PROTOCOL COVER PAGE

PROTOCOL TITLE: Belongingness in Nursing through Mindfulness – BEING Mindful: A Pilot Study

PRINCIPAL INVESTIGATOR: Sharon L. Ruyak, PhD, CNM, RN, FACNM Department

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Be*longingness* ***i****n* ***N****ursing* *through* ***Mindful****ness* – ***BEING Mindful:*** *A Pilot Study*

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Department

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REGULATORY FRAMEWORK (The federal regulatory framework governing human subjects research is found in the US Department of Health and Human Services Policy for the Protection of Human Subjects (45 CFR 46).):

Please indicate all that apply (please note that the regulatory framework **does not** mean the funding source):

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

Indicate if the protocol is funded. If so, provide sponsor and SPO Huron ERA record number (FPXXXXX).

This protocol is not funded

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

"A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or

subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." (https://grants.nih.gov/policy/clinical-trials/definition.htm)

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to all the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

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1. Objectives

1.1. Describe the purpose, specific aims, or objectives.

Our long-term goal is to develop a mindfulness-based intervention (MBI) program that significantly decreases stress/burnout and increases belongingness and connectedness among nurse faculty and staff. The overall objective of this pilot project, which is the next step in toward achievement of our long-term goal, is to examine the feasibility and preliminary efficacy of MBIs as an intervention for University of New Mexico (UNM) Health Sciences Center (HSC) nurse faculty and staff. Our central hypothesis is that this MBI intervention will improve the psychosocial outcomes (sense of belonging) and physiological outcomes (HRV) among HSC nurse faculty and staff. To test our central hypothesis and attain the overall objective, we will pursue the following specific aims:

Aim 1. To evaluate the feasibility and acceptability of MBIs (meditation or yoga) for HSC nurse faculty and staff. Acceptability will be assessed qualitatively from analyses of interviews with participants. Feasibility will be assessed as rates of recruitment, retention, and adherence to the MBI (% training sessions attended).

Aim 2. To evaluate the preliminary effect of MBI (meditation; yoga) in HSC nurse faculty and staff on: psycho-social outcomes (burnout; sense of belonging, stress, anxiety) and physiological outcomes (HRV evaluated by wearable electronics). We hypothesize that: a) psycho-social outcomes will improve post-intervention and b) physiologic measures (HRV) will improve post intervention compared to preintervention.

1.2. State the hypotheses to be tested.

Our central hypothesis is that this MBI intervention will improve the psychosocial outcomes (sense of belonging) and physiological outcomes (HRV) among HSC nurse faculty and staff.

2. Background

2.1. Describe the relevant prior experience and gaps in current knowledge.

Background: Nurses are the foundation of health care in the United States (US). Critically, **there is a growing shortage of academic nurse faculty resulting in limited capabilities to enroll future nurses and thus increase the nursing workforce**. Factors attributed to this shortage include stress and burnout,[1–3] lack of collegiality and non-inclusive environment.[4] These factors lead to significant adverse behavioral, psychological and physiological outcomes.[1,5] Staff, who are critical to the foundation for learning and innovation in academic nursing,[6] likely experience similar outcomes.[7] Notably, the American Association of Colleges of Nursing (AACN; 2024) states a sense of belonging is imperative for successful achievement of academic nursing's mission and priorities which focus on preparing the next

generation of nurses. A sense of belonging goes beyond the subjective feeling of connectedness with a community to a sense of a shared mission and ownership of common outcomes. There is emerging literature surrounding the role of faculty and staff in increasing belonging among students as well as strategies for leaders to create and sustain a culture of belonging. **However, a notable gap in the science is the absence of clinical trials examining the integration of interventions, such as mindfulness-based interventions (MBI), aimed at improving a sense of belonging and connectedness in academic nursing faculty and staff.** This study addresses this critical gap by examining the effect of MBIs on psychosocial and physiological outcomes in faculty and staff, thus directly addressing the number one recommendation from the AACN Leading Across Multidimensional Perspectives (LAMP) Culture and Climate survey to increase belongingness through community connectedness and cohesion.

2.2. Describe any relevant preliminary data.

Preliminary Data: The AACN LAMP Culture and Climate Survey was developed to assess the experiences of students, faculty and staff at nursing schools across the nation.[7] The survey provides a means to gather input from all constituents (students, faculty, staff) regarding what is working well at an organization and where there are opportunities for improvement. Results are grouped into 5 thematic areas: Perceptions of Culture and Climate, Fair Treatment and Observations of Discrimination, Belongingness, Value of Diversity, Equity and Inclusion, and Campus Services and Clinical Training. Of specific interest to this project is the thematic area of Belongingness.

The UNM AACN LAMP Survey was deployed to all University of New Mexico (UNM) College of Nursing (CON) students, faculty, and staff from March 2023 to April 2023. In total, 47 (57%) faculty and 36 (48%) administrators/staff completed the survey. Faculty and staff responded to 10 items focused on perception of connection to others and feelings of isolation. Approximately 28% of faculty reported when they interacted with other people at the CON, they did not feel included. Roughly 30% of faculty reported they felt their campus did not care about them. Thirty-nine percent of faculty reported they felt isolated from others on their campus and 38% reported they lacked a sense of belonging with their campus community. Finally, an alarming 49% of faculty reported feeling like a stranger when they where with other people from their campus.

Answers by faculty and staff to the question *"to improve the campus climate at my nursing program we need to do more of"* included multiple comments related to: 1) "promoting a sense of belonging", 2) "building community", and 3) "fostering cohesiveness and collaboration". Thus justifying the focus of this project.

2.3. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

It is long been established that mindfulness practices like meditation and yoga are associated with positive mental health outcomes.[8,9] In addition, mindfulness practices are known to support interpersonal relationships.[10] In the workplace, mindfulness practice improves communication, builds a sense of shared goals leading to greater productivity and retention, and helps to decrease burnout.[11,12] Furthermore, mindfulness practices foster resilience. Mindfulness practices are also associated with improved physiologic function including autonomic nervous system (ANS) function.[13] Peripheral ANS activity, including cardiac vagal activity (indexed by heart rate variability [HRV]), regulates dynamic fine-tuning of feedback loops between emotion-related brain circuitry and the heart.[14] HRV is known to be a robust biomarker of health, wellness, stress, and the ability to self-regulate.[15] By instructing individuals in MBIs homeostasis in brain-heart feedback loops is promoted leading to autonomic stability.[16] Given the potential impact of MBI to promote individual and workplace wellness, investigation of this intervention to improve wellness in academic faculty and staff is critical.

3. Study Design

3.1. Describe the study design (e.g., observational; randomized placebo-controlled clinical trial, etc.)

This study is a minimal-risk, single site, quasi-experimental study.

3.2. Describe blinding, if applicable

4. Inclusion and Exclusion Criteria

4.1. Describe how individuals will be screened for eligibility.

The UNM CON currently employs 71 faculty and 71 staff. In addition there are nurses who hold appointment with other departments and the UNM hospital. Using convenience sampling we will recruit and enroll 60 participants into two study groups: 1) mindfulness mediation and 2) yoga. Interested study participants will be contacted by study staff and screened to determine study eligibility (See Attachment A). The screener is approximately 1-page in length and takes approximately 5 minutes to complete. The screener includes queries related to inclusion and exclusion criteria. Participants will also complete an Exercise Participation Screening (see Attachment B).[17]

4.2. Describe the criteria that define who will be included or excluded in your final study sample, including age. "Age" can be part of a de-identified data set provided ages over 89 are not included. In order to maintain a de-identified classification, all ages over age 89 may be aggregated into a single category of "age 90 or older". If specific ages over 89 are included, then this would be considered a Limited Data Set.

Inclusion criteria for the study include: 1) 18 years of age or older, 2) in general good health, 3) employed as HSC nurse faculty or staff, 4) reside in the state of New Mexico and able to attend 6 weeks of in-person research sessions, 5) willing to complete research assessments, 6) own a smart phone.

Exclusion criteria for the study include: 1) major medical illness making individual unable to participate in the research.

Additional Screening Criteria*:* Vigorous-intensity exercise is accompanied by a small risk of cardiovascular complications, however, proper screening minimizes these risks.[17] The American College of Sports Medicine's (ACSM) guidelines are designed to eliminate barriers for an individual to begin a regular exercise program. Additional screening criteria will include completion of the Preparticipation Exercise Participation Screening (See Attachment B).

4.3. Special Populations: Will any of the following populations be included in this study? Indicate specifically whether or not you will include each of the following special populations below.

- Adults unable to consent: ☐Yes ☒No
- Pregnant women: ☒Yes ☐No **or** ☐Not targeted nor is pregnancy screened for
- Minors (individuals who are under the age of 18): ☐Yes ☒No
- Mothers who are minors cannot enroll their child into a research study without the consent of their parent or parents, as applicable. Clarify if applicable.
- Minors in foster care must be excluded from research per NM state law. Please state minors in foster care will be excluded, if applicable.
- Minors that are wards of the state must have additional safeguards met; Please consult with the HRPO if not excluding minors who are wards of the state. Otherwise state that wards of the state will be excluded.
- Prisoners ☐Yes ☒No; If yes, please contact HRPO; Inclusion of prisoners requires approval from the Office for Human Research Protections (OHRP) and from the NM Corrections Department.
- Non-English speakers ☐Yes ☒No; If yes, please clarify specific languages enrolling: Note: State congruently in section 25. Consent Process, subsection, Subjects not fluent in English.

4.4. Indicate if you excluding any particular populations (e.g., women, children, persons not fluent in English, a particular racial or ethnic group, etc.) and provide justification.

This study excludes individuals under that age of 18 due to the focus on adult faculty and staff employed at the UNM HSC. We will exclude pregnant individuals due to specific activity modifications that would be required to assure the safety of these individuals during yoga. We will not recruit individuals unable to provide written consent in English.

4.4.1. If excluding pregnant women, please indicate how investigators will screen for pregnancy.

5. Number of Subjects

5.1. If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

N/A. this study is not a multicenter study.

5.2. Indicate the number of subjects to be recruited at this site.

We will enroll 60 faculty and staff in this study. Once we have enrolled 30 participants, we will waitlist individuals for a second six-week intervention session after the completion of the first session. This will result in a possible enrollment 60 individuals.

5.3. Provide sample size justification

The planned overall sample size of 30 is consistent with recommendations for pilot studies seeking to build evidence in the context of medium effect size differences between two groups.[18]

6. Study Timelines

6.1. Describe:

- *The duration of an individual subject's participation in the research*
- *The duration anticipated to enroll all subjects*
- *The expected duration for the investigators to complete the study (complete analysis)*

Participants will be enrolled until the allotted 30 participants for the first 6 weeks of the study is reached. The study is comprised of a pre-intervention assessment, followed by 6 weeks of meditation/yoga attendance (twice/week). Upon completion of the 6-week intervention, participants will complete a post intervention assessment (See Table 1.).

Table 1. Study Timeline	**Months**									
	1	2	3	4	5	6	7	8	9	10
Prepare research and data management tools.	→									
Session 1										
Recruitment		→								
Intervention		→	→	→						
Data Collection		→	→	→						
Preliminary Data Analyses				→	→	→				
Session 2										
Intervention				→	→					
Data Collection				→	→					
Analyses					→	→	→			
Prepare R01 proposal						→	→	→	→	→
Dissemination						→	→	→	→	→

7. Study Endpoints: *Primary endpoint(s) are typically efficacy measures that address the main research question. Secondary endpoints are generally not sufficient to influence decision-making alone, but may support the claim of efficacy by demonstrating additional effects or by supporting a causal mechanism.*

7.1. Describe the primary and secondary study endpoints.

Primary outcomes of interest of this study include the feasibility and acceptability of mindfulness-based interventions (MBI) (Aim 1). We will also examine the preliminary effect of these interventions on psychosocial outcomes (primary: sense of belonging; secondary: burnout, stress) and physiologic outcomes (HRV) (Aim 2).

7.2. Describe any primary or secondary safety endpoints.

This is a minimal risk study.

7.3. Describe any exploratory endpoints.

N/A There are no anticipated exploratory endpoints.

8. Research Setting

8.1. Describe the sites or locations where your research team will conduct the research.

Potential participants will be recruited from the UNM HSC. The UNM HSC currently employs 71 faculty and 71 staff in the CON, plus nurse faculty and staff in other HSC programs. Study personnel will conduct all screenings in the private clinical research rooms housed within the CON Research Laboratory suite.

8.2. Identify where your research team will identify and recruit potential subjects.

Potential participants will be identified and recruited from the UNM CON.

8.3. Identify where research procedures will be performed including any laboratory analytics

Informed consent and research visit interviews will occur in private clinical research rooms housed within the UNM CON Research Laboratory suite. Questionnaires will be administered via secure REDCap survey. Garmin devices will be distributed and/or collected after completion of questionnaires. Meditation and yoga sessions will occur in the Collaborative Research Space housed within the CON Research Laboratory suite.

8.4. Describe the composition and involvement of any community advisory board

N/A, this study does not involve a community advisory board.

8.5. For research conducted outside of UNM HSC and its affiliates describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure/requirements (Note: include any approvals (IRB, facility, or other) with your submission)*

N/A, this is a single site study.

9. Resources Available

9.1. Describe the qualifications of the PI and study staff (e.g., training, experience, oversight) as required to perform the research. When applicable describe their knowledge of the local study sites, culture, and society.

The PI, Dr. Sharon Ruyak, has been a registered nurse for the past 37 years. In addition, Dr. Ruyak is an Associate Professor in the UNM CON and has been a faculty member of the UNM CON since 2013. She has extensive experience in the evaluation of stress and collection of both biological and behavioral research data. Additionally, Dr. Ruyak has successfully conducted research employing mobile ecological momentary assessment.[19,20] Dr. Ruyak is also a Registered Yoga Teacher (RYT) 200 and will lead the yoga intervention.

Dr. Roberta Lavin (Co-Investigator) has been a registered nurse for the past 35 years, a professor for 14 years and at the UNM CON for 4 years. She is part of a fellowship in contemplative medicine. In addition, she has 15 years of mindfulness practice and is an ordained Soto Zen Priest.

Dr. Mary Pat Couig (Co-investigator) has been a registered nurse for the past 47 years and faculty at the UNM CON for 5 years. Dr. Couig has expertise in new registered nurse graduate transition to practice residency programs and faculty mentoring programs. She is part of the leadership team that developed and implemented a new facilitated peer group mentoring program for new CON faculty.

Dr. April Tafoya (Co-investigator) has been a registered nurse for the past 10 years. Dr. Tafoya is a Lecturer II in the UNM CON and has been a faculty member for the past four years. Dr. Tafoya is a Registered Yoga Teacher (RYT) 200 and will work with Dr. Ruyak to lead the yoga intervention.

Clinton Mitch Irvin, MSN, RN, (Co-investigator) has been a registered nurse for 14 years and a UNM CON faculty member for the past 4 years. In addition, Mr. Irvin is a Lecturer II at the UNM CON. Mr. Irvin also has a BA in Religious Studies. He will work closely with Dr. Lavin to facilitate meditation sessions.

Stephen Van Roper, PhD, RN, FNP-BC, FAANP (C0-investigator) Has been a registered nurse for 30 years and a UNM CON faculty member for the past 12 years. Dr. Roper is a Clinical Professor and is a certified yoga instructor. He will work closely with Dr. Ruyak to facilitate yoga sessions.

9.2. When applicable, describe which licensed physicians/providers will be responsible for medical decision-making and ordering and evaluation of necessary diagnostics and therapeutics.

N/A, this is a minimal risk study that does not involve medical decision making.

9.3. Describe other resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that will be devoted to conducting and completing the research.*
- *Describe the facilities available to conduct the research.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
- *Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*
- *If CTSC resources are being accessed, please provide the IRB submission and approval deadline dates on the CTSC Submission page in Huron IRB.*

Feasibility of recruitment: The UNM CON currently employs 71 faculty members and 71 staff members with additional nurse faculty in other HSC schools and colleges and the hospital. The planned overall sample size of 30 per cohort is consistent with recommendations for pilot studies seeking to build evidence in the context of medium effect size differences between two groups.[18] Furthermore, objectives of pilot studies include assessment of recruitment and retention rates.[18]

The UNM College of Nursing is housed in the College of Nursing/College of Population Health Building. The UNM College of Nursing has a state-of-the-art Research Laboratory suite that includes private clinical research rooms as well as a large collaborative research space to conduct the intervention.

This is a minimal risk study that is not expected to have adverse psychological or medical consequences for participants. However, if needed there are providers available for referral and referral procedures are described below in Section 18 - Risks to Subjects.

Prior to beginning recruitment and enrollment, all study personnel will be trained on the protocol as well as consent and interview procedures for the study. All study personnel will have completed training for the ethical conduct of research. Study coordinators will routinely monitor the approved study team member list to ensure all team members remain current in their training.

10. Prior Approvals

10.1. Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.) N/A

10.2. Upload the required Departmental Review Form signed by your Department Chair (or authorized designee if the PI is the Department Chair) into Huron IRB under "supporting documents." The signed, required Departmental Review form has been uploaded under "supporting documents".

10.3. If a study includes ionizing radiation, the Radiation Safety Attachment (HUS-FORM_1) must be uploaded (attached) in Huron IRB with your submission. The consent should include radiation exposure information in the Risks section.

N/A

10.4. If applicable to the study, include the signed "Biological Specimens" and/or "Drug Attachment" in Huron IRB with your submission.

N/A

11.Multi-Site Research

11.1. If this is a multi-site study where the UNM HSC PI is the lead investigator, or UNM HSC is the coordinating site, describe the processes to ensure communication among sites, such as:

- *All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators will conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.*

11.2. Describe the method for communicating to engaged participating sites:

- *Adverse events*
- *Problems*
- *Interim results*
- *Data and safety monitoring reports*
- *The closure of a study*

11.3. If the UNM HSC investigator is serving as the "sponsor-investigator" of a FDA-regulated trial, describe how sponsor responsibilities will be fulfilled, including, but not limited to:

- *Trial Monitoring*
- *Investigational Product Accountability*
- *Safety and other interim reporting to investigators and FDA*
- *Unanticipated Problem reporting to investigators, IRBs, and FDA*

N/A

12.Study Procedures

12.1. List any collaborating site where human subject research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research (if applicable). N/A

12.2. Provide a thorough description of all study procedures, assessments and subject activities in a logical and sequential format.

The UNM CON currently employs 71 faculty and 71 staff and the HSC has additional nurse faculty and staff. We will employ a quasi-experimental design to assess feasibility, acceptability, and preliminary efficacy of MBIs (meditation; yoga) to increase a sense of belonging and connectedness in academic nursing faculty and staff. Using convenience sampling we will recruit and enroll 60 participants in to two study groups: 1) mindfulness mediation and 2) yoga. Interested study participants will be contacted by study staff and screened to determine study eligibility (See Attachment A). The screener is approximately 1-page in length and takes approximately 5 minutes to complete. The screener includes queries related to inclusion and exclusion criteria. Participants will also complete an Exercise Participation Screening (see Attachment B).[17]

Pre-data collection:

We will assign 15 individuals to each condition. Across both conditions, all participants will participate in one baseline assessment/training session, 6 weeks of MBIs (participants will be required to attend 2 sessions per week), and a post-intervention assessment session. Following screening for inclusion/exclusion criteria, eligible participants will complete the BEING Mindful Exercise participation screening. Eligible participants will provide informed consent.

After informed consent is obtained, research staff will allocate individuals to meditation vs yoga on 1:1 basis. If an individual is unable to participate in the yoga arm based on the BEING Mindful Exercise participation screening, they will be assigned to meditation and the next two participants will be assigned to yoga.

All participants will be given an anonymous study ID number once they are enrolled in the study. The only link between the study ID number and any identifier will be stored in a secure N:\Research-Studies network drive, in a folder to which only the investigators will have access. Any link between the study ID and identifiers will be destroyed when data analysis is complete.

Once we have enrolled 30 participants we will waitlist individuals for a second six-week intervention session after the completion of the first session. This will result in a possible enrollment 60 individuals.

12.3. For studies that collect existing or prospective data, describe the source of information, whether collected prospective or retrospectively.

Data collection:

Participants who express interest and meet inclusion criteria will meet with the PI or trained research personnel to review the study protocol, including risks and benefits. Participants will be asked to read and sign the informed consent (Attachment C) and HIPPA agreement following the procedure described in Section 25 – Consent Procedure.

Baseline Assessment session: During the baseline assessment session, participants will be administered a structured questionnaire with a research team member via the secure REDCap system. Baseline self-report questionnaires will be completed: 1) Sense of Belonging Scale (SBS); 2) Mindfulness Attention Awareness Scale (MASS) 15-item; 3) Generalized Anxiety Disorder-7 (GAD-7); 4) NIH toolbox measure of perceived stress

Sample Descriptors: Sociodemographic characteristics (age, sex, physical ability, staff vs faculty, years in profession, years employment at HSC, previous mindfulness practice) will be assessed at the baseline session.

Assessment of belonging: Belonging will be assessed using the 8-item Sense of Belonging Scale (SBS). The SBS measures the sense of belongingness or feelings of acceptance and inclusion in a community experienced by an individual.[21] The SBS was developed to be adapted to specific contexts.[21] Using the method described by Mellinger and Park (2023), we adapted the scale to be specific to UNM HSC nurse faculty and staff. Response categories range from 1 (*Strongly disagree*) to 5 (*strongly agree*). Responses are summed and the mean is calculated with higher scores corresponding to a stronger sense of belonging.[22] The SBS-8 demonstrated high levels of reliability with a Cronbach's alpha coefficient of .96.[21]

Assessment of mindfulness: *Trait mindfulness:* Trait mindfulness will be assessed using the 15-item Mindfulness Attention Awareness Scale (MAAS).[23] The MAAS was designed to assess core characteristics of mindfulness. The MAAS has demonstrated consistent reliability with Cronbach's alpha coefficients ranging from .80 to .90 in undergraduate, community, and nationally sampled adult populations.[23]

Assessment of burnout: The Copenhagen Burnout Inventory is a valid and reliable, 19-item, self-report measure of burnout.[24] Originally designed to measure burnout in among human service workers, it includes 3 scales. The personal burnout scale has six items and measures prolonged physical and emotional exhaustion. The work-related burnout scale has seven items that measure prolonged physical and emotional exhaustion secondary to work. The third scale, client-related burnout, has six items that measure burnout related to working with clients (client may be patients, students, service recipients). Each subscale can be scored separately.[24] The three subscales have demonstrated good reliability and criterion related validity in a variety of samples.[24,25]

Assessment of anxiety and stress: The Generalized Anxiety Disorder-7 screener (GAD-7) is a 7-item self-report-measure of generalized anxiety disorder.[26] Response categories range from 0 (*Not at* all) to 3 (*Nearly every* day). Responses are summed (range, 0 to 21) with higher scores corresponding to more severe levels of anxiety. Using a cut-off of 8, the GAD-7 has a sensitivity of 92% and specificity of 76% for diagnosis of generalized anxiety disorder.[27,28] The NIH toolbox measure of perceived stress is a 10-item fixed form. Responses are measured on a 5-point Likert scale ranging from 1 (*Never*) to 5 (*Very Often*) with higher scores indicating higher levels of perceived stress.[29,30]

Brief Reflective Feedback: At the end of each mindfulness session, participants will be given a card on which to write two words that embody how they are feeling right now (no

identifying information will be on the card). Participants will be asked to share their two words with the group if they feel comfortable.

Mobile Ecological Momentary Assessment (mEMA): Ambulatory assessment via mEMA allows for real time sampling within the individual's natural environment at multiple time points throughout the day. The Ilumivu mEMA (https://ilumivu.com) platform (iOS and Android compatible) is HIPPA compliant. The platform does not require any personally identifying information from participants. The platform automatically generates a unique identifying code. A research team member will provide this code to the participant to enter into their mobile app. Data are sent from the sensor to the mEMA app on the phone directly via Bluetooth. Data are then uploaded to Ilumivu's servers when the individual is within range of WiFi. Surveys are timestamped upon completion. All data are encrypted on transmission and stored securely. Datasets are only available to authorized research team members.

Following completion of baseline surveys, participants will be instructed to install the Ilumivu mEMA application on their smart-phone. The participants will be trained on how to access and respond to mEMA surveys. Participants will be asked to complete three mEMA assessments per day (morning, afternoon, and evening). An alert will be programmed to be sent at pre-determined times to remind the participant to complete the survey. All questions will be multiple choice (see MAAS-State below).

mEMA outcome: *State mindfulness* will be measured using the 5-item MAAS-State scale completed on the IlumiIvu mEMA app. The MAAS-State was designed to assess the expression of the core characteristic of mindfulness in real-time.[23]

Physiologic Outcome Measures. Ambulatory assessment of physiological processes within the context of an individual's daily life will occur through use of a wearable wrist electronic sensor. This platform provides direct, real-time data which is sent from the wearable sensor to the mEMA app, by Bluetooth.

Physiologic measures: inter-beat-interval will be collected via a Garmin Vivosmart5® device. This device has been shown to produce reliable heart rate data with the mean absolute percentage error below the designated acceptable 10% threshold.[31] Each participant will receive training for use of the sensor and written instructions will be provided for future reference. Participants will wear the device on their non-dominant hand in their daily environment every day for six weeks. Daily reminders to wear the device and to check the battery level will be delivered via the mEMA to increase compliance with the protocol.

HRV outcome measures: Garmin Vivosmart5® uses optical technology in which a series of lights emitted by photoplethysmography (PPG) sensors against the skin illuminate capillaries to detect changes in blood volume and providing heart rate data in real time.[31] Raw data is collected from the device and sent to the phone via Bluetooth. Using the pulse to pulse (P-P) interval, inter-beat-interval (IBI) is derived via Ilumivu software. HR epochs of five-minute intervals immediately preceding and corresponding to each mEMA survey will be selected for analysis. Time and frequency domain analysis will be performed by Ilumivu using proprietary software. Time Domain measures: Time domain measures are based on the time difference between easily detectable QRS complexes.

Using PPG technology, these measures are derived from the P-P interval (distance in milliseconds between each P). Simple time domain measures (standard deviation of P-P interval, mean HR) will be calculated. Frequency domain measures estimate frequency spectrum. The general bands are low frequency (LF; 0.04–0.15 Hz) and high frequency (HF; 0.15–0.40 Hz). Low frequency measures, high frequency measures, and LF/HF ratio of HRV will be computed.[32]

Long-term HRV, 24 hour time windows, will be determined by dividing the 24 hour time period into consecutive 5 minute epochs and averaging the individual values of the HRV metrics to obtain the mean of the value within the 24 hour time window.[32,33] Five-minute heart rate epochs immediately following completion of each mEMA survey will also be selected for analysis.[20,34] Between subject variability, in which relatively stable variation is compared between individuals, and within-subject (WS) variability, in which variation within the same individual across time will be examined.

12.4. Indicate what study activities happen when and where.

12.5. Describe, in chronological order, all research procedures and interventions being performed and when they are performed. Include:

- *Each specific intervention, procedure, examination, imaging, laboratory test, etc. that subjects will undergo for the purposes of the research and the purpose of it.*
- *Each drug, biologic, device, or other such product used in the research, the purpose, and the regulatory status (e.g., investigational, marketed – on label, marketed – off label, etc.)*
- *Each survey, questionnaire, interview, focus group, etc., that subjects will be asked to complete or participate in for the research and the purpose of it.*
- *Each data source that will be used to gather information about subjects and the purpose of it (confidentiality will be addressed later.*
- *Indicate whether subjects would already be expected to undergo any of the procedures for clinical, diagnostic, or other non-research purposes*
- *Include all referenced study instruments, such as questionnaires, scripts, diaries, and data collection forms with your submission as separate attachments.*
- *For HUDs, provide a description of the device, a summary of how you propose to use the device, including any screening procedures, the HUD procedure, and any patient follow-up visits, tests, or procedures. Note whether the HUD is being used for clinical purposes only or if you are proposing to study the safety or effectiveness of the device.*
- *Whole genome sequencing (WGS) or whole exome sequencing (WES) requires the following: (1) Subjects must opt-in or opt-out in the consent form for the WGS and/or WES. (2) Clinically actionable findings from WGS or WES must be confirmed in a CLIA certified laboratory. (3) Subjects must be given the option in the consent to receive the CLIA certified laboratory test results. (4) If the subject would like to be informed of clinically actionable CLIA certified findings, they must be given option for genetic counseling, and the genetic*

counseling must be paid by the researchers. All of these steps must be detailed in the protocol and congruently stated in lay-terms in the consent form.

Alternatively, subjects can be informed in the consent form that there are no identifiers linking to their samples where WGS and/or WES will be performed, and as such, clinically actionable findings will not be reported back to them. If applicable, state in the protocol and congruently in lay-terms in the consent form.

Description of Intervention Delivery

These guidelines detail the procedures used to conduct Mindful Meditation or Yoga sessions.

We will employ a quasi-experimental design to assess feasibility, acceptability, and preliminary efficacy of MBIs (meditation; yoga) to increase a sense of belonging and connectedness in academic nursing faculty and staff. We will assign 15 individuals to each condition. Across both conditions, all participants will participate in one baseline assessment/training session, 6 weeks of MBIs (participants will be required to attend 2 sessions per week), and a post-intervention assessment session. Following screening for inclusion/exclusion criteria, eligible participants will complete the **BEING Mindful** Exercise participation screening. Eligible participants will provide informed consent.

Assignment of Participants:

After informed consent is obtained, research staff will allocate individuals to meditation vs yoga on a 1:1 basis. If an individual is unable to participate in the yoga arm, they will be assigned to meditation and the next two participants will be assigned to yoga.

Retention:

To promote retention, we will reach out to participants with frequent reminders via text messages and emails.

Baseline Assessment session: During the baseline assessment session, participant characteristics will be collected. Baseline self-report questionnaires will be completed: 1) Sense of Belonging Scale (SBS); 2) Mindfulness Attention Awareness Scale (MASS) 15-item; 3) Generalized Anxiety Disorder-7 (GAD-7); 4) NIH toolbox measure of perceived stress.

Intervention Delivery:

The meditation and yoga interventions are 6-week protocols. We will offer meditation sessions 4 times per week and yoga sessions 4 times per week. We will require participants to attend two sessions per week. Attendance will be tracked via the Ilumivu platform. Participants will be requested to log attendance at each session via the app.

The meditation intervention will be led by Dr Roberta Lavin and Mr. Mitch Irvin. Meditation is a practice of mental exercises designed to increase focus and cultivate a desire to relieve suffering in self and other.[35,36] The practice dates back millennia to Buddhist and Hindu sages, but more recent work focuses on stress.[37] More recently, the term mindfulness has been used which means awareness, attention, and remembering.[37] Many religious traditions have a form of meditation based practice. This study will focus

on two forms of meditation both of which are focused on right mindfulness: 1) zazen which is a seated meditation primarily focused on the breath, posture, and sensation without attaching judgment. This is meant to develop awareness, equanimity, and insight, and 2) kinhin which is a walking meditation which is meant to connect mindfulness in one's movement by synchronizing breath and movement. It also focuses on development of awareness, equanimity, and insight. The two activities combined help the individual to nurture a thread of mindfulness. Instructors have developed a protocol (see attachment E). to standardize the delivery of the meditation intervention. The protocol includes a description of the amount of time for each phase of the practice. The protocol also includes suggested cues and dialogue which can be expressed or paraphrased in the instructors' own words.

The yoga intervention will be led by certified, 200-hour registered yoga instructors, Drs Sharon Ruyak, Dr. Van Roper, andApril Tafoya. Yoga is a wholistic, multidimensional practice. There are three fundamental limbs of yoga: 1) breathwork (pranyanma), 2) physical postures with breathing techniques (asanas), and 3) meditation and visualization (Dhyana).[38] Yoga practice unites the mind, body and spirit leading to psychophysiological changes within the individual including improved self-regulation ability and stress response, mood, well-being, and quality of life.[8,9,13] Yoga instructors will offer modifications and props such as blocks to ensure sessions are accessible to individuals of various abilities and minimize the risk of injury. Instructors have developed a detailed manual to standardize the delivery of the yoga intervention (see Attachment F). The manual includes photos and descriptions of how to perform the pose. The manual also includes suggested cues and dialogue which can be expressed or paraphrased in the instructors' own words. Additionally, the manual includes suggested modifications or amplifications for poses so the participant can practice to their level. This allows for personalization of the yoga flow while preserving treatment fidelity.

For each yoga class, the instructor will lead the student through a series of yoga poses. Class will begin with centering and breathwork (pranayama) for 5-10 minutes. This will be followed by a series of warm-up poses (~5-10 minutes). After the warm-up sequence, students will flow through traditional sun salutations (~10-15 minutes). This will be followed by a series of standing poses (~ 15 minutes). Students will then be guided to flow through a series of cool-down poses on the floor (~10 minutes). Class will conclude with traditional Savasana during which affirmations or meditation are provided (~5-10 minutes).

Treatment fidelity:
Delivery: Standard treatment manuals and checklists have been developed. To ensure that the interventions are delivered as intended, yoga instructors will complete standardized checklists after each in-person session.[39] In addition, we will select one yoga session every 2 weeks for rating by trained research personnel. The PI and interventionists will meet to discuss results and problem solve. We will track participant's completion of study components using summary sheets for each visit. Participants will log attendance at intervention sessions using the mEMA app.

Post-intervention session: During the post-intervention assessment session, participants be administered a structured questionnaire with a research team member via the secure REDCap system. Self-report questionnaires will be completed: 1) Sense of Belonging Scale (SBS); 2) Mindfulness Attention Awareness Scale (MASS) 15-item; 3) Generalized Anxiety Disorder-7 (GAD-7); 4) NIH toolbox measure of perceived stress. Participants will complete semi-structured (See Attachment G) interviews to help us collect data pertaining to the MBIs and delivery preferences. Interview responses will be transcribed in the REDCap system. These data will be used to adjust the content and format of the intervention based on feedback from participants who are our intended users.

13.Data Analysis

13.1. Describe the data analysis plan, including any statistical procedures.

Consistent with the scope of pilot projects, the proposed study will allow us to examine barriers to successful completion of the study, evaluation of acceptability of methods to participants, and estimates for future power analysis for a subsequent NIH R01 application. Numerical and graphical summaries will be computed for all measurements.

Aim 1: To assess precision of estimates, 95% confidence intervals will be calculated for rates of recruitment into study, retention to end of study, and participants completing all training sessions. Overall adherence will also be described by calculating the mean and standard deviation of the number of completed training sessions per participant. *Qualitative Analyses:* Qualitative descriptive analysis[40] will be used to create a comprehensive summary of the acceptability of the MBI to participants. Deductive analysis will be used to determine common themes related to acceptability in the domains of affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy.[41] Interview responses will be reviewed by two members of the research team to identify themes. Themes and preliminary interpretations will be regularly presented to the larger research team to resolve any discrepancies or disagreements and check for alternative interpretations.

Aim 2: Participant characteristics and baseline survey responses will be described using means and standard deviations (SD) for continuous variables and number (percentage) for categorical variables. Continuous intervention outcomes will be described using means and standard deviations and, due to sample size, difference scores from baseline for intervention outcomes will be compared between groups using non-parametric statistical tests. Cohen's d, as a descriptive statistic, will be used as an effect size measure to quantify the extent of within group and between group differences in means over time.[42] Long-term HRV (time domain and frequency domain measures derived for each 5 minute epoch within a 24 hour period will be averaged) measures will be compared between meditation and yoga groups by t-test. EMA and HRV data will be merged into a single dataset, matching upon timestamp.

Five-minute heart rate epochs immediately following completion of each mEMA survey will be selected for analysis.[20,34]

13.2. Provide a power analysis, if applicable.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects. Describe:

N/A – The PI believes this study constitutes no more than minimal risk for potential participants. Therefore, a Data and Safety Monitoring Plan is not required.

14.1. The entity (e.g., DMC, DSMB) or individuals (e.g., medical monitor) who will perform data and safety monitoring. Describe whether they are independent of or affiliated with the sponsor or investigator. If a DMC or DSMB is planned, describe the composition of the committee or board. Generally, a DSMB or DMC should be composed of experts in all scientific disciplines needed to analyze and interpret the data (e.g., epidemiologists, biostatisticians, subject matter experts).

14.2. The safety information that will be collected and monitored.

14.3. The frequency or periodicity of review of data, such as specified points in time or after a specific number of participants have been enrolled.

14.4. The plans for review of scientific literature and data from other sources that may inform the safety or conduct of the study.

14.5. The procedures for analysis and interpretation of the safety data.

14.6. The conditions that would trigger a suspension or termination of the research (i.e., stopping rules), if appropriate.

14.7. The plan for reporting findings to the sponsor, investigators, and HRRC.

15. Withdrawal of Subjects

15.1. Describe any anticipated circumstances under which subjects may be withdrawn from the research without their consent.

A study investigator may withdraw a participant from the study if, in the investigator's judgment, it would be in the participant's best interest not to continue participating in the study.

15.2. Describe any procedures for orderly termination/safe withdrawal (e.g., tapering of meds, physical exams, laboratory or other tests, etc.). N/A

15.3. Describe any procedures for partial withdrawal (e.g., from procedures but allowing continued data collection by record review, phone contact, etc.).

Participants are allowed to withdraw from the study at any time without penalty. At the time of withdrawal, the participant will be asked if he or she wishes to

withdraw authorization for use of the data collected to that point. However, any data that has already been deidentified and analyzed cannot be withdrawn.

15.4. Describe the disposition of existing data/specimens when a subject withdraws. Describe any restrictions on a subject's ability to withdraw any already gathered data or specimens (e.g., unable to retrieve because it has been stripped of identifiers and no code exists to allow re-linking). (Note: FDA requires that existing data be maintained for studies subject to FDA oversight.)

Participants are allowed to withdraw from the study at any time without penalty. At the time of withdrawal, the participant will be asked if he or she wishes to withdraw authorization for use of the data collected to that point. However, any data that has already been deidentified and analyzed cannot be withdrawn.

15.5. Describe withdrawal procedures and any limitations in the consent document.

16.Data Management/Confidentiality

If data or specimens will be transferred/shared with an external entity (institution, company, etc.), please complete Checklist sections 47 and 48, as applicable.

16.1. *All electronic research data and electronic research records MUST be stored on the N:\Research-Studies network drive. This drive is not the same as the N: departmental drive.*

The N:\Research-Studies network drive is established by the Information Security Office (ISO), and it is Part 11 compliant. The N:\Research-Studies network drive must be established after the protocol is approved. If you do not have this network drive setup, contact the ISO at HSC-ISO@salud.unm.edu.

All data files will be stored on the N:\Research-Studies network drive.

16.2. Indicate how the research team is permitted to access any sources of information about the subjects.

Participants will be administered a structured questionnaire with a research team member via the secure REDCap system. Data collected will be stored on the secure REDCap server at the UNM HSC CTSC and on the N:\Research-Studies network drive. Data will be accessible to the PI and other trained research personnel. Both REDCap and the UNM HSC N:\Research-Studies network or VPN support multi-factor authentication. Any paper records, will be stored in a locked file cabinet in the UNM HSC locked office of the PI after retrieval. Only the PI or designated research coordinator will have access to any identifiers. The REDCap data collection tool is both encrypted and password protected. The PI has undergone the introductory training and has established an account. All data files used during the data analysis will be stored on the N:\Research-Studies network drive. Only de-identified data in aggregate will be exported from REDCap and used in analyses. All data will be kept for a minimum of six years and then destroyed.

16.3. Note whether the research requires the access, use, or disclosure of Protected Health Information including direct identifiers (e.g., name, medical record

number etc. or a limited data set. See Data Classification definitions in section 47, after question P.

Protected health information will not be collected.

16.4. *Several zip codes are below the 20,000-census mark, and HIPAA regulations require that the three first digits of the zip code are replaced with "000" in order to create a de-identified data set. Based on the 2010 Census, the sparsely populated zip codes in New Mexico are as follows: 878, 879, and 884 pre-fixes. Please indicate if these zip codes will be included, and if so, indicate they will be replaced with "000" in order to create a de-identified data set. If utilizing these zip codes, the data set would be a limited data set.*

These zip codes will not be collected.

16.5. *If data will be coded, describe the nature of the code and mechanisms that will be used to protect the code (e.g., secure storage, limited access, separate location from research data). A subject list linking the unique subject code with the subject identifier needs to be kept in a separate location from the data collection sheets. Please indicate if such a list will be maintained and where it will be maintained separately from the data collection sheets. Please indicate where in N:\Research-Studies network drive the link will be stored when storing electronically.*

All surveys, and study materials will be coded with a unique study ID number assigned at enrollment. The link to study ID numbers will be stored on the secure REDCap server at the UNM HSC CTSC and only authorized, IRB approved study team members will have access to the information. The link will be destroyed when the study is complete. Only de-identified data labeled with the unique study ID will be exported from REDCap and used in analyses. All data files used during the data analysis will be stored on the N:\Research-Studies network drive. Only de-identified data in aggregate will be exported from REDCap and used in analyses.

All data collected via mEMA are de-identified. The mEMA platform does not require collection of any personal identifying information. The system automatically generates a unique identifying code that is assigned to participants to enter into the mEMA App. The key linking this code to the unique participant study ID is stored outside of the Ilumivu mEMA system in the secure HSC REDCap database and only authorized study personnel will have access. Data are sent from the wearable Garmin sensor to the mEMA app on the participant's smart phone and then uploaded to Ilumivu's servers when the participant is within WiFi range. All data are encrypted before being pushed to the Ilumivu cloud-based storage database. Access to the database is restricted to authorized research personnel. Only research personnel authorized by the PI can directly access the secure cloud-based storage database to download data in CSV file format. All data files will be stored on the N:\Research-Studies network drive

16.6. *Note whether the data is publicly available. If the data is publicly available a data use agreement is not required. "Publicly available" refers to data and/or*

biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges. Examples include data/biospecimens available for public purchase, searchable online, or available at a library.

N/A

16.6.1. Examples of types of identifiable data/biospecimens that are not considered publicly available are as follows:

- *Data in the electronic medical record;*
- *Social media data labeled as "private" by the data owner, or not readily available without permission of the site Owner/Administrator under the Terms of Service of the site;*
- *Data protected by Copyright; and*
- *Data or biospecimens that have access restrictions (e.g. are only available to clinicians or qualified researchers or may only be accessed on a secure server.*

16.7. Note whether the data includes information that may be considered sensitive or require additional protections such as HIV, genetic test results, mental health information, substance abuse information, criminal records, etc. If HIV records are being accessed, the protocol must contain the following language: The data does include information on HIV. This information has been disclosed from records whose confidentiality is protected by state law. State law prohibits investigators from making any further disclosure of this information without the specific written consent of the person to whom this information pertains or as otherwise permitted by law. A person who makes an unauthorized disclosure of this information is guilty of a petty misdemeanor and shall be sentenced to imprisonment in the county jail for a definite term not to exceed six months or the payment of a fine of not more than five hundred dollars ($500), or both.

The data will include information related to participants mental health.

16.8. Indicate whether a Certificate of Confidentiality (CoC)will be used to protect data from forced release (e.g., subpoena) and whether the certificate is in place or will be applied for once IRB approval is in place. Please note: NIH funded studies are automatically covered under a CoC. More information on Certificates of Confidentiality is available here: http://grants.nih.gov/grants/policy/coc/index.htm

N/A

16.9. Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption in transmission and at rest, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, transmission and transport.

16.9.1. The UNM Health Sciences REDCap system managed by Clinical and Translational Science Center (CTSC) is also considered a secure method for

data collection and maintenance during the life of the study. The UNM Hospital REDCap cannot be used for human subjects research. Also note that multi-factor authentication (MFA), which UNM Health Sciences REDCap supports, is required when using another institutions REDCap. ***The data cannot be stored in REDCap after the study closure, and the protocol must indicate where data will be stored after the study closes.***

16.9.2. ***After study closure, long-term data storage must be in the N:\Research-Studies network drive. Please indicate this in this section.***

NOTE: Email HSC-ISO@salud.unm.edu to set up the N:\Research-Studies network Drive, if needed. For any questions regarding REDCap, please contact the UNM Health Sciences Clinical and Translational Center (CTSC).

All surveys, and study materials will be coded with a unique study ID number assigned at enrollment. The link to study ID numbers will be stored on the secure REDCap server at the UNM HSC CTSC and only authorized, IRB approved study team members will have access to the information. The link will be destroyed when the study is complete. Only de-identified data labeled with the unique study ID will be exported from REDCap and used in analyses. All data files used during the data analysis will be stored on the N:\Research-Studies network drive. Only de-identified data in aggregate will be exported from REDCap and used in analyses.

All data collected via mEMA are de-identified. The mEMA platform does not require collection of any personal identifying information. The system automatically generates a unique identifying code that is assigned to participants to enter into the mEMA App. The key linking this code to the unique participant study ID is stored outside of the Ilumivu mEMA system in the secure HSC REDCap database and only authorized study personnel will have access. Data are sent from the wearable Garmin sensor to the mEMA app on the participant's smart phone and then uploaded to Ilumivu's servers when the participant is within WiFi range. All data are encrypted before being pushed to the Ilumivu cloud-based storage database. Access to the database is restricted to authorized research personnel. Only research personnel authorized by the PI can directly access the secure cloud-based storage database to download data in CSV file format. All data files will be stored on the N:\Research-Studies network drive

Research records will be maintained for at least 6 years after study completion and then destroyed per the following policy: HSC-R-801 PR.1 "Research Data and Materials Retention Policy" and then destroyed. After study closure, long-term data storage must be in the N:\Research- Studies network drive.

16.10. *Describe any procedures that will be used for quality control of collected data and/or specimens.*

- *What information will be included in the data or associated with the specimens?*

- *How will data be collected and what is the data type (i.e. electronic, hard copy, specimen, etc.)?*

  Data will collected via survey using the secure REDCap server at the UNM HSC CTSC and only authorized.

  All data collected via mEMA are de-identified. The mEMA platform does not require collection of any personal identifying information. The system automatically generates a unique identifying code that is assigned to participants to enter into the mEMA App. Data are sent from the wearable Garmin sensor to the mEMA app on the participant's smart phone and then uploaded to Ilumivu's servers when the participant is within WiFi range. All data are encrypted before being pushed to the Ilumivu cloud-based storage database. Access to the database is restricted to authorized research personnel. Only research personnel authorized by the PI can directly access the secure cloud-based storage database to download data in CSV file format. All data files will be stored on the N:\Research-Studies network drive.

  The PI has completed the HSC-ISO Cloud Bases Security System Review (see attachment H) as well as the required User Policy (see Attachment I)

- *How long will the data or specimens be stored? See sections 16.15 – 16.17 for data storage requirements.*

  Research records will be maintained for at least 6 years after study completion and then destroyed per the following policy: HSC-R-801 PR.1 "Research Data and Materials Retention Policy" and then destroyed. After study closure, long-term data storage must be in the N:\Research- Studies network drive.

- *Who will have access to each method of data collection and/or specimens?*

  Only authorized, IRB approved study team members will have access to the information.

16.11. How will the data and specimens be transported. Describe if data will be collected, transmitted, and/or stored via the internet, the identifiability of the data, and the security measures that will be employed to protect it (if data is de-identified, explicitly state that).

All data collected via mEMA are de-identified. The mEMA platform does not require collection of any personal identifying information. The system automatically generates a unique identifying code that is assigned to participants to enter into the mEMA App. Data are sent from the wearable Garmin sensor to the mEMA app on the participant's smart phone and then uploaded to Ilumivu's servers when the participant is within WiFi range. All data are encrypted before being pushed to the Ilumivu cloud-based storage database. Access to the database is restricted to authorized research personnel. Only research personnel authorized

by the PI can directly access the secure cloud-based storage database to download data in CSV file format. All data files will be stored on the N:\Research-Studies network drive.

The PI has completed the HSC-ISO Cloud Bases Security System Review (see attachment H) as well as the required User Policy (see Attachment I)

16.12. *Describe if data will be collected by audio or video recording, how the recordings will be secured, whether and when recordings will be transcribed, if the transcription will include identifiers, if, when, and how the recordings will be deleted. Describe if the subjects will have the opportunity to review the recordings and request full or partial deletion. If the recordings may include persons other than the subjects, describe how this will be managed.*

N/A

16.13. *Describe if the data will include photographs, what will be included in the photographs, and how the photographs will be secured. Describe if subjects will have the opportunity to review the photographs and request destruction. If the photographs may include persons other than the subjects, describe how this will be managed.*

N/A

16.14. *The National Institutes of Health (NIH) has issued the Data Management and Sharing (DMS) policy effective January 25, 2023, to promote the sharing of scientific data. The NIH Policy for Data Management and Sharing (NOT-OD-21-013) requires researchers to include a data management and sharing (DMS) plan in funding applications. The DMS Policy applies to all research, funded in whole or in part by NIH, that results in the generation of scientific data. If applicable, complete HRP – 234 – FORM – NIH Data Management and Sharing Policy and upload to the study record at time of initial new study submission. At time of study closure, complete HRP-235 – FORM – NIH Data Management & Sharing Policy_Study Closure Form. Clarify if this policy applies.*

N/A

16.15. *State how long research record will be maintained. Note: Federal regulations require that research records will be maintained for at least 3 years after study completion and then will be destroyed.*

Research records will be maintained for at least 6 years after study completion and then destroyed per the following policy: HSC-R-801 PR.1 “Research Data and Materials Retention Policy” and then destroyed. After study closure, long-term data storage must be in the N:\Research- Studies network drive.

16.16. *Research records of minors (under 18) must be retained until the minor turns 22 years old per the following policy: HSC-R-801 PR.1 “Research Data and Materials Retention Policy” and then will be destroyed.*

N/A

16.17. HIPAA Requirements: Any research that involved collecting identifiable health information is subject to HIPAA requirements. As a result, records must be retained for a minimum of 6 years after each subject signed an authorization, and then will be destroyed.

17. Data and Specimen Banking

17.1. If data or specimens will be banked or archived locally for future use, provide the name and study number of the repository that they will be deposited into. Describe exactly what data or specimens will be banked and for what purposes, and whether the data or specimens will include identifiers, be coded, or be fully stripped of all identifiers with no code or key that would allow relinking. Be certain to describe the banking in the primary consent. A separate consent and authorization, if applicable, will be necessary for the banking activity itself and is typically provided by the repository. If you need to establish a repository for the purposes of banking or archiving data or specimens, a separate submission for the repository is needed as this is considered to be a distinct research activity under the regulations.

N/A: we will not be banking data or specimens. All data will be stored in the HSC-maintained and secured REDCap data base or on the N:\Research-Studies network Drive.

17.2. If this is a multi-center study, and/or if data or specimens will be banked or archived elsewhere, identify who the holder of the data or specimens will be, exactly what data or specimens will be banked and for what purposes, and whether the data or specimens will include identifiers, be coded, or be fully stripped of identifiers with no code or key that would allow relinking. A Materials Transfer or other agreement may be necessary, please consult with the HSC Sponsored Projects Office at 505-272-6264 or by email at hsc-preaward@salud.unm.edu. Material Transfer Agreement procedures may be found at http://hsc.unm.edu/financialservices/preaward/ancillary-agreements/material-transfer-agreements/procedures.html. Be certain to describe the banking in the consent and authorization, using opt-in procedures, and the procedures for subjects to request withdrawal of their data or specimens and any limitations on their ability to do so.

18. Risks to Subjects

18.1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Note that almost all research includes the risk of a breach of confidentiality and/or privacy.

18.2. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

There are minimal risks to participants from this research. Since breach of confidentiality is the most likely risk, participants will be administered informed consent privately in order to insure anonymity. All data collected as part of the study will be identified with a study number. Any forms and survey results that are obtained will be securely stored in either an encrypted database or on the N:\Research-Studies network Drive. Any links between personal identifying information and study ID will be destroyed upon completion of the study.

Each participant will complete surveys regarding mental well-being (e.g. anxiety, stress). These surveys may cause discomfort or stress. To minimize stress, all interviews will be conducted in a private room in a non-judgmental manner by trained research personnel. We will encourage all study participants to discuss concerns about mental health or other health issues with their health-care provider. Additionally, meditation is generally not considered harmful, however, it is possible a participant may experience some discomfort while participating in meditation. Meditation can reveal uncomfortable thoughts or emotions. If a participant experiences distress, a trained research team member will provide the participant with information related to the UNM Counseling, Assistance, & Referral Services (CARS).

Yoga is generally considered to be a safe form of physical activity when performed properly under the guidance of trained instructors. However, as with other forms of physical activity, there is always a chance that an injury may occur. Most common discomforts include muscle soreness, pain, fatigue, or emotional discomfort. We will ask participants to complete an Exercise Participation Screener to determine exercise readiness. The certified yoga instructors are trained to provide guidance on modifications to make sure everyone can participate safely. In the rare event of an injury, research personnel will assist the participant to make an appointment at the UNM LoboCare Clinic.

18.3. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If pregnancy testing or birth control provisions are required, describe these.

N/A

18.4. If applicable, describe risks to others who are not subjects.

N/A

18.5. Describe the steps being taken to minimize the probability or magnitude of risks.

Note: All risks described here should also be described in the consent document.

19. Potential Benefits to Subjects

19.1. Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential

benefits. Note: Compensation for research participation is not considered a benefit.

19.2. Indicate if there is no direct benefit. Do not include benefits to society or others in this section.

Note: All potential benefits described here should also be described in the consent document.

Participants will be participating in either meditation or yoga which may provide them with direct individual benefits. It has long been established that mindfulness practices like meditation and yoga are associated with positive mental health outcomes.[8,9] Mindfulness practices are also associated with improved physiologic function including autonomic nervous system (ANS) function.[13]

20. Recruitment Methods

20.1. Describe when, where, and how potential subjects will be recruited.

20.2. Describe the methods that will be used to identify potential subjects (e.g., chart review, referral, etc.).

20.3. Describe materials that will be used to recruit subjects (e.g., emails, scripts, advertisements, brochures, flyers, etc.). Attach draft copies of the documents or audio or video recordings with the application. Once the draft has been approved, the final copy of the printed material, audio or video recording must be submitted for review and approval prior to implementation. Please see Worksheet HRP-315 for information on advertisement standards. The preference is recruitment materials are submitted on Word document(s), however, this is not required when not possible. Clarify accordingly in this section.

We will recruit participants from the UNM HSC. The UNM CON currently employs 71 faculty and 71 staff with additional nurse faculty and staff within the HSC. Participants will be recruited in-person during monthly faculty, staff, and all college meetings. We will also recruit participants through college email listservs using IRB approved flyers (see Attachment D) and by posting IRB approved fliers in common areas of the CON and Public Health Excellence Building. Interested participants will be contacted by study staff and screened for eligibility.

21. Provisions to Protect the Privacy Interests of Subjects

21.1. Describe the steps that will be taken to protect subjects' privacy interests. "Privacy" refers to persons and their interest in controlling the access that others have to themselves. For example, based on their privacy interests, people may want to control:

- *The time and place/setting where they are examined or provide information*
- *The nature of the information they provide*
- *The nature of the experiences they are exposed to*

- *Who may observe or have access to information about them*

  For example, individuals may not want to be approached for participation, provide responses to a research interview, or undergo a research procedure in a location where they may be seen or overheard.

The risk of loss of privacy is the greatest risk in this study. All reasonable attempts to maintain the privacy of participants will be taken.

Screening for study eligibility will take place in a private room with a closed door. This will occur in the Clinical Research Rooms housed within the CON Research Laboratory suite.

21.2. Describe the steps that will be taken to protect subjects' privacy including privacy protections during recruitment, consent, and data collection. Issues related to data are addressed in the Data Management/Confidentiality Section.

The consent process and the study visit will take place in a private room with a closed door in the Clinical Research Rooms housed within the CON Research Laboratory.

Only study members who have completed training will be authorized to administer informed consent and interviews.

22. Economic Burden to Subjects

22.1. Describe any costs that subjects may be responsible for because of participation in the research. Clearly stipulate what procedures are standard of care and what procedures are research-related in the table below. Please place an X in the box for the responsible party for each procedure involved.

List any costs to participants (or their 3rd party payer); include any charges for study procedures, visits, or drug/devices.

There is no cost to participants to participate in this study.

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
Standard of Care Procedures	**Number of**	**Responsible Party**	

	Samples/Procedures	Study	3rd Party Payer or Participant
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐

22.2. List any other costs to participants not already described above.

22.3. Indicate whether subjects will be charged for investigational drugs, devices, procedures

22.4. Explain who will be responsible for paying for treatment of adverse events

22.5. Ensure that the cost section of the consent form reflects the cost that are covered by the sponsor and the costs for which the subjects (or 3rd party payers) are responsible.

23. Compensation

23.1. Describe any plans for compensation or reimbursement for subjects (amounts, methods (e.g., merchandise card), and payment schedule; cash and checks are institutionally prohibited). Describe why the proposed amount is reasonable and appropriate for the subjects' time and inconvenience. Credit for payment should be prorated and not be contingent upon the participant completing the entire study. Any amount paid as bonus for completion of the entire study should not be so great that it could unduly induce subjects to remain in the study when they otherwise would have withdrawn. Note: Consult with your department official for reporting requirements associated with merchandise cards distributed to research subjects. De-identified reporting of the distribution of merchandise cards to department officials is preferred.

Participants will not receive compensation other than the meditation or yoga sessions they are allocated to as part of the study.

24. Compensation for Research-Related Injury

24.1. If the research involves more than Minimal Risk to subjects, describe the plan for compensation in the event of research related injury.

There is no compensation for costs related to treating any injuries incurred during the course of the study

24.2. If subjects are responsible for seeking their own form of care for research-related injury, describe how this will be communicated and what options are available to participants.

Each participant will complete surveys regarding mental well-being (e.g. anxiety, stress). These surveys may cause discomfort or stress. To minimize stress, all interviews will be conducted in a private room in a non-judgmental manner by trained research personnel. We will encourage all study participants to discuss concerns about mental health or other health issues with their health-care provider. Additionally, meditation is generally not considered harmful, however, it is possible a participant may experience some discomfort while participating in meditation. Meditation can reveal uncomfortable thoughts or emotions. If a participant experiences distress, a trained research team member will provide the participant with information related to the UNM Counseling, Assistance, & Referral Services (CARS).

Yoga is generally considered to be a safe form of physical activity when performed properly under the guidance of trained instructors. However, as with other forms of physical activity, there is always a chance that an injury may occur. Most common discomforts include muscle soreness, pain, fatigue, or emotional discomfort. We will ask participants to complete an Exercise Participation Screener to determine exercise readiness. The certified yoga instructors are trained to provide guidance on modifications to make sure everyone can participate safely. In the rare event of an injury, research personnel will assist the participant to make an appointment at the UNM LoboCare Clinic.

25.Consent Process

25.1. Indicate whether you will you be obtaining consent, and if so describe:

25.1.1. Who will be responsible for obtaining consent and their qualifications/training to do so. Be certain to identify which study team members will obtain consent in Huron IRB under Project Contacts.

Study personnel with training and experience related to consenting participants will be authorized to obtain participant consent for this study. All study team members will be current in their HIPAA and CITI trainings.

25.1.2. Where will the consent process take place and the provisions for privacy.

Study participants will meet with a member of the study team in a private room Clinical Research Room housed within the CON Research Laboratory suite.

25.1.3. The steps that will be taken to minimize the possibility of coercion or undue influence

Participants will be informed, both in writing and verbally, that their participation in the study is voluntary. They will also be informed that they may discontinue the study at any point in time and that their decision to participate or decline will not affect their employment at UNM HSC or their ability to participate in the yoga and meditation sessions.

25.1.4. The waiting period available between reviewing the study and consent with the potential subject and obtaining the consent.

Participants who are eligible will be given the opportunity to take the consent form home for review prior to deciding whether to participate or not in the study. Potential participants will be encouraged to think about their decision and will be provided with contact information to schedule an appointment at their convenience.

25.1.5. Processes to ensure ongoing consent throughout the study.

25.1.6. Any steps that will be taken to enhance understanding

All participants will be provided a copy of the informed consent to read along with the research personnel throughout the consent discussion processes. Participants will be encouraged to ask questions throughout the process. As consent is administered, research personnel will periodically stop to ask participants to provide their understanding of what was just discussed. If the participant does not indicate understanding, information will be reviewed and questions answered until the participant states they fully understand. Every participant will be asked if all of their questions about volunteering in the study have been answered prior to completing the consent form.

25.1.7. Any procedure/testing for ensuring that the consent is understood by the potential subject (e.g., teach back)

See above

25.1.8. There are no provisions for a waiver of consent for FDA regulated research.

25.1.9. NOTE: For adults and per NM state law, consent and HIPAA authorization are required in order to access their mental health information or developmental disabilities information if access is before July 1, 2019. For adults records only, information can be accessed from July 1, 2019 onwards without consent and HIPAA authorization.

Subjects not fluent in English

25.1.10. Indicate what language(s) other than English speakers will be enrolled as participants.

25.1.11. If you anticipate enrolling subjects who do not understand or have limited fluency in English, describe the process to ensure that the oral and written information provided to those subjects initially and throughout their participation will be in the language they understand (e.g., use of translations and interpreters). Please note that translations of consent documents and subject materials will likely be required once the content of the English-language version is approved.

25.1.12. Short-form consent documents are available for unanticipated enrollments of persons who don't understand or have limited fluency in English. However, based upon the nature of the research (e.g., clinical trials) subsequent translation of the consent document may be required so

that the subject has access to written information about the research in a language they understand. Clarify that the English consent will be used as the summary of the research in combination with the short form consent.

This study will only enroll participants fluent in English. Non-English speaking individuals are excluded because the ability to accurately and completely communicate study information, answer questions about the study, and obtain consent are necessary.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

N/A. This study will not enroll cognitively impaired adults unable to provide consent

25.1.13. The HRRC must specifically approve the enrollment of adults unable to consent and adults with cognitive impairment or limited decision-making capacity. Complete the applicable checklist in the Checklists Section of this Protocol Template.

25.1.14. Describe whether the entire subject population or a portion of it is expected to have limited or no ability to provide legally effective consent.

25.1.15. Describe the process to determine whether an individual is capable of consent.

25.1.16. Describe the process to determine whether a prospective subject is capable of providing consent. Include who will be responsible for determining capacity and how it will be documented.

25.1.17. Describe how the participant's decisional capacity will be assessed as the study proceeds in order to evaluate any fluctuation in the participant's level of capacity to consent.

25.1.18. If it can be anticipated that some or all subjects will regain capacity to provide consent, describe the provisions to provide them with information about their participation in the research and to seek their consent for ongoing participation, if applicable.

25.1.19. For research conducted in New Mexico, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative."

25.1.20. For research conducted outside of the New Mexico, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research.

25.1.21. Describe how the representative's authority to provide consent will be confirmed.

25.1.22. Describe the process for assent of the subjects. Indicate whether:

- *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
- *If assent will not be obtained from some or all subjects, an explanation of why not.*
- *Describe whether assent of the subjects will be documented and the process to document assent.*

Minor Subjects (*individuals who are under the age of 18)*

N/A/ This study will not enroll individuals under the age of 18. We are recruiting individuals employed as nurse faculty or staff at the UNM HSC.

25.1.23. Provide the age range of the children anticipated to be enrolled in the research.

25.1.24. Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.

- *For research conducted in New Mexico, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*
- *For research conducted outside of New Mexico, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted.*

25.1.25. Describe whether parental permission will be obtained from:

- *One parent (may be permissible, if the HRRC approves, for (1) research not involving greater than minimal risk, or (2) research involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects)*
- *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. (Permissible for research involving greater than minimal risk and no prospect of direct benefit to individual subjects.)*

25.1.26. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent.

25.1.27. Indicate whether the children to be enrolled in the research should be capable of providing assent.

25.1.28. Indicate if assent will be obtained from all, some, or none of the children and provide justification. If assent will be obtained from some children, indicate which children will be asked for assent.

25.1.29. When assent of children will be obtained describe the proposed assent process and whether and how assent will be documented. The assent process and documentation of assent should be age-appropriate and may consist of different procedures for different age groups.

25.1.30. NOTE: For minors (less than 18 years of age) and per NM state law, consent and HIPAA authorization are required in order to access their mental health information and/or developmental disabilities information.

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

- *Complete the applicable checklists in the Checklists section of this Protocol Template if you are requesting a waiver or alteration of consent for this research*
- *Consent can be waived for all of some subjects (e.g., the research includes a retrospective cohort)*
- *Consent can be waived in full or in part (e.g., partial waiver for recruitment purposes)*

26. Documentation of Consent

26.1. Describe if you plan to use a consent form to document consent. Use one of the consent templates available on the HRPO website. Attach consent documents as fully editable Word documents (i.e., please don't submit protected documents or pdfs). Please include page numbers in the footer (e.g., Page 1 of XX).

A written consent form will be used to document consent for the study. Please see the attached consent form (Attachment C).

26.2. If the study is collecting and/or storing tissue samples, include a Tissue Banking Consent Form (and Authorization if the specimens will be accompanied by PHI).

26.3. Describe if you plan to obtain consent but will be using a script, information sheet, or other mechanism. If you will obtain consent verbally, attach a consent script and information sheet, if you will be providing one. If you will be obtaining consent via an on-line survey, please use the survey cover letter consent template on the HRPO website and include your email script with your submission.

Complete the checklist for "Waiver of Documentation of Consent" in the Checklists section of this Protocol Template. If you will be excluding or modifying one or more of the required elements of consent you will also need to request an Alteration of Consent.

NOTE: If FDA regulated, there is no provision for waiver of written documentation of consent.

27.Study Test Results/Incidental Findings

27.1. ***Individual Results:*** *Indicate whether you intend to share study test or procedure results with study participants. If so, describe which results will be shared, whom the results will be shared with (e.g., subjects, parents, primary care physicians), and how the findings will be communicated (e.g., in person consultation, posting in medical record, etc.). If the findings are the results of laboratory tests, indicate whether the tests will be processed in a CLIA-certified lab.*

Specific results of questionnaires and physiologic data will not be shared with individual study participants.

27.2. ***Incidental Findings:*** *Based upon the nature of the research, and the tests that will be performed, indicate if you anticipate that the research may result in incidental findings (traditionally defined as results that arise that are outside the original purpose for which the test or procedure was conducted (for example, a potential tumor is identified but this is not the reason imaging was obtained). If so, please describe your plans for communication of such results to subjects and their health care providers, if appropriate. If there are limitations on the accepted validity of the results (e.g., test performed in non-CLIA lab, test available in the context of research only), please describe and provide a plan for confirmatory testing or justification for why it is not recommended, not necessary, or not possible. If you do not plan to provide results, provide justification.*

- *Be certain to describe your plans for provision of study results and incidental findings in your consent documents.*
- *For more information on incidental findings, please consult the President's Bioethics Commission Report "Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts":* https://bioethicsarchive.georgetown.edu/pcsbi/node/3183.html
- *For information specific to Whole Genome Sequencing, please consult the President's Bioethics Commission Report "Privacy and Progress in Whole Genome Sequencing":* https://bioethicsarchive.georgetown.edu/pcsbi/node/764.html

Incidental Findings: It is possible that during this study unexpected findings may arise during structured interviews and we acknowledge these in the consent form. Anticipated potential findings may include clinically significant symptoms of anxiety. A trained research team member will provide the participant with information related to the UNM Counseling, Assistance, & Referral Services (CARS).

28.Sharing Study Progress or Results with Subjects

28.1. Describe whether you intend to provide subjects with a summary of the trial progress while the study remains underway. If so, describe your plans and the mechanisms that you will use (e.g., newsletter, handouts, mailings, etc.). Please

note that all written materials that will be provided to subjects need to be reviewed and approved by the HRRC prior to use.

While the study is underway, we will not provide summaries of progress.

28.2. Describe whether you intend to provide subjects with a summary of the study results after the study is complete. If so, indicate if the information will include study arm assignment if the study involved blinding. Please describe your plans for dissemination of results and the mechanisms that you will use. Please note that HRRC review of materials may be required, consult with the HRPO prior to distribution.

After completion of the study, de-identified, aggregate results will be disseminated through presentations and publications.

29. Inclusion of Vulnerable Populations

29.1. If the research involves individuals who are vulnerable to coercion or undue influence, describe who will be included, why their participation is necessary or warranted, and any additional safeguards included to protect their rights and welfare. The following is not intended to serve as a comprehensive list, rather to provide some examples for your consideration.

29.1.1. If the research includes students or employees, describe protections to promote the voluntary nature of participation and minimize the risks associated with access to or use of data by persons in a position of actual or perceived authority.

In order to promote the voluntary nature of participation of UNM HSC employees, during the consent process, potential participants will be informed, both in writing and verbally, that their participation in the study is voluntary and that they may participate in the program without being part of the study. They will also be informed that they may discontinue the study at any point in time and that their decision to participate or decline will not affect their employment at UNM HSC or their ability to attend the yoga and meditation sessions.

29.1.2. If the research includes economically disadvantaged persons, describe the mechanisms to promote the voluntary nature of participation and to minimize economic risks associated with participation.

29.1.3. If the research includes educationally disadvantaged persons, describe the mechanisms to ensure that they are provided information and materials that enhance their ability to understand the research initially and throughout their participation in the research.

29.1.4. If the research includes seriously or terminally ill patients, describe the mechanisms to ensure that they understand the true purposes of the research, the risk it entails, and what is known or not understood about the likelihood of individual benefit

29.1.5. If the research involves pregnant women, note this here and complete the Pregnant Women Checklist in the Checklist Section of this Protocol Template.

29.1.6. If the research involves neonates of uncertain viability or non-viable neonates, note this here and complete the applicable checklist in the Checklist Section of this Protocol Template.

Note: For the purposes of the federal research regulations, viability is established shortly after delivery. "Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration." Once a neonate has been determined viable, they are considered a child under the regulations.

29.1.7. If the research involves prisoners, note this here and complete the Prisoners Checklist in the Checklist Section of this Protocol Template.

29.1.8. If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), note this here and complete the Children Checklist in the Checklist Section of this Protocol Template.

29.1.9. If the research involves cognitively impaired adults, note this here and complete the Cognitively Impaired Adults Checklist in the Checklist Section of this Protocol Template.

30.Community-Based Participatory Research

30.1. Describe involvement of the community in the design and conduct of the research. If members of the community will fulfill key research responsibilities such as recruitment and consent, describe what research activities community members will be responsible for, how they will be trained, and the plan for quality oversight. When relevant, please include information regarding the approval of the research at collaborating sites (e.g., Albuquerque Public Schools).

Note: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

N/A. This study is not community-based participatory research.

31.Research Involving American Indian/Native Populations

31.1. Please provide detailed information of the local research context including how the research questions are sensitive to community attitudes and how the PI has ascertained that the proposed research is acceptable to the local population in terms of tribal regulations, applicable law and standards of professional

conduct and practice. Attach any supporting documents from tribal officials or entities addressing the status or requirements for review of the research activity from tribal officials or tribal entities (for example, Indian Health Services, the Navajo Nation IRB).

This research does not specifically sample American Indian/Native Populations.

32. Transnational Research

32.1. When conducting transnational research, you must ensure that subjects are provided equivalent and appropriate protections for human subjects located outside of the United States. Please refer to the following website for current OHRP interpretations of research standards, equivalent protections, and for a current compilation of international research standards and regulatory agencies. http://www.hhs.gov/ohrp/international/index.html

N/A

32.2. ***Location:*** *Describe the research locale and how and why the setting was chosen. Describe significant cultural norms, local laws, and differences with U.S. culture with respect to autonomy, perception of research, recruitment, consent, age of majority, parental permission, etc.*

32.3. ***Study Personnel:*** *Describe the qualifications of the researcher and research team to perform research in the community/culture where it will occur. Indicate the research team's ability to speak, read, and write the language of the subjects. Describe the researcher's knowledge of or expertise in local or state laws, culture, and community norms. Indicate if the researcher was invited into the community (provide documentation, if available). If not invited, then describe how the researcher will have culturally appropriate access to the community.*

32.4. ***Consent:*** *Describe the consenting procedure that you intend to use for the research and why it is appropriate for the community where the research will occur. Describe how you will ensure that potential subjects understand the research, and the voluntariness of their participation.*

32.5. ***Community Consultation:*** *Describe any plans for community consultation to assess receptiveness to the proposed research and to obtain feedback on how it should be conducted and any limitations or boundaries that should be respected. Describe plans for dissemination of results to subjects and to the community.*

33. Drugs or Devices

33.1. If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

This study will use a commercially available Garmin device. Garmin Vivosmart5® uses optical technology in which a series of lights emitted by

photoplethysmography (PPG) sensors against the skin illuminate capillaries to detect changes in blood volume and providing heart rate data in real time.[31]

33.2. If the drug is investigational (has an IND), identify the holder of the IND/IDE/Abbreviated IDE.

33.3. For research involving drugs, complete and attach a signed "Drug Attachment", available in Huron IRB or the HRPO website

33.4. For research involving devices, complete the "Device Checklist" in the Checklist Section of this template.

N/A

34. Principal Investigator's Assurance

By submitting this study in the Huron IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ The PI attests that all electronic research records/data will be locally stored on the N:\Research-Studies network drive. This drive is established by the Information Security Office (HSC-ISO@salud.unm.edu).

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is to be directly entered onto a data collection form that is stored in a secured access folder on HSC central IT managed network storage (N:\Research-Studies network drive), or in a secure HSC Information Security approved system such as REDCap during the data collection phase. At the time of the study closure, the data needs to be transferred to the N:\Research-Studies network drive.
2. **Temporary storage -- de-identified data collection**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be temporarily stored using encrypted removable (e.g. CD-ROM (a compact disc used as a read-only optical memory device for a computer system), USB flash/thumb drive (a small external flash drive that can be used with any computer that has a USB port), etc.) media or a university owned electronic storage device or hard copy document. This temporarily stored data must be transferred to HSC central IT managed network storage and deleted from the temporary device as soon as possible. **The important security safeguard is that no identifiers be included if the data is entered or stored using a storage container that is not managed by HSC central IT.**
3. **Permanent (during data analysis, after study closure) storage** must reside on HSC central IT managed network storage (N:\Research-Studies network drive). Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted or unsecure storage devices/computers

(an example of an unapproved storage location would be storing the data locally on your HSC computer hard drive rather than on the HSC network drives). Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.

4. **Alternate storage media** must be approved by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

35.CHECKLIST SECTION

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

36.Partial Waiver of Consent for Screening/Recruitment

Complete this checklist if you are requesting a partial waiver of consent so that you can review private information to identify potential subjects and/or determine eligibility prior to approaching potential subjects for consent or parental permission.

A. Describe the data source that you need to review (e.g., medical records):

B. Describe the purpose for the review (e.g., screening):

C. Describe who will conducting the reviews (e.g., investigators, research staff):

D. Do all persons who will be conducting the reviews already have permitted access to the data source?

☐ Yes

☐ No. Explain:

i. Verify that each of the following are true or provide an alternate justification for the underlined regulatory criteria:

1. <u>The activity involves no more than minimal risk to the subjects</u> because the records review itself is non-invasive and the results of the records review will not be used for any purposes other than those described above.

☐True

☐Other justification:

2. <u>The waiver or alteration will not adversely affect the rights and welfare of the subjects</u> because eligible subjects will be approached for consent to participate in the research and are free to decline. Further, the information accessed during the records review will not be disclosed to anyone without a legitimate purpose (e.g., verification of eligibility).

☐ True

☐ Other justification:

3. The research could not practicably be carried out without the waiver or alteration because there is no other reasonably efficient and effective way to identify who to approach for possible participation in the research.

   ☐True

   ☐Other justification:

4. Whenever appropriate, potentially eligible subjects will be presented with information about the research and asked to consider participation. *(Regulatory criteria: Whenever appropriate, the subjects will be provided with additional pertinent information after participation.)*

   ☐True

   ☐Other justification:

37.Partial Waiver of HIPAA Authorization for Screening/Recruitment

Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

   ☐ Yes. Describe:

   ☐ No

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

   ☐ True

   ☐ False

38.Waiver of Documentation of Consent

Complete this checklist if you intend to obtain consent verbally but will not be obtaining signatures from subjects on a consent form to document consent. Waivers of documentation of consent are commonly requested when using scripts, information sheets, or email or survey introductions to present the elements of consent instead of using a traditional consent form.

A. Are you requesting a waiver of documentation of consent for some or all subjects?

☐All

☐Some. Explain:

B. Provide justification for one of the following:

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

ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

C. Do you intend to provide subjects with a written statement regarding the research in lieu of a traditional consent form?

☐Yes. Please attach a copy to your submission in Huron IRB.

☐No

39.Alteration of Consent

Complete this checklist if you intend to obtain consent but will be eliminating or altering one or more of the required elements of consent. Alterations of consent are commonly requested for research involving deception or for minimal risk research when an abbreviated consent is desired and one or more of the required elements are not relevant to the research.

Note: FDA-regulated research is not eligible for an alteration of consent.

A. Which element(s) of consent do you wish to eliminate and why?

B. Which element(s) of consent do you wish to alter and why?

C. Provide justification for each of the following regulatory criteria:

i. The research involves no more than minimal risk to the subjects:

ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects:

iii. The research could not practicably be carried out without the waiver or alteration:

iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

40. Full Waiver of Consent/Parental Permission

Complete this checklist if you are requesting a full waiver of consent for all subjects or certain subject groups (e.g., retrospective cohort). Full waivers of consent are commonly requested when the research does not include any opportunity for interaction with subjects (e.g., chart review).

Note: FDA-regulated research is not eligible for a full waiver of consent using these criteria. If you believe that your FDA-regulated research may be eligible for a waiver under another mechanism, such as planned emergency research, contact the HRPO for assistance in determining what information to provide to the HRRC.

A. Are you requesting a waiver for some or all subjects?

☐All

☐Some. Explain:

B. Provide justification for each of the following regulatory criteria:

i. The research involves no more than minimal risk to the subjects:

ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects:

iii. The research could not practicably be carried out without the waiver or alteration:

iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

41. Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs)

Complete this checklist if you are requesting a full waiver of consent for all subjects or certain subject groups (e.g., retrospective cohort) and the research involves the evaluation of a public benefit or service program.

A. Are you requesting a waiver for some or all subjects?

☐All

☐Some. Explain:

B. Provide justification for each of the following regulatory criteria:

i. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs:

ii. The research could not practicably be carried out without the waiver or alteration.

42. Full Waiver of HIPAA Authorization (Checklist)

Complete this checklist if you are requesting a full waiver of the requirement to obtain HIPAA authorization for all subjects or certain subject groups (e.g., retrospective cohort). Full waivers of HIPAA authorization are commonly requested when the research does not include any opportunity for interaction with subjects (e.g., chart review).

A. Are you requesting a waiver of authorization for some or all subjects?

☐All

☐Some. Explain:

B. Describe your plan to protect health information identifiers from improper use and disclosure:

C. Describe your plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so):

D. Describe why the research could not practicably be conducted without the waiver or alteration:

E. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

☐True

☐False

43. Other Waiver Types (Checklist)

If you are seeking another waiver type (e.g., Planned Emergency Research, Waiver of Parental Permission to Protect Child Participants, Enforcement Discretion for In Vitro Diagnostics, etc. contact the HRPO office for assistance in determining what information to submit for the HRRC's consideration.

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44. Vulnerable Populations (Checklist)

A. Adults with Cognitive Impairments

Complete this checklist if the subject population will include adults with cognitive impairments.

This checklist does not need to be completed if the research doesn't involve interactions or interventions with subjects and will be conducted under a waiver of consent.

1. Describe why the objectives of the study cannot be met without inclusion of adults with cognitive impairments.

2. Describe how capacity to consent will be evaluated.

3. If subjects may regain capacity to consent, or if subjects may have fluctuating capacity to consent, describe your plans to evaluate capacity to consent throughout the research and to obtain consent to continue participation if capacity is regained.

4. Describe your plans, if any, to provide information about the research to subjects and the steps you will take to assess understanding.

5. Describe your plans to obtain assent, including whether assent will be obtained from none, some, or all subjects.

6. Describe why risks to subjects are reasonable in relation to anticipated benefits to the subjects.

7. If this study involves a health or behavioral intervention, describe why the relation of the anticipated benefit to the risk of the research is at least as favorable to the subjects as that presented by alternative procedures.

8. Describe your plans for monitoring the well-being of subjects including any plans to withdraw subjects from the research if they appear to be unduly distressed.

B. Children

Complete this checklist if the subject population will include children.

1. Select the category of research that you believe this research falls within and provide justification for any associated criteria. If there are different assessments for different groups of children or arms (e.g., placebo vs. drug), include a memo to provide an assessment for each group.

   ☐Research not involving greater than minimal risk. *(Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*

   ☐Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

   Provide justification for each of the following criteria:

   (1) The risk is justified by the anticipated benefit to the subjects:

(2) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches:

☐Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Provide justification for each of the following criteria:

(1) The risk represents a minor increase over minimal risk:

(2) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

(3) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition

C. Pregnant Women and Fetuses

Complete this checklist if the subject population will include pregnant women and fetuses.

This checklist does not need to be completed if the research is both minimal risk and is not conducted, funded, or otherwise subject to regulation by DHHS, DOD, EPA, or VA.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; ***or***, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

3. Any risk is the least possible for achieving the objectives of the research.

D. Neonates of Uncertain Viability or Nonviable Neonates
Complete this checklist if the subject population will include neonates of uncertain viability.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

3. Individuals engaged in the research will have no part in determining the viability of a neonate.

4. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, ***or***, the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research

E. Nonviable Neonates
Complete this checklist if the subject population will include nonviable neonates.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

3. Individuals engaged in the research will have no part in determining the viability of a neonate.

4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Verify each of the following:

5. Vital functions of the neonate will not be artificially maintained

   ☐True

   ☐False

6. The research will not terminate the heartbeat or respiration of the neonate

   ☐True

   ☐False

7. There will be no added risk to the neonate resulting from the research

   ☐True

   ☐False

F. Biomedical and Behavioral Research Involving Prisoners

Complete this checklist if the subject population will include prisoners.

Note: Minimal risk for research involving prisoners is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

1. Select and justify which allowable category of research involving prisoners this research falls within:

   ☐Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

   ☐Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

☐Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)

☐Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject

☐Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than Minimal Risk and no more than inconvenience to the subjects, and Prisoners are not a particular focus of the research.

2. Provide justification for each of the following regulatory criteria:

    a) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired

    b) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers

    c) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless justification is provided, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project

    d) The information is presented in language which is understandable to the subject population

e) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole

f) When appropriate, adequate provision has been made for follow up examination or care after research participation, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact

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45.Medical Devices (Checklist)

Complete this checklist if the research evaluates the safety or effectiveness of a medical device. If more than one medical device is being evaluated, provide the requested information for each.

Ambulatory assessment of physiological processes will occur through use of a wearable wrist electronic sensor, Garmin Vivosmart5®, which uses optical technology. The Garmin device is commercially available and being used for the intended purpose. The Garmin device is not being used as a medical device it is only a research measurement tool and the data that it records is not being monitored in real-time by the study team. Safety and effectiveness of this device are not being evaluated.

A. Device Name:

B. Manufacturer:

C. Does the research involve a Significant Risk Device under an IDE?

☐Yes. Include documentation of the FDA approval of the IDE with your submission. *Acceptable methods of documentation include: (1) FDA letter noting IDE number and approval status; (2) Industry sponsor letter noting IDE number and FDA approval status; or (3) FDA-approved industry sponsor protocol with IDE number noted*

☐No

D. Is the research IDE-exempt?

☐Yes. Include a FDA letter with your submission noting the determination that the research is IDE-exempt or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is IDE-exempt*.

☐No

E. Does the research involve a Non-Significant Risk (NSR) Device?

☐Yes. Include a FDA letter with your submission noting the determination that the research is NSR or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is NSR**.

☐No

* This FDA guidance includes a description for when a device study is exempt from the IDE requirements:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf

**This FDA guidance includes information on how to differentiate between Significant Risk and Non-Significant Risk device studies:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

46. Export Control (Checklist)

Indicate if there will be export control concerns (i.e., select agents or select toxins involved in the project, collaboration with foreign institution or foreign nationals, publication restrictions, foreign travel, etc.).

47. Data Transfer/Sharing/Storage (Checklist) (required –do not delete even if the answer is "No")

Data Use Agreement (DUA) Contacts:
Sponsored Projects Office

- HSC-PreAward@salud.unm.edu

Privacy Office

- HSC-Privacy@salud.unm.edu

Information Security Office

- HSC-ISO@salud.unm.edu

NOTE: For any data transfer/sharing questions or for help filling out this section, please email all contacts listed above.

All information stated in this section must be congruently stated in all other applicable sections of the protocol.

Provide all information requested, meaning all questions must be answered, if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will UNM data be transferred/shared with an external entity (i.e. another institution, company, etc.) or will an external entity's data be transferred/shared with UNM?

☐Yes. **If yes, all questions must be answered congruently based on protocol provisions.**

- If yes, does this research involve federal funding: ☐Yes ☐No
  - If yes, provide the name of the funder:

☐ No. **If no, the remainder of this section does not apply.**

☐ The data is publicly available. **If the data is publicly available a data use agreement is not required and the remainder of this section does not apply.** "Publicly available" refers to data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges. Examples include data/biospecimens available for public purchase, searchable online, or available at a library.

Examples of types of identifiable data/biospecimens that are not considered publicly available are as follows:

Data in the electronic medical record;

Social media data labeled as "private" by the data owner, or not readily available without permission of the site Owner/Administrator under the Terms of Service of the site;

Data protected by Copyright; and

Data or biospecimens that have access restrictions (e.g. are only available to clinicians or qualififed researchers or may only be accessed on a secure server.

B. Indicate if the data is incoming, outgoing or both:

C. Provide the name of the entity(s) that data will be transferred/shared with, if incoming:

D. Provide the name of the entity(s) that data will be transferred/shared with, if outgoing:

E. Provide the external entity(s) contact name, email and phone number with whom the data agreement is going to be negotiated and executed with (i.e. Sponsored Projects Office contact or contracts department as applicable). List contact information for each external entity(s) that are involved with the project.

Contact Name	External Entity	Email	Phone Number

F. Who is responsible for transmission of the data (include name, email address and phone number)?

G. Who is responsible for receiving the data (include name, email address and phone number)?

H. Describe how the data will be securely transmitted/shared. If using an externally managed data transfer system, please include details about the system such as the URL for the site and information about who manages the security and maintenance. **Please note data cannot be transmitted/shared without assistance from UNM HSC Central IT. Request UNM HSC Central IT transfer from the ISO office at HSC-ISO@salud.unm.edu. This means data cannot be transferred via email, cloud storage services such as Dropbox, OneDrive, and fax.**

☐ UNM HSC Secure File Transfer Protocol (SFTP)

☐ UNM HSC REDCap

☐ Other External Solution, and clarify:

I. For data being received/shared with non-HSC locations or entities, describe the following:

1. Where will data be stored and how will it be protected? UNM HSC requires data storage on the N:\Research -Studies network drive (i.e. encryption, password protection, access controls, use of REDCap, etc)?
    - **If** REDCap, who manages/owns REDCap (i.e. UNM HSC or other external entity)?
    - **If** REDCap or other external system is not UNM HSC REDCap managed/owned, please provide the name and contact information of owner and the access (login) link?

        Provide IT security point of contact details for externally managed/owned REDCap:
2. What is the method being used for data collection and storage (i.e. electronic, hard copy, etc.)?
3. How long will the data be stored? Must be congruent with section 16.
4. Who will have access to data?

J. Please list all specific data elements to be sent out (outgoing) and/or received (incoming) in the table below. If there are extensive data elements being shared, please summarize in the table below, and provide the document file name that contains the full list of data elements.

List Sponsor or Outside Entity	What is the classification of the data? Please indicate which of the following applies:	List Incoming Data Elements	List Outgoing Data Elements

	De-identified Data; Limited Data Set; Protected Health Information See definitions after question "P".		

K. If the research requires the access, use, or disclosure of **any** of the 18 individually identifiable protected health information (PHI) identifiers that can be used to identify, contact, or locate a person (e.g., name, medical record number, etc.), are the subjects going to consent to or authorize the disclosure of their individually identifiable health information?

☐Yes (If yes, ensure section 25. Consent Process completed)

☐No. If no, is HIPAA authorization altered or waived? If altered or waived, provide details:

L. Does the request to transfer/share data include clinical data that belongs to the UNM Health System? If data originates from the UNM Health System medical records, this question should be answered "Yes". ☐Yes ☐No

M. Is the external entity a "covered entity"? (HIPAA-covered entities include health care providers (i.e. hospitals, doctors, academic health centers), health plans, and clearinghouses.): ☐Yes ☐No

N. For outgoing data, is the data that is going to be transferred/shared owned or partially owned by another party? ☐Yes ☐No ☐NA, data is incoming only
If yes, please provide details:

O. Does the data have any restrictions other than HIPAA? ☐Yes ☐No
If yes, please provide details:

P. Does the data include information about substance abuse treatment, sexually transmitted diseases, genetic testing results, HIV/AIDS testing results, and/or mental health?
☐Yes ☐No
If yes, please provide details:

DEFINITIONS

DE-IDENTIFIED DATA: Identifiers That Must Be Removed to Make Health Information De-Identified:

(i) The following 18 identifiers must be removed of the individual or of relatives, employers or household members of the individual must be removed: (A) Names; (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; ***and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;*** (D) Telephone numbers; (E) Fax numbers; (F) Electronic mail addresses; (G) Social security numbers; (H) Medical record numbers; (I) Health plan beneficiary numbers; (J) Account numbers; (K) Certificate/license numbers;(L) Vehicle identifiers and serial numbers, including license plate numbers; (M) Device identifiers and serial numbers; (N) Web Universal Resource Locators (URLs); (O) Internet Protocol (IP) address numbers; (P) Biometric identifiers, including finger and voice prints; (Q) Full face photographic images and any comparable images; and (R) Any other unique identifying number, characteristic, or code; and (ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

LIMITED DATA SET: A "limited data set" is a limited set of identifiable patient information as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act (HIPAA). A "limited data set" is information from which "facial" identifiers have been removed. A "limited data set" is information from which "facial" identifiers have been removed. Specifically, as it relates to the individual or his or her relatives, employers or household members, all the following identifiers must be removed in order for health information to be a "limited data set": names; street addresses (other than town, city, state and zip code); telephone numbers; fax numbers; e-mail addresses; Social Security numbers; medical records numbers; health plan beneficiary numbers; account numbers; certificate license numbers; vehicle identifiers and serial numbers, including license plates; device identifiers and serial numbers; URLs; IP address numbers; biometric identifiers (including finger and voice prints); and full-face photos (or comparable images).
The health information that may remain in the information disclosed includes: dates such as admission, discharge, service, DOB, DOD;
city, state, five digit or more zip code; and
ages in years, months or days or hours.
It is important to note that this information is still protected health information or "PHI" under HIPAA. As a limited data set the information is still subject to the requirements of the federal and state privacy and security regulations.

PROTECTED HEALTH INFORMATION (PHI): PHI is defined as any individually identifiable health information collected or created as a consequence of the provision of

health care by a covered entity, in any form, including verbal communications. PHI is information that can be linked to a particular person and that is created, used, or disclosed in the course of providing a health care service (i.e., diagnosis or treatment). There are 18 PHI identifiers as listed in the de-identified data definition section.

48. Specimen Transfer/Sharing (Checklist) (required –do not delete even if the answer is "No")

Please submit your material transfer agreement (MTA) request through Click ERA Agreements module so that Sponsored Projects Office (SPO) can begin working with you on the MTA. For any questions contact SPO via HSC-PreAward@salud.unm.edu.

Provide all requested information if the research involves transferring/sharing of specimens with an external entity (institution, company, etc.).

A. Will specimens be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes. **If yes, all questions must be answered congruently based on protocol provisions.**

☒No. **If no, the remainder of this section does not apply.**

B. Indicate if the specimens are incoming and/or outgoing:

C. Provide a description of the material/specimen that will be transferred/shared with the external entity:

D. Provide the name of the entity that specimens will be being transferred/shared with:

E. Provide the contact name, email and phone number with whom specimens are being transferred/shared with:

F. Who is responsible for sending out the specimens? Please note specimens cannot be sent out without a fully executed material transfer agreement.

G. Who is responsible for receipt of the specimens? Please note specimens cannot be received without a fully executed material transfer agreement.

H. For specimens being transferred/shared with outside locations or entities, describe the following:

1. *Where is specimen storage and how will it be maintained in a secure manner?*
2. *What is method in which specimens will be collected and stored?*
3. *How long will the specimens be stored?*
4. *Who will have access to the specimens?*