This access will be temporary and followed by full, signed authorization upon enrollment into the study, thereby obtaining full authorization for further use of the PHI for research analysis. If a potential participant chooses not to enroll in the study, no information about that potential participant will be retained or stored once study accrual objectives are met thereby posing no greater than minimal risk to privacy.

3. * **If you selected "Identify possible participants to recruit" above, describe when will the 18 HIPAA identifiers be destroyed for those who do not eventually enroll in the study?**
- [ ] Following Participant Contact
- [x] **Upon Reaching Study Accrual Objectives**
- [ ] Other

4. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
No one. Only as required by law.

5. * **Explain why the study cannot practicably be conducted without the partial waiver of authorization:**
(Alternative question phrasing: Why is this partial waiver necessary to make the study achievable or viable?)
We cannot identify individuals who meet inclusion and exclusion criteria without the partial waiver of consent (access to the PHI for screening purposes).

6. * **In applying for a partial waiver of authorization, the PI agrees to the following:**

A) The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in this application), except as required by law.

B) If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB/Privacy Board.

C) I will comply with VCU HIPAA policies and procedures and to the use and disclosure restrictions described above.

D) I assume responsibility for all uses and disclosures of the PHI by members of my study team.
(●) **Yes**
( ) No

ID: MS12_HM20027241 View: SF2 - Institutional Requirements Complete

Institutional Requirements Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS12_HM20027241 View: SF2 - Documents

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission:**
   A list of potential documents is given in the help text.

   NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

   Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:
   - Click the Update button located to the left of the document to be updated.
   - In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
   - Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

   To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.
   - Click the View or Update button located to the left of the document you wish to access.
   - In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
   - A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.docx	Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.pdf	0.03	6/7/2024 1:56 PM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx	Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx	0.01	5/22/2024 3:53 PM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Consent Form	Weight Blanket Study Consent Form_10-11- 2023 - Copy - Copy.pdf	0.04	10/11/2023 11:35 AM	Heather Fudala	Consent/Assent/Information Sheet	Yes
View	Weighted Blanket Device Information	Weighted Blanket Info for IRB_07 27 2023.docx	0.02	7/27/2023 10:29 AM	Shelly Orr	Other	Yes
View	Data Collection Spreadsheet	Weighted Blanket Data Spreadsheet 5 23 2023.xlsx	0.01	5/23/2023 11:02 AM	Heather Fudala	Other	Yes
View	Patient Participant Experience Survey	Weighted Blanket Participant Survey 5 23 2023.pdf	0.01	5/23/2023 11:02 AM	Heather Fudala	Research Measure	Yes
View	Legally Authorized Representative (LAR) Experience Survey	Weighted Blanket Legally Authorized Representative Survey 05 23 2023.pdf	0.01	5/23/2023 11:02 AM	Heather Fudala	Research Measure	Yes
View	Healthcare Provider Perception of Participant Experience Survey	Weighted Blanket Healthcare Provider Perception of Participant Survey 05 23 2023.pdf	0.01	5/23/2023 11:01 AM	Heather Fudala	Research Measure	Yes
View	Healthcare Provider Experience Survey	Weighted Blanket Healthcare Provider Experience Survey 05 23 2023.pdf	0.01	5/23/2023 11:01 AM	Heather Fudala	Research Measure	Yes
View	PROC Approval Letter	VCU ONETRAC Notifier - PROC Request #397 - Approval Without Revision.pdf	0.01	5/21/2023 10:26 PM	Shelly Orr	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Fudala Biosketch	Weighted Blanket Fudala Biosketch Wright Center Rural Pilot.docx	0.01	5/21/2023 10:17 PM	Shelly Orr	CV/Biosketch	Not Applicable

ID: MS12_HM20027241 View: SF2 - Documents Complete

Documents Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

End of Application

Click Continue below to exit and submit this project

ID: MS12_HM20027241 View: Copy of Bio-Med Devices

Bio-Medical Devices

1. * **Name:**
   Weighted Blanket
2. * **Manufacturer:**
   Sensory Goods
3. * **What risk has the sponsor or sponsor-investigator designated the device:**
   Non-Significant Risk
4. * **Indicate the device's IDE number if a protocol was submitted to the FDA for any investigational device or new use of a marketed device (regardless of what the FDA's determination was).**

   Or, if a protocol was not submitted to the FDA:
   - Enter "Abbreviated IDE" if the sponsor or sponsor-investigator has designated the device as a Non-Significant Risk device
   - Enter "IDE Exempt" if the sponsor or sponsor-investigator has determined that the device qualifies for IDE exemption
   - Enter "Regulatory Discretion" for a mobile application with regulatory discretion
   - Enter the FDA-provided HDE number if a HUD is being used in a clinical investigation for the HDE-approved indication(s).

   Abbreviated IDE
5. * **Select who holds the Investigational Device Exemption (FDA-granted IDE or Abbreviated IDE) for the device:**

   ○ External to VCU Sponsor or Investigator
   ○ VCU Sponsor-Investigator
   ○ VCU Sponsor who is not the Investigator
   ● **Not Required**
6. **If someone other than the PI is the sponsor for the IDE, name the entity or individual who will be the IDE sponsor.**

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.docx
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Version 3_Weight Blanket Study Consent Form_5-23-2024_Clean.pdf(0.03)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Version 3_Weight Blanket Study Consent Form_5-22-2024_Redlined.docx(0.01)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent Form
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Weight Blanket Study Consent Form_10-11- 2023 - Copy - Copy.pdf(0.04)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Weighted Blanket Device Information
2. * **Type:**
   Other
3. * **File:**
   Weighted Blanket Info for IRB_07 27 2023.docx(0.02)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Data Collection Spreadsheet
2. * **Type:**
   Other
3. * **File:**
   Weighted Blanket Data Spreadsheet 5 23 2023.xlsx(0.01)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Patient Participant Experience Survey
2. * **Type:**
   Research Measure
3. * **File:**
   Weighted Blanket Participant Survey 5 23 2023.pdf(0.01)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Legally Authorized Representative (LAR) Experience Survey
2. * **Type:**
   Research Measure
3. * **File:**
   Weighted Blanket Legally Authorized Representative Survey 05 23 2023.pdf(0.01)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Healthcare Provider Perception of Participant Experience Survey
2. * **Type:**
   Research Measure
3. * **File:**
   Weighted Blanket Healthcare Provider Perception of Participant Survey 05 23 2023.pdf(0.01)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Healthcare Provider Experience Survey
2. * **Type:**
   Research Measure
3. * **File:**
   Weighted Blanket Healthcare Provider Experience Survey 05 23 2023.pdf(0.01)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   PROC Approval Letter
2. * **Type:**
   Other
3. * **File:**
   VCU ONETRAC Notifier - PROC Request #397 - Approval Without Revision.pdf(0.01)

ID: MS12_HM20027241 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Fudala Biosketch
2. * **Type:**
   CV/Biosketch

3. * **File:**
   Weighted Blanket Fudala Biosketch Wright Center Rural Pilot.docx(0.01)

ID: MS12_HM20027241 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Patient Participant

2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☑	**Signed Parent/Guardian Permission or Legally Authorized Representative Consent**
☑	**Signed Assent by Child or Decisionally Impaired Adult**
☑	**Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult**
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☑ **Not using electronic signature platforms**
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ iMedConsent (Veterans Affairs studies)
   - ☐ Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of All Consent or Some Elements in Consent Form
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☐	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐	Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☑	**Principal Investigator**
☑	**Co/Sub-Investigator**
☐	Medical or Psychological Responsible Investigator
☐	Lead Student/Trainee Investigator (leading their own project)
☑	**Research Coordinator**
☐	Research Nurse
☐	Consultant
☐	Research Assistant
☐	Pharmacist
☐	Statistician

☐	Regulatory Coordinator
☐	Trainee/Student(working on project)
☐	Other
☐	N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

   - When and where consent will occur
   - What will be covered during the consent discussion
   - How the consent discussion will occur (e.g. in-person, phone, video conference)
   - How you will reconfirm consent on an ongoing basis, if applicable

   At the VCU Health Medical Center Main Hospital, the informed consent process will occur in an in-patient (bedside or unoccupied family conference room) or telephone setting. If the patient is decisionally competent (alert and oriented), the patient will be approached. If the patient is decisionally impaired in any capacity, the legally authorized representative (LAR) will be approached for consent. In that case, the patient will give a signed, verbal, or other indication of assent, if possible. During the informed consent process, an unbiased review of the trial and consent form will be discussed. It will be stated that the patient will continue to receive standard of care, with or without consenting for the voluntary trial. A physical copy of a consent form will be used. If the LAR is not available in person, the consent discussion may occur via telephone.
   At the VCU Health Community Memorial Hospital, consent will in the same manner as it will at the VCU Medical center but all in-person activities will occur using remote technology (i.e., Zoom). A designated study team member at the CMH site will provide the patient and/or their LAR a study-specific iPad so that the study team member conducting the ICF process can speak with them using live communication via Zoom. The CMH team member will provide the patient and/or LAR a physical copy of the ICF to review during the discussion. If the patient and/or LAR agree to enroll the patient, they will sign the form and will give it to the CMH study team member who will place it in a locked cabinet at CMH dedicated for the study until it is transported by the study PI or Co-I to the study office at VCU Medical Center.

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
   - ☑ **Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion**
   - ☑ **Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion**
   - ☑ **Removing physical symbols of authority like white coats or police badges**
   - ☑ **Sitting down beside the participant instead of standing over them**
   - ☑ **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
   - ☐ Moving to a more neutral location like a conference room
   - ☑ **Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)**
   - ☐ Having a mandatory wait period for the participant to go home and think before they sign consent /assent
   - ☐ Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
   - ☐ Other protection(s) not listed here describe below
   - ☐ N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   The study team will emphasize that the trial is voluntary and standard of care will be performed with or without consenting.

10. * **How much time will participants be given to make a decision:**
    The patient and/or their LAR will be given as much time as possible to make a decision, as long as it is within the indicated 72 hour time frame.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
    Continual assent will be sought for any patient enrolled that is decisionally impaired. This will enable the team to ensure their assent if they become no longer decisionally impaired.

ID: MS12_HM20027241 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Healthcare Provider

2. * **Select all that apply to this consent / assent group:**

	Name
☐	Signed Consent by Participant
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult

Name
☐ Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐ Short Form Consent (limited applicability)
☑ **None of the Above (select waiver below)**

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☑ **Not using electronic signature platforms**
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ iMedConsent (Veterans Affairs studies)
   - ☐ Other electronic signature platform
4. **If Other is selected, explain:**
5. * **Select any waivers that apply to this consent / assent group:**

☐ No Waivers Requested
☑ **Waiver of All Consent or Some Elements in Consent Form**
☐ Waiver of Parental Permission or Legally Authorized Representative Consent
☐ Waiver of All Assent by Child or Decisionally Impaired Adult
☐ Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐ Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☐ Principal Investigator
☐ Co/Sub-Investigator
☐ Medical or Psychological Responsible Investigator
☐ Lead Student/Trainee Investigator (leading their own project)
☐ Research Coordinator
☐ Research Nurse
☐ Consultant
☐ Research Assistant
☐ Pharmacist
☐ Statistician
☐ Regulatory Coordinator
☐ Trainee/Student(working on project)
☐ Other
☑ **N/A: Requesting Waiver of Consent**

7. * **Describe the consent procedures used for this group. Address each point below:**

   - When and where consent will occur
   - What will be covered during the consent discussion
   - How the consent discussion will occur (e.g. in-person, phone, video conference)
   - How you will reconfirm consent on an ongoing basis, if applicable

   At the end of the patient's participation (withdrawn or removed from ICU level of care), the healthcare provider (nurse, physicians, and/or APPs) will be asked to partake in a study survey with which we are asking for a waiver of consent. The survey will contain directions that specify that the survey is voluntary and that the answers provided will not be identifiable to others in any way. An iPad will be brought to the healthcare provider by a member of the study team with the healthcare provider survey opened. After reading the directions, the healthcare provider's decision to complete their survey will indicate their consent to participate. This activity will only be done in person using a study-specific iPad.

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
   - [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
   - [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
   - [ ] Removing physical symbols of authority like white coats or police badges
   - [ ] Sitting down beside the participant instead of standing over them
   - [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
   - [ ] Moving to a more neutral location like a conference room
   - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
   - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
   - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
   - [ ] Other protection(s) not listed here describe below
   - [x] **N/A: Requesting Waiver of Consent**

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   The study team will emphasize that the completion of the survey is voluntary and will in no way affect care of the patient enrolled in the study. The study team member will remain close by to ensure only the intended recipient receives the survey. However, they will be sure to not hover and allow the healthcare provider as much time as needed to complete the survey.

10. * **How much time will participants be given to make a decision:**
    Once the healthcare provider is provided the survey and they have a chance to read the instructions, they will immediately be asked to complete the survey or return the iPad to the study team member without completing the survey.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS12_HM20027241 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Legally Authorized Representative (LAR)

2. * **Select all that apply to this consent / assent group:**

	Name
☐	Signed Consent by Participant
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☑	**None of the Above (select waiver below)**

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - [x] **Not using electronic signature platforms**
   - [ ] DocuSign Part 11 (FDA regulated studies)
   - [ ] DocuSign (standard platform for non-FDA regulated studies)
   - [ ] REDCap e-Consent
   - [ ] iMedConsent (Veterans Affairs studies)
   - [ ] Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☐	No Waivers Requested
☑	**Waiver of All Consent or Some Elements in Consent Form**
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult

- [ ] Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
- [ ] Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [x] **N/A: Requesting Waiver of Consent**

7. * **Describe the consent procedures used for this group. Address each point below:**

- When and where consent will occur
- What will be covered during the consent discussion
- How the consent discussion will occur (e.g. in-person, phone, video conference)
- How you will reconfirm consent on an ongoing basis, if applicable

At the end of the patient's participation (withdrawn or removed from ICU level of care), the LAR will be asked to partake in a study survey with which we are asking for a waiver of consent. The survey will contain directions that specify that the survey is voluntary and that the answers provided will not be identifiable to others in any way. An iPad will be brought to the LAR by a member of the study team with the LAR survey opened. After reading the directions, the LAR's decision to complete their survey will indicate their consent to participate. This activity will only be done in person using a study-specific iPad.

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**

- [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
- [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
- [ ] Removing physical symbols of authority like white coats or police badges
- [ ] Sitting down beside the participant instead of standing over them
- [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
- [ ] Moving to a more neutral location like a conference room
- [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
- [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
- [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
- [ ] Other protection(s) not listed here describe below
- [x] **N/A: Requesting Waiver of Consent**

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
The study team will emphasize that the completion of the survey is voluntary and will in no way affect care of the patient enrolled in the study. The study team member will remain close by to ensure only the intended recipient receives the survey. However, they will be sure to not hover and allow the LAR as much time as needed to complete the survey.

10. * **How much time will participants be given to make a decision:**
Once the LAR is provided the survey and they have a chance to read the instructions, they will immediately be asked to complete the survey or return the iPad to the study team member without completing the survey.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS12_HM20027241 View: Personnel

Personnel

1. * **Name:**
   Shelly Orr

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

☐	Principal Investigator
☑	**Co/Sub-Investigator**
☐	Medical or Psychological Responsible Investigator
☐	Lead Student/Trainee Investigator (leading their own project)
☐	Research Coordinator
☐	Research Nurse
☐	Consultant
☐	Research Assistant
☐	Pharmacist
☐	Statistician
☐	Regulatory Coordinator
☐	Trainee/Student(working on project)
☐	Other

4. * **Study related responsibilities:**

☑	**Study Design**
☐	Data Collection - Lab
☑	**Data Collection - Clinical**
☑	**Data Collection - Interviews/Surveys**
☐	Data Collection - Direct Observation
☐	Clinical Services
☑	**Intervention Services**
☑	**Data Entry**
☑	**Data Coding**
☑	**Data Management**
☑	**Data Analysis**
☑	**Project Coordination**
☑	**Participant Identification**

- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS12_HM20027241 View: Personnel

Personnel

1. * **Name:**
   Heather Fudala

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

- [x] **Principal Investigator**
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)

- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [x] **Data Collection - Lab**
- [x] **Data Collection - Clinical**
- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [x] **Intervention Services**
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS12_HM20027241 View: Personnel

Personnel

1. * **Name:**
Kinker

2. * **Is this individual a 'COI Investigator'?**

Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

- (●) **Yes**
- ( ) No

3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [x] **Research Nurse**
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [x] **Data Collection - Lab**
- [x] **Data Collection - Clinical**
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [x] **Intervention Services**
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**

- [ ] Experience - Research
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS12_HM20027241 View: Personnel

Personnel

1. * **Name:**
   Keila Najera
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - ○ Yes
   - ● **No**
3. * **Roles:**
   - [ ] Principal Investigator
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [x] **Research Coordinator**
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other
4. * **Study related responsibilities:**
   - [ ] Study Design
   - [ ] Data Collection - Lab
   - [x] **Data Collection - Clinical**
   - [x] **Data Collection - Interviews/Surveys**
   - [ ] Data Collection - Direct Observation
   - [ ] Clinical Services

- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [ ] Data Analysis
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS12_HM20027241 View: Personnel

Personnel

1. * **Name:**
   Catherine Grossman

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse

- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [x] **Data Collection - Lab**
- [x] **Data Collection - Clinical**
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
- [x] **Clinical Services**
- [x] **Intervention Services**
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Kim Harrison

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - ○ Yes
   - ● **No**

3. * **Roles:**

☐	Principal Investigator
☐	Co/Sub-Investigator
☐	Medical or Psychological Responsible Investigator
☐	Lead Student/Trainee Investigator (leading their own project)
☑	**Research Coordinator**
☐	Research Nurse
☐	Consultant
☐	Research Assistant
☐	Pharmacist
☐	Statistician
☐	Regulatory Coordinator
☐	Trainee/Student(working on project)
☐	Other

4. * **Study related responsibilities:**

☐	Study Design
☐	Data Collection - Lab
☑	**Data Collection - Clinical**
☑	**Data Collection - Interviews/Surveys**
☐	Data Collection - Direct Observation
☐	Clinical Services
☐	Intervention Services
☑	**Data Entry**
☑	**Data Coding**
☑	**Data Management**
☐	Data Analysis
☑	**Project Coordination**
☑	**Participant Identification**
☑	**Participant Recruitment**
☑	**Participant Consent**

- [x] **Regulatory Management**
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS12_HM20027241 View: Personnel

Personnel

1. * **Name:**
   Yongyun Shin

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - ○ Yes
   - ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [x] **Statistician**
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS12_HM20027241 View: Personnel

Personnel

1. * **Name:**
   Alexandra Gerveni

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [x] **Statistician**
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [ ] Experience - Research
- [ ] Experience - Clinical
- [ ] Experience - Related Skills

- [x] **Trainee**
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**