Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 6, 21, 22, 24, 25, 26 and 27 do not apply.*
    - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response Example
Intervention Group:
Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Piloting an evidence-based mobile mindfulness practice to support self-management among Underserved and Racial Minority Adults with Pulmonary Hypertension

PRINCIPAL INVESTIGATOR:

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Department
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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response: Version 6

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	8/24/21	Original	
2	9/13/21	To provide details about waiver of signature consent. Verbal consent as described in Section 29.1, 29.2, 29.3, and 29.4	
3	3/9/22	Change health related quality of life questionnaire from CAMPHOR to EmPHasis-10 and change the method of payment to US Bank Debit card	
4	4/28/22	Change to expand inclusion criteria to include PH patients throughout the US.	
5	6/13/22	Change Study inclusion criteria to include PH patients of ALL ethnicity, not just PH patients who self-identified as an underserved racial minority (URM) group.	

6	7/17/22	Change Study exclusion criteria to remove the first two exclusions: "Current user of mindfulness mobile App" and "Current participation in mind-body practice (yoga, Tai chi, or Qi Gong)."	
7	9/15/22	Clarification of research activity participation by PH doctors at URMC and Rochester Regional Health	yes

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response: CTSI Pilot Study Grant, a Seed grant from UB SON

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: Potential funding from the 2021 CTSI Pilot Study

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response: Electronic research files will be kept in a dedicated Folder for this specific research project in UB Box, password protected according to the UB SON guidelines.

Location: UB BOX Research File

Address: 3435 Main Street Wende Hall # 201F, Buffalo, NY, 14214

Department: School of Nursing

1.0 Study Summary

Study Title	Piloting an evidence-based mobile mindfulness practice to support self-management among Underserved and Racial Minority Adults with Pulmonary Hypertension

Study Design	two-group comparative study design where waitlisted participants will serve as controls.
Primary Objective	to determine the feasibility, acceptability, and preliminary impacts of the Mindfulness Meditation for PH (MMPH) mobile-health program in URM adults with PH in symptom management and quality-of-life
Secondary Objective(s)	None
Research Intervention(s)/ Investigational Agent(s)	Mindfulness Meditation for PH (MMPH) mobile-health program
IND/IDE #	None
Study Population	Community-dwelling URM adults diagnosed with PH condition
Sample Size	20
Study Duration for individual participants	16 weeks (2 months) 18 participation (8 weeks for the intervention and eight weeks for follow up)
Study Specific Abbreviations/ Definitions	URM=underserved racial minority; PH=pulmonary hypertension; HRQOL=health-related quality of life; MMPH=mindfulness meditation for PH; GBM=gentle body movement; BAM=body awareness meditation; PAHSS= Pulmonary Arterial Hypertension Symptoms Scale; EmPHasis-10= Health-related quality of life in pulmonary arterial hypertension; PHQ-9=Patient Health Questionnaire; CAMS-R= Cognitive and Affective Mindfulness Scale-Revised; SUS= System Usability Scale

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives of this research.

Aim 1: To determine the feasibility and acceptability of the MMPH in community-dwelling URM adults with PH as a symptom self-management tool.

Aim 1a: Feasibility will be assessed by 1) frequency of home practice (> 2/week) and 2) retention rate (>70% of participants remaining at study completion).

Aim 1b: Acceptability will be determined by 1) participants' evaluation of the MMPH program (composite mean System Usability Scale score > 5, scale 1-7), 2) session completion rate (at least 6 of 8 [75% attendance] by the participants retained at the study end), and 3) qualitative thematic analysis of participants.

Aim 2: To determine the clinical impacts of an MMPH program in PH-symptom, anxiety, and depression reduction among community-dwelling URM adults with PH for symptom management.

2.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Hypothesis 1: MMPH will meet feasibility and acceptability targets for URM adults with PH

Hypothesis 2: Participants will report reductions in symptom severity of pain, anxiety, dyspnea, and fatigue at the end of the MMPH modules (short-term impacts). Participants will report decreases in the prevalence and intensity of PH-related symptoms, depression, and improved quality of life at the end of the MMPH program (long-term impacts).

3.0 Scientific Endpoints*

3.1 Describe the scientific endpoint(s), the main result or occurrence under study.

*NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should **not** be a date.*

Response: Symptom Severity Reduction per PAHSS and HRQOL improvement per EmPHasis-10.

4.0 Background*

4.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Patients with pulmonary hypertension (PH) live with a plethora of bothersome symptoms,1 of which are consequences of the severe cardiopulmonary deterioration of right-sided heart failure. Because PH pathophysiology is complicated due to multiple causes, PH diagnosis is confirmed with right-sided cardiac catheterization documenting the elevation of mean pulmonary arterial pressure > 25 mmHg with pulmonary wedge pressure < 15 mmHg.2 There are five etiological classifications of PH: idiopathic (Class I), due to left-heart diseases (Class II), due to lung diseases (Class III), due to chronic thrombolytic/embolic diseases (Class IV), and other causes (Class V).2 Class I PH or pulmonary arterial hypertension (PAH) is considered the most severe form of PH and comprises approximately 50% of the PH population. Regardless of the cause, normalizing pulmonary pressure using PH-specific drugs is the main objective of medical management. Little evidence is currently

available regarding effective self-management strategies to reduce symptom burden among under-served racial minority (URM) patients with PH. Early diagnosis and prompt initiation of pharmacological treatment have shown to improve clinical outcomes, two critical ingredients often not available to URM adults. Among patients with a sub-type of PH, PAH (pulmonary arterial hypertension), African-Americans (AA) have higher mortality rates than Caucasians, and AA women had the highest mortality rates across all ages. (3.0, 3.1) Among patients diagnosed with incidental PH, AAs were younger with significantly higher right ventricular dysfunction and were more frequently covered by Medicare than private insurance. (3.2). Therefore, URM PH patients are disproportionately affected by the disease: experiencing a significant burden of healthcare needs related to existing health disparity and limited psychological, economic, and healthcare resources. (3.3, 3.4). Even though there have been tremendous medical and pharmacologic advances in PH treatment in the past decades, patients continue to live with unmet psycho-social and behavioral health needs that impact their long-term prognoses. Despite these advancements, patients living with PH continue to suffer psychological distress such as depression, anxiety, and stress,4-10, along with a high symptom burden.11,12 Poor physiologic conditions and high psychological distress are predictive of poor quality of life among patients with PH.13-16 The physiological and psychological distress often leads to challenges in successfully managing PH conditions. A culturally tailored, innovative complementary health approach to addressing this gap is needed to augment symptom self-management, reduce symptom burden, promote health and wellness, and health-related quality of life (HRQOL).

Complementary Health Approach (CHA), defined as non-mainstream integrative therapy self-management practice of chronic conditions, has been shown to reduce symptom severity and improve quality of life (https://nccih.nih.gov/health/integrative-health).17 A mindfulness-based stress reduction (MBSR) intervention program, which includes eight 2.5-hour-weekly sessions, has been shown to reduce depression and anxiety symptoms among patients with psychiatric conditions.18 Modified MBSR programs have shown effectiveness in symptom burden,19 fatigue,19-22 and HRQOL22 among persons with cancer. While patients with cancer and other chronic conditions use the mind-body intervention (MBI) to a greater extent, MBI use among patients with PH is somewhat limited and even more so among URM adults with PH. A gentle walking exercise program is associated with improvements in six-minute walk distance, lung functions, depression, anxiety, and HRQOL.23,24 In a randomized controlled trial of 103 PAH patients, a 12-weeks progressive muscle relaxation program improved anxiety, depression, and HRQOL.25 Eight-weeks of slow-paced breathing technique was associated with a reduction in depressive symptoms, improved sleep, and HRQOL.26 A pilot, randomized controlled trial of MBSR demonstrated some improvement in psychological symptoms (depression and anxiety).27 Pilot single-group

testing of an Urban Zen Integrative Therapy (UZIT) is associated with symptom burden reduction and HRQOL improvement.28 In this UZIT study, there were pre-post session reductions in pain, anxiety, fatigue, and dyspnea, and pre-post UZIT program reductions in PH-related symptoms.28 These CHA's show positive effects on the overall psychological health; however, practical implementation of CHA is limited to the patients' ability to attend in-person sessions, adherence to prescribed home practice, and more importantly, availability of culturally tailored MBI content.

Complementary Health Approach (CHA), such as in-person MBI, has moderate effects in reducing depression and anxiety across chronic health conditions, including PH. However, these benefits were mostly demonstrated among participants who had high adherence to the intervention practice.27 Technology-assisted MBI (TeleMBI) has shown comparable efficacy with in-person MBI among persons with chronic conditions; TeleMBI has the added benefits of cost reduction and ease of implementation.29-31 TeleMBI for patients with multiple sclerosis via skype shows improvement in HRQOL, depression, anxiety, and sleep disturbance when delivered at a 5:1 ratio of participants and instructor.29 TeleMBI for patients with spinal cord injury with depression and chronic pain was superior to psychoeducational intervention in reducing depressive symptoms, anxiety, pain, and improving HRQOL.30 Online TeleMBI reduces depression and anxiety significantly compared to the control group among pregnant women with high depressive symptoms.31 The use of TeleMBI via Mobile-APP among post ICU patients has comparable impacts on depression, anxiety, and post-traumatic distress symptoms to telephone-based mindfulness delivery.32 This pilot RCT study is advancing to a large-scale study to implement TeleMBI Mobile-APP to treat post ICU symptoms. While mobile- and in-person MBI have comparable efficacy, we postulate that the mobile-MBI has the advantages of user-activated, "as needed" delivery, consistent dose delivery, and ease of use for symptom management for adults with PH. Clearly, given these advantages of mobile-MBI and in keeping with the social distancing demand of the current COVID-19 pandemic, it is imperative to test MMPH mobile MBI for PH in URM communities to address our research aims.

MMPH is a TeleMBI program tailored for URM patients with PH. The intervention is modified from an in-person UZIT program that showed clinical results in symptom severity reduction and HRQOL improvement among 14 adults with PH.28 This 8-weeks program will engage participants, employing both instructor-led and self-guided delivery of mindfulness practices (via Zoom and APP) to introduce and facilitate the training. Our experience in developing and modification of mobile-MBI APP is gleaned from current testing of a mobile-MBI APP among high-stress college students and URM African-Americans participants in Buffalo, NY. Preliminary testing of mobile-MBI among URM adults with PH is invaluable from the perspective of addressing health disparity,

making available a culturally tailored evidence-based intervention of Mindfulness for reduction of symptom burden and psychological stress reduction. More importantly, the mobile-MBI prototype can be modified and tailored with broader applications to other chronic cardiopulmonary conditions, such as chronic obstructive pulmonary disease (COPD), Asthma, and COVID-19 long-haul.

4.2 Include complete citations or references.

1. Matura LA, McDonough A, Carroll DL. Symptom prevalence, symptom severity, and health-related quality of life among young, middle, and older adults with pulmonary arterial hypertension. American Journal of Hospice & Palliative Medicine. 2016;33(3):214-221.

2. Galie N, Humbert M, Vachiery JL, et al. 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension: The joint task force for the diagnosis and treatment of pulmonary hypertension of the european society of cardiology (ESC) and the european respiratory society (ERS): Endorsed by: Association for european paediatric and congenital cardiology (AEPC), international society for heart and lung transplantation (ISHLT). Eur Heart J. 2016;37(1):67-119.

3.0 Davis, K.,K., Lilienfeld, D.,E., Doyle, R.,L., Parikh, K.,S., Stackhouse, K.,A., Hart, S.,A., Bashore, T.,M., Krasuski, R.,A., Ryan, J.,T., de Jesus Perez, V.,A., Ryan, J.,J., Talwar, ,Arunabh, Garcia, J. G.,N., Tsai, ,Halley, Moreno, ,Matthew, Lahm, ,Tim, Zamanian, R.,T., Machado, ,Roberto, Kawut, S.,M., . . . Mathai, ,Stephen. (2008). Increased mortality in african americans with idiopathic pulmonary arterial hypertension; health insurance and racial disparities in pulmonary hypertension outcomes; health disparities in pulmonary arterial hypertension and the impact of the COVID-19 pandemic; health disparities in patients with pulmonary arterial hypertension: A blueprint for action. an official american thoracic society statement. J Natl Med Association, 100(1), 69-72.

3.1 Ryan, J.,T., de Jesus Perez, V.,A., Ryan, J.,J., Talwar, ,Arunabh, Garcia, J. G.,N., Tsai, ,Halley, Moreno, ,Matthew, Lahm, ,Tim, Zamanian, R.,T., Machado, ,Roberto, Kawut, S.,M., Selej, ,Mona, & Mathai, ,Stephen. (2021). Health disparities in pulmonary arterial hypertension and the impact of the COVID-19 pandemic; health disparities in patients with pulmonary arterial hypertension: A blueprint for action. an official american thoracic society statement. Advances in Pulmonary Hypertension, 20(1), 6-15.

3.2 Parikh, K.,S., Stackhouse, K.,A., Hart, S.,A., Bashore, T.,M., Krasuski, R.,A., Ryan, J.,T., de Jesus Perez, V.,A., Ryan, J.,J., Talwar, ,Arunabh, Garcia, J. G.,N., Tsai, ,Halley, Moreno, ,Matthew, Lahm, ,Tim, Zamanian, R.,T., Machado, ,Roberto, Kawut, S.,M., Selej, ,Mona, & Mathai, ,Stephen. (2017). Health insurance and racial disparities in

pulmonary hypertension outcomes; health disparities in pulmonary arterial hypertension and the impact of the COVID-19 pandemic; health disparities in patients with pulmonary arterial hypertension: A blueprint for action. an official american thoracic society statement. Am J Manag Care. 2017;23(8):474-480, 23(8), 474-480.

3.3 Talwar, ,Arunabh, Garcia, J. G.,N., Tsai, ,Halley, Moreno, ,Matthew, Lahm, ,Tim, Zamanian, R.,T., Machado, ,Roberto, Kawut, S.,M., Selej, ,Mona, & Mathai, ,Stephen. (2017). Health disparities in patients with pulmonary arterial hypertension: A blueprint for action. an official american thoracic society statement. American Journal of Respiratory and Critical Care Medicine, 196(8), e32-e47.

3.4 DuBrock, ,H.M., Burger, ,C.D., Bartolome, ,S., Feldman, ,J.P., Rosenzweig, ,E.B., Sager, ,J.S., Presberg, ,K.W., Mathai, ,S.C., Lammi, ,M.R., & Klinger, ,J.R. (2021). Health disparities and treatment patterns in portopulmonary hypertension and idiopathic pulmonary arterial hypertension: An analysis of the pulmonary hypertension association registry. Pulmonary Circulation, 11(3), 1-10.

4. Halimi L, Marin G, Molinari N, et al. Impact of psychological factors on the health-related quality of life of patients treated for pulmonary arterial hypertension. Journal of psychosomatic research. 2018;105:45-51.

5. Harzheim D, Klose H, Pinado FP, et al. Anxiety and depression disorders in patients with pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. Respiratory research. 2013;14(104):1-10.

6. J MMV, Delcroix M, Vandevelde E, et al. Emotional symptoms and quality of life in patients with pulmonary arterial hypertension. Journal of Heart and Lung Transplantation. 2014;33(8):800-8.

7. McCollister DH, Beutz M, McLaughlin V, et al. Depressive symptoms in pulmonary arterial hypertension: Prevalence and association with functional status. Psychosomatics: Journal of Consultation and Liaison Psychiatry. 2010;51(4):339-339.

8. Somaini G, Hasler ED, Saxer S, et al. Prevalence of anxiety and depression in pulmonary hypertension and changes during therapy. Respiration. 2016;91(5):359-66.

9. Von Visger TT, Kuntz KK, Phillips GS, Yildiz VO, Sood N. Quality of life and psychological symptoms in patients with pulmonary hypertension. Heart & Lung: The Journal of Acute and Critical Care. 2018;47(2):115-121.

10. Aguirre-Camacho A, Moreno-Jimenez B. Depression and anxiety in patients with pulmonary hypertension: The role of life satisfaction and optimism. Psychosomatics. 2018;59(6):575-583.

11. Matura LA, McDonough A, Carroll DL. Health-related quality of life and psychological states in patients with pulmonary arterial hypertension. Journal of Cardiovascular Nursing. 2014;29(2):178-184.

12. Matura LA, McDonough A, Carroll DL. Symptom interference severity and health-related quality of life in pulmonary arterial hypertension. Journal of pain and symptom management. 2016;51(1):25-32.

13. Halank M, Einsle F, Lehman S, et al. Exercise capacity affects quality of life in patients with pulmonary hypertension. Lung. 2013;191(4):337-43.

14. Talwar A, Sahni S, Kim EJ, Verma S, Kohn N. Dyspnea, depression and health related quality of life in pulmonary arterial hypertension patients. Journal of exercise and rehabilitation. 2015;11(5):259-65.

15. Tartavoulle TM. A predictive model of the effects of depression, anxiety, stress, 6-minute-walk distance, and social support on health-related quality of life in an adult pulmonary hypertension population. Clinical nurse specialist CNS. 2015;29(1):22-8.

16. Yorke J, Deaton C, Campbell M, et al. Symptom severity and its effect on health-related quality of life over time in patients with pulmonary hypertension: A multisite longitudinal cohort study. Nursing & health sciences. 2018;5(1):1-8.

17. NCCIH. Complementary, alternative, or integrative health: What's in a name? https://nccih.nih.gov/health/integrative-health#types. Updated June, 2016.

18. Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. J Consult Clin Psychol. 2010;78(2):169-183.

19. Kenne Sarenmalm E, Martensson LB, Andersson BA, Karlsson P, Bergh I. Mindfulness and its efficacy for psychological and biological responses in women with breast cancer. Cancer Med. 2017;6(5):1108-1122.

20. Johns SA, Brown LF, Beck-Coon K, et al. Randomized controlled pilot trial of mindfulness-based stress reduction compared to psychoeducational support for persistently fatigued breast and colorectal cancer survivors. Support Care Cancer. 2016;24(10):4085-4096.

21. Lengacher CA, Reich RR, Paterson CL, et al. Examination of broad symptom improvement resulting from mindfulness-based stress reduction in breast cancer survivors: A randomized controlled trial. J Clin Oncol. 2016;34(24):2827-2834.

22. Reich RR, Lengacher CA, Alinat CB, et al. Mindfulness-based stress reduction in post-treatment breast cancer patients: Immediate and

sustained effects across multiple symptom clusters. J Pain Symptom Manage. 2017;53(1):85-95.

23. Bussotti M, Gremigni P, Pedretti RFE, et al. Effects of an outpatient service rehabilitation programme in patients affected by pulmonary arterial hypertension: An observational study. Cardiovasc Hematol Disord Drug Targets. 2017;17(1):3-10.

24. Brown MB, Kempf A, Collins CM, et al. A prescribed walking regimen plus arginine supplementation improves function and quality of life for patients with pulmonary arterial hypertension: A pilot study. Pulmonary circulation. 2018;8(1):1-12.

25. Li Y, Wang R, Tang J, et al. Progressive muscle relaxation improves anxiety and depression of pulmonary arterial hypertension patients. Evidence-Based Complement and Alternative Medicine. 2015;2015:1-8.

26. Matura LA, Fargo J, Fritz JS, et al. Slow-paced respiration therapy to treat symptoms in pulmonary arterial hypertension. Heart & Lung. 2017;46(1):7-13.

27. Tulloh RMR, Garratt V, Tagney J, et al. A pilot randomised controlled trial investigating a mindfulness-based stress reduction (MBSR) intervention in individuals with pulmonary arterial hypertension (PAH): The PATHWAYS study. Pilot Feasibility Study. 2018;4(78):1-11.

28. Von Visger TT, Thrane SE, Klatt MD, et al. The impact of urban zen integrative therapy on symptoms and health-related quality of life for patients with pulmonary hypertension. Journal of Palliative Care Medicine. 2019;23(5):703-711.

29. Cavalera,C., Rovaris,M., Mendozzi,L., et al. Online meditation training for people with multiple sclerosis: A randomized controlled trial; Multiple Sclerosis. 2018;25(4):610-617.

30. Hearn J,H., Finlay K,A., Yang,E., Schamber,E., Meyer RM,L., Gold J,I. Internet-delivered Mindfulness for people with depression and chronic pain following spinal cord injury: A randomized, controlled feasibility trial. Spinal Cord. 2018;56(8):750-756.

31. Yang,E., Schamber,E., Meyer RM,L., Gold J,I. Happier healers: Randomized controlled trial of mobile Mindfulness for stress management. The Journal of Alternative and Complementary Medicine. 2018;24(5):505-513.

32. Cox C,E., Hough C,L., Jones D,M., et al. Effects of mindfulness training programmes delivered by a self-directed mobile app and by telephone compared with an education programme for survivors of critical illness: A pilot randomised clinical trial. Thorax. 2018;74(1):33-42.

33. Elflein J. Percentage of adults in the US with chronic obstructive pulmonary disease (COPD) as of 2017, by smoking status and age.

https://www.statista.com/statistics/1019957/copd-prevalence-among-adults-us-by-smoking-status-and-age/. Updated 2020.

34. In,J. Introduction of a pilot study. Korean Journal of Anesthesiology. 2017;56(8):601-605.

35. Saldana J. First cycle coding methods & second cycle coding methods. In: The coding manual for qualitative researchers. 2nd ed. SAGE Publications Ltd; 2010:45-182.

5.0 Study Design*

5.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

This study will engage community-dwelling URM adults with PH living in the United States. We will use a two-group comparative study design where waitlisted participants will serve as controls. Considering a 20% attrition rate in a behavioral health intervention study, we aim to enroll a total of 20, with at least 16 participants to address study aims (8-10 in each Group).34 As a pilot study, power analysis is not necessary. Statistical analysis will include descriptive statistics, mixed-effect modeling for repeated measures, and within-group and between-groups comparisons using t-tests or Wilcoxon signed-rank test as appropriate and Cohen's d effect size calculation. Multi-time data collection will be done via daily mobile-APP use.

6.0 Study Intervention/Investigational Agent

6.1 Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

The MMPH program will include two Zoom-delivered sessions (Weeks #1 & #4), six video-recorded sessions (Weeks #2, #3, #5, #6, #7, #8), and daily mindfulness meditation practice using a mobile APP during an eight-week study period. Similar to the UZIT intervention, each MMPH session will include Gentle Body Movement (GBM,10-min), Restorative Pose (Pose,10-min), and Body Awareness Meditation (BAM, 20-min). Self-guided audio-video modules of various durations will be available according to participants' preference and level of comfort (5, 10, 20 minutes). The mobile-APP content will reinforce Zoom content such as mindful breathing, GBM of upper extremities, GBM of lower extremities, Pose sitting, Pose lying, and BAM practices. The MMPH content will be tailored to health management needs specific to PH with cultural consideration of mindfulness-related concepts (stress, responding to stress, resiliency).

6.2 Drug/Device Handling: If the research involves drugs or device, 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.

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response: NOT APPLICABLE

6.3 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: *NOT APPLICABLE*

7.0 Local Number of Subjects

7.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: 20 participants

7.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response: Potentially eligible patients from UBMD clinic, URMC, RRH, as well as patients across the US from sources such as Research Match and Facebook will be screened by research team at UB. Potentially eligible and interested PH patients will self-refer and contact us for screening. We will also invited PH patients across the US to participate in the study using additional recruitment sources such as Research Match, across the US CTSA Hub advertisement, and

Social media (Facebook) advertisement. With the approved amendment to include all ethnicity, we will be able to reach the target enrollment goal as planned.Our enrollment goal is 20 patients.

7.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: An enrollment rate to a mind-body intervention is approximately 30%, yielding about 103 participants. Considering a 15% attrition rate, we will enroll 20 participants to achieve at least 8 in each Group. We received verbal agreements from PH specialists at these locations to assist in referring, of eligible participants in the study.

8.0 Inclusion and Exclusion Criteria*

*8.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

1) adults (>18 years), 2) PH confirmed by standard guidelines; 3) willingness to participate in the mindfulness practice program for the duration of the study period; 4) able to ambulate independently; 5) English-speaking, and 6) have access to a mobile phone.

*8.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

1) known pregnancy; 2) have psychiatric conditions requiring hospitalization within the last year; 3) deaf or hard of hearing.

8.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

8.4 Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may ***not*** *be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

The study will exclude non-English speaking individuals because the questionnaires used to obtain data are available in English format. Furthermore, the intervention will be delivered in the English language only.

9.0 Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

9.1 For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

☒ **N/A**: This research does not involve pregnant women.

9.2 For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

9.3 For research that involves ***prisoners****, safeguards include:*

NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

9.4 *For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

9.5 *For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

9.6 *Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. **Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Our target population is adults with PH living throughout the United States. There is a high likelihood that our study participants may include economically disadvantaged persons. The study recruitment and enrollment process will occur in collaboration with PH doctors and nurses from these 3 locations and across the country who are likely aware of their vulnerability. We will follow the standardized and consistent approach in presenting the study material and remuneration for their participation. We will provide a sufficient amount of time and information to consider their involvement in the study.

10.0 Eligibility Screening*

10.1 *Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Screening for inclusion criteria includes a YES response to the following questions:

Is the subject have a current diagnosis of pulmonary hypertension?

Is the subject > 18 years old

Does the subject have access to an electronic device: iPhone, iPad, Android Phone, Laptop?

Is the subject proficient in English?

Screening for exclusion criteria includes a YES response to the following questions:

Has the subject been hospitalized for a psychiatric reason during the past 12 months?

Is the subject hearing-impaired?

Is the subject pregnant? (for female person)

1. Via our referring partners and electronic advertisements (using Research Match, CTSA Hub advertising and social media [e.g., Facebook]), participants will receive an invitation to participate in the study. All communications include the contact information to the PI of the study, email address and phone number.

2. Participants may contact the research coordinator by the included phone number or email address if they want to learn more about the study. A research team member will contact the interested participant and arrange a convenient time for a Zoom meeting.

3. During the Zoom meeting, the research staff member will describe the study and review the consent document. If the participants decides to participate in the study, the research staff will obtain verbal informed consent.

4. The participant will be provided a link (via email or text) to the REDCap database to complete a screening questionnaire.

☐ **N/A:** There is no screening as part of this protocol.

11.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

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

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

There are two ways we will make the study known to potential eligible participants (1) They may hear about the study from their PH doctors during routine clinic visits (2) They may see study flyers in recruiting partners' offices or clinics during their routine care.

Even though we originally proposed that PH doctors send out emails inviting their patients to contact us for potential enrollment, none of the doctors used the letter. They chose to tell their patients about the study verbally, and we only got one referral from RRH. That was the recruitment process we did. As I previously indicated, we are no longer enrolling and will not use it. We only want to complete the study.

Electronic recruitment will include direct email sent using the University at Buffalo's Clinical and Translational Science Institute's (CTSI) Buffalo Research Registry and social media (Facebook). The registry includes names of individuals who have expressed interest in participating in research studies. Facebook-based recruitment will consist of advertisements for the study.

Flyers will be distributed to our referring partners and will be recruited by PH physician referral, self-referral, the use of Buffalo Research Registry, CTSA Hub advertisement, Social Media posts (Facebook), and Research Match. Flyers will be placed by the Research Coordinator at their locations (our referring partners at URMC and RRH). These flyers will be made available in waiting rooms as well as in healthcare professionals' offices.

In both recruitment methods, interested participants will contact the study team directly to initiate the screening as described in section 10.1. None of the referring partners will participate in any screening activities, only referrals.

11.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

The recruitment email and flyer information offers individuals the freedom to participate in the study only if they are interested in doing so.

Screening interviews will take place by Zoom and will be recorded. Recordings will be destroyed after transcripts are created. Participants may take part in the interview at a place and time of their choosing.

Potential research participants will know about the study from PH providers, paper brochures, Buffalo Research Registry, or the ResearchMatch registry. Researchers will make initial contact with potential participants only after a clear indication that they are interested to learn more about the study. These indications are referral from their PH provider, email or phone contact from the participants, or "yes" response through the ResearchMatch registry.

(Please refer to the Recruitment and Enrollment Protocol)

After the Introductory meeting, if prospective participants decline to participate in the study, the research staff will destroy any personal information written down on paper or delete electronic notes. If they express interest and want to meet for the Zoom Consent meeting, we will keep their information as a reference for that meeting. After the Zoom Consent meeting, if prospective participants decline to participate in the study, the research staff will destroy any personal information written down on paper or delete electronic notes immediately. We will only keep the documentation if they agree to participate in the study.

After enrollment, each subject in all phases of the study will be assigned a unique study identification number to be used on all forms. All personally identifiable information will be kept strictly confidential.

Prospective eligible participants will have access to a written version of the consent form that the IRB has approved. There will be instruction for the participant to read the consent form to gain a further, detailed understanding of what the study is about, study participation requirement, and other general information about the human research subject. The participant will then contact the study coordinator to set a convenient time for a virtual meeting or phone call, providing verbal informed consent.

We will keep all records about the recruitment process in password-protected data files according to each institution. Only staff members who are involved in this research will have access to this recruitment record.

11.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

1) Screening protocol; 2) Screening sheet; 3) email invitation script; 4) Advertisement

12.0 Procedures Involved*

*12.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Table 1. *Study Procedure*

Procedure	w0-w1 MMPH-1 (Zoom #1)	w1-w2 MMPH-2 (video)	w2-w3 MMPH-3 (video)	w3-w4 MMPH-4 (Zoom #2)	w4-w5 MMPH-5 (video)	w5-w6 MMPH-6 (video)	w6-w7 MMPH-7 (video)	w7-w8 MMPH-8 (video) Zoom #3
Instructor-led (min X day)	60 X 1	60 X 1	60 X 1	60 X 1	60 X 1	60 X 1	60 X 1	60 X 1
Self-guided (min X day)	20 X 6	20 X 6	20 X 6	20 X 6	20 X 6	20 X 6	20 X 6	20 X 6
Consent	X							
Demographics	X							
PAHSS	X			X				X
EmPHasis-10	X			X				X
PHQ-9	X			X				X
CAMS-R	X			X				X
Pain (1-10)	X*	X*	X*	X*	X*	X*	X*	X*
Anxiety (1-10)	X*	X*	X*	X*	X*	X*	X*	X*
Fatigue (1-10)	X*	X*	X*	X*	X*	X*	X*	X*
Dyspnea (1-10)	X*	X*	X*	X*	X*	X*	X*	X*
SUS-modified MMPH								X
Interview -MMPH								X
Reminder (via phone or App) - MMPH	X	X	X	X	X	X	X	X

Note: *X* = symptom assessment before and after daily use of MMPH module; PAHSS, Pulmonary Arterial Hypertension Symptoms Scale; EmPHasis-10, Health-related quality of life in pulmonary arterial hypertension; PHQ-9, Patient Health Questionnaire; CAMS-R, Cognitive and Affective Mindfulness Scale-Revised; SUS, System Usability Scale; MMPH, Mindfulness Meditation for Pulmonary Hypertension.*

Table 1 outlines the detail and sequence of study intervention. Enrolled participants will receive 60-min-weekly intervention for 8 weeks period; 2 of which will include video conference practice and the other 6 will include audio-video recording of the sessions. During the study period, they will complete self-guided meditation using M-App for 20 min/day.

12.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Please refer to Table 1 regarding data that will be collected: symptom presence and severity, health-related quality of life, depressive symptoms, mindfulness score, clinical and demographic data.

12.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response: The following questionnaires will be included in this study:

- Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)
- The Patient Health Questionnaire-9 (PHQ-9)
- Pulmonary Arterial Hypertension Symptom Scale (PAHSS)

- Health-related quality of life in pulmonary arterial hypertension (EmPHass-10)
- System Usability Scale – MMPH (SUS)
- Pain Scale, Anxiety, Fatigue, Dyspnea
-

12.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

We will not use an additional source of records to collect data about subjects in this study.

*12.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

NOT APPLICABLE

*12.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

NOT APPLICABLE

13.0 Study Timelines*

13.1 Describe the anticipated duration needed to enroll all study subjects.

As previously described, we anticipate enrolling all 20 subjects within three months.

13.2 Describe the duration of an individual subject's participation in the study. Include the length of study visits and overall study follow-up time.

The duration of an individual subject's participation in the entire study (consent to the completion of focused-group interview) will be three months or less. There will be no physical study visits, only virtual study visits for Zoom participation and individual interview sessions.

- Enrollment, consenting, baseline data = 30 minutes
- Completion of all 8 sessions (60 min/each) = 480 minutes for the 8 weeks
- 20min/day practice for 8 weeks = 56 days X 20 min = 1,120 min = 18.7 hours over 8 weeks = 2.3 hours per week.
- Focused interview = 1 hour
- Questionnaires completion = 10 min X 8 weeks = 80 min total

13.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

The estimated duration for the investigators to complete this study will be about 12 months (recruitment, enrollment, intervention, data collection, data analysis).

14.0 Setting

14.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

All research procedures will be conducted from participants' private space (home) because we will deliver MMPH intervention via Zoom connection, video-recording viewing, and Mindfulness App use. Study participants will download the mindfulness App to their mobile devices. Research staff and interventionists will interact with study participants through Video conference connections from the privacy of their own work space.

14.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response: NOT APPLICABLE

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

15.0 Community-Based Participatory Research

15.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR 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.

Response: NOT APPLICABLE

☒ **N/A:** This study does not utilize CBPR.

15.2 Describe the composition and involvement of a community advisory board.

Response: NOT APPLICABLE

☒ **N/A:** This study does not have a community advisory board.

16.0 Resources and Qualifications

*16.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Dr. Tania Von Visger is the **PI** of this study. She is a tenure track Assistant Professor at UB SON with experience conducting a clinical trial with patients with PH using Urban Zen Integrative Therapy intervention. In the UZIT study, she created the study protocol, trained and maintain the interventionists' competency for the duration of the UZIT study. She also has experience conducting clinical studies involving multi-disciplinary team members with Critical Care and Transplant patients.

Dr. Yu-Ping Chang is the primary **co-Investigator** in this study. She is the Senior Assistant Dean at UBSON and Director of SON Center of Nursing Research (CNR). Dr. Chang leads a PCORI-funded study using a video-conference mindfulness program in African American community participants living in Buffalo. She is a mental health expert and familiar with systems and processes at SUNY UB.

A qualified and experienced **Research Assistant/Research Coordinator** from the UBSON will coordinate participant activities in this MMPH project. She will be responsible for the overall recruitment and enrollment of study participants in the study. The RA is trained through the UBSON CNR with familiarity in the conduct of various types of research. They also have extensive experience working with many research faculty members at the SON.

MMPH Interventionist who is familiar with the delivery of Mindfulness practice via Zoom to URM participants will be an integral member of the research team. They will assist the PI in content development and creating the AV recording of MMPH presentations and modules. In our current collaborative research projects (PI = Chang), we have identified four potential interventionists with these experiences that we can tap into based on their interests and availability.

CSE 611 Independent Project Course. In collaboration with the UB School of Engineering Professor, study PI will secure student interest in the MMPH App study. A dedicated group of engineering students will design and develop an MMPH mindfulness App for course credit during their enrollment in the Fall 2021 semester. We have full support from the UB SOE.

Describe other resources available to conduct the research.

16.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: **Dr. Von Visger (PI)** will dedicate her full-time commitment to this project as she is a tenure-track Assistant Professor. She currently has a five credit-hours teaching commitment.

Co-I will dedicate 10% of her FTE to this project.

Per the contract, the UBSON will provide 10 hours per week of **RA/ Clinical Research Coordinator** time in this project.

MMPH Interventionists will dedicate 0.5 FTE for 26 weeks (6 months), including the time to design and review MMPH content, record the audio App and deliver the Zoom interventions. Their engagement in this project will also include training time to get familiar with the research protocol and time for re-trained if the study takes longer than anticipated.

16.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Participants will be referred to their primary healthcare providers for further assessment if/when the need arises concerning participants' mental health needs. We will also provide community-based resources if they need additional support.

16.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

We will have at least monthly Research Team meetings to review participant recruitment, enrollment, research procedures, research-related issues. Team members will receive weekly updates about the overall progress of the study.

17.0 Other Approvals

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

Response:

☒ **N/A:** This study does not require any other approvals.

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

To protect participants' privacy interests and safety during the study, a research team member will only contact the participants on the phone in a private office where no one can overhear the conversation. Any email communications with participants will be kept private and confidential. All data collected during the study will be stored on a secure, password-protected cloud that only the research team has access to.

About Zoom communication, participants will meet with a study coordinator from the privacy of their home where no one can overhear the discussion about their participation in the study. Participants will be reminded not to discuss any personal information outside of the group discussion during the Zoom intervention.

The participant will be reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.

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

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

Sources of information about the subjects before enrollment will only be accessible to PH doctors. Once enrolled, research data will be stored in Research Files at UBSON, and only research team members (PI, co-I, RA) will have access. There will be no need for medical record review because the outcome data will be participant-reported outcomes (symptom presence, symptom severity, quality of life).

19.0 Data Management and Analysis*

19.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

As a pilot study, power analysis is not necessary. Statistical analysis will include descriptive statistics, mixed-effect modeling for repeated measures, and within-group and between-groups comparisons using t-tests or Wilcoxon signed-rank test as appropriate and Cohen's d effect size calculation. Multi-time data collection will be done via daily mobile-APP use.

We will follow the standard procedure in quantitative data analysis that includes general data inspection to verify the accuracy, completeness, and normality of the dataset using the SPSS23 program. We will compare clinical outcomes within-group (pre-post) as well as between groups in the post-intervention period. We will follow the recommendation of inappropriate statistical analysis and interpretation specific to each survey. For continuous variables, we will use a paired student t-test, independent t-test analytical approaches. For categorical variables and non-normally distributed variables, we will use non-parametric statistical methods (X2). Frequency distributions will be produced for all variables, and demographic information will be used to describe the sample. The impact of the M-App use on outcome variables will be analyzed using paired t-test and repeated measure ANOVA.

Qualitative data (focused-group interview data) will be analyzed using the standard qualitative thematic analysis procedure. We will transcribe the audio-recorded data and upload it into NViVo data management system. We will adhere to the thematic analysis method, described as follows:

1. A researcher will read and re-read the entire text to get a general sense of the participants' whole experience of being a student during the COVID-19 pandemic. While reading through the transcript, the researcher will take initial notes and perform a general review to get familiar with the data before analyzing the data.

2. The researcher will descriptively open code by dividing the significant text segments into 'meaningful units', keeping the participants' own words. The researcher will re-read all the codes again to eliminate redundancies.

The comparative discussion of these codes with other research team members to achieve a consensus will provide a validation step.

3. The researcher will use an inductive approach to look over the consensus codes, identify patterns among them, and start coming up with categories that describe 'critical moments,' significant aspects of the experiences.

4. The researcher will categorize the codes into overarching elements and higher-level categories and then cluster similar categories into the related themes. To make sure that the themes are useful and accurately represent the data, the researcher will return to the original data set and reflectively compare the categories against it.

5. The researcher will discuss with the research team members to refine the themes and develop the central theme. The researcher will then define and name the central theme by formulating its meanings and figuring out how it helps understand participants' experiences.

6. Finally, the researcher will develop an overall description of the essence of the participants' experience by merging the themes into the central theme/s in a flowing narration.

19.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

NOT APPLICABLE

19.3 Describe any procedures that will be used for quality control of collected data.

We will set up the required data entry field within the M-App and REDCap function to ensure that the data entry is accurate and complete. Erroneous (out-of-range) data entry will be less likely, as controlled by the proper setup of the data fields. Also, the system will remind participants to enter data into the required data field before proceeding to the following sections. A dedicated research coordinator will review data entry once a week to verify survey completion and confirm no missing data. In the case of missing data discovery, the research coordinator will contact and ask participants to complete it as soon as possible.

Before the data analysis process, two researchers will review the dataset for accuracy and discuss any possible reliability issues in data collection.

20.0 Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*20.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

With the use of M-App and REDCap programs, there will be minimal paper documentation of study data. In the rare instances where paper data collection is needed, they will be kept in a locked cabinet located in the PI's office (Wende 201F). The paper documentation will contain only participant study numbers without an identifiable name. Record linking study ID numbers with their names will be kept in a separate locked cabinet.

We will upload data from M-App and REDCap into the SPSS and NViVO without any identifiable information. We will use only study ID numbers during data analysis.

We will upload audio voice recordings captured from Zoom directly to the NiVIVO database, locked and secured with password-protected access.

20.2 A. How long will the data be stored?

The researchers will keep paper documentation (if any) and de-identified data for five years until we complete other associated studies. The expired, signed consent forms and materials will be deposited with the UB repository, whose security policy has been written according to best practice. All electronic data will be de-identified and stored on a secure, password-protected cloud.

20.3 A. Who will have access to the data?

Only the PI and other research team members will have access to both paper documentation and the cloud data.

20.4 A. Who is responsible for the receipt or transmission of the data?

The PI and other research team members are responsible for the receipt and transmission of the data.

20.5 A. How will the data be transported?

We will transport the data since it will be stored on a secure, password-protected cloud.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 21.0)*

20.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response: NOT APPLICABLE

20.7 B. How long will the specimens be stored?

Response: NOT APPLICABLE

20.8 B. Who will have access to the specimens?

Response: NOT APPLICABLE

20.9 B. Who is responsible for receipt or transmission of the specimens?

Response: NOT APPLICABLE

20.10 B. How will the specimens be transported?

Response: NOT APPLICABLE

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

21.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

The PI will be responsible for safeguarding data integrity and safety monitoring for human subjects and communicating any negative outcomes or serious events to the IRB and other applicable offices/agencies.

The research team will meet weekly to review participant data and accrual. If participant accrual or retention drop under the requirement to complete the study, the PI and research team will discuss and develop strategies to overcome the identified issues. Record from the participants enrolled during each will be reviewed to ensure that all participants are eligible for the study. The research team will also monitor developments in the literature and results of related studies that may impact the participants or the ethics of the research.

21.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

To ensure the integrity of the research study, we will review progress relevant to study recruitment and enrollment, intervention fidelity, clinical outcomes, and safety data. With the minimal to low risk associated with this research, there are no anticipated life-threatening adverse events for this proposed research project. In the rare occurrence, it will be reported to the PI and research team immediately. Researchers will notify the IRB within seven days of the adverse event occurrence. A thorough investigation will be initiated, including a review of the protocol to ensure no undue exposure to risk occurred.

21.3 Describe any safety endpoints.

There is a potential risk of emotional distress to participants when answering survey questions about symptoms or feelings. Although unlikely, participants may experience sensations of anxiety, depression, and worse physical symptoms. Participants will be instructed to rest and re-focus their attention from completing the survey in such a scenario. Suppose a participant expresses any distress, or the research team suspects the participant is experiencing distress for any reason during the research. In that case, the participant may be removed from the study and offered a referral to mental health services. The adverse events will be reported to the IRB by the PI within the required timeframe.

21.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

The PI will collect safety data during telephone calls with the participant(s) and during data collection from the participant's self-evaluations.

21.5 Describe the frequency of safety data collection.

Safety data collection occurs once every two weeks for eight weeks and one hour during the focus group interview.

21.6 Describe who will review the safety data.

The PI and research team will review the safety data.

21.7 Describe the frequency or periodicity of review of cumulative safety data.

The review of cumulative safety data will occur weekly.

21.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

We will use descriptive statistics (counts of the event) to determine the events of distress.

21.9 Describe any conditions that trigger an immediate suspension of the research.

We do not anticipate any situation that would trigger an immediate suspension of the study.

22.0 Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

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

Participants may be withdrawn from the research without their consent if the PI or research team member discovers a participant is in severe psychological distress or is admitted into the hospital for a psychiatric condition.

22.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

NOT APPLICABLE

22.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

We will attempt to use all the available data obtained from all participants (intention to treat). Pre and post comparison of the experimental Group will be conducted as aggregate means using all available data collected.

When participants decide to leave the study, we will ask them if they would allow us to use the data we have collected before their decision to withdraw. If the subjects agree to use the data, the collected data will be handled and analyzed the same as research data. If the participants do not allow the use of the data, we will make every attempt to destroy the data.

23.0 Risks to Subjects*

23.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

There are no foreseeable physical risks, discomfort, hazard, or inconveniences to the subjects related to their participation in this research. However, there is potential physical harm if participants use the M-App in circumstances that require total attention, such as driving or operating heavy machinery. There is an inherent risk of participants becoming so relaxed and drift off into a sleep state, which may put them in danger during these activities. Therefore, we will instruct participants in the proper use of the M-App and the environment/conditions they need to avoid practicing with the M-App.

For a Zoom intervention group, there is always the chance that someone will share something someone else said (confidentiality breach). At the beginning of the interview, we will remind participants not to share this information with anyone. (This information will be a part of the consent document, indicating no guarantee that this may not occur).

There is a potential risk of emotional discomfort to participants when answering survey questions about symptoms or feelings. Although unlikely, participants may experience sensations of anxiety, depression, and worse physical symptoms. Participants will be instructed to rest and re-focus their attention from completing the survey in such a scenario. If needed, participants will be given the contact information in their local areas (according to their primary care doctors). Questionnaires included in this research study are standardized tools used widely with no reported adverse harm. Fatigue is possible when answering questions from a battery of questionnaires. However, most surveys used in this study are shortened versions that generally require less than 10 minutes to complete.

23.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

To address potential physical harm (mentioned above), we will provide specific instructions on how to complete the M-App modules at home.

To monitor subjects for safety risk, we will conduct weekly research meetings to review the progress of the research activity and any participants' safety concerns. We will create action plans to mitigate any issues that may arise.

We will employ all reasonable efforts to protect the confidentiality of the participants' protected health information. Identifiable data is immediately de-identified, and de-identified data is stored separately from identifiable data. We will keep participants' names and other identifying information confidential when the data is prepared or oral or written publications.

Specific to participants' interviews, there is a potential risk of emotional distress due to the sensitive nature of the topics. We will provide all interviewed participants with information on mental health resources and support groups at the time of enrollment.

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

None other than the potentiality of "falling asleep" during the practice.

23.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response:

NONE

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

Response:

NONE

24.0 Potential Benefits to Subjects*

24.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

There are potential benefits that individual subjects may experience by taking part in the research. Based on existing literature reporting on the use of M-App, mindfulness practice can increase one's level of Mindfulness that may help with focus and attention beneficial to their mental health and well-being. Participation in this study may benefit from stress and anxiety reduction, which can be helpful to their academic learning and social interaction.

25.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*25.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

NOT APPLICABLE

25.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

NOT APPLICABLE

26.0 Economic Burden to Subjects

26.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

The only anticipated cost to participants relevant to the study includes data charges from their phone carrier if they are not using a Wi-Fi service or go over the allotted data usage with their phone carrier.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

27.0 Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Participants will be compensated at four timepoints with US Bank Prepaid Cards, in a total value up to $90.00 after completing the study.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

28.0 Consent Process

28.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 29.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 29.0)*

28.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Once it is determined a participant is qualified, they will have access to a written version of the consent form that the IRB has approved. We will email a copy of the consent form to review at least two days before providing consent. They will gain a further, detailed understanding of the study, participation requirement, and other general information about the human research subject in the privacy of their homes. The consent process will take place during a virtual meeting between a member of the research team and the interested, eligible participant to review the content of the consent form. The research coordinator will put the consent form

up on the screen and go through it and then ask the participant to either orally agree or not. If they don't consent, they may leave by logging out. If they stay, they are verbally demonstrating their consent. During this meeting, we will provide the participant with plenty of opportunities to ask additional questions about the study. If it is agreeable with the participant, the researcher will obtain verbal consent.

28.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

The participant will receive a written consent form at least two days before the virtual meeting between the eligible participant and the research coordinator. The participant will have sufficient time to ask further questions about the study during the meeting. If they are unsure whether to participate at that time, they will be given an additional day to decide their participation. In such a case, the research coordinator can schedule another virtual meeting convenient for the participant.

28.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Emails will be sent to the participants each week by the research team to remind participants of their volunteer status and ability to withdraw from participation at any time.

28.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

We will be following HRP-900 with the exception that consent provisions will not be made to conduct consent in languages other than English even if this is preferred by the participant because we expect that the participants will speak English sufficiently to understand the consent form.

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 28.8)

28.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 8.4 of this protocol.

Response:

NOT APPLICABLE

28.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

NOT APPLICABLE

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 28.9)

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

Response: NOT APPLICABLE

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 28.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 28.11 and 28.12).*

28.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response: NOT APPLICABLE

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

*28.10 **For research conducted outside of New York State**, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: NOT APPLICABLE

*28.11 Describe the process for **assent of the adults**:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. **If some, indicate which adults will be required to assent and which will not.***

Response: NOT APPLICABLE

- ***If assent will not be obtained from some or all subjects, provide an explanation of why not.***

Response: NOT APPLICABLE

*28.12 Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response: NOT APPLICABLE

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 29.0)*

*28.13 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 **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response: NOT APPLICABLE

*28.14**For research conducted outside of New York State**, 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. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: NOT APPLICABLE

28.15 Describe whether parental permission will be obtained from:

Response:

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ 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.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*28.16Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response: NOT APPLICABLE

*28.17 Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response: NOT APPLICABLE

28.18 When assent of children is obtained, describe how it will be documented.

Response: NOT APPLICABLE

29.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☐ **N/A:** A waiver or alteration of consent is not being requested.

29.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

Enrolled participants will receive 60-min-weekly intervention for 8 weeks period; 2 of which will include video conference practice and the other 6 will include audio-video recording of the sessions. During the study period, they will complete self-guided meditation using M-App for 20 min/day. These procedures are not beyond the risks presented by everyday life.

29.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

We will email a copy of the consent form to review at least two days before providing consent. They will gain a further, detailed understanding of the study, participation requirement, and other general information about the human research subject in the privacy of their homes. Doing this via Zoom is more

practicable than in-person and follows UB guides for COVID safety of research volunteers.

9.3/ The waiver or alteration will NOT adversely affect the rights and welfare of the subjects: The consent process will take place during a virtual meeting between a member of the research team and the interested, eligible participant to review the content of the consent form. The research coordinator will put the consent form up on the screen and go through it and then ask the participant to either orally agree or not.

9.4/ Whenever appropriate, the subjects will be provided with additional pertinent information after participation: It is not necessary in a low risk study such as this.

30.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

30.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response:

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

31.0 Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

31.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Not Applicable

31.2 *If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following. See "WORKSHEET: Communication and Responsibilities (HRP-830).":*

- *All sites have the most current version of the IRB documents, including 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 conduct the study appropriately in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Not Applicable

31.3 *Describe the method for communicating to engaged participating sites (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):*

- *Problems (inclusive of reportable events)*
- *Interim results*
- *Study closure*

Not Applicable

31.4 *If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality. (See "WORKSHEET: Communication and Responsibilities (HRP-830).")*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response: NOT APPLICABLE

31.5 *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national*

advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.

- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response: NOT APPLICABLE

32.0 Banking Data or Specimens for Future Use*

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*32.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response: NOT APPLICABLE

32.2 List the data to be stored or associated with each specimen.

Response: NOT APPLICABLE

32.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: NOT APPLICABLE