Mindfulness-based Intervention to Address PTSD in Trauma-exposed, Homeless Women

STUDY PROTOCOL

K01 MD013910-01
National Institute of Health (Institute of Minority Health and Health Disparities)

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Table of Contents

SECTION 1A. RESEARCH STUDY OVERVIEW 4

Subsection 1A.1 - Overview & Introduction 4

Subsection 1A.2 - Overall Structure of Study Team 5

Subsection 1A.3 - Research Team and Responsibilities 6

Subsection 1A.4 - Research Study Contact List (2/21) 6

Subsection 1A.5 - Phase II Timeline 1

6 - Basic Definitions 1

SECTION 1B. INTRODUCTION TO PTSD AND MBSR 2

Subsection 1B.1 - PTSD Basics 2

Subsection 1B.2 - MBSR Basics 4

SECTION 2. INTERVENTION DELIVERY 6

Subsection 2.1 - Phase II Overview 6

Subsection 2.2 - Phase II Scope of Work & Participant Flow Diagram 7

Subsection 2.3 - Phase II Recruitment & Treatment Overview 9

Subsection 2.4 - Phase II Recruitment & Screening 9

Subsection 2.5 - Phase II Eligibility Criteria 10

Subsection 2.6 - Phase II Laboratory Tests/Sample Collection 11

Subsection 2.7 - Phase II Intervention Program Description 11

Subsection 2.8 - Phase II Pre-intervention Assessments 12

Subsection 2.9 - Phase II Brief Stress Task (Trauma Imagery Task) 12

Subsection 2.10 - Phase II Biospecimen Collection 13

Subsection 2.11 - Phase II Biospecimen Analysis 14

Subsection 2.12 - Phase II MBSR-based Intervention 14

Subsection 2.13 - Phase II Health Promotion Intervention 16

Subsection 2.14 - Phase II Post-Assessment 17

Subsection 2.15 - Phase II Team Management of Biospecimen Collection Refusal 17

Subsection 2.16 - Phase II Dealing with Intervention Program Attrition 17

Subsection 2.17 - Phase II Follow-Up Focus Groups 18

Subsection 2.18 - Phase II Compensation 18

Subsection 2.19 - Program Fidelity 18

Subsection 2.20 - Research Staff Competencies and Mock Sessions 18

Subsection 2.21 - Data Entry, Management & Confidentiality 19

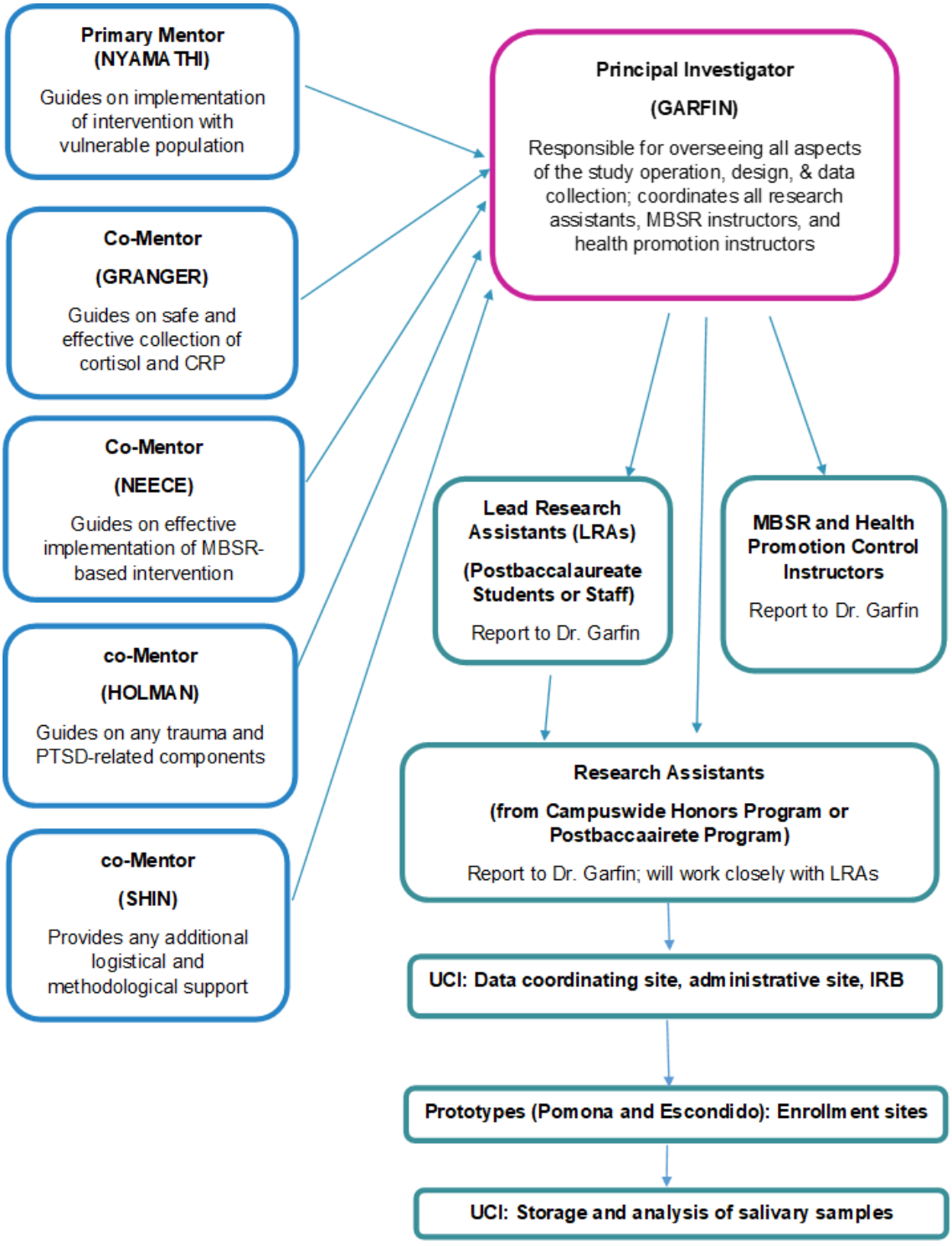
Subsection 2.22 – Using REDCap 20
Subsection 2.23 - Data Security 20
Subsection 2.24 - Post Data Collection 21
Subsection 2.25 - End of Study 21
SECTION 4. RECRUITMENT 22
Subsection 4.1 - Phase II Flyer 22
Subsection 4.2 - Phase II MBSR – Script for Introduction at Recruitment Site: For Non-Research Staff Member 23
SECTION 5. SCREENING, INFORMED CONSENT, AND ENROLLMENT 24
Subsection 5.1 Screening Protocol 24
Instructions: 24
Subsection 5.2 Informed Consent 24
Subsection 5.3 Baseline Protocol 24
APPENDIX I: What to bring to site 25
APPENDIX II: Trauma Imagery Script (Brief Stress Task) 26
APPENDIX III: Data Safety and Monitoring Plan 28
Possible Serious Adverse Events or Adverse Events 30
Serious adverse events 30
Other adverse events 30
Risk Management Protocols in Place to Deal with Adverse Events 30
Data and Safety Monitoring Procedures 31
Data Safety and Monitoring Board (DSMB) 31
Training in Red Flag Procedures 31
RED FLAG – SUICIDE 31
Harm to others 33
APPENDIX IV: Citations for Study Measures 35
APPENDIX VII: RECap for Screener (Section 1) and Baseline, Immediate-follow-up, and 6-months (Section 2) 40

SECTION 1A. RESEARCH STUDY OVERVIEW

Subsection 1A.1 - Overview & Introduction

This study aims to determine the effectiveness of a mindfulness-based intervention (MBI) on the reduction of posttraumatic stress disorder (PTSD) symptoms (primary outcome) and depression substance use disorder (SUD), inflammation, and cortisol reactivity (secondary outcomes) in homeless women with PTSD. Biological markers (i.e., cortisol reactivity, C-reactive protein [CRP]) of the stress response will be evaluated as correlates of MBI treatment-response will help clarify mixed findings regarding dysregulation of the HPA-axis as a function of amount, type, and timing of trauma exposure. It will advance theory regarding the use of MBIs for PTSD while exploring biological markers that might maintain PTSD symptoms over time. The project has the potential to bolster the capacity of service providers to offer feasible and acceptable MBI interventions to homeless women and other vulnerable populations. If the proposed aims are achieved, they may provide several valuable insights. They will examine the efficacy of MBI to address PTSD in homeless women (inform & improve services, interventions, treatments); improve on methodological limitations of prior research on MBIs for PTSD (including small sample sizes, lack of attention control group, incomplete trauma history); and explore biological markers that correlate with PTSD-symptom maintenance or reduction post-MBI (expand concepts). Importantly, the MBI that will be used in the intervention was the product of a rigorous preliminary mixed-methods inquiry that including a Community Advisory Board (consisting of site staff, clinicians, and homeless women) and focus groups with women from the community (i.e., homeless women currently residing at a residential drug treatment facility). The results of these formative activities resulted in the modification of an evidenced-based MBI – Mindfulness-based Stress Reduction (MBSR) for cultural sensitive and appropriateness, increasing acceptability and feasibility. Importantly, findings from this proposal may provide a low-cost method to improve services for homeless women as they begin to answer key theoretical questions regarding the relationship between biological markers of stress regulation and reactivity, the inflammatory response, PTSD and related comorbidities (SUD, depression), and MBIs.

Subsection 1A.2 - Overall Structure of Study Team



Subsection 1A.3 - Research Team and Responsibilities

Principal Investigator (PI): Dana Rose Garfin, PhD.
Makes executive decisions regarding the implementation of the study, data entry and data analysis approaches, and interpretation of study findings. She will train the research staff and assistants to perform content. Dr. Garfin will develop all questionnaires and oversee the design and implementation of the MBI and the health promotion attention control.

K01 Mentor: Adeline M. Nyamathi, ANP, PhD, FAAN
Dr. Nyamathi will advise Dr. Garfin on conducting mix-methods research including qualitative focus groups and clinical trials with vulnerable populations.

K01 Mentor: Douglas Granger, PhD, Chancellors Professor of Psychology and Social Behavior and Director of the Institute for Interdisciplinary Salivary Bioscience Research (IISBR
Dr. Granger will advise on all aspects of the project related to saliva collection and analysis and the theoretical and statistical integration of salivary measures into psychosocial research.

Secondary K01 co-mentors: Drs. Cameron Neece, E. Alison Holman, & Sanghyuk Shin provide guidance on K01, but do not interact with any human subjects participants, will not engage with the data, and thus are not included on the IRB forms.

Lab Manager and Lab Coordinator: First line contact for RAs, responsible for RA scheduling, delegates lab responsibilities to other RAs, drafts lab meeting agenda, keeps track of conference submission deadlines, ensures study supplies are available, oversees budget expense tracking and reimbursements.

Biosalivary coordinator: Ensures that cortisol collection is done according to all protocols, ensures that collection tubes are labeled ISBBR.

REDCap coordinator: Ensures all updated to REDCap are entered accurately. Tracks participant payments for cash advances and payment reconciliation.

Subsection 1A.4 - Research Study Contact List (2/21)

Name	Role	Organization	Phone Number	Email
Dana Rose Garfin, PhD	PI	UCLA	(415)407-9498	dgarfin@ucla.edu
Adey Nyamathi	K01 Mentor	UCI		anyamath@uci.edu
Doug Granger	K01 Mentor	UCI		dagrange@uci.edu
Michelle Zernick	Lab Manager	UCI		zernickm@uci.edu

Subsection 1A.5 - Phase II Timeline

YEAR 1 (2020)												
	19-May	**19-Jun**	**19-Jul**	**19-Aug**	**19-Sep**	**19-Oct**	**19-Nov**	**19-Dec**	**20-Jan**	**20-Oct**	**20-Nov**	**21-Dec**
PRIMARY ACTIVITIES	SITE START UP & VISIT			Community Advisory Board		Focus Groups		Finalize Intervention & Qualitative Analysis		Recruit Cohort1	HP Cohort1	
Space/time needed				1 meeting per week (1-2 hours)		Four meetings total, each 2 hours		1 weekly meeting (1-2 hours) for 4 weeks		Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)	
YEAR 2 (2021)												
	21-Jan	**21-Feb**	**21-Mar**	**21-Apr**	**21-May**	**21-June**	**21-July**	**21-Aug**	**21-Sept**	**21-Oct**	**21-Nov**	**21-Ded**
PRIMARY ACTIVITIES	Recruit Cohort 2	MBI & HP C2			Recruit Cohort 3	MBI & HP Cohort 3			Recruit Cohort 4	MBI & BP Cohort 4		
Space/time needed	Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)			Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)			Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)		
Follow-up				Cohort 1 follow-up				Cohort 2 follow-up				Cohort 3 follow-up
YEAR 3 (2022)												
	22-Jan	**22-Feb**	**22-Mar**	**22-Apr**	**22-May**	**22-June**	**22-July**	**22-Aug**	**22-Sept**	**22-Oct**	**22-Nov**	**22-Dec 23 Jan-Feb**
PRIMARY ACTIVITIES	Recruit Cohort 5	MBI & HP Cohort 5				Recruit Cohort 6-7		MBI Cohorts 6-7				
Space/time needed	Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)				Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)					
Follow-up				Cohort 4 follow up			Cohort 5 follow up				Cohorts 6-7 follow ups	

6 - Basic Definitions

Mindfulness: The process of focusing one's attention on the present moment (including thoughts, feelings, and sensations) without judgement (Kabat-Zinn, 1990; Lang, 2017).

Mindfulness-Based Stress Reduction (MBSR): MBSR is an 8-week, 9 session manualized mindfulness-based intervention that is appropriate for participants from different religious, spiritual, or ethnic background and is not grounded in religious ideology. During MBSR, participants will be trained in mindfulness meditation and the applicability of mindfulness to daily life.

Post-traumatic Stress Disorder (PTSD): PTSD is a psychological pathology characterized by re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal after experiencing a traumatic event.

Trauma: According to the DSM-5, must involve actual or threatened death, serious injury, or sexual violence.

Arm: The different groups of the intervention. In this study, Arm 1 is the health promotion attention control and Arm 2 is the MBSR. Participants at a given site are assigned to one Arm or the other, by cohort).

Cohort: The group of people that are doing the interventions at the same time.

Cortisol: The body's main stress hormone, triggered by the adrenal glands. Cortisol is a glucocorticoid and is released in the body about 20 minutes after a stressor. The immediate stress response hormones (adrenaline and epinephrine) are released within seconds or minutes; if the brain continues to perceive something as stressful, then cortisol is released.

C-Reactive Protein (CRP): This is a protein made in the liver. CRP tends to increase when there is inflammation occurring in the body, (Lindqvist et al., 2014, 2017) induced by proinflammatory cytokines in the liver (Eklund, 2009). These heightened inflammatory responses can lead to health impairments including atherosclerosis (Wong et al., 2012) and cardiovascular disease (Coughlin, 2011) compounding health disparities in disadvantaged populations; CRP, in particular, has been linked with obesity (Visser et al., 2011) metabolic syndrome (Ridker et al., 2003) and CVD.(Ridker et al., 1998) Thus CRP can be used as marker for general inflammation and risk for inflammatory-related problems.

Other acronyms used in this protocol:

IISBR – Institute for Interdisciplinary Salivary Bioscience Research - https://iisbr.uci.edu/

- IISBR is a shared resource and scientific hub; researchers can gain practical experience/knowledge in salivary bioscience through the training programs (e.g., Spit

Camp). IISBR also provides the storage and analyses of the salivary samples collected in this study.

SECTION 1B. INTRODUCTION TO PTSD AND MBSR

Subsection 1B.1 - PTSD Basics

PTSD Diagnosis

PTSD occurs as the result of direct exposure to experiencing, witnessing, or learning of an event that involves actual or threatened death or serious injury or harm to self of others (American Psychiatric Association, 2013). For a diagnosis of PTSD, symptoms must be present for at least one month prior to diagnosis and must include at least one re-experiencing symptom, one avoidance symptom, two arousal and reactivity symptoms and two cognition and mood symptoms. Re-experiencing symptoms can include flashbacks, nightmares, and invasive thoughts. Avoidance symptoms are related to an individual actively avoiding locations, thoughts, events, or objects that are reminiscent of the trauma. Arousal and reactivity symptoms include feeling easily frightened, tense, increased anger, and having issues sleeping. Cognitive and mood symptoms include but are not limited to having trouble remembering key features of the trauma, distorted feelings, and loss of interest in previously enjoyable activities. PTSD must be diagnosed by a mental health professional, but a variety of measures have been validated for use as screens or by non-clinical for research purposes. In our study, we use the Posttraumatic Stress Disorder Checklist, Civilian (PCL- C) (Bovin et al., 2016; Wortmann et al., 2016).

***DSM-5* Criteria for PTSD**

The following text summarizes the diagnostic criteria for PTSD and was obtained from the ptsd.va.gov website.

Criterion A (one required): The person was exposed to: death, threatened death, actual or threatened serious injury, or actual or threatened sexual violence, in the following way(s):

- Direct exposure
- Witnessing the trauma
- Learning that a relative or close friend was exposed to a trauma
- Indirect exposure to aversive details of the trauma, usually in the course of professional duties (e.g., first responders, medics)

Criterion B (one required): The traumatic event is persistently re-experienced, in the following way(s):

- Unwanted upsetting memories
- Nightmares
- Flashbacks
- Emotional distress after exposure to traumatic reminders
- Physical reactivity after exposure to traumatic reminders

Criterion C (one required): Avoidance of trauma-related stimuli after the trauma, in the following way(s):

- Trauma-related thoughts or feelings
- Trauma-related reminders

Criterion D (two required): Negative thoughts or feelings that began or worsened after the trauma, in the following way(s):

- Inability to recall key features of the trauma
- Overly negative thoughts and assumptions about oneself or the world
- Exaggerated blame of self or others for causing the trauma
- Negative affect
- Decreased interest in activities
- Feeling isolated
- Difficulty experiencing positive affect

Criterion E (two required): Trauma-related arousal and reactivity that began or worsened after the trauma, in the following way(s):

- Irritability or aggression
- Risky or destructive behavior
- Hypervigilance
- Heightened startle reaction
- Difficulty concentrating
- Difficulty sleeping

Criterion F (required): Symptoms last for more than 1 month.

Criterion G (required): Symptoms create distress or functional impairment (e.g., social, occupational).

Criterion H (required): Symptoms are not due to medication, substance use, or other illness.

Two specifications:

1. **Dissociative Specification.** In addition to meeting criteria for diagnosis, an individual experiences high levels of either of the following in reaction to trauma-related stimuli:
    - Depersonalization. Experience of being an outside observer of or detached from oneself (e.g., feeling as if "this is not happening to me" or one were in a dream).
    - Derealization. Experience of unreality, distance, or distortion (e.g., "things are not real").
2. **Delayed Specification.** Full diagnostic criteria are not met until at least six months after the trauma(s), although onset of symptoms may occur immediately.

How is PTSD Typically Treated?
CBT, cognitive processing therapy, prolonged exposure therapy (PE), eye movement desensitization and reprocessing (EMDR), stress inoculation training, psychopharmalogical treatments are all common treatments for PTSD. Cognitive behavioral therapy (CBT) often occurs once a week and works with the client to reframe thoughts surrounding the event (i.e. feelings of guilt). Similarly, in cognitive processing therapy the client recounts the event and related thoughts to a therapist and subsequently processes and learns new ways to live with the thoughts and trauma. PE takes place in eight to fifteen ninety minute sessions in which the client is taught breathing techniques to combat anxiety before making a list of avoidances and learning to face them. EMDR asks the client to watch or listen to something, such as a light flashing or sound, while concentrating on the traumatic event so that over time, the client can think about something positive while remember the trauma. Stress inoculation training focuses on how the client responds to the stress of the trauma and works to teach them methods to cope such as breathing techniques and thought stopping. Medications frequently prescribed to individuals with PTSD are SSRIs and SNRIs such as Prozac and Zoloft. We are testing whether MBSR is an effective complementary treatment for PTSD. Complementary means that it will be used in addition to any other interventions used in standard treatment of PTSD.

Subsection 1B.2 - MBSR Basics

MBSR is a way to teach mindfulness, or the process of focusing one's attention on the present moment without judgement (Kabat-Zinn, 1990). It has have shown promise for reducing symptoms of PTSD (Khusid & Vythilingam, 2016; Polusny et al., 2015) and associated biological markers of the stress response (Black & Slavich, 2017; Bower et al., 2017) by lowering physiological arousal and improving attention and acceptance of the past and present (Lang et al., 2012). MBSR is relatively low cost and has demonstrated acceptability and feasibility in trauma-exposed, low-SES, high-minority samples (Dutton et al., 2014). An RCT of MBSR for PTSD in a sample of veterans demonstrated improved PTSD symptoms at immediate follow-up with clinically significant improvement sustained 2-months later (Polusny et al., 2015). Congruent findings were indicated in veterans using a one-armed-repeated-measures design (Kearney et al., 2012). MBIs have also been linked with statistically significant reductions in markers of inflammation (Bower et al., 2017; Rosenkranz et al., 2013). that are associated with PTSD, including CRP (Creswell & Irwin, 2012; Malarkey et al., 2013). In relation to stress reactivity, in repeated measures analyses, an MBI significantly reduced cortisol reactivity to a stress task (Rosenkranz et al., 2013). Participation in an MBI compared to a treatment-as-usual condition in veterans with PTSD was associated with reduced cortisol, suggesting a brief MBI might have beneficial responses on stress physiology (Bergen-Cico et al., 2014). Data suggests that biological dysregulation may precede the development of – and at a minimum mutually maintain – PTSD symptoms (van Zuiden et al., 2013). This means that the physiological response may actually occur prior to the psychological symptoms, but more research is needed. Moreover, participation in MBIs have been associated with effective relapse prevention in those with SUD (Bowen et al., 2006) and lower depression in a sample of economically disadvantaged women (Burnett-Zeigler et al., 2016). As such, MBIs, which concurrently target regulation of the physiological stress responses, emotional cognitive symptoms of PTSD, and related

psychological comorbidities may provide a low-cost, feasible method to address the complexity of PTSD symptom maintenance over time.

MBSR was first developed in the 1970s by Dr. Jon Kabat-Zinn at the University of Massachusetts Medical Center (Kabat-Zinn, 1990). MBSR uses many practices that have been around for thousands of years, but manualized these practices into an 8 week, 9 session program. MBSR has been used in hospital, school, work, athletic, and prison settings with beneficial results. MBSR is a group-based class and is not therapy. It generally should be used as an adjunct to other psychiatric and physical healthcare, not as a supplement.

The general flow of the eight-week program is as follows:

Week 1: Introductory Material. This includes an overview of the course, building trust within the group, introduction to mindful eating, some standing yoga stretches, mindful breathing and body scan meditation (Homework: Body Scan recording using MP3 player; eating one meal mindfully; optional informal meditation practice.)

Week 2: Understanding Perceptions. This session focuses on self-responsibility and short and long-term changes for health enhancing behaviors; how you see things determines how you react or respond. (Homework: Body Scan recording using MP3; fill out Pleasant Events Calendar; select one activity to bring full awareness to).

Week 3: Hatha Yoga, Sitting Meditation, Walking Meditation. The theme is the pleasure and power of being present; this week teaches how to investigate the mind and body through yoga and meditation. (Homework: Alternate Body Scan recording with Lying-down Yoga using MP3 player; fill out Unpleasant Events Calendar; sitting meditation).

Week 4: Concentration and Awareness. This theme relates to how conditioning and perception influence one's experience and new ways to relate to stress. (Homework: Alternate Body Scan recording with Lying-down Yoga using MP3 player; be aware of being stuck, sitting meditation).

Week 5: Unhealthy Patterns and Getting Unstuck. This week examines conditioned patterns and the passive ways that people cope (e.g., numbing, denial, passive-aggressiveness, suppression of feelings, substance dependency). (Homework: Fill out Difficult Communications Calendar; Sitting Meditation and Standing Yoga Sequence).

Week 6: Transformational Coping Strategies. This for this week include how to deal with stressful communication and knowing and expressing your feelings. (Homework: Alternate Sitting Meditation recording with Body Scan and/or Standing or Lying down Yoga recording).

Week 7: Retreat. This will be a silent class, with sitting and walking practice. Guided meditations will include loving-kindness meditation.

Week 8: Maintaining Discipline and Flexibility. This class focus on how to more fully integrate mindfulness into daily life. Instructors and participants discuss lifestyle choices and limiting patterns. (Homework: no recordings; try to practice formal sitting meditation; recordings can be used if necessary.)

Week 9: Course Review. In this session, students will reflect on the course, the instructor provides additional resources, participants discuss their experiences with the group.

Common Uses:
MBSR is used as a complementary treatment for anxiety, panic, depression, eating disorders, pain, sleep issues, and a growing number of additional maladies. MBSR is also used increase productivity, performance, emotion regulation, and general wellbeing.

SECTION 2. INTERVENTION DELIVERY

Subsection 2.1 - Phase II Overview

In Phase II, we will assess the potential benefit of MBSR to reduce PTSD (primary outcomes) and secondary outcomes (e.g., depression, SUD, CRP, cortisol reactivity), among 130 eligible homeless women who exhibit likely subthreshold or threshold PTSD living at one of two residential drug treatment facilities. MBSR will be compared to an attention-control group (Health Promotion Wellness Classes; HP). There originally intended to be five cohorts of women, each with 12-15 women (total of 24-30 women per cohort). However, due to COVID-19 adjustments have been made in terms of the class size and randomization procedure. At each cohort, sites will be randomized to receive either the MBSR or the HP. Although sites will alternate between MBSR and HP by cohort, each participant will receive either the MBSR or the HP. Randomization will occur using RedCAP. The women participate in either MBSR or HP for 9 weeks. Psychosocial data will be collected at baseline, immediately following final intervention session, and at 6-month follow-up via tablet questionnaires. After psychosocial data collection, a stress task (Trauma Imagery Task) will be conducted at each time point, with saliva collected both before and after the task to assay cortisol and CRP. This proposal will improve on the methodological rigor of prior research on MBIs for PTSD in disadvantaged populations by using: randomization procedures that account for cross-contamination; blind evaluators; longitudinal follow-up; an attention control group equal to the MBI intervention in both contact visits and hours; increased demographic diversity; comprehensive lifetime trauma assessment; and inclusion of objective indices of stress responses to accurately evaluate the effectiveness of MBIs in treating trauma-related symptoms.

Confidentiality and Ethical Issues

All program staff must follow confidentiality and ethical procedures throughout this program to ensure that everybody is treated with respect and dignity.

1. Communication with study participants must remain confidential. To maintain confidentiality for participants, any personal information provided, such as participants' name, age, etc., will

be protected by use of subject code on all data and questionnaires. Data including subject identifiable information will be linked to a code on RedCap for this study for access and only research staff will have access. An exception to this rule is the clinic provider and site staff who work directly with the women onsite.

Program Team

The Lab Manager and Lab Coordinator will help the PI (Dr. Garfin) in organizing all aspects of the study. These individuals will be current or former students from the Department of Psychological Science's Postbaccalaureate Program. They will be responsible for tracking recruitment, scheduling research assistants, and ensuring that the site is well-stocked with necessary supplies. Weekly, the Lab Manager and Lab Coordinator will meet with Dr. Garfin to review all aspects of the study, troubleshoot any problems, and create schedule for the other Research Assistants (RAs). The RAs will be highly trained Postbaccalaureate, graduate, or undergraduate students from the University of California, Irvine.

Safety of Program Staff

While we believe that conducting this study is highly important for public health, it is critical that the program staff prioritize their own safety first. If you feel that you are in danger (physically, emotionally, psychologically) in any way, end the study activities and inform the research coordinator or the PI as soon as you can safely do so. This is particularly important during COVID-19. Please report any lapses in COVID-19 protocol to Dr. Garfin and the Leadership team immediately. If there is any chance you have been exposed, it is imperative *that you do not come to site*. The study leadership (Dr. Garfin and the Lab Manager / Lab Coordinator)

Subsection 2.2 - Phase II Scope of Work & Participant Flow Diagram

1. **General Recruitment**
    a. We will recruit 5 cohorts of women from the two sites by research staff via flyers and announcements during site programming. Due to COVID-19, this strategy may change as the situation evolves.
    b. Participants will then be given an eligibility screener via tablet with either Dr. Garfin or the Lab Manager/Lab Coordinator available to answer any questions.
        i. A key inclusion criteria is subthreshold current PTSD. Thus, the women will be given a PTSD screener for the trauma that is bothering them most right now. There may be multiple traumas the women have experienced – they should be prompted to pick the one that is most troubling to them at the time of screener completion.
    c. Tablets will be programmed by the Research Director from the School of Nursing and responses will be automatically, electronically scored. All participants who complete the screener will receive $3.
        i. Note: those who complete the screener must complete the consent to screen, but are not assigned a participant ID at this time as they have not completed the **Informed Consent**. As such it is imperative that accurate information be obtained with respect to the individual's name as that will be used to link it to their subsequent data.

2. **Group Assignment and Intervention Procedure (may chance due to evolving circumstances due to COVID-19)**
    a. Prior to recruitment, the Residential Treatment Sites (RTS; Pomona and Escondido) will be randomized to receive the MBI or serve as the attention-control (HP); recruitment and research procedures (MBI or attention-control) will occur at both sites simultaneously. Women will live at sites prior to recruitment.
    b. **Informed consent** – there are TWO versions of the Informed Consent documents. One is for the MBSR course; the other is for the HP course. Women will complete ONE of the Informed Consent forms, depending on which group they are in. It is imperative that the correct form is filled out and uploaded onto REDCap.
    c. Baseline questionnaire administered:
        i. After informed consent, participants will complete a baseline questionnaire. In addition to the traumas indicated in the PCL-5, participants will report **lifetime** history of trauma (including whether events occurred in adulthood, childhood, or both).
        ii. Questionnaire data will be collected via tablet and transferred to RedCap.
        iii. Participants will provide a urine sample for a drug test to validate self-report. Then participants will complete the brief stress (Trauma task providing saliva samples both before and after the task.
    d. Locator guide: this is a critical part of maintaining contact with our participants. However, they may not be inclined to provide all the information on the first or second meeting. **PLEASE TAKE THE PICTURE AT THE TIME OF ADMINISTERING INFORMED CONSENT.** The rest of the locator guide can be filled out over the course of the study. Given issues with COVID-19, we will start completing the Locator Guide after session 2 or 3. Please see PI or Lab Management Team for further guidance.
    e. Intervention
        i. Participants will begin MBSR/HP activities within one month of baseline assessment, dependent on the time of their baseline assessment within recruitment schedule
        ii. Both groups (MBSR and HP) will consist of nine sessions, each approximately 2 hours in length.
    b. Immediate follow-up
        i. After the 9th session, participants will complete a questionnaire via tablet that will assess PTSD (primary outcome), secondary outcomes (e.g., depression, substance use), and traumatic events that occurred since first assessment, as well as key covariates (e.g., fidelity to intervention) and additional outcomes (e.g., mindfulness, emotion regulation).
        ii. Women will provide urine for drug test and repeat the Trauma Imagery Stress Task, providing saliva samples before and after the task.
    c. 6-month follow-up
        i. Primary and secondary outcomes and covariates (e.g., fidelity to intervention) will be reassessed via tablet
        ii. Women will provide urine for a drug test and repeat the Trauma Imagery Stress Task, providing saliva samples before and after the stress task.

3. **Phase II Reimbursement**
    d. Women will receive $15 for the baseline assessment, $10 per MBSR/HP session, $15 for completing the post-intervention assessment, and $30 for the 6-month follow-up assessment.

i. Women are paid in cash and must sign on the iPad (via REDCap) that they have received the payment. This must also be initialed, signed, and dated by the RA in charge of payment.

Subsection 2.3 - Phase II Recruitment & Treatment Overview

Table 4: Overview of Phase II: Timeline of Mindfulness Trial Procedures & Assessments

PRE-ASESSESSMENTS			MBSR or HP Control		POST-ASSESSMENTS			
Baseline			Sessions 1-8	Session 9			6-months post-intervention	
Eligibility Screen PTSD dx	Psychosocial Questionnaire [a,b]	Trauma Imagery Task	Groups meet once per week	Final intervention session	Psychosocial Questionnaire [b,c] PTSD dx	Trauma Imagery Task	Psychosocial Questionnaire [b,c] PTSD dx	Trauma Imagery Task

KEY ⬆ = Urine collected for drug screen ⬆ = Saliva collected immediately before & 20 min post trauma imagery task [a] Measures: lifetime trauma exposure (+ occurrence in adulthood, childhood or both); demographics [b] Updated adversity history (traumatic & stressful events, including incarceration), PTSD dx [c] Depression, self-report substance use, perceived stress, mindfulness, fidelity/ adherence to program, quality of life

Subsection 2.4 - Phase II Recruitment & Screening

The study was designed so that recruitment at Pomona would be paced to match that at the Escondido site so that all procedures across sites happen in tandem, thus avoiding history effects; recruitment data will be evaluated weekly to inform pacing. Site staff at Prototypes will assist with participant recruitment, informing Prototypes residents of the opportunity during formal announcements during programing. Recruitment flyers will also be posted around the RTS. RAs will help recruit women and conduct the initial screening in a private room after obtaining informed consent; progress will be monitored closely by Dr. Garfin the Lab Management team. Modifications will be made to allow for the study to continue during the COVID-19 pandemic to ensure safety of Ras, site staff, and participants.

Ideally, recruitment will be staggered according to cohorts and paced equally across sites. In total, five cohorts of women will be recruited. Each will have approximately 26- 28 women in each group/site (n=13-14 MBSR; n=13-14 attention control); recruitment proceeds for one month, the intervention runs for approximately 2 months (9 weeks), then there is one month break. ***However, this schedule may vary due to COVID-19 restrictions, limitations, and other feasibility issues***.

Dr. Garfin will explain the study during an initial meeting with potential participants and answer any questions. Then women will be screened for eligibility. Prior to obtaining any data, the women will provide a “consent to screen”. This is because we need to obtain data from the women to determine if they are eligible, but they are not officially enrolled as human subjects. By providing their “consent to screen”, we are obtaining verbal consent/permission to ask them questions. Their data will not be used by the research team if they are not eligible.

The RA will read the consent to screen script on REDCap. Potential participants are free to stop at any time – remind them that all procedures are completely voluntary. Dr. Garfin and/or someone from the Lab Management team will always be onsite to help answer questions.

Participants will then be given an eligibility screener via tablet with either Dr. Garfin or a trained research assistant available to answer any questions. The screener will first assess for age, prior homelessness, and cognitive competence. The screener then screens for PTSD using the PTSD Checklist for DSM-5 (PCL-5) for ***the worst event in their life***. We will assess PTSD to their most recent event (in the past year) during the baseline and follow-up assessments. The standard PCL-5 initially starts with the identification of the presence of exposure to a DSM-5 traumatic event and then assesses whether it involved actual or threatened death, serious injury or sexual violence. The RA may need to prompt the potential participant with examples to keep them on track and to ensure that the participant is responding to an actual DSM-5 traumatic event. The next 20 items on the PCL-5 assess all four B-E PTSD criterion (re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal), assessed on a Likert-type scale 0 "not at all", 1 "a little bit", 2 "moderately", 3 "quite a bit", 4 "extremely". Subthreshold PTSD will be defined as endorsing "moderately" or more to at least 2 B-E criteria; probable-PTSD will be measured by meeting criteria A-G for PTSD.

Data collection method: All data will be collected via encrypted tablets will be programmed by the Research Director from the School of Nursing and responses will be automatically, electronically scored. Data is not stored on the tablets. It is automatically transferred to the All participants who complete the screener will receive $3.

Subsection 2.5 - Phase II Eligibility Criteria

Inclusion Criteria:

1) Homeless women (N=134; 67 in each group)
    a. Women over 18 years of age
    b. Able to speak English
    c. Homeless in the last 6 months: a homeless person is defined as anyone who spent the previous night in a public or private shelter, or on the street.
    d. Lifetime exposure to trauma as defined by the Diagnostic and Statistical Manual for Mental Disorders, 5th Edition (DSM-5).
    e. Likely subthreshold or threshold PTSD, as measured by the PCL-5.

Exclusion Criteria:

The following will **not** be eligible for participating:

1) Persons who are:
    a. Not able to speak English
    b. Judged to be cognitively impaired, as indicated by score > 10 on the Short-Blessed Screener

Subsection 2.6 - Phase II Laboratory Tests/Sample Collection

Saliva Sampling and Results

Saliva Collection

- Pre-task, saliva will be collected. All saliva collection will occur between 10am-2pm to minimize diurnal fluctuation effects. (Study procedures may start before 10, but first saliva sample must be collected after 10:00am; the second sample must be collected before 2pm – participants must be scheduled according to these specifications).
- Two whole saliva samples will be collected using an unstimulated passive drool technique.
- Women will be instructed to avoid eating, brushing teeth, or smoking for one hour prior to the assessment and will be asked to wait to begin the task if they have.
- Participants will rinse their mouths thoroughly with water for 10 minutes before samples are collected. Participants will then passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected.
- Saliva samples will be immediately placed in the on-site freezer (or ice cooler) and be taken to IISBR within 36 hours to be frozen at -80°C until assayed.
- All samples will be assayed for salivary cortisol and CRP using a highly sensitive enzyme immunoassay (Salimetrics, IISBR).
- ***Twenty minutes after task completion***, saliva samples will be collected again in an identical manner to that described above.
- Participants will then be offered snacks and a drink and be debriefed to ensure they are not experiencing severe task-related psychological distress. In the unlikely event of participant distress, an immediate referral will be made to on-site professional staff.

Subsection 2.7 - Phase II Intervention Program Description

General Description: Among 134 eligible trauma-exposed homeless women, assess the impact of the MBSR intervention program PTSD symptoms (primary outcomes), and substance abuse, depression, cortisol reactivity, and inflammation (secondary outcomes).

Data Collection Time points: Baseline, 2 months, and 6 months

Total Duration: 6 months

The following sections will outline the intervention process:

- Pre-intervention Assessments
- Brief Stress Task (Trauma Imagery Stress Task)
- Biospecimen Collection
- Biospecimen Analysis
- MBSR Intervention
- Health Promotion Intervention
- Post-Assessment
- Team Management of Biospecimen Collection Refusal
- Dealing with Program Attrition

Subsection 2.8 - Phase II Pre-intervention Assessments

After Informed Consent, participants will complete a series of self-report measures. These measures will be administered by Research Staff at a private location at the site. Responses options to each question will be provided to the participant, organized in a clearly labeled binder. The Research Staff will display the response options for each measure, read the options out loud, and then record the response on the tablet. At the end of each measure, the RA will "lock" the measure. There will be a prompt if any items have been missed. Please check that there is no missing data. The participant may take a break at any time. However, the participant should refrain from eating, drinking (except for water ~ 10 minutes prior to stress task), or smoking until after the second saliva collection to ensure the accuracy of the saliva sample.

Order of assessments

1. Drug test (urine)
2. TCU Drug Screen (self-report)
3. Self-compassion scale – short form
4. General self-efficacy scale
5. Mindful Attention Awareness Scale
6. Difficulties I Emotion Regulation Scale
7. Satisfaction with Life Scale
8. Quality of Life Enjoyment and Satisfaction Questionnaire
9. MOS Social Support
10. Perceived Stress Scale
11. Dimensions of Anger Reactions
12. PROMIS – Anxiety
13. PROMIS – Depression

*NOTE: For time constraints, the urine test can be administered during the waiting period prior to the second cortisol sample.

AT THIS POINT, THE FIRST SALIVARY SAMPLE IS COLLECTED

14. Negative Life Events Inventory
15. PCL 5- ***Worst life event*** (this is the event that bothers them the most, from their entire life)
16. PCL 5 – ***Recent (past year)*** this is a traumatic event that has happened to them recently (in the past year) – it may or may not be the same as #16
17. Trauma Imagery Stress Task (the Negative Life Events Inventory and the PCL build up to this)

Subsection 2.9 - Phase II Brief Stress Task (Trauma Imagery Task)

After completing the PROMIS Depression, the participant will provide a saliva sample. They will then complete the negative life events inventory and the PCL 5 (for worst event in their life and a recent event). The reason that the saliva sample is taken before these measures and not directly before the Trauma Imagery Task is because in pilot studies the women began to

become distressed when recounting their traumas during the Negative Life Events Inventory and the PCL; thus, the “baseline” for cortisol is now taken PRIOR to these items.

After completing the PCL for worst event and recent event, the participant will complete a a modified script-driven imagery task (Seo et al., 2013), derived from prior research with women with PTSD. Participants will be asked to recount a traumatic event via written response. The RA will provide a paper and pen and instruct the participant to recall the event exactly as it happened. The RA can offer prompts to recall sight, smell, and sound. The participant will then recount the event to the RA. Script driven imagery tasks have been effectively and safely used to assess traumatic-stress responses in individuals with PTSD. However, RAs will be highly trained to assess any severe distress that may arise and will immediately notify the PI and site clinical staff immediately. Responses will be subsequently destroyed. ***AFTER THE COMPLETION OF THE TRAUMA IMAGERY TASK THE 20 MINUTE POST-SALIVA SAMPLE TIMER STARTS!*** When the timer starts, the RA will not interact with the participant. They should sit quietly or may read.

Subsection 2.10 - Phase II Biospecimen Collection

Urine Collection: Participants will provide a urine sample to validate self-report drug use. A 5-panel FDA-approved urine test cup will be used in this study. The participant will be instructed to urinate in the cup, close the cup, and then bring it back to the RA to read. Gloves will be used at all times and the RA should read the cup without touching it if possible. The participant will then be instructed to dispose of their urine in the restroom.

Saliva Collection: Before and twenty minutes after the brief stress task (Trauma Imagery Stress Task), women will be asked to provide a salivary sample. Women will be instructed to avoid eating, brushing teeth or smoking for one hour prior to the collection of saliva and will be asked to wait to begin the task if they have. Participants will passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected.

Saliva samples will be immediately placed in the on-site freezer or cooler and be taken to IISBR or to Dr. Garfin’s research lab for storage. Saliva samples will be transferred to IISBR within 36 hours to be frozen at -80°C until assayed. After the second and final collection, participants will be offered snacks and a drink and be debriefed using an IRB-approved script (see below).

Debriefing script:

> Thanks so much for your participation. I know that might have been difficult for you to recall this event. I want to thank you and let you know that we think your participation in this task will help other women who have experienced adversity. While feeling a little distressed might be expected, we want to make sure you are not experiencing a lot of distress. Right now are you are experiencing a lot of distress?

If yes, ask if they want you to get a site staff from Prototypes/Serenity House AND contact the Principal Investigator, Dr. Dana Rose Garfin immediately AND provide Dr. Garfin's contact information to them).

If no, thank them for their time and remind them if anything comes up they can call the Principal Investigator, Dr. Dana Rose Garfin and/or talk to any of the Prototypes/Serenity House site staff. (Provide Dr. Garfin's contact information to them).

Provide water and snacks at this time and pay close attention to any noticeable changes in mood until they are released to the care of the Prototypes/Serenity House site staff. Immediately inform Dr. Garfin AND Prototypes/Serenity House site staff of any potential issues.

Subsection 2.11 - Phase II Biospecimen Analysis

Urine Sample: The 5-panel FDA-approved urine test cup screens for metabolites of the following drugs of abuse at the established cut-off levels and is used for qualitative purposes: Amphetamines (1000 ng/mL), Cocaine (300 ng/mL), Methamphetamines/ MDMA (500 ng/mL), Opiates (2000 ng/mL), and THC (50 ng/mL). Urine sample validity checks will be provided by temperature and adulterant monitoring strips built into the test cup. Participants whose urine does not pass validity checks will be counted as positive for drugs. Results will be coded qualitatively (above or below threshold). All positive results will be interpreted as positive, regardless of self-report.

Saliva Sample: The saliva sample is collected to determine resting cortisol, cortisol reactivity, and C-RP (a marker of inflammation). All saliva will be assayed in duplicate using standard manufacturer's protocol (Salimetrics). The concentration of CRP in saliva will be determined using a Salivary C-Reactive Protein ELISA kit, an enzyme-linked immunoassay. The standard curve is run on every assay plate and must have an R2 value of > 0.99. The replicates must have a %CV < 15 or an absolute difference <0.030 between the replicates. The mean values across saliva duplicates will be computed for each sample and used in the statistical analyses.

Subsection 2.12 - Phase II MBSR-based Intervention

Standard MBSR is an eight-week long mindfulness-based intervention (MBI) with one 1.5-2.5 hour session per week (the seventh week has two sessions as one is a mini-retreat). The intervention will be run by a highly experienced instructor with prior experience conducting MBSR with individuals exposed to trauma with PTSD.

During MBSR, participants are trained in mindfulness meditation and the applicability of mindfulness to daily life. During MBSR programing, teachers will lecture about key topics in mindfulness and lead class discussions. Participants are given opportunities to ask the instructor questions and to share their experiences with each other. Snacks and drinks will be provided. Important to note, the intervention in this study is not true MBSR. It has been modified to fit the specific needs of the target population. This includes shorter sessions and shorter meditations, and additional flexibility on the part of the trainer. Although many of the same tools and procedures in traditional MBSR will be utilized, given these critical differences the intervention administered in this study is *not* true MBSR.

Each week in the MBSR program focuses on a different theme and has specific short homework assignments that students are asked to complete. The sessions are as follows:

- **Week 1**: Introductory Material. This includes an overview of the course, building trust within the group, introduction to mindful eating, some standing yoga stretches, mindful breathing and body scan meditation
    - **Homework**: Body Scan recording using MP3 player; eating one meal mindfully; optional informal meditation practice. Participants will also complete a trauma-informed safety plan to ensure that, although MBSR is given in a group format, the MBSR trainer is responsive to the unique needs of the individual.
- **Week 2**: Understanding Perceptions. This session focuses on self-responsibility and short and long-term changes for health enhancing behaviors; how you see things determines how you react or respond.
    - **Homework**: Body Scan recording using MP3; fill out Pleasant Events Calendar; select one activity to bring full awareness to.
- **Week 3**: Hatha Yoga, Sitting Meditation, Walking Meditation. The theme is the pleasure and power of being present; this week teaches how to investigate the mind and body through yoga and meditation.
    - **Homework**: Alternate Body Scan recording with Lying-down Yoga using MP3 player; fill out Unpleasant Events Calendar; sitting meditation.
- **Week 4**: Concentration and Awareness. This theme relates to how conditioning and perception influence one's experience and new ways to relate to stress.
    - **Homework**: Alternate Body Scan recording with Lying-down Yoga using MP3 player; be aware of being stuck, sitting meditation.
- **Week 5**: Unhealthy Patterns and Getting Unstuck. This week examines conditioned patterns and the passive ways that people cope (e.g., numbing, denial, passive-aggressiveness, suppression of feelings, substance dependency).
    - **Homework**: Fill out Difficult Communications Calendar; Sitting Meditation and Standing Yoga Sequence.
- **Week 6**: Transformational Coping Strategies. This week includes how to deal with stressful communication and knowing and expressing your feelings.

    - **Homework**: Alternate Sitting Meditation recording with Body Scan and/or Standing or Lying down Yoga recording.
- **Week 7a**: Retreat. This will be a silent class, with sitting and walking practice. Guided meditations will include loving-kindness meditation.
- **Week 7b**: Maintaining Discipline and Flexibility. This class focuses on how to more fully integrate mindfulness into daily life. Instructors and participants discuss lifestyle choices and limiting patterns.
    - **Homework**: no recordings; try to practice formal sitting meditation; recordings can be used if necessary.
- **Week 8**: Course Review. In this session, students will reflect on the course, the instructor will provide additional resources, and participants will discuss their experiences with the group.

Subsection 2.13 - Phase II Health Promotion Intervention

The Health Promotion program is eight weeks long with one 1.5-2 hour session per week (the seventh week has two sessions to ensure the same number of contact hours as the "mini-retreat" in the MBSR course). The Health Promotion Classes were designed to be analogous to the MBSR classes in terms of length and contact hours. This is because the effect of being in a group and participating in a study could help participants, without the benefit having much – if anything – to do with the actual intervention.

The program will be run by a UCI graduate or postbac student with a BA or higher. The SMART (Specific Measurable Achievable Relevant Time-based) framework will be used for goal setting. In this framework, specific, achievable goals are outlined by the participant as relevant to each class. This helps with information retention and helps reinforce concepts and positive behaviors. Snacks and drinks will be provided.

Each week in the Health Promotion program focuses on a different theme. The sessions are as follows:

1. Introduction & overview
2. Envisioning Health through Art
3. Chronic Disease I – Heart Health
4. Chronic Disease II – Diabetes
5. Nutrition and Hydration
6. Infectious Disease Prevention
7. Skin Care
8. Oral Health
9. Promoting Social Integration & Course Graduation

Subsection 2.14 - Phase II Post-Assessment

After the ninth session (of either MBSR or Health Promotion), a post-assessment will be administered via tablet. Urine will again be collected to validate self-report drug use. Participants will repeat the brief stress task (Trauma Imagery Task) using an identical strategy and provide saliva samples before and after. The Lead Researcher or a postbac student researcher will be on site to answer any questions or clarify any items. Urine and saliva samples will both be stored in a freezer on-site or at Dr. Garin's research office and then transferred to UCI for analysis within 36 hours. Follow-ups will occur on site unless participant has moved to sober living or other location. Zoom or phone will be implemented for those who moved out of state

Subsection 2.15 - Phase II Team Management of Biospecimen Collection Refusal

Participants have the right to refuse the collection of urine or saliva and it is important to understand that an individual may want to refuse due to the following:

Step 1: Assess reasons why participant does not want to have their sample collected.

- May experience concern that their friends, acquaintances, or shelter staff will be informed of the results of their surveys or urine.
- Other possible reasons?

In the event a participant refuses the sample collection, inquire about the following:

Step 2: Respond to their reasons why they do not want to give urine or saliva samples.

We encourage our participants to complete as many of the procedures as they are comfortable with. Please offer to have Dr. Garfin or Lab Management answer any questions the participant may have regarding the measures. However, participation is completely voluntary, and the participant may skip any aspect of the procedure that they chose without penalty and still be in the study.

Subsection 2.16 - Phase II Dealing with Intervention Program Attrition

Attrition is conservatively estimated at 10% for first follow-up and 20% for 6 month follow-up. To account for an estimated 30% of women to be screened with subthreshold or threshold PTSD, 448 women will be screened, approximately 134 enrolled, with approximately 120 for immediate post-intervention assessment and 96 at 6-month follow-up. This may change due to COVID-19, but we will work hard to ensure retention of participants during the study. The Locator Guide is key to maintaining effective follow-up.

- Completion of the intervention program is defined by completing at least 6 out of the 9 classes. We will keep track of the number of classes using the adherence tracker on REDCap. Make-up classes will be offered to women who can not make the class,

particularly as it pertains to COVID-19 or other obligations the women have such as court appearances.
    - The minimum amount of time required for the regimen is 8 weeks and the maximum is 10 weeks.

Subsection 2.17 - Phase II Follow-Up Focus Groups

At six-month follow-up, we will contact the women with assistance from the site supervisor or by using our Locator Guide (see Appendix). Research Staff will travel to the participant's location, as they may not be available to return to site due to COVID-19 restrictions or other factors. If participant moved out of state, the follow-ups may be conducted over Zoom or phone.

Subsection 2.18 - Phase II Compensation

The Phase II compensation is listed below. Each participant will receive a total of up to $153 over the course of the study.

$3 – screener (after completing screener)
$15 – baseline measures (after completing)
$10 – per class (at the end of each class; for a total of 9 classes)
$15 – immediate post-intervention follow-up measures (after the 9th class)
$30 – 6-month follow-up (after completion)

Participants who complete 6 or more of the sessions will also be given a Certificate of Completion. Participants who complete all 9 sessions will be given a Certificate of Perfect Attendance (see Appendix).

Subsection 2.19 - Program Fidelity

To ensure program fidelity, all procedures will be closely supervised by the PI, Dr. Garfin. Detailed training materials will be provided to all staff, and staff will be required to complete a quiz prior to working on site. For those involved in administering the interventions, a detailed teachers manual will be provided, and all staff will be expected to adhere to the manual, with some flexibility allowed depending on the needs of the group.

Subsection 2.20 - Research Staff Competencies and Mock Sessions

UC Irvine has implemented an educational program on the protection of human research subjects. All study personnel who are responsible for the design and conduct of this project must complete the Collaborative Institutional Training Initiative Human Research Curriculum (CITI program), with the confirmation of completion of the trainings on file. The following courses should be completed by all staff prior to engaging in study activities.

- Human Research - Social & Behavioral Researchers & Staff

- Good Clinical Practices (GCP) courses
- Refresher courses are also available on CITI website https://about.citiprogram.org/en/homepage/) as needed.

Further, all research staff will be highly trained by the PI in the following:

- Trained in specific protocols for dealing with emotional and mental distress (e.g., remaining calm, immediately finding appropriate onsite clinical staff).
- Trained in observational and communication skills, and in providing psychosocial support, particularly as it relates to emotional and information support
- Trained in the California Mandatory Reporting Laws governing reporting of child abuse, domestic violence, and elder/dependent abuse. Protocols governing reports to the California Department of Family and Child Protective Services, or (in the case of domestic violence) local police, will be carefully followed. Study participants will receive full disclosure regarding mandatory reporting laws during the informed consent process and discussion of confidentiality. In terms of current or recent abuse experience, research staff will refer the participants to the onsite Prototypes clinical staff.

During research study training, Research Staff will be evaluated using the competency grid and mock session review. Research Staff will also complete a quiz to be reviewed with the PI prior to interacting with the participants.

Subsection 2.21 - Data Entry, Management & Confidentiality

In Phase 2, secure and encrypted platforms will be used:

- **REDCap:** Interview data will be captured electronically using REDCap (Research Electronic Data Capture; http://project-redcap.org/), a secure, web-based application designed to support data entry and storage for research studies. Participants will answer surveys via an electronic tablet and the data will be uploaded in real-time. Possible errors, including incomplete responses, logic checks, and data range checks will be flagged by the RedCap software during input so that they can be corrected immediately. Laboratory data will be entered in REDCap electronic forms.
- Dr. Garfin will routinely check to ensure data is accurately entered. The Data Safety and Monitoring Board (DSMB) will also meet after the enrollment of every 30 participants to review/

Procedures to safeguard confidentiality

Confidentiality of data will be protected by use of subject code on all data and questionnaires. Any forms that link participant with their codes will be stored electronically on UCI's secure server and only senior research staff and the PI will have access. All self-report data will be immediately uploaded onto UCI's secure server via RedCAP. Saliva samples will use the subject code number and will not be labeled with the participant's name.

- Participants will be reminded that their interview questions will be provided over a tablet that will immediately transfer the data to the UCI secure server and site staff will not see their data.
- We will minimize the risk by strictly adhering to confidentiality procedures. All study staff will be rigorously trained in methods to promote confidentiality. The staff will also be taught to treat participants in a non-judgmental, professional and confidential manner.
- A Data Safety and Monitoring Board will be put in place for monitoring of the data collected.
- Confidentiality of data will be protected by use of subject code on all data and questionnaires. Data including subject identifiable information (eg: locator form etc) will be linked to a code on REDCap for access in real time to track participants and only research staff will have access. REDCap also allows for participant's names and IDs to be viewed without access to their responses to the other items in the survey. Tracking of participants for their follow-ups will be based upon the information the participant reveals on their Locator Guide. When contacting people over the phone, we will use their preferred method and the research staff will identify themselves per participants' wishes.
- To protect confidentiality and reassure subjects, the research staff will be providing explicit explanations in the beginning of the program that they will share no confidential information. The trained research staff will administer the questionnaires individually to the participants.
- Subject identifiable data will be destroyed upon completion of the study. All the data will be stripped off any identifiable information and only de-identified database will be kept for analysis and dissemination.

Subsection 2.22 – Using REDCap

- For electronic data entry, log onto RedCap (https://redcap.med.upenn.edu/) with your user ID and password.
- RedCap also incorporates suitable validity checks at the point of data entry to prevent "out of range," "missing" or other checkable data entry errors.

Subsection 2.23 - Data Security

- All CRFs and questionnaires must be identified by a code number (Study ID) only and patient identifier information will also be linked on REDCap through this code.
- The informed consent with the participants' names and signature will be on REDCap and a digital copy should be printed out of REDCap and stored in a local hard drive not connected to server.
- All databases are accessible only to key investigators and senior leadership of the project.
- The electronic data files are stored on the secure, password-protected UCI Health Science server.

- This data is available for analyses on the UCI server to authorized users through a web VPN application.
- Authorized users can export the data into Excel or other statistical software sheets for further analyses.
- The de-identified database will be archived for future analyses and all other identifying data will be destroyed at the end of the study as per NIH policy.

Subsection 2.24 - Post Data Collection

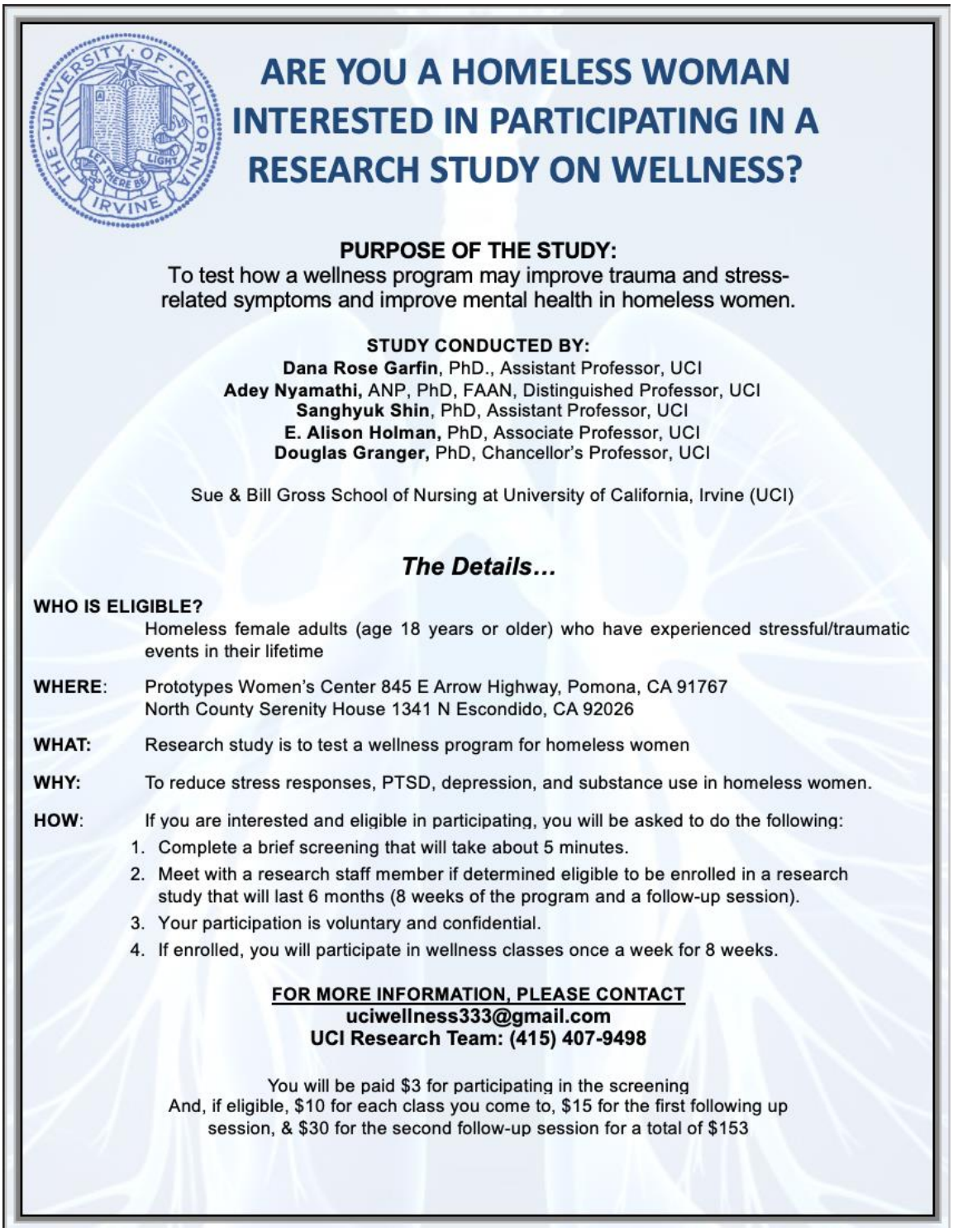
- Validity checks on REDCap should be done right after any interview or other data collection is completed.
- Routine statistical validity checks should identify missing or suspect entries at agreed defined intervals (twice per month or as needed) by approved study staff, so that correct data can be obtained from the research staff, participants or their records if needed.
- Thorough data cleaning should be performed before any data analysis.

Subsection 2.25 - End of Study

- De-identified electronic data will be maintained for the period agreed in the study protocol (indefinitely).
- Final cleaned electronic data will be used for all statistical analyses.

SECTION 4. RECRUITMENT

Subsection 4.1 - Phase II Flyer



ARE YOU A HOMELESS WOMAN INTERESTED IN PARTICIPATING IN A RESEARCH STUDY ON WELLNESS?

PURPOSE OF THE STUDY:

To test how a wellness program may improve trauma and stress-related symptoms and improve mental health in homeless women.

STUDY CONDUCTED BY:

Dana Rose Garfin, PhD., Assistant Professor, UCI
Adey Nyamathi, ANP, PhD, FAAN, Distinguished Professor, UCI
Sanghyuk Shin, PhD, Assistant Professor, UCI
E. Alison Holman, PhD, Associate Professor, UCI
Douglas Granger, PhD, Chancellor's Professor, UCI

Sue & Bill Gross School of Nursing at University of California, Irvine (UCI)

The Details…

WHO IS ELIGIBLE?
Homeless female adults (age 18 years or older) who have experienced stressful/traumatic events in their lifetime

WHERE: Prototypes Women's Center 845 E Arrow Highway, Pomona, CA 91767
North County Serenity House 1341 N Escondido, CA 92026

WHAT: Research study is to test a wellness program for homeless women

WHY: To reduce stress responses, PTSD, depression, and substance use in homeless women.

HOW: If you are interested and eligible in participating, you will be asked to do the following:

1. Complete a brief screening that will take about 5 minutes.
2. Meet with a research staff member if determined eligible to be enrolled in a research study that will last 6 months (8 weeks of the program and a follow-up session).
3. Your participation is voluntary and confidential.
4. If enrolled, you will participate in wellness classes once a week for 8 weeks.

FOR MORE INFORMATION, PLEASE CONTACT
uciwellness333@gmail.com
UCI Research Team: (415) 407-9498

You will be paid $3 for participating in the screening
And, if eligible, $10 for each class you come to, $15 for the first following up session, & $30 for the second follow-up session for a total of $153

Subsection 4.2 - Phase II MBSR – Script for Introduction at Recruitment Site: For Non-Research Staff Member

Introduction: Hello, my name is_____. I'm a staff member from Prototypes/Serenity House Residential Treatment Center. I would like to inform you about a research study by sharing a flyer with you. This study is conducted by Dr. Dana Rose Garfin of the UCI, Sue & Bill Gross School of Nursing.

Question: Would you like to receive a flyer?

- ❑ Yes, I would like to receive more information.
- ❑ No, not at this time. [If not interested, thank person for their time]

Directions: If interested, hand flyer and say: The research study being conducted at Prototypes/Serenity House and is a separate activity from the services offered by this site. If you decide to participate, your decision to participate in the research will not affect your relationship with Prototypes/Serenity House.

Directions: If you are interested, an information session will be held at _____ [DATE] at _____ [TIME] for you to learn more.

Question: Would you like to attend an information session and be screened to see if you are eligible to participate in this study?

- ❑ Yes [If yes, refer participant to Project Director]
- ❑ No [If no, thank person for their time]

SECTION 5. SCREENING, INFORMED CONSENT, AND ENROLLMENT

Subsection 5.1 Screening Protocol

Instructions:

1. Read participant consent to screen document (listed in Appendix)
2. If they agree to consent to screen, you will open the Screening Module in REDCap.
    1. Age? (Must be 18 or older)
    2. Able to speak English (infer, don't ask)
    3. Homeless in the last 6 months.
        i. Homeless is defined as anyone who spent the previous night in a public or private shelter, or on the street. Some women will have been incarcerated. If this is the case and they did not have another residence to return to, they are eligible to be in the study.
    4. Administer Short Blessed Test.
        i. Must meet (Normal Cognition 0-4)
    5. Meet likely subthreshold or threshold PTSD as measured by PCL-5 (see Appendix).
    6. Subthreshold PTSD
        i. Must meet Criteria A (exposure to a traumatic event).
        ii. Must endorse "moderately" or more to at least 2 B-E criteria. This will be automatically scored in REDCap.

Subsection 5.2 Informed Consent

1. If eligible, read to them the informed consent, going over key highlighted areas.
    i. Provide them a paper copy of the consent, and highlight the contact information for Dr. Garfin and the IRB.
    ii. Download a copy of informed consent (save in downloads). Have them sign. Then re-upload and delete from downloads.
2. START locator guide.
    i. Make sure you get their FULL LEGAL NAME!
    ii. **TAKE PICTURE USING THE "ADD DOCUMENT" ITEM, DO NOT SAVE TO CAMERA AND THEN UPLOAD.**

Subsection 5.3 Baseline Protocol

1. Tell them there will be a urine test. They can take it before or after interview (their choice). You will hand them a cup. They will return the cup and you will record their urine results in REDCap. Use gloves. **It is not considered a biohazard** so can be thrown in trash (or urine poured in toilet).

APPENDIX I: What to bring to site

Screening

- Charged iPads
- Charged iPencils
- Compensation in 1 dollar bills, as participants will be paid $3 per screening
- Light snacks
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.

Baseline, immediate follow-up, and 6-month follow-up

- Charged iPads
- Charged iPencils
- Compensation in $10- and $5-dollar bills, as participants will be paid $15 each (Note: for 6-month follow-up please bring $10 dollar bills as participants will be paid $30.)
- Light snacks
- Bottles of water
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.
- Color coded and labeled vials for saliva collection
- White boxes to store saliva samples
- **Cooler with ice**
- Drug test kits
- Paper and pens for stress task (trauma imagery task)

Weekly – Health Promotion class

- Charged iPads
- Charged iPencils
- Compensation in $5 or $10 dollar bills, as participants will be paid $10 each
- Light snacks
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.
- Teacher manual
- Extra participant book
- Materials for each week – please see teacher manual for weekly supply list

Weekly – MBSR class

- Charged iPads
- Charged iPencils
- Compensation in $5 or 10 bills, as participants will be paid $10 each
- Light snacks
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.
- Extra participant book
- Extra MP3 players
- Extra yoga mat or two

APPENDIX II: Trauma Imagery Script (Brief Stress Task)

TRAUMA IMAGERY SCRIPT

***NOTE TO RA**: Make sure the participant has not had anything to eat or drink for one hour and that they had some water to drink at least 10 minutes before starting the task.*

RA: Thank you for your participation in this part of the project. We are going to be asking you to recall and describe a stressful or traumatic event. We want to remind you that you can stop at any time if you are uncomfortable, although your participation will help us understand more about the stress process in women who have experienced adversity. The general overview of this procedure is that we are going to take a saliva sample to assess your stress hormones; have you participate in a short stress task; and then take another saliva sample to assess your stress hormones after the task. If this gets to be too intense for you, you can stop at any time. If you experience any severe distress, let me know and we will stop the task and immediately contact your onsite clinician/therapist. I want to remind you that this is completely voluntary and you can stop at any time and can still be in the study. Are you ready to begin? Do you have any questions?

***NOTE TO RA:** Participants will then passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected. Instruct to lean forward, and allow saliva to pool at the bottom of your mouth. Instruct to use tongue to slowly push the saliva into a straw-like collection tool that leads into a tube until you have collected roughly 1 teaspoon of saliva. Immediately put saliva in cooler!*

RA: First, I am going to ask you to recall a stressful or traumatic event for a few minutes. Some examples are a serious accident, fire, disaster, physical assault, abuse, war, homicide or suicide. Then, you will write about it and then read or describe it aloud. I can also take notes for you if you prefer to do it that way. You can face whatever direction you want and you can have your eyes open or closed. However, I ask that you try to recall each part of the event in as much detail as you can in your mind's eye. Think of the actions, events, thoughts, feelings, smells, and sensations. Try to remember how you felt and what was happening in your body. Do you have any questions?

I am going to give you a few minutes to imagine the event and write some notes. Here is a pen and some paper. Anything you write will be destroyed after the task.

***NOTE TO RA**: Give the participant some time to write. Re-iterate any of the instructions if they ask or seem stuck. **Stop the procedure if the participant is extremely distressed and contact a Prototypes site staff and Dr. Garfin**. Remind them they can still be in the study if they don't want to complete this part of the procedures.*

RA: Now please read what you wrote aloud and vividly imagine it in your mind's eye. (*Time ~ 5 minutes*).

NOTE TO RA**:** *20 minutes after completion, collect saliva samples in an identical manner to the first sample. Participants will then passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected. Instruct to lean forward, and allow saliva to pool at the bottom of your mouth. Instruct to use tongue to slowly push the saliva into a straw-like collection tool that leads into a tube until you have collected roughly 1 teaspoon of saliva. Immediately put saliva in cooler!*

POST-TASK DEBRIEFING

Thanks so much for your participation. I know that might have been difficult for you to recall this event. I want to thank you and let you know that we think your participation in this task will help other women who have experienced adversity. While feeling a little distressed might be expected, we want to make sure you are not experiencing a lot of distress. Right now are you are experiencing a lot of distress?

If yes, ask if they want you to get a site staff from Prototypes/Serenity House ***AND*** contact the Principal Investigator, Dr. Dana Rose Garfin ***immediately AND*** provide Dr. Garfin's contact information to them).

If no, thank them for their time and remind them if anything comes up they can call the Principal Investigator, Dr. Dana Rose Garfin and/or talk to any of the Prototypes/Serenity House site staff. (Provide Dr. Garfin's contact information to them).

Provide water and snacks at this time and pay close attention to any noticeable changes in mood until they are released to the care of the Prototypes/Serenity House site staff. ***Immediately inform Dr. Garfin AND Prototypes/Serenity House site staff of any potential issues***.

NOTE TO RA**:** *Please provide the following to the participant (note: can also remind the participant this is also included in the informed consent).*

CONTACT INFORMATION

If you have any concerns please contact the Principal Investigator, Dr. Dana Rose Garfin at dgarfin@uci.edu or (657) 251-9219. You can also call the University of California, Irvine Institutional Review Board at Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

APPENDIX III: Data Safety and Monitoring Plan

UCI Office of Research	**Institutional Review Board** **Human Research Protections** **Appendix S – DESCRIPTION OF DATA SAFETY MONITORING PLAN (DSMP) FOR CLINICAL/ BIOMEDICAL RESEARCH** *Version 09-19-2018*
Researchers: • All studies involving greater than minimal risk to participants are, at a minimum, required to develop a detailed plan to ensure that there is appropriate safety oversight. • For clinical studies involving a test article, it is common to have an independent Data Safety Monitoring Board (DSMB). • Please read the applicable HRP webpage for further guidance.	**HS#:** *(to be completed by the IRB)*
Lead Researcher/Investigator Name: Dana Rose Garfin	

Researchers may *cut and paste into Appendix S from the following sources*, as applicable.
Please remember to submit the following documents with your IRB APP:

- For NIH-sponsored clinical trials, the DSMP should be part of the grant application.
- For industry sponsor-initiated clinical trials, a FDA-approved DSMP should be part of the Master Protocol or the Data Safety Monitoring Committee/Board Charter.
- For studies conducted at the Institute for Clinical and Translational Science (ICTS) or Cancer Center (PRMC), the DSMP information approved by one of these committees should be inserted into this appendix.

Please answer all of the following:

1. Provide details of those individuals who will be responsible for the safety oversight of your study, including the relevant experience/expertise of each individual (for UCI investigator initiated studies conducted only at UCI, provide the names and titles as well).

   The study will have a Data Safety and Monitoring Board (DSMB)

   1. **Dana Rose Garfin, PhD** (Assistant Adjunct Professor and Lead Investigator, Sue & Bill Gross School of Nursing). Dr. Garfin has over 12 years of experience researching stress and trauma in both epidemiological and community-based samples. She has conducted prior studies with vulnerable populations (e.g., homeless women, trauma-exposed children; post-disaster survivors, demographically diverse samples). Dr. Garfin's recent work has explored the efficacy of community-based interventions on high risk samples (i.e., HIV-positive women in India). Dr. Garfin has recently completed a qualitative study exploring the acceptability and feasibility of a mindfulness-based intervention for trauma-exposed, homeless women. Dr. Garfin has an MA in Social Ecology and a PhD in Psychology.
   2. **Adeline M. Nyamathi, PhD, ANP, FAAN** (Founding Dean and Distinguished Professor, Sue & Bill Gross School of Nursing). Dr. Nyamathi has been Principal Investigator of more than

one dozen NIH-funded intervention studies with high risk groups that have resulted in significant reductions in drug and/or alcohol use and risky sexual behaviors, high rates of HBV vaccine completion, latent TB treatment completion, and improvement in emotional health and substance use outcomes. She has worked with homeless adults for over 32 years as well as other vulnerable populations both domestically and internationally.

3. **E. Alison Holman, PhD, FNP** (Associate Professor, Sue & Bill Gross School of Nursing).) Dr. Holman is a health psychologist and family nurse practitioner with over 20 years of clinical experience working with sick children and their families as well as survivors of a variety of traumatic life events. Over the past 20 years, she has served as Principal Investigator and/or co-PI on several studies of individuals coping with trauma (e.g., 9/11, incest, war, and natural disaster). She has also served as the data manager and analyst for several studies including her prospective longitudinal study of coping with the September 11th terrorist attacks. She is PI of an ongoing epidemiological study of American's responses to traumatic events and an NIH-funded R01 studying the acute stress response in stroke survivors.
4. **Sanghuk S. Shin, PhD** (Assistant Professor, Sue & Bill Gross School of Nursing) Dr. Shin is an epidemiologist and biostatistician with expertise in data management, biostatistics, and protocol development and adherence. He has been PI or co-I and lead statistician for numerous NIH-funded intervention studies with high risk samples including homeless individuals and those with infectious diseases including TB and HIV.
5. **Jung-Ah Lee, PhD, BSM, MN** (Associate Professor, Sue & Bill Gross School of Nursing) Dr. Lee's expertise is in healthcare systems and how the structure and processes of a healthcare system affects patient safety and clinical and organizational outcomes. She has investigated quality improvement techniques, patient safety issues, effective healthcare delivery models, and cost-effectiveness of care. She has expertise working with vulnerable populations including older adults and those with chronic diseases. Dr. Lee is is not a member of the research team and will provide independent oversight.
6. **Yuqing Guo, PhD, MN** (Associate Professor, Sue & Bill Gross School of Nursing). Dr. Guo has expertise in women's health and health disparities. She has run numerous family-centered interventions in community settings. She is PI of a study examining maternal care for underserved communities and is well equipped to provide consult and oversight on potential problems with the population of interest. Dr. Guo is not a member of the research team and will provide independent oversight.

2. Indicate how frequently accumulated study data will be reviewed and evaluated for participant safety, study conduct and progress, and, when appropriate, efficacy.

   They will meet face-to-face at least once a year and maintain and approve minutes of meetings. Every 30 participants.

3. Describe the events that would trigger an unscheduled review. Also include stopping guidelines and un-blinding rules if applicable.

   Events where the participant became extremely distressed as part of the research procedure or expressed suicidality or if they were a harm/threat to self or others. The Data Safety and Monitoring Plan (attached, submitted in the NIH grant that funded this application), we provide specific guidelines to assess suicidality or harm to others. The research staff would follow all

procedures to ensure the safety of the participant. And the DSMB would be

4. List who will be *locally* monitoring and collecting information on adverse events and/or unanticipated problems (e.g., UCI Lead Researcher, Research Coordinator, etc.). Include the name, title and experience of the individual(s) and further describe each individual's role in the oversight of subject participating in the study.

   The Principal Investigator (Dr. Dana Rose Garfin) will be responsible for locally monitoring and collecting information on adverse events and unanticipated problems. Dr. Garfin will be onsite during participant recruitment and during the administration of intervention procedures. In the event that Dr. Garfin is not able to be onsite, a senior staff will be in contact directly with Dr. Garfin should any problems arise. Moreover, when Dr. Garfin is not onsite, staff will report daily on study progress and any potential issues. Dr. Garfin will monitor all data weekly.

5. Describe the plan for annual reporting of the participants' safety, and the study's conduct, progress, and efficacy, when appropriate. *Note: At the Continuing Review, please provide all relevant documentation related to the review of the accumulated data for safety. For the case your submission includes a DSMB charged with the oversight of data safety, include all available DSMB reports as part of your submission.*

   Annual reporting will occur at the DSMB meeting. The Principal Investigator will keep detailed notes from the meeting and evaluate the study's conduct (e.g., any unanticipated problems), progress (e.g., recruitment, retention), and efficacy (e.g., results of any preliminary data analyses).

DATA SAFETY AND MONITORING PLAN

Possible Serious Adverse Events or Adverse Events

Serious adverse events

- Suicide attempt, severe violence to another person

Other adverse events

- Inadvertent disclosure of illegal immigrant status
- Adverse reaction to stress task

Risk Management Protocols in Place to Deal with Adverse Events

- Date Safety and Monitoring (DSM) issues are raised at quarterly meetings with all research staff
- Events will be reported as they occur
- A certificate of confidentiality will be secured.
- Research staff will administer the questionnaires individually.
- Participants will be cautioned not to disclose any confidential information within the group sessions.
- Unique identifiers are used on all data. Access to identifiers is restricted to the study PI, lead mentors and data manager by a combination lock.

Data and Safety Monitoring Procedures

- Serious adverse events (SAE) must be reported to the NIH Project Officer (PO) by email or telephone within 24 hours of the SAE. A more complete written report documenting the event must occur within 72 hours of the event.
- All adverse events will be reported by email to the NIH PO twice a year: six months after the Notice of Grant Award (NGA) and at the end of the budget year.

Data Safety and Monitoring Board (DSMB)

The board will be composed of six members, including the PI, mentors (Nyamathi, Shin, Holman) and two mid-level to senior investigators from our institution with psychological expertise (Dr. Yuqing Guo and Dr. Jung-Ah Lee). They will meet face-to-face at least once a year and maintain and approve minutes of meetings. The NIH PO will be kept informed regarding changes to the membership of the DSM board. Data will be reviewed as every 30 participants enter the study.

Training for all staff

During the orientation prior to start of the grant, all research staff and research assistants will be trained on recognizing all types of potential crises, how to make a thorough assessment, and role play protocols that are featured below and in the DSMB section. During these meetings, in services that address mental health crises and associated symptomatology will be provided to enhance the staffs' ability to confidently engage in the protocols for participants who may be experience psychiatric or psychological distress. All research assistants will also meet weekly with the PI to review challenging interactions, circumstances, or situations that may have arisen with the participants. Discussions will focus on how the incident could have been handled differently and what the ideal outcome for that situation might have been.

Training in Red Flag Procedures

Research staff will be trained to assess and react as follows:

RED FLAG – SUICIDE

During your work as a research staff, you may encounter a respondent who expresses suicidal intentions, or you may suspect that a respondent may be suicidal. Be sure to document all the information in sections I and II as you will need to provide that information to the treatment program counselor or on-call clinician.

I. Is this person a suicide risk?

____ The individual is currently thinking about suicide.
____ The individual has a plan and the means to commit suicide.
____ The individual has attempted suicide in the past.

If any of the above are true or if you suspect the client is suicidal, also note if:

____ The individual is currently exhibiting serious depression/anxiety.

____ The individual is experiencing stressful life events.

II. Assessment of support system:

a) Is the individual under professional care (i.e., psychologist, psychiatrist, counselor)?

b) Does the individual have a social support network (i.e., friends, family, sponsor)?

c) Has the individual talked with any of the members of his or her social support network in the last 30 days?

d) Is the individual able to talk about this issue with his or her support system?

e) Is the individual aware of available social service programs?

III. If the person appears to be suicidal or has attempted suicide since the last interview:

a) Let the respondent know that you are concerned, and that you need to inform a clinician and your supervisor.

b) If you are not at a treatment program, have the client wait with you or hold on the line while you take the following steps:
   1) If the client has indicated that he/she is under professional care, ask the client for permission to contact his/her clinician and, if permission is granted, obtain the clinician's contact information. Be sure to document the client's permission and clinician contact information, you will need to provide it to the on-call clinician who will confirm client permission and make the contact.
   2) Contact the on-call clinician at the Los Angeles County Mobile Crisis Response Team (MCRT); _____. A clinician is on call 24 hours a day. Provide the clinician with all the suicidality information you have gathered. Facilitate phone contact between your client and the MCRT clinicians. The clinician will make the decision about what steps to take with this client. Document the details of the clinician call.

d) Report back to the PI immediately.

- Your Principal Investigator Dana Rose Garfin Ph.D., 415-407-9498

The situation will be evaluated by the group and a decision will be made if it should be reported to the LAC MCRT; they will advise us on how we need to proceed.

e) If the person attempts to harm himself or herself in your presence, contact the police (911). The police may place the person in a psychiatric facility for a 72-hour observational hold. Get the police report number.

f) Complete an Incident Report detailing the problem and action taken. Be sure that the Incident Report is placed in the respondent's file.

g) Make arrangements to follow-up on your client's status with the treatment program counselor, supervising counselor, or on-call clinician within the next seven days.

If the MCRT is called, an assessment will be done by the MCRT staff at the location of the participant. Based on the assessment of the MCRT, the participant may be transported to a hospital for inpatient treatment. If it is determined that the person does not need to be hospitalized, the participant will be referred to the outpatient services at the neighborhood clinic. If the participant is at the same location as the staff, the staff will find out if the participant has taken any active steps such as already having taken pills, etc. If the participant is not in immediate danger, the staff will find out the following: history of drug and alcohol abuse; history of familial suicide; history of familial mental illness. The staff will find out if the participant has a plan for how he would commit suicide. If she does have a plan, the staff will find out if she/he has any weapons, pills, etc, and remove all weapons from her possession, and explore the nature of her various plans. The PI, once they have arrived, will continue to focus on the reasons the participant wants to live and build on his support system. The staff will get phone numbers from the participant of those of his outside support system with whom he wishes to be in contact, for future use in case of another emergency. The research staff will collaborate with the treating psychiatrist to facilitate referral and follow through with a counseling psychiatrist/psychotherapist after discharge from the hospital. The staff/PC will document each step of this process.

If it is determined that the person does not need to be hospitalized, any additional treatment will be facilitated with Prototypes staff. To facilitate communication the participant will be asked to sign a Release of Information. If the participant provides a Release of Information, the PC will follow-up to ensure that the participant is receiving the necessary treatment. Depending on the outcome of the event, the PI may recommend that the participant withdraw from study participation. The staff/PC will document each step of this process in an adverse event log.

In addition, the DSMB will be informed of reports of suicidal ideation and current or recent abuse, reported by the staff to the proper authorities. Further, the DSMB will monitor that these reports are made expeditiously and with the full knowledge of the respondent. Monitoring information is also provided in the HSPC segment of this application.

Harm to others

I. Is this respondent dangerous to others?
The individual expressed intent to harm or kill a specified person.
The individual has the means (gun, knife, etc.) to harm that person.
The individual has a thought-out plan.

II. If you feel that the person is dangerous to others, and is likely to follow through with his/her plans:

Assess the situation. If it is safe, complete the study protocol is the participant desires. Report the information to your supervisor, the PI and the licensed clinician on staff at Prototypes. If you

feel unsafe or are not sure about it, complete the research procedures; only if possible. But if the situation is volatile, terminate immediately. Try to be as graceful and subtle as possible. For example, complete the specific task you are on or make up some reason for leaving, and say you will have to reschedule the rest of the procedures. Pay the subject in full, or leave immediately if you don't feel safe to do so. Trust your sense of the situation, and act accordingly.

Report back to your supervisor or call in immediately. If something takes place outside of the work hours, call your supervisor at home. The supervisor should then immediately contact the project's PI. Supervisors are:

Your Principal Investigator Dana Rose Garfin, Ph.D., 415-407-9498

The situation will be evaluated quickly by the group and a decision will be made if the LAC MCRT needs to be called; they will advise us on how we need to proceed. If the situation is reported to the police, get the report number from the police.

III. Complete an Incident Report. Be sure to put a copy of the Incident Report in the respondent's file so that those working with the file in the future know an incident occurred. Aside from the DSMB, the PI will carefully monitor the data weekly.

APPENDIX IV: Citations for Study Measures

Primary Outcome:

PTSD Checklist for DSM-5 (PCL-5; Weathers, Litz, Keane, Palmieri, Marx, & Schnurr, 2013). Responses will be scored continuously and according to diagnostic criteria as implemented in previous research.(143) The PCL-5 initially starts with the identification of the presence of exposure to a DSM-V traumatic event (i.e., "Briefly identify the worst event (if you feel comfortable doing so)") and then assesses whether it involved actual or threatened death, serious injury or sexual violence; whether the person directly experienced it (through direct exposure, witness to the event, occurred to a close friend or family member, or exposed as part of job). There are then twenty-items that assess all four B-E criterion (re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal), assessed on a Likert-type scale 0 "not at all", 1 "a little bit", 2 "moderately", 3 "quite a bit", 4 "extremely".

Secondary outcomes:

Substance use:
Self-report drug use: Texas Christian University (TCU) Screen at Baseline and 6-month follow up. Yes/No to each drug will be assessed for use vs dependency. The total score ranges from 0 - 9; higher scores (> 3) correspond to the DSM drug dependence diagnosis. This will be assessed at baseline, immediately following 9th/final intervention session, and 6-month follow-u (Institute of Behavioral Research, 2017).

Objective drug use assessment: A 5-panel FDA-approved urine test cup will be used in this study. The test cup screens for metabolites of the following drugs of abuse at the established cut-off levels and is used for qualitative purposes: Amphetamines (1000 ng/mL), Cocaine (300 ng/mL), Methamphetamines/ MDMA (500 ng/mL), Opiates (2000 ng/mL), and THC (50 ng/mL). Urine sample validity checks will be provided by temperature and adulterant monitoring strips built into the test cup. Participants whose urine does not pass validity checks will be counted as positive for drugs. Results will be coded qualitatively (above or below threshold). All positive results will be interpreted as positive, regardless of self-report.

Depression: will be assessed using the PROMIS measure for depression (Emotional Distress). The 8-tem form will be used. It assesses negative mood, views of self (e.g., worthlessness), decreased positive affect and anhedonia. In self-report when all participants are given the same questions, it is desirable to use the 8-item short form, which has reliability and validity comparable to the 28-item computer adaptive form (PROMIS Health Organization, 2019).

Cortisol reactivity: Saliva samples will be collected via passive drool before and after a modified script driven imagery task. Saliva All saliva will be assayed in duplicate using standard manufacturers protocol (Salimetrics). The concentration of CRP in saliva will be determined using a Salivary C-Reactive Protein ELISA kit, an enzyme-linked immunoassay. The standard curve is run on every assay plate and must have an R2 value of > 0.99. The

replicates must have a %CV < 15 or an absolute difference <0.030 between the replicates. The mean values across saliva duplicates will be computed for each sample and used in the statistical analyses.

C-reactive protein (CRP) All saliva will be assayed in duplicate using standard manufacturers protocol (Salimetrics). The concentration of CRP in saliva will be determined using a Salivary C-Reactive Protein ELISA kit, an enzyme-linked immunoassay. The standard curve is run on every assay plate and must have an R2 value of > 0.99. The replicates must have a %CV < 15 or an absolute difference <0.030 between the replicates. The mean values across saliva duplicates will be computed for each sample and used in the statistical analyses.

Perceived stress scale: 10-item Perceived Stress Scale (PSS) will be used to measure participant's perception of stress (Cohen, 1993).

Quality of life: will be measured using the 10-item short form of the Quality of Life Enjoyment and Satisfaction Questionnaire. Participants indicate their satisfaction with health, finances, and other life domains during the past week on a scale of 0 (very unsatisfied) to 3 (very satisfied) (Endicottt, Nee, Harrison, & Blumenthal, 1993).

Satisfaction with life scale: A 5-item scale designed to measure global cognitive judgments of one's life satisfaction (not a measure of either positive or negative affect) (Diener, Emmons, Larsen, & Griffin, 1985).

Mindful awareness attention scale (MAAS): is a 15-item scale designed to assess a core characteristic of mindfulness, namely, a receptive state of mind in which attention, informed by a sensitive awareness of what is occurring in the present, simply observes what is taking place (Brown & Ryan, 2003; Carlson & Brown, 2005).

Five facet Mindfulness Questionnaire (FFMQ) is a 39 item questionnaire that assesses five independent sub-scales: observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience (Baer et al., 2008).

Life event history: Life events history will be assessed by asking respondents whether they ever experienced each of 40 specific negative life events (NLEs; will include both trauma and stressors), and, if so, at what age(s) this occurred. This will also be updated with respect to recent events upon immediate completion of the 9 week courses as well as at the 6-month follow up. The measure was modified from the Diagnostic Interview Schedule trauma section (Robins, Helzer,
Croughan, & Ratcliff, 1981) by including several stressful or traumatic events reported by primary care patients (Holman, Silver, & Waitzkin, 2000) and has provided rates of events comparable to other community-based studies (e.g., Seery et al., 2010).

Emotion regulation: will be assessed with the Difficulties in Emotion-Regulation Scale (DERS; Gratz & Roemer, 2004; Kaufman et al., 2016), short form. DERS is a 18- item questionnaire that aims to measure how much one is able to regulate/deregulate their emotions. The 41 questions are based off of six factors including acceptance of emotions, impulsiveness, ability to work towards goals, awareness of own emotions, clarity of emotions, and accessibility to emotion-regulation strategies

Social support will be assessed using the MOS Social Support scale (Sherbourne & Stewart, 1993) This 19 item measure assesses social support.

Anxiety: will be assessed using the PROMIS measure for anxiety (Emotional Distress). The 8-tem form will be used. It assesses symptoms of Generalized Anxiety Disorder. it is desirable to use the 8-item short form, which has reliability and validity comparable to the 28-item computer adaptive form (PROMIS Health Organization, 2019).

General Self-efficacy scale: This 10-item scale was created to assess a general sense of perceived self-efficacy (Schwarzer & Jerusalem, 1995).

Demographics: Age, ethnicity, sexual orientation, incarceration history, religion, income, education, number of children, pregnancy status, mental health history (previous diagnosis) employment history.

Prior Doctor-diagnosed Health Conditions. This survey, modified from the CDC's National Center for Health Statistics Annual National Health Interview Survey, asks respondents to report doctor diagnosed health ailments. This will be assessed at baseline, immediately following 9th/final intervention session, and 6-month follow-up.

Adherence. Measured by class attendance and self-reported time in mindfulness meditation and doing at-home assignment.

Short self-compassion scale. This 12-item scale assesses self-compassion (Raes, Pommier, Neff, & Van Gucht, 2011).

Free Response: Participants will be given the opportunity to provide written feedback regarding their experiences that may not have been captured with these quantitative measures. Prompt will include: We will ask: "Do you have any other thoughts and/or feelings about your participation in this program? Is there anything that you wish to share with us regarding your experience?"

APPENDIX V: Salivary Data Collection During COVID-19

UCI Institute for Interdisciplinary Salivary Bioscience Research

Collection Procedure*

*Please keep a roster of all samples collected from October 2019 onwards. Samples may contain SARS- CoV-2, and this will ensure safe handling in the future as labs may take extra precautions when handling samples collected during this time.

1. Participants wash hands for 20 seconds prior to collecting the saliva sample(s).
2. Collect saliva sample as normal (follow typical passive drool or swab collection protocols). Tubes should be labeled prior to providing them to participants.
3. Sample tubes should be immediately capped and sealed. Outsides of tubes should be disinfected following collection. Disinfectants are listed on the CDC website (https://www.epa.gov/pesticide- registration/list-n-disinfectants-use-against-sars-cov-2). Ensure no disinfectants leak into the tube via an unsealed or partially sealed tube.
4. Samples should be placed in a secondary container (sealed plastic bag with absorbent material, freezer box, etc.) that is labeled, then placed in a freezer (-20°C) as soon as possible. See below for more guidelines.
5. Participants should wash hands for at least 20 seconds after collecting the saliva sample(s).

Sample Storage and Shipping

Always check with your EHS and IRB groups at your institution before collecting and/or shipping saliva samples to ensure you have received proper training and are following appropriate rules/regulations. Additionally, please refer to the following link for CDC guidelines prior to shipping samples: https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html

Sample storage:

1. Once collected, samples should be stored in a freezer between -20°C (home freezer) or -80°C (ultra-cold lab grade freezer) when possible
2. Samples should be placed inside sample storage boxes (or biohazard Ziploc bags + absorbent material for home collections)
3. The sample storage box should be placed inside a large biohazard Ziploc bag (or Ziploc bag with a biohazard sticker on it)
4. A piece of absorbent material (paper towel, etc.) should be placed inside the Ziploc bag to absorb any potential spillageSample Pickup/Shipping:

1. Samples in bags or boxes should be placed inside cooler or in a bioshipper on dry ice.
2. Bioshipper should be labeled with the following:
    a. Hazard labeled with UN Identification Number already on label – UN 3373
    b. Biological Substance, Category B
    c. Hazard Labeled with UN Identification Number- UN 1845
    d. Dry Ice along with the net weight (kg) of the dry ice
    e. Shipper's name and address
    f. Receiver's name and address
    g. Name and phone number of a responsible person.

Receiving samples:

1. Lab personnel receiving samples should wear appropriate PPE before handling samples.
2. Ensure samples are labelled, are frozen, and tubes are in good condition (no cracks or leaks).
3. Sample collection tubes should be disinfected once received by the lab. Disinfectants are listed on the CDC website (https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against- sars-cov-2).
4. Boxes with samples can be marked with date received, and a label noting if the samples were collected during the COVID-19 pandemic. This can act as an indicator to use extra safety precautions while handling those samples in the future. Samples should be stored in -80°C as soon as possible.
5. Sample processing should be performed in a biological safety cabinet.

APPENDIX VII: RECap for Screener (Section 1) and Baseline, Immediate-follow-up, and 6-months (Section 2)

MINDFULNESS-BASED INTERVENTION FOR TRAUMA-EXPOSED, HOMELESS WOMEN

STUDY PROTOCOL

K01 MD013910-01
National Institute of Health (Institute of Minority Health and Health Disparities)

Principal Investigator: Dana Rose Garfin, PhD
Updated: July 2022

Table of Contents

SECTION 1A. RESEARCH STUDY OVERVIEW 4

Subsection 1A.1 - Overview & Introduction 4

Subsection 1A.2 - Overall Structure of Study Team 5

Subsection 1A.3 - Research Team and Responsibilities 6

Subsection 1A.4 - Research Study Contact List (2/21) 6

Subsection 1A.5 - Phase II Timeline 1

6 - Basic Definitions 1

SECTION 1B. INTRODUCTION TO PTSD AND MBSR 2

Subsection 1B.1 - PTSD Basics 2

Subsection 1B.2 - MBSR Basics 4

SECTION 2. INTERVENTION DELIVERY 6

Subsection 2.1 - Phase II Overview 6

Subsection 2.2 - Phase II Scope of Work & Participant Flow Diagram 7

Subsection 2.3 - Phase II Recruitment & Treatment Overview 9

Subsection 2.4 - Phase II Recruitment & Screening 9

Subsection 2.5 - Phase II Eligibility Criteria 10

Subsection 2.6 - Phase II Laboratory Tests/Sample Collection 11

Subsection 2.7 - Phase II Intervention Program Description 11

Subsection 2.8 - Phase II Pre-intervention Assessments 12

Subsection 2.9 - Phase II Brief Stress Task (Trauma Imagery Task) 12

Subsection 2.10 - Phase II Biospecimen Collection 13

Subsection 2.11 - Phase II Biospecimen Analysis 14

Subsection 2.12 - Phase II MBSR-based Intervention 14

Subsection 2.13 - Phase II Health Promotion Intervention 16

Subsection 2.14 - Phase II Post-Assessment 17

Subsection 2.15 - Phase II Team Management of Biospecimen Collection Refusal 17

Subsection 2.16 - Phase II Dealing with Intervention Program Attrition 17

Subsection 2.17 - Phase II Follow-Up Focus Groups 18

Subsection 2.18 - Phase II Compensation 18

Subsection 2.19 - Program Fidelity 18

Subsection 2.20 - Research Staff Competencies and Mock Sessions 18

Subsection 2.21 - Data Entry, Management & Confidentiality 19

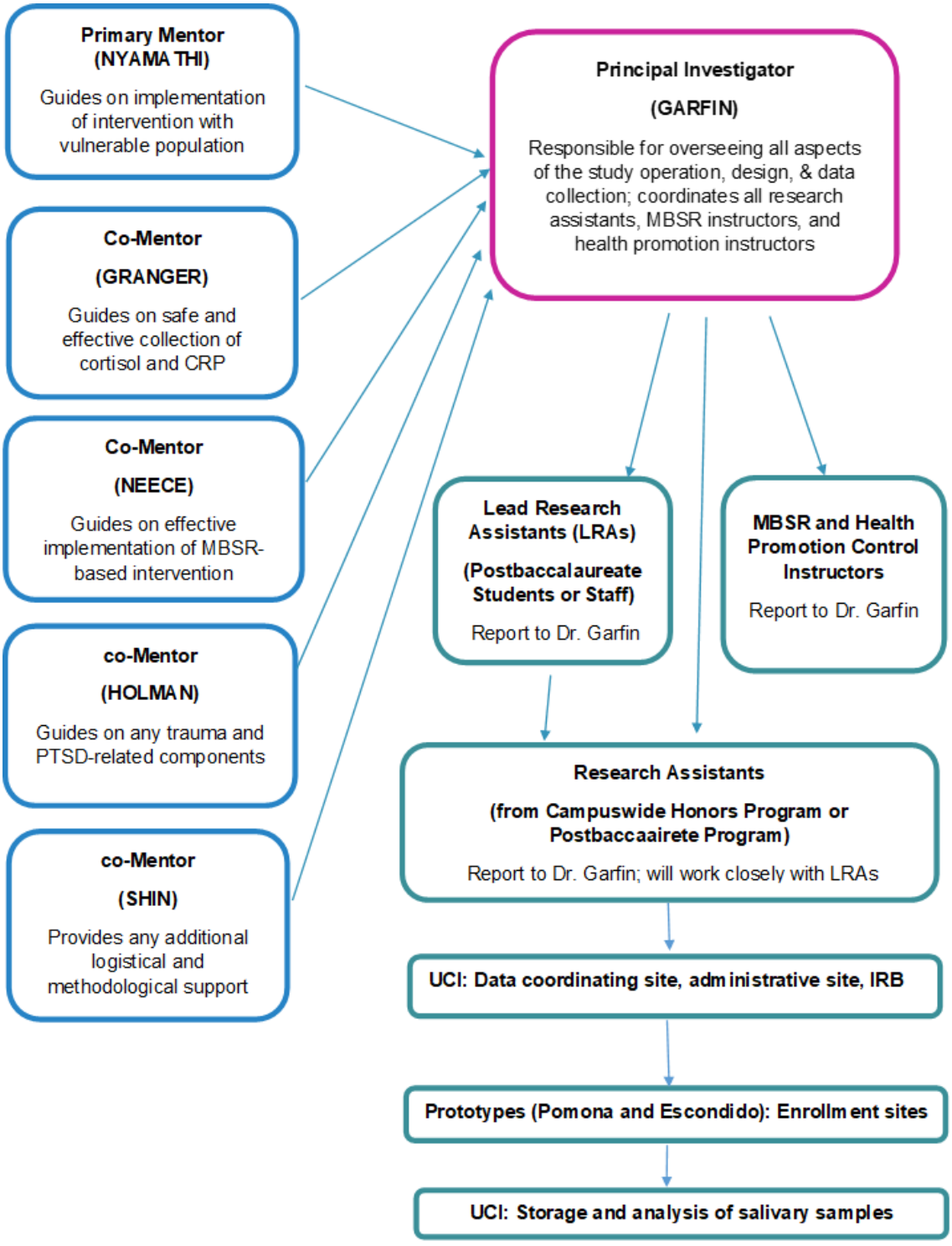
Subsection 2.22 – Using REDCap 20
Subsection 2.23 - Data Security 20
Subsection 2.24 - Post Data Collection 21
Subsection 2.25 - End of Study 21
SECTION 4. RECRUITMENT 22
Subsection 4.1 - Phase II Flyer 22
Subsection 4.2 - Phase II MBSR – Script for Introduction at Recruitment Site: For Non-Research Staff Member 23
SECTION 5. SCREENING, INFORMED CONSENT, AND ENROLLMENT 24
Subsection 5.1 Screening Protocol 24
Instructions: 24
Subsection 5.2 Informed Consent 24
Subsection 5.3 Baseline Protocol 24
APPENDIX I: What to bring to site 25
APPENDIX II: Trauma Imagery Script (Brief Stress Task) 26
APPENDIX III: Data Safety and Monitoring Plan 28
Possible Serious Adverse Events or Adverse Events 30
Serious adverse events 30
Other adverse events 30
Risk Management Protocols in Place to Deal with Adverse Events 30
Data and Safety Monitoring Procedures 31
Data Safety and Monitoring Board (DSMB) 31
Training in Red Flag Procedures 31
RED FLAG – SUICIDE 31
Harm to others 33
APPENDIX IV: Citations for Study Measures 35
APPENDIX VII: RECap for Screener (Section 1) and Baseline, Immediate-follow-up, and 6-months (Section 2) 40

SECTION 1A. RESEARCH STUDY OVERVIEW

Subsection 1A.1 - Overview & Introduction

This study aims to determine the effectiveness of a mindfulness-based intervention (MBI) on the reduction of posttraumatic stress disorder (PTSD) symptoms (primary outcome) and depression substance use disorder (SUD), inflammation, and cortisol reactivity (secondary outcomes) in homeless women with PTSD. Biological markers (i.e., cortisol reactivity, C-reactive protein [CRP]) of the stress response will be evaluated as correlates of MBI treatment-response will help clarify mixed findings regarding dysregulation of the HPA-axis as a function of amount, type, and timing of trauma exposure. It will advance theory regarding the use of MBIs for PTSD while exploring biological markers that might maintain PTSD symptoms over time. The project has the potential to bolster the capacity of service providers to offer feasible and acceptable MBI interventions to homeless women and other vulnerable populations. If the proposed aims are achieved, they may provide several valuable insights. They will examine the efficacy of MBI to address PTSD in homeless women (inform & improve services, interventions, treatments); improve on methodological limitations of prior research on MBIs for PTSD (including small sample sizes, lack of attention control group, incomplete trauma history); and explore biological markers that correlate with PTSD-symptom maintenance or reduction post-MBI (expand concepts). Importantly, the MBI that will be used in the intervention was the product of a rigorous preliminary mixed-methods inquiry that including a Community Advisory Board (consisting of site staff, clinicians, and homeless women) and focus groups with women from the community (i.e., homeless women currently residing at a residential drug treatment facility). The results of these formative activities resulted in the modification of an evidenced-based MBI – Mindfulness-based Stress Reduction (MBSR) for cultural sensitive and appropriateness, increasing acceptability and feasibility. Importantly, findings from this proposal may provide a low-cost method to improve services for homeless women as they begin to answer key theoretical questions regarding the relationship between biological markers of stress regulation and reactivity, the inflammatory response, PTSD and related comorbidities (SUD, depression), and MBIs.

Subsection 1A.2 - Overall Structure of Study Team



Subsection 1A.3 - Research Team and Responsibilities

Principal Investigator (PI): Dana Rose Garfin, PhD.
Makes executive decisions regarding the implementation of the study, data entry and data analysis approaches, and interpretation of study findings. She will train the research staff and assistants to perform content. Dr. Garfin will develop all questionnaires and oversee the design and implementation of the MBI and the health promotion attention control.

K01 Mentor: Adeline M. Nyamathi, ANP, PhD, FAAN
Dr. Nyamathi will advise Dr. Garfin on conducting mix-methods research including qualitative focus groups and clinical trials with vulnerable populations.

K01 Mentor: Douglas Granger, PhD, Chancellors Professor of Psychology and Social Behavior and Director of the Institute for Interdisciplinary Salivary Bioscience Research (IISBR
Dr. Granger will advise on all aspects of the project related to saliva collection and analysis and the theoretical and statistical integration of salivary measures into psychosocial research.

Secondary K01 co-mentors: Drs. Cameron Neece, E. Alison Holman, & Sanghyuk Shin provide guidance on K01, but do not interact with any human subjects participants, will not engage with the data, and thus are not included on the IRB forms.

Lab Manager and Lab Coordinator: First line contact for RAs, responsible for RA scheduling, delegates lab responsibilities to other RAs, drafts lab meeting agenda, keeps track of conference submission deadlines, ensures study supplies are available, oversees budget expense tracking and reimbursements.

Biosalivary coordinator: Ensures that cortisol collection is done according to all protocols, ensures that collection tubes are labeled ISBBR.

REDCap coordinator: Ensures all updated to REDCap are entered accurately. Tracks participant payments for cash advances and payment reconciliation.

Subsection 1A.4 - Research Study Contact List (2/21)

Name	Role	Organization	Phone Number	Email
Dana Rose Garfin, PhD	PI	UCLA	(415)407-9498	dgarfin@ucla.edu
Adey Nyamathi	K01 Mentor	UCI		anyamath@uci.edu
Doug Granger	K01 Mentor	UCI		dagrange@uci.edu
Michelle Zernick	Lab Manager	UCI		zernickm@uci.edu

Subsection 1A.5 - Phase II Timeline

YEAR 1 (2020)												
	19-May	**19-Jun**	**19-Jul**	**19-Aug**	**19-Sep**	**19-Oct**	**19-Nov**	**19-Dec**	**20-Jan**	**20-Oct**	**20-Nov**	**21-Dec**
PRIMARY ACTIVITIES	SITE START UP & VISIT			Community Advisory Board		Focus Groups		Finalize Intervention & Qualitative Analysis		Recruit Cohort1	HP Cohort1	
Space/time needed				1 meeting per week (1-2 hours)		Four meetings total, each 2 hours		1 weekly meeting (1-2 hours) for 4 weeks		Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)	
YEAR 2 (2021)												
	21-Jan	**21-Feb**	**21-Mar**	**21-Apr**	**21-May**	**21-June**	**21-July**	**21-Aug**	**21-Sept**	**21-Oct**	**21-Nov**	**21-Ded**
PRIMARY ACTIVITIES	Recruit Cohort 2	MBI & HP C2			Recruit Cohort 3	MBI & HP Cohort 3			Recruit Cohort 4	MBI & BP Cohort 4		
Space/time needed	Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)			Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)			Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)		
Follow-up				Cohort 1 follow-up				Cohort 2 follow-up				Cohort 3 follow-up
YEAR 3 (2022)												
	22-Jan	**22-Feb**	**22-Mar**	**22-Apr**	**22-May**	**22-June**	**22-July**	**22-Aug**	**22-Sept**	**22-Oct**	**22-Nov**	**22-Dec 23 Jan-Feb**
PRIMARY ACTIVITIES	Recruit Cohort 5	MBI & HP Cohort 5				Recruit Cohort 6-7		MBI Cohorts 6-7				
Space/time needed	Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)				Screening space 1-2 days/week per site	Room for intervention 1 X per week at each site for 1-2 hours (same time each week)					
Follow-up				Cohort 4 follow up			Cohort 5 follow up				Cohorts 6-7 follow ups	

6 - Basic Definitions

Mindfulness: The process of focusing one's attention on the present moment (including thoughts, feelings, and sensations) without judgement (Kabat-Zinn, 1990; Lang, 2017).

Mindfulness-Based Stress Reduction (MBSR): MBSR is an 8-week, 9 session manualized mindfulness-based intervention that is appropriate for participants from different religious, spiritual, or ethnic background and is not grounded in religious ideology. During MBSR, participants will be trained in mindfulness meditation and the applicability of mindfulness to daily life.

Post-traumatic Stress Disorder (PTSD): PTSD is a psychological pathology characterized by re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal after experiencing a traumatic event.

Trauma: According to the DSM-5, must involve actual or threatened death, serious injury, or sexual violence.

Arm: The different groups of the intervention. In this study, Arm 1 is the health promotion attention control and Arm 2 is the MBSR. Participants at a given site are assigned to one Arm or the other, by cohort).

Cohort: The group of people that are doing the interventions at the same time.

Cortisol: The body's main stress hormone, triggered by the adrenal glands. Cortisol is a glucocorticoid and is released in the body about 20 minutes after a stressor. The immediate stress response hormones (adrenaline and epinephrine) are released within seconds or minutes; if the brain continues to perceive something as stressful, then cortisol is released.

C-Reactive Protein (CRP): This is a protein made in the liver. CRP tends to increase when there is inflammation occurring in the body, (Lindqvist et al., 2014, 2017) induced by proinflammatory cytokines in the liver (Eklund, 2009). These heightened inflammatory responses can lead to health impairments including atherosclerosis (Wong et al., 2012) and cardiovascular disease (Coughlin, 2011) compounding health disparities in disadvantaged populations; CRP, in particular, has been linked with obesity (Visser et al., 2011) metabolic syndrome (Ridker et al., 2003) and CVD.(Ridker et al., 1998) Thus CRP can be used as marker for general inflammation and risk for inflammatory-related problems.

Other acronyms used in this protocol:

IISBR – Institute for Interdisciplinary Salivary Bioscience Research - https://iisbr.uci.edu/

- IISBR is a shared resource and scientific hub; researchers can gain practical experience/knowledge in salivary bioscience through the training programs (e.g., Spit

Camp). IISBR also provides the storage and analyses of the salivary samples collected in this study.

SECTION 1B. INTRODUCTION TO PTSD AND MBSR

Subsection 1B.1 - PTSD Basics

PTSD Diagnosis

PTSD occurs as the result of direct exposure to experiencing, witnessing, or learning of an event that involves actual or threatened death or serious injury or harm to self of others (American Psychiatric Association, 2013). For a diagnosis of PTSD, symptoms must be present for at least one month prior to diagnosis and must include at least one re-experiencing symptom, one avoidance symptom, two arousal and reactivity symptoms and two cognition and mood symptoms. Re-experiencing symptoms can include flashbacks, nightmares, and invasive thoughts. Avoidance symptoms are related to an individual actively avoiding locations, thoughts, events, or objects that are reminiscent of the trauma. Arousal and reactivity symptoms include feeling easily frightened, tense, increased anger, and having issues sleeping. Cognitive and mood symptoms include but are not limited to having trouble remembering key features of the trauma, distorted feelings, and loss of interest in previously enjoyable activities. PTSD must be diagnosed by a mental health professional, but a variety of measures have been validated for use as screens or by non-clinical for research purposes. In our study, we use the Posttraumatic Stress Disorder Checklist, Civilian (PCL- C) (Bovin et al., 2016; Wortmann et al., 2016).

***DSM-5* Criteria for PTSD**

The following text summarizes the diagnostic criteria for PTSD and was obtained from the ptsd.va.gov website.

Criterion A (one required): The person was exposed to: death, threatened death, actual or threatened serious injury, or actual or threatened sexual violence, in the following way(s):

- Direct exposure
- Witnessing the trauma
- Learning that a relative or close friend was exposed to a trauma
- Indirect exposure to aversive details of the trauma, usually in the course of professional duties (e.g., first responders, medics)

Criterion B (one required): The traumatic event is persistently re-experienced, in the following way(s):

- Unwanted upsetting memories
- Nightmares
- Flashbacks
- Emotional distress after exposure to traumatic reminders
- Physical reactivity after exposure to traumatic reminders

Criterion C (one required): Avoidance of trauma-related stimuli after the trauma, in the following way(s):

- Trauma-related thoughts or feelings
- Trauma-related reminders

Criterion D (two required): Negative thoughts or feelings that began or worsened after the trauma, in the following way(s):

- Inability to recall key features of the trauma
- Overly negative thoughts and assumptions about oneself or the world
- Exaggerated blame of self or others for causing the trauma
- Negative affect
- Decreased interest in activities
- Feeling isolated
- Difficulty experiencing positive affect

Criterion E (two required): Trauma-related arousal and reactivity that began or worsened after the trauma, in the following way(s):

- Irritability or aggression
- Risky or destructive behavior
- Hypervigilance
- Heightened startle reaction
- Difficulty concentrating
- Difficulty sleeping

Criterion F (required): Symptoms last for more than 1 month.

Criterion G (required): Symptoms create distress or functional impairment (e.g., social, occupational).

Criterion H (required): Symptoms are not due to medication, substance use, or other illness.

Two specifications:

1. **Dissociative Specification.** In addition to meeting criteria for diagnosis, an individual experiences high levels of either of the following in reaction to trauma-related stimuli:
    - Depersonalization. Experience of being an outside observer of or detached from oneself (e.g., feeling as if "this is not happening to me" or one were in a dream).
    - Derealization. Experience of unreality, distance, or distortion (e.g., "things are not real").
2. **Delayed Specification.** Full diagnostic criteria are not met until at least six months after the trauma(s), although onset of symptoms may occur immediately.

How is PTSD Typically Treated?
CBT, cognitive processing therapy, prolonged exposure therapy (PE), eye movement desensitization and reprocessing (EMDR), stress inoculation training, psychopharmalogical treatments are all common treatments for PTSD. Cognitive behavioral therapy (CBT) often occurs once a week and works with the client to reframe thoughts surrounding the event (i.e. feelings of guilt). Similarly, in cognitive processing therapy the client recounts the event and related thoughts to a therapist and subsequently processes and learns new ways to live with the thoughts and trauma. PE takes place in eight to fifteen ninety minute sessions in which the client is taught breathing techniques to combat anxiety before making a list of avoidances and learning to face them. EMDR asks the client to watch or listen to something, such as a light flashing or sound, while concentrating on the traumatic event so that over time, the client can think about something positive while remember the trauma. Stress inoculation training focuses on how the client responds to the stress of the trauma and works to teach them methods to cope such as breathing techniques and thought stopping. Medications frequently prescribed to individuals with PTSD are SSRIs and SNRIs such as Prozac and Zoloft. We are testing whether MBSR is an effective complementary treatment for PTSD. Complementary means that it will be used in addition to any other interventions used in standard treatment of PTSD.

Subsection 1B.2 - MBSR Basics

MBSR is a way to teach mindfulness, or the process of focusing one's attention on the present moment without judgement (Kabat-Zinn, 1990). It has have shown promise for reducing symptoms of PTSD (Khusid & Vythilingam, 2016; Polusny et al., 2015) and associated biological markers of the stress response (Black & Slavich, 2017; Bower et al., 2017) by lowering physiological arousal and improving attention and acceptance of the past and present (Lang et al., 2012). MBSR is relatively low cost and has demonstrated acceptability and feasibility in trauma-exposed, low-SES, high-minority samples (Dutton et al., 2014). An RCT of MBSR for PTSD in a sample of veterans demonstrated improved PTSD symptoms at immediate follow-up with clinically significant improvement sustained 2-months later (Polusny et al., 2015). Congruent findings were indicated in veterans using a one-armed-repeated-measures design (Kearney et al., 2012). MBIs have also been linked with statistically significant reductions in markers of inflammation (Bower et al., 2017; Rosenkranz et al., 2013). that are associated with PTSD, including CRP (Creswell & Irwin, 2012; Malarkey et al., 2013). In relation to stress reactivity, in repeated measures analyses, an MBI significantly reduced cortisol reactivity to a stress task (Rosenkranz et al., 2013). Participation in an MBI compared to a treatment-as-usual condition in veterans with PTSD was associated with reduced cortisol, suggesting a brief MBI might have beneficial responses on stress physiology (Bergen-Cico et al., 2014). Data suggests that biological dysregulation may precede the development of – and at a minimum mutually maintain – PTSD symptoms (van Zuiden et al., 2013). This means that the physiological response may actually occur prior to the psychological symptoms, but more research is needed. Moreover, participation in MBIs have been associated with effective relapse prevention in those with SUD (Bowen et al., 2006) and lower depression in a sample of economically disadvantaged women (Burnett-Zeigler et al., 2016). As such, MBIs, which concurrently target regulation of the physiological stress responses, emotional cognitive symptoms of PTSD, and related

psychological comorbidities may provide a low-cost, feasible method to address the complexity of PTSD symptom maintenance over time.

MBSR was first developed in the 1970s by Dr. Jon Kabat-Zinn at the University of Massachusetts Medical Center (Kabat-Zinn, 1990). MBSR uses many practices that have been around for thousands of years, but manualized these practices into an 8 week, 9 session program. MBSR has been used in hospital, school, work, athletic, and prison settings with beneficial results. MBSR is a group-based class and is not therapy. It generally should be used as an adjunct to other psychiatric and physical healthcare, not as a supplement.

The general flow of the eight-week program is as follows:

Week 1: Introductory Material. This includes an overview of the course, building trust within the group, introduction to mindful eating, some standing yoga stretches, mindful breathing and body scan meditation (Homework: Body Scan recording using MP3 player; eating one meal mindfully; optional informal meditation practice.)

Week 2: Understanding Perceptions. This session focuses on self-responsibility and short and long-term changes for health enhancing behaviors; how you see things determines how you react or respond. (Homework: Body Scan recording using MP3; fill out Pleasant Events Calendar; select one activity to bring full awareness to).

Week 3: Hatha Yoga, Sitting Meditation, Walking Meditation. The theme is the pleasure and power of being present; this week teaches how to investigate the mind and body through yoga and meditation. (Homework: Alternate Body Scan recording with Lying-down Yoga using MP3 player; fill out Unpleasant Events Calendar; sitting meditation).

Week 4: Concentration and Awareness. This theme relates to how conditioning and perception influence one's experience and new ways to relate to stress. (Homework: Alternate Body Scan recording with Lying-down Yoga using MP3 player; be aware of being stuck, sitting meditation).

Week 5: Unhealthy Patterns and Getting Unstuck. This week examines conditioned patterns and the passive ways that people cope (e.g., numbing, denial, passive-aggressiveness, suppression of feelings, substance dependency). (Homework: Fill out Difficult Communications Calendar; Sitting Meditation and Standing Yoga Sequence).

Week 6: Transformational Coping Strategies. This for this week include how to deal with stressful communication and knowing and expressing your feelings. (Homework: Alternate Sitting Meditation recording with Body Scan and/or Standing or Lying down Yoga recording).

Week 7: Retreat. This will be a silent class, with sitting and walking practice. Guided meditations will include loving-kindness meditation.

Week 8: Maintaining Discipline and Flexibility. This class focus on how to more fully integrate mindfulness into daily life. Instructors and participants discuss lifestyle choices and limiting patterns. (Homework: no recordings; try to practice formal sitting meditation; recordings can be used if necessary.)

Week 9: Course Review. In this session, students will reflect on the course, the instructor provides additional resources, participants discuss their experiences with the group.

Common Uses:
MBSR is used as a complementary treatment for anxiety, panic, depression, eating disorders, pain, sleep issues, and a growing number of additional maladies. MBSR is also used increase productivity, performance, emotion regulation, and general wellbeing.

SECTION 2. INTERVENTION DELIVERY

Subsection 2.1 - Phase II Overview

In Phase II, we will assess the potential benefit of MBSR to reduce PTSD (primary outcomes) and secondary outcomes (e.g., depression, SUD, CRP, cortisol reactivity), among 130 eligible homeless women who exhibit likely subthreshold or threshold PTSD living at one of two residential drug treatment facilities. MBSR will be compared to an attention-control group (Health Promotion Wellness Classes; HP). There originally intended to be five cohorts of women, each with 12-15 women (total of 24-30 women per cohort). However, due to COVID-19 adjustments have been made in terms of the class size and randomization procedure. At each cohort, sites will be randomized to receive either the MBSR or the HP. Although sites will alternate between MBSR and HP by cohort, each participant will receive either the MBSR or the HP. Randomization will occur using RedCAP. The women participate in either MBSR or HP for 9 weeks. Psychosocial data will be collected at baseline, immediately following final intervention session, and at 6-month follow-up via tablet questionnaires. After psychosocial data collection, a stress task (Trauma Imagery Task) will be conducted at each time point, with saliva collected both before and after the task to assay cortisol and CRP. This proposal will improve on the methodological rigor of prior research on MBIs for PTSD in disadvantaged populations by using: randomization procedures that account for cross-contamination; blind evaluators; longitudinal follow-up; an attention control group equal to the MBI intervention in both contact visits and hours; increased demographic diversity; comprehensive lifetime trauma assessment; and inclusion of objective indices of stress responses to accurately evaluate the effectiveness of MBIs in treating trauma-related symptoms.

Confidentiality and Ethical Issues

All program staff must follow confidentiality and ethical procedures throughout this program to ensure that everybody is treated with respect and dignity.

1. Communication with study participants must remain confidential. To maintain confidentiality for participants, any personal information provided, such as participants' name, age, etc., will

be protected by use of subject code on all data and questionnaires. Data including subject identifiable information will be linked to a code on RedCap for this study for access and only research staff will have access. An exception to this rule is the clinic provider and site staff who work directly with the women onsite.

Program Team

The Lab Manager and Lab Coordinator will help the PI (Dr. Garfin) in organizing all aspects of the study. These individuals will be current or former students from the Department of Psychological Science's Postbaccalaureate Program. They will be responsible for tracking recruitment, scheduling research assistants, and ensuring that the site is well-stocked with necessary supplies. Weekly, the Lab Manager and Lab Coordinator will meet with Dr. Garfin to review all aspects of the study, troubleshoot any problems, and create schedule for the other Research Assistants (RAs). The RAs will be highly trained Postbaccalaureate, graduate, or undergraduate students from the University of California, Irvine.

Safety of Program Staff

While we believe that conducting this study is highly important for public health, it is critical that the program staff prioritize their own safety first. If you feel that you are in danger (physically, emotionally, psychologically) in any way, end the study activities and inform the research coordinator or the PI as soon as you can safely do so. This is particularly important during COVID-19. Please report any lapses in COVID-19 protocol to Dr. Garfin and the Leadership team immediately. If there is any chance you have been exposed, it is imperative *that you do not come to site*. The study leadership (Dr. Garfin and the Lab Manager / Lab Coordinator)

Subsection 2.2 - Phase II Scope of Work & Participant Flow Diagram

1. **General Recruitment**
    a. We will recruit 5 cohorts of women from the two sites by research staff via flyers and announcements during site programming. Due to COVID-19, this strategy may change as the situation evolves.
    b. Participants will then be given an eligibility screener via tablet with either Dr. Garfin or the Lab Manager/Lab Coordinator available to answer any questions.
        i. A key inclusion criteria is subthreshold current PTSD. Thus, the women will be given a PTSD screener for the trauma that is bothering them most right now. There may be multiple traumas the women have experienced – they should be prompted to pick the one that is most troubling to them at the time of screener completion.
    c. Tablets will be programmed by the Research Director from the School of Nursing and responses will be automatically, electronically scored. All participants who complete the screener will receive $3.
        i. Note: those who complete the screener must complete the consent to screen, but are not assigned a participant ID at this time as they have not completed the **Informed Consent**. As such it is imperative that accurate information be obtained with respect to the individual's name as that will be used to link it to their subsequent data.

2. **Group Assignment and Intervention Procedure (may chance due to evolving circumstances due to COVID-19)**
    a. Prior to recruitment, the Residential Treatment Sites (RTS; Pomona and Escondido) will be randomized to receive the MBI or serve as the attention-control (HP); recruitment and research procedures (MBI or attention-control) will occur at both sites simultaneously. Women will live at sites prior to recruitment.
    b. **Informed consent** – there are TWO versions of the Informed Consent documents. One is for the MBSR course; the other is for the HP course. Women will complete ONE of the Informed Consent forms, depending on which group they are in. It is imperative that the correct form is filled out and uploaded onto REDCap.
    c. Baseline questionnaire administered:
        i. After informed consent, participants will complete a baseline questionnaire. In addition to the traumas indicated in the PCL-5, participants will report **lifetime** history of trauma (including whether events occurred in adulthood, childhood, or both).
        ii. Questionnaire data will be collected via tablet and transferred to RedCap.
        iii. Participants will provide a urine sample for a drug test to validate self-report. Then participants will complete the brief stress (Trauma task providing saliva samples both before and after the task.
    d. Locator guide: this is a critical part of maintaining contact with our participants. However, they may not be inclined to provide all the information on the first or second meeting. **PLEASE TAKE THE PICTURE AT THE TIME OF ADMINISTERING INFORMED CONSENT.** The rest of the locator guide can be filled out over the course of the study. Given issues with COVID-19, we will start completing the Locator Guide after session 2 or 3. Please see PI or Lab Management Team for further guidance.
    e. Intervention
        i. Participants will begin MBSR/HP activities within one month of baseline assessment, dependent on the time of their baseline assessment within recruitment schedule
        ii. Both groups (MBSR and HP) will consist of nine sessions, each approximately 2 hours in length.
    b. Immediate follow-up
        i. After the 9th session, participants will complete a questionnaire via tablet that will assess PTSD (primary outcome), secondary outcomes (e.g., depression, substance use), and traumatic events that occurred since first assessment, as well as key covariates (e.g., fidelity to intervention) and additional outcomes (e.g., mindfulness, emotion regulation).
        ii. Women will provide urine for drug test and repeat the Trauma Imagery Stress Task, providing saliva samples before and after the task.
    c. 6-month follow-up
        i. Primary and secondary outcomes and covariates (e.g., fidelity to intervention) will be reassessed via tablet
        ii. Women will provide urine for a drug test and repeat the Trauma Imagery Stress Task, providing saliva samples before and after the stress task.

3. **Phase II Reimbursement**
    d. Women will receive $15 for the baseline assessment, $10 per MBSR/HP session, $15 for completing the post-intervention assessment, and $30 for the 6-month follow-up assessment.

i. Women are paid in cash and must sign on the iPad (via REDCap) that they have received the payment. This must also be initialed, signed, and dated by the RA in charge of payment.

Subsection 2.3 - Phase II Recruitment & Treatment Overview

Table 4: Overview of Phase II: Timeline of Mindfulness Trial Procedures & Assessments

PRE-ASESSESSMENTS			MBSR or HP Control		POST-ASSESSMENTS			
Baseline			Sessions 1-8	Session 9			6-months post-intervention	
Eligibility Screen PTSD dx	Psychosocial Questionnaire [a,b]	Trauma Imagery Task	Groups meet once per week	Final intervention session	Psychosocial Questionnaire [b,c] PTSD dx	Trauma Imagery Task	Psychosocial Questionnaire [b,c] PTSD dx	Trauma Imagery Task

KEY ⬆ = Urine collected for drug screen ⬆ = Saliva collected immediately before & 20 min post trauma imagery task [a] Measures: lifetime trauma exposure (+ occurrence in adulthood, childhood or both); demographics [b] Updated adversity history (traumatic & stressful events, including incarceration), PTSD dx [c] Depression, self-report substance use, perceived stress, mindfulness, fidelity/ adherence to program, quality of life

Subsection 2.4 - Phase II Recruitment & Screening

The study was designed so that recruitment at Pomona would be paced to match that at the Escondido site so that all procedures across sites happen in tandem, thus avoiding history effects; recruitment data will be evaluated weekly to inform pacing. Site staff at Prototypes will assist with participant recruitment, informing Prototypes residents of the opportunity during formal announcements during programing. Recruitment flyers will also be posted around the RTS. RAs will help recruit women and conduct the initial screening in a private room after obtaining informed consent; progress will be monitored closely by Dr. Garfin the Lab Management team. Modifications will be made to allow for the study to continue during the COVID-19 pandemic to ensure safety of Ras, site staff, and participants.

Ideally, recruitment will be staggered according to cohorts and paced equally across sites. In total, five cohorts of women will be recruited. Each will have approximately 26- 28 women in each group/site (n=13-14 MBSR; n=13-14 attention control); recruitment proceeds for one month, the intervention runs for approximately 2 months (9 weeks), then there is one month break. ***However, this schedule may vary due to COVID-19 restrictions, limitations, and other feasibility issues***.

Dr. Garfin will explain the study during an initial meeting with potential participants and answer any questions. Then women will be screened for eligibility. Prior to obtaining any data, the women will provide a “consent to screen”. This is because we need to obtain data from the women to determine if they are eligible, but they are not officially enrolled as human subjects. By providing their “consent to screen”, we are obtaining verbal consent/permission to ask them questions. Their data will not be used by the research team if they are not eligible.

The RA will read the consent to screen script on REDCap. Potential participants are free to stop at any time – remind them that all procedures are completely voluntary. Dr. Garfin and/or someone from the Lab Management team will always be onsite to help answer questions.

Participants will then be given an eligibility screener via tablet with either Dr. Garfin or a trained research assistant available to answer any questions. The screener will first assess for age, prior homelessness, and cognitive competence. The screener then screens for PTSD using the PTSD Checklist for DSM-5 (PCL-5) for ***the worst event in their life***. We will assess PTSD to their most recent event (in the past year) during the baseline and follow-up assessments. The standard PCL-5 initially starts with the identification of the presence of exposure to a DSM-5 traumatic event and then assesses whether it involved actual or threatened death, serious injury or sexual violence. The RA may need to prompt the potential participant with examples to keep them on track and to ensure that the participant is responding to an actual DSM-5 traumatic event. The next 20 items on the PCL-5 assess all four B-E PTSD criterion (re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal), assessed on a Likert-type scale 0 "not at all", 1 "a little bit", 2 "moderately", 3 "quite a bit", 4 "extremely". Subthreshold PTSD will be defined as endorsing "moderately" or more to at least 2 B-E criteria; probable-PTSD will be measured by meeting criteria A-G for PTSD.

Data collection method: All data will be collected via encrypted tablets will be programmed by the Research Director from the School of Nursing and responses will be automatically, electronically scored. Data is not stored on the tablets. It is automatically transferred to the All participants who complete the screener will receive $3.

Subsection 2.5 - Phase II Eligibility Criteria

Inclusion Criteria:

1) Homeless women (N=134; 67 in each group)
    a. Women over 18 years of age
    b. Able to speak English
    c. Homeless in the last 6 months: a homeless person is defined as anyone who spent the previous night in a public or private shelter, or on the street.
    d. Lifetime exposure to trauma as defined by the Diagnostic and Statistical Manual for Mental Disorders, 5th Edition (DSM-5).
    e. Likely subthreshold or threshold PTSD, as measured by the PCL-5.

Exclusion Criteria:

The following will **not** be eligible for participating:

1) Persons who are:
    a. Not able to speak English
    b. Judged to be cognitively impaired, as indicated by score > 10 on the Short-Blessed Screener

Subsection 2.6 - Phase II Laboratory Tests/Sample Collection

Saliva Sampling and Results

Saliva Collection

- Pre-task, saliva will be collected. All saliva collection will occur between 10am-2pm to minimize diurnal fluctuation effects. (Study procedures may start before 10, but first saliva sample must be collected after 10:00am; the second sample must be collected before 2pm – participants must be scheduled according to these specifications).
- Two whole saliva samples will be collected using an unstimulated passive drool technique.
- Women will be instructed to avoid eating, brushing teeth, or smoking for one hour prior to the assessment and will be asked to wait to begin the task if they have.
- Participants will rinse their mouths thoroughly with water for 10 minutes before samples are collected. Participants will then passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected.
- Saliva samples will be immediately placed in the on-site freezer (or ice cooler) and be taken to IISBR within 36 hours to be frozen at -80°C until assayed.
- All samples will be assayed for salivary cortisol and CRP using a highly sensitive enzyme immunoassay (Salimetrics, IISBR).
- ***Twenty minutes after task completion***, saliva samples will be collected again in an identical manner to that described above.
- Participants will then be offered snacks and a drink and be debriefed to ensure they are not experiencing severe task-related psychological distress. In the unlikely event of participant distress, an immediate referral will be made to on-site professional staff.

Subsection 2.7 - Phase II Intervention Program Description

General Description: Among 134 eligible trauma-exposed homeless women, assess the impact of the MBSR intervention program PTSD symptoms (primary outcomes), and substance abuse, depression, cortisol reactivity, and inflammation (secondary outcomes).

Data Collection Time points: Baseline, 2 months, and 6 months

Total Duration: 6 months

The following sections will outline the intervention process:

- Pre-intervention Assessments
- Brief Stress Task (Trauma Imagery Stress Task)
- Biospecimen Collection
- Biospecimen Analysis
- MBSR Intervention
- Health Promotion Intervention
- Post-Assessment
- Team Management of Biospecimen Collection Refusal
- Dealing with Program Attrition

Subsection 2.8 - Phase II Pre-intervention Assessments

After Informed Consent, participants will complete a series of self-report measures. These measures will be administered by Research Staff at a private location at the site. Responses options to each question will be provided to the participant, organized in a clearly labeled binder. The Research Staff will display the response options for each measure, read the options out loud, and then record the response on the tablet. At the end of each measure, the RA will "lock" the measure. There will be a prompt if any items have been missed. Please check that there is no missing data. The participant may take a break at any time. However, the participant should refrain from eating, drinking (except for water ~ 10 minutes prior to stress task), or smoking until after the second saliva collection to ensure the accuracy of the saliva sample.

Order of assessments

1. Drug test (urine)
2. TCU Drug Screen (self-report)
3. Self-compassion scale – short form
4. General self-efficacy scale
5. Mindful Attention Awareness Scale
6. Difficulties I Emotion Regulation Scale
7. Satisfaction with Life Scale
8. Quality of Life Enjoyment and Satisfaction Questionnaire
9. MOS Social Support
10. Perceived Stress Scale
11. Dimensions of Anger Reactions
12. PROMIS – Anxiety
13. PROMIS – Depression

*NOTE: For time constraints, the urine test can be administered during the waiting period prior to the second cortisol sample.

AT THIS POINT, THE FIRST SALIVARY SAMPLE IS COLLECTED

14. Negative Life Events Inventory
15. PCL 5- ***Worst life event*** (this is the event that bothers them the most, from their entire life)
16. PCL 5 – ***Recent (past year)*** this is a traumatic event that has happened to them recently (in the past year) – it may or may not be the same as #16
17. Trauma Imagery Stress Task (the Negative Life Events Inventory and the PCL build up to this)

Subsection 2.9 - Phase II Brief Stress Task (Trauma Imagery Task)

After completing the PROMIS Depression, the participant will provide a saliva sample. They will then complete the negative life events inventory and the PCL 5 (for worst event in their life and a recent event). The reason that the saliva sample is taken before these measures and not directly before the Trauma Imagery Task is because in pilot studies the women began to

become distressed when recounting their traumas during the Negative Life Events Inventory and the PCL; thus, the “baseline” for cortisol is now taken PRIOR to these items.

After completing the PCL for worst event and recent event, the participant will complete a a modified script-driven imagery task (Seo et al., 2013), derived from prior research with women with PTSD. Participants will be asked to recount a traumatic event via written response. The RA will provide a paper and pen and instruct the participant to recall the event exactly as it happened. The RA can offer prompts to recall sight, smell, and sound. The participant will then recount the event to the RA. Script driven imagery tasks have been effectively and safely used to assess traumatic-stress responses in individuals with PTSD. However, RAs will be highly trained to assess any severe distress that may arise and will immediately notify the PI and site clinical staff immediately. Responses will be subsequently destroyed. ***AFTER THE COMPLETION OF THE TRAUMA IMAGERY TASK THE 20 MINUTE POST-SALIVA SAMPLE TIMER STARTS!*** When the timer starts, the RA will not interact with the participant. They should sit quietly or may read.

Subsection 2.10 - Phase II Biospecimen Collection

Urine Collection: Participants will provide a urine sample to validate self-report drug use. A 5-panel FDA-approved urine test cup will be used in this study. The participant will be instructed to urinate in the cup, close the cup, and then bring it back to the RA to read. Gloves will be used at all times and the RA should read the cup without touching it if possible. The participant will then be instructed to dispose of their urine in the restroom.

Saliva Collection: Before and twenty minutes after the brief stress task (Trauma Imagery Stress Task), women will be asked to provide a salivary sample. Women will be instructed to avoid eating, brushing teeth or smoking for one hour prior to the collection of saliva and will be asked to wait to begin the task if they have. Participants will passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected.

Saliva samples will be immediately placed in the on-site freezer or cooler and be taken to IISBR or to Dr. Garfin’s research lab for storage. Saliva samples will be transferred to IISBR within 36 hours to be frozen at -80°C until assayed. After the second and final collection, participants will be offered snacks and a drink and be debriefed using an IRB-approved script (see below).

Debriefing script:

> Thanks so much for your participation. I know that might have been difficult for you to recall this event. I want to thank you and let you know that we think your participation in this task will help other women who have experienced adversity. While feeling a little distressed might be expected, we want to make sure you are not experiencing a lot of distress. Right now are you are experiencing a lot of distress?

If yes, ask if they want you to get a site staff from Prototypes/Serenity House AND contact the Principal Investigator, Dr. Dana Rose Garfin immediately AND provide Dr. Garfin's contact information to them).

If no, thank them for their time and remind them if anything comes up they can call the Principal Investigator, Dr. Dana Rose Garfin and/or talk to any of the Prototypes/Serenity House site staff. (Provide Dr. Garfin's contact information to them).

Provide water and snacks at this time and pay close attention to any noticeable changes in mood until they are released to the care of the Prototypes/Serenity House site staff. Immediately inform Dr. Garfin AND Prototypes/Serenity House site staff of any potential issues.

Subsection 2.11 - Phase II Biospecimen Analysis

Urine Sample: The 5-panel FDA-approved urine test cup screens for metabolites of the following drugs of abuse at the established cut-off levels and is used for qualitative purposes: Amphetamines (1000 ng/mL), Cocaine (300 ng/mL), Methamphetamines/ MDMA (500 ng/mL), Opiates (2000 ng/mL), and THC (50 ng/mL). Urine sample validity checks will be provided by temperature and adulterant monitoring strips built into the test cup. Participants whose urine does not pass validity checks will be counted as positive for drugs. Results will be coded qualitatively (above or below threshold). All positive results will be interpreted as positive, regardless of self-report.

Saliva Sample: The saliva sample is collected to determine resting cortisol, cortisol reactivity, and C-RP (a marker of inflammation). All saliva will be assayed in duplicate using standard manufacturer's protocol (Salimetrics). The concentration of CRP in saliva will be determined using a Salivary C-Reactive Protein ELISA kit, an enzyme-linked immunoassay. The standard curve is run on every assay plate and must have an R2 value of > 0.99. The replicates must have a %CV < 15 or an absolute difference <0.030 between the replicates. The mean values across saliva duplicates will be computed for each sample and used in the statistical analyses.

Subsection 2.12 - Phase II MBSR-based Intervention

Standard MBSR is an eight-week long mindfulness-based intervention (MBI) with one 1.5-2.5 hour session per week (the seventh week has two sessions as one is a mini-retreat). The intervention will be run by a highly experienced instructor with prior experience conducting MBSR with individuals exposed to trauma with PTSD.

During MBSR, participants are trained in mindfulness meditation and the applicability of mindfulness to daily life. During MBSR programing, teachers will lecture about key topics in mindfulness and lead class discussions. Participants are given opportunities to ask the instructor questions and to share their experiences with each other. Snacks and drinks will be provided. Important to note, the intervention in this study is not true MBSR. It has been modified to fit the specific needs of the target population. This includes shorter sessions and shorter meditations, and additional flexibility on the part of the trainer. Although many of the same tools and procedures in traditional MBSR will be utilized, given these critical differences the intervention administered in this study is *not* true MBSR.

Each week in the MBSR program focuses on a different theme and has specific short homework assignments that students are asked to complete. The sessions are as follows:

- **Week 1**: Introductory Material. This includes an overview of the course, building trust within the group, introduction to mindful eating, some standing yoga stretches, mindful breathing and body scan meditation
    - **Homework**: Body Scan recording using MP3 player; eating one meal mindfully; optional informal meditation practice. Participants will also complete a trauma-informed safety plan to ensure that, although MBSR is given in a group format, the MBSR trainer is responsive to the unique needs of the individual.
- **Week 2**: Understanding Perceptions. This session focuses on self-responsibility and short and long-term changes for health enhancing behaviors; how you see things determines how you react or respond.
    - **Homework**: Body Scan recording using MP3; fill out Pleasant Events Calendar; select one activity to bring full awareness to.
- **Week 3**: Hatha Yoga, Sitting Meditation, Walking Meditation. The theme is the pleasure and power of being present; this week teaches how to investigate the mind and body through yoga and meditation.
    - **Homework**: Alternate Body Scan recording with Lying-down Yoga using MP3 player; fill out Unpleasant Events Calendar; sitting meditation.
- **Week 4**: Concentration and Awareness. This theme relates to how conditioning and perception influence one's experience and new ways to relate to stress.
    - **Homework**: Alternate Body Scan recording with Lying-down Yoga using MP3 player; be aware of being stuck, sitting meditation.
- **Week 5**: Unhealthy Patterns and Getting Unstuck. This week examines conditioned patterns and the passive ways that people cope (e.g., numbing, denial, passive-aggressiveness, suppression of feelings, substance dependency).
    - **Homework**: Fill out Difficult Communications Calendar; Sitting Meditation and Standing Yoga Sequence.
- **Week 6**: Transformational Coping Strategies. This week includes how to deal with stressful communication and knowing and expressing your feelings.

    - **Homework**: Alternate Sitting Meditation recording with Body Scan and/or Standing or Lying down Yoga recording.
- **Week 7a**: Retreat. This will be a silent class, with sitting and walking practice. Guided meditations will include loving-kindness meditation.
- **Week 7b**: Maintaining Discipline and Flexibility. This class focuses on how to more fully integrate mindfulness into daily life. Instructors and participants discuss lifestyle choices and limiting patterns.
    - **Homework**: no recordings; try to practice formal sitting meditation; recordings can be used if necessary.
- **Week 8**: Course Review. In this session, students will reflect on the course, the instructor will provide additional resources, and participants will discuss their experiences with the group.

Subsection 2.13 - Phase II Health Promotion Intervention

The Health Promotion program is eight weeks long with one 1.5-2 hour session per week (the seventh week has two sessions to ensure the same number of contact hours as the "mini-retreat" in the MBSR course). The Health Promotion Classes were designed to be analogous to the MBSR classes in terms of length and contact hours. This is because the effect of being in a group and participating in a study could help participants, without the benefit having much – if anything – to do with the actual intervention.

The program will be run by a UCI graduate or postbac student with a BA or higher. The SMART (Specific Measurable Achievable Relevant Time-based) framework will be used for goal setting. In this framework, specific, achievable goals are outlined by the participant as relevant to each class. This helps with information retention and helps reinforce concepts and positive behaviors. Snacks and drinks will be provided.

Each week in the Health Promotion program focuses on a different theme. The sessions are as follows:

1. Introduction & overview
2. Envisioning Health through Art
3. Chronic Disease I – Heart Health
4. Chronic Disease II – Diabetes
5. Nutrition and Hydration
6. Infectious Disease Prevention
7. Skin Care
8. Oral Health
9. Promoting Social Integration & Course Graduation

Subsection 2.14 - Phase II Post-Assessment

After the ninth session (of either MBSR or Health Promotion), a post-assessment will be administered via tablet. Urine will again be collected to validate self-report drug use. Participants will repeat the brief stress task (Trauma Imagery Task) using an identical strategy and provide saliva samples before and after. The Lead Researcher or a postbac student researcher will be on site to answer any questions or clarify any items. Urine and saliva samples will both be stored in a freezer on-site or at Dr. Garin's research office and then transferred to UCI for analysis within 36 hours. Follow-ups will occur on site unless participant has moved to sober living or other location. Zoom or phone will be implemented for those who moved out of state

Subsection 2.15 - Phase II Team Management of Biospecimen Collection Refusal

Participants have the right to refuse the collection of urine or saliva and it is important to understand that an individual may want to refuse due to the following:

Step 1: Assess reasons why participant does not want to have their sample collected.

- May experience concern that their friends, acquaintances, or shelter staff will be informed of the results of their surveys or urine.
- Other possible reasons?

In the event a participant refuses the sample collection, inquire about the following:

Step 2: Respond to their reasons why they do not want to give urine or saliva samples.

We encourage our participants to complete as many of the procedures as they are comfortable with. Please offer to have Dr. Garfin or Lab Management answer any questions the participant may have regarding the measures. However, participation is completely voluntary, and the participant may skip any aspect of the procedure that they chose without penalty and still be in the study.

Subsection 2.16 - Phase II Dealing with Intervention Program Attrition

Attrition is conservatively estimated at 10% for first follow-up and 20% for 6 month follow-up. To account for an estimated 30% of women to be screened with subthreshold or threshold PTSD, 448 women will be screened, approximately 134 enrolled, with approximately 120 for immediate post-intervention assessment and 96 at 6-month follow-up. This may change due to COVID-19, but we will work hard to ensure retention of participants during the study. The Locator Guide is key to maintaining effective follow-up.

- Completion of the intervention program is defined by completing at least 6 out of the 9 classes. We will keep track of the number of classes using the adherence tracker on REDCap. Make-up classes will be offered to women who can not make the class,

particularly as it pertains to COVID-19 or other obligations the women have such as court appearances.
    - The minimum amount of time required for the regimen is 8 weeks and the maximum is 10 weeks.

Subsection 2.17 - Phase II Follow-Up Focus Groups

At six-month follow-up, we will contact the women with assistance from the site supervisor or by using our Locator Guide (see Appendix). Research Staff will travel to the participant's location, as they may not be available to return to site due to COVID-19 restrictions or other factors. If participant moved out of state, the follow-ups may be conducted over Zoom or phone.

Subsection 2.18 - Phase II Compensation

The Phase II compensation is listed below. Each participant will receive a total of up to $153 over the course of the study.

$3 – screener (after completing screener)
$15 – baseline measures (after completing)
$10 – per class (at the end of each class; for a total of 9 classes)
$15 – immediate post-intervention follow-up measures (after the 9th class)
$30 – 6-month follow-up (after completion)

Participants who complete 6 or more of the sessions will also be given a Certificate of Completion. Participants who complete all 9 sessions will be given a Certificate of Perfect Attendance (see Appendix).

Subsection 2.19 - Program Fidelity

To ensure program fidelity, all procedures will be closely supervised by the PI, Dr. Garfin. Detailed training materials will be provided to all staff, and staff will be required to complete a quiz prior to working on site. For those involved in administering the interventions, a detailed teachers manual will be provided, and all staff will be expected to adhere to the manual, with some flexibility allowed depending on the needs of the group.

Subsection 2.20 - Research Staff Competencies and Mock Sessions

UC Irvine has implemented an educational program on the protection of human research subjects. All study personnel who are responsible for the design and conduct of this project must complete the Collaborative Institutional Training Initiative Human Research Curriculum (CITI program), with the confirmation of completion of the trainings on file. The following courses should be completed by all staff prior to engaging in study activities.

- Human Research - Social & Behavioral Researchers & Staff

- Good Clinical Practices (GCP) courses
- Refresher courses are also available on CITI website https://about.citiprogram.org/en/homepage/) as needed.

Further, all research staff will be highly trained by the PI in the following:

- Trained in specific protocols for dealing with emotional and mental distress (e.g., remaining calm, immediately finding appropriate onsite clinical staff).
- Trained in observational and communication skills, and in providing psychosocial support, particularly as it relates to emotional and information support
- Trained in the California Mandatory Reporting Laws governing reporting of child abuse, domestic violence, and elder/dependent abuse. Protocols governing reports to the California Department of Family and Child Protective Services, or (in the case of domestic violence) local police, will be carefully followed. Study participants will receive full disclosure regarding mandatory reporting laws during the informed consent process and discussion of confidentiality. In terms of current or recent abuse experience, research staff will refer the participants to the onsite Prototypes clinical staff.

During research study training, Research Staff will be evaluated using the competency grid and mock session review. Research Staff will also complete a quiz to be reviewed with the PI prior to interacting with the participants.

Subsection 2.21 - Data Entry, Management & Confidentiality

In Phase 2, secure and encrypted platforms will be used:

- **REDCap:** Interview data will be captured electronically using REDCap (Research Electronic Data Capture; http://project-redcap.org/), a secure, web-based application designed to support data entry and storage for research studies. Participants will answer surveys via an electronic tablet and the data will be uploaded in real-time. Possible errors, including incomplete responses, logic checks, and data range checks will be flagged by the RedCap software during input so that they can be corrected immediately. Laboratory data will be entered in REDCap electronic forms.
- Dr. Garfin will routinely check to ensure data is accurately entered. The Data Safety and Monitoring Board (DSMB) will also meet after the enrollment of every 30 participants to review/

Procedures to safeguard confidentiality

Confidentiality of data will be protected by use of subject code on all data and questionnaires. Any forms that link participant with their codes will be stored electronically on UCI's secure server and only senior research staff and the PI will have access. All self-report data will be immediately uploaded onto UCI's secure server via RedCAP. Saliva samples will use the subject code number and will not be labeled with the participant's name.

- Participants will be reminded that their interview questions will be provided over a tablet that will immediately transfer the data to the UCI secure server and site staff will not see their data.
- We will minimize the risk by strictly adhering to confidentiality procedures. All study staff will be rigorously trained in methods to promote confidentiality. The staff will also be taught to treat participants in a non-judgmental, professional and confidential manner.
- A Data Safety and Monitoring Board will be put in place for monitoring of the data collected.
- Confidentiality of data will be protected by use of subject code on all data and questionnaires. Data including subject identifiable information (eg: locator form etc) will be linked to a code on REDCap for access in real time to track participants and only research staff will have access. REDCap also allows for participant's names and IDs to be viewed without access to their responses to the other items in the survey. Tracking of participants for their follow-ups will be based upon the information the participant reveals on their Locator Guide. When contacting people over the phone, we will use their preferred method and the research staff will identify themselves per participants' wishes.
- To protect confidentiality and reassure subjects, the research staff will be providing explicit explanations in the beginning of the program that they will share no confidential information. The trained research staff will administer the questionnaires individually to the participants.
- Subject identifiable data will be destroyed upon completion of the study. All the data will be stripped off any identifiable information and only de-identified database will be kept for analysis and dissemination.

Subsection 2.22 – Using REDCap

- For electronic data entry, log onto RedCap (https://redcap.med.upenn.edu/) with your user ID and password.
- RedCap also incorporates suitable validity checks at the point of data entry to prevent "out of range," "missing" or other checkable data entry errors.

Subsection 2.23 - Data Security

- All CRFs and questionnaires must be identified by a code number (Study ID) only and patient identifier information will also be linked on REDCap through this code.
- The informed consent with the participants' names and signature will be on REDCap and a digital copy should be printed out of REDCap and stored in a local hard drive not connected to server.
- All databases are accessible only to key investigators and senior leadership of the project.
- The electronic data files are stored on the secure, password-protected UCI Health Science server.

- This data is available for analyses on the UCI server to authorized users through a web VPN application.
- Authorized users can export the data into Excel or other statistical software sheets for further analyses.
- The de-identified database will be archived for future analyses and all other identifying data will be destroyed at the end of the study as per NIH policy.

Subsection 2.24 - Post Data Collection

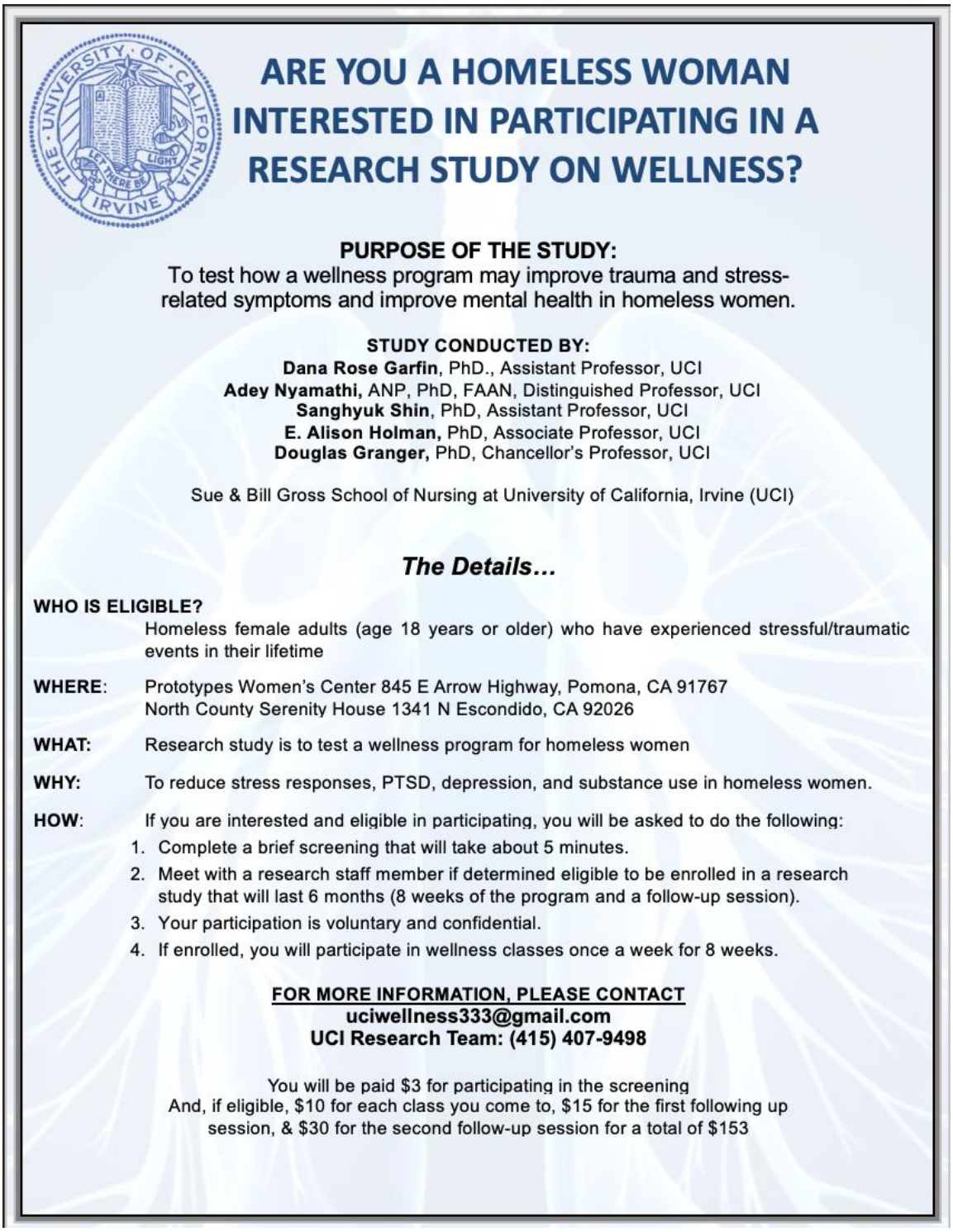
- Validity checks on REDCap should be done right after any interview or other data collection is completed.
- Routine statistical validity checks should identify missing or suspect entries at agreed defined intervals (twice per month or as needed) by approved study staff, so that correct data can be obtained from the research staff, participants or their records if needed.
- Thorough data cleaning should be performed before any data analysis.

Subsection 2.25 - End of Study

- De-identified electronic data will be maintained for the period agreed in the study protocol (indefinitely).
- Final cleaned electronic data will be used for all statistical analyses.

SECTION 4. RECRUITMENT

Subsection 4.1 - Phase II Flyer



ARE YOU A HOMELESS WOMAN INTERESTED IN PARTICIPATING IN A RESEARCH STUDY ON WELLNESS?

PURPOSE OF THE STUDY:

To test how a wellness program may improve trauma and stress-related symptoms and improve mental health in homeless women.

STUDY CONDUCTED BY:

Dana Rose Garfin, PhD., Assistant Professor, UCI
Adey Nyamathi, ANP, PhD, FAAN, Distinguished Professor, UCI
Sanghyuk Shin, PhD, Assistant Professor, UCI
E. Alison Holman, PhD, Associate Professor, UCI
Douglas Granger, PhD, Chancellor's Professor, UCI

Sue & Bill Gross School of Nursing at University of California, Irvine (UCI)

The Details…

WHO IS ELIGIBLE?
Homeless female adults (age 18 years or older) who have experienced stressful/traumatic events in their lifetime

WHERE: Prototypes Women's Center 845 E Arrow Highway, Pomona, CA 91767
North County Serenity House 1341 N Escondido, CA 92026

WHAT: Research study is to test a wellness program for homeless women

WHY: To reduce stress responses, PTSD, depression, and substance use in homeless women.

HOW: If you are interested and eligible in participating, you will be asked to do the following:

1. Complete a brief screening that will take about 5 minutes.
2. Meet with a research staff member if determined eligible to be enrolled in a research study that will last 6 months (8 weeks of the program and a follow-up session).
3. Your participation is voluntary and confidential.
4. If enrolled, you will participate in wellness classes once a week for 8 weeks.

FOR MORE INFORMATION, PLEASE CONTACT
uciwellness333@gmail.com
UCI Research Team: (415) 407-9498

You will be paid $3 for participating in the screening
And, if eligible, $10 for each class you come to, $15 for the first following up session, & $30 for the second follow-up session for a total of $153

Subsection 4.2 - Phase II MBSR – Script for Introduction at Recruitment Site: For Non-Research Staff Member

Introduction: Hello, my name is_____. I'm a staff member from Prototypes/Serenity House Residential Treatment Center. I would like to inform you about a research study by sharing a flyer with you. This study is conducted by Dr. Dana Rose Garfin of the UCI, Sue & Bill Gross School of Nursing.

Question: Would you like to receive a flyer?

- ❑ Yes, I would like to receive more information.
- ❑ No, not at this time. [If not interested, thank person for their time]

Directions: If interested, hand flyer and say: The research study being conducted at Prototypes/Serenity House and is a separate activity from the services offered by this site. If you decide to participate, your decision to participate in the research will not affect your relationship with Prototypes/Serenity House.

Directions: If you are interested, an information session will be held at _____ [DATE] at _____ [TIME] for you to learn more.

Question: Would you like to attend an information session and be screened to see if you are eligible to participate in this study?

- ❑ Yes [If yes, refer participant to Project Director]
- ❑ No [If no, thank person for their time]

SECTION 5. SCREENING, INFORMED CONSENT, AND ENROLLMENT

Subsection 5.1 Screening Protocol

Instructions:

1. Read participant consent to screen document (listed in Appendix)
2. If they agree to consent to screen, you will open the Screening Module in REDCap.
    1. Age? (Must be 18 or older)
    2. Able to speak English (infer, don't ask)
    3. Homeless in the last 6 months.
        i. Homeless is defined as anyone who spent the previous night in a public or private shelter, or on the street. Some women will have been incarcerated. If this is the case and they did not have another residence to return to, they are eligible to be in the study.
    4. Administer Short Blessed Test.
        i. Must meet (Normal Cognition 0-4)
    5. Meet likely subthreshold or threshold PTSD as measured by PCL-5 (see Appendix).
    6. Subthreshold PTSD
        i. Must meet Criteria A (exposure to a traumatic event).
        ii. Must endorse "moderately" or more to at least 2 B-E criteria. This will be automatically scored in REDCap.

Subsection 5.2 Informed Consent

1. If eligible, read to them the informed consent, going over key highlighted areas.
    i. Provide them a paper copy of the consent, and highlight the contact information for Dr. Garfin and the IRB.
    ii. Download a copy of informed consent (save in downloads). Have them sign. Then re-upload and delete from downloads.
2. START locator guide.
    i. Make sure you get their FULL LEGAL NAME!
    ii. **TAKE PICTURE USING THE "ADD DOCUMENT" ITEM, DO NOT SAVE TO CAMERA AND THEN UPLOAD.**

Subsection 5.3 Baseline Protocol

1. Tell them there will be a urine test. They can take it before or after interview (their choice). You will hand them a cup. They will return the cup and you will record their urine results in REDCap. Use gloves. **It is not considered a biohazard** so can be thrown in trash (or urine poured in toilet).

APPENDIX I: What to bring to site

Screening

- Charged iPads
- Charged iPencils
- Compensation in 1 dollar bills, as participants will be paid $3 per screening
- Light snacks
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.

Baseline, immediate follow-up, and 6-month follow-up

- Charged iPads
- Charged iPencils
- Compensation in $10- and $5-dollar bills, as participants will be paid $15 each (Note: for 6-month follow-up please bring $10 dollar bills as participants will be paid $30.)
- Light snacks
- Bottles of water
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.
- Color coded and labeled vials for saliva collection
- White boxes to store saliva samples
- **Cooler with ice**
- Drug test kits
- Paper and pens for stress task (trauma imagery task)

Weekly – Health Promotion class

- Charged iPads
- Charged iPencils
- Compensation in $5 or $10 dollar bills, as participants will be paid $10 each
- Light snacks
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.
- Teacher manual
- Extra participant book
- Materials for each week – please see teacher manual for weekly supply list

Weekly – MBSR class

- Charged iPads
- Charged iPencils
- Compensation in $5 or 10 bills, as participants will be paid $10 each
- Light snacks
- PPE for COVID-19, including face masks, face shields, tissues, Clorox wipes, hand sanitizer, and gloves.
- Extra participant book
- Extra MP3 players
- Extra yoga mat or two

APPENDIX II: Trauma Imagery Script (Brief Stress Task)

TRAUMA IMAGERY SCRIPT

***NOTE TO RA**: Make sure the participant has not had anything to eat or drink for one hour and that they had some water to drink at least 10 minutes before starting the task.*

RA: Thank you for your participation in this part of the project. We are going to be asking you to recall and describe a stressful or traumatic event. We want to remind you that you can stop at any time if you are uncomfortable, although your participation will help us understand more about the stress process in women who have experienced adversity. The general overview of this procedure is that we are going to take a saliva sample to assess your stress hormones; have you participate in a short stress task; and then take another saliva sample to assess your stress hormones after the task. If this gets to be too intense for you, you can stop at any time. If you experience any severe distress, let me know and we will stop the task and immediately contact your onsite clinician/therapist. I want to remind you that this is completely voluntary and you can stop at any time and can still be in the study. Are you ready to begin? Do you have any questions?

***NOTE TO RA:** Participants will then passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected. Instruct to lean forward, and allow saliva to pool at the bottom of your mouth. Instruct to use tongue to slowly push the saliva into a straw-like collection tool that leads into a tube until you have collected roughly 1 teaspoon of saliva. Immediately put saliva in cooler!*

RA: First, I am going to ask you to recall a stressful or traumatic event for a few minutes. Some examples are a serious accident, fire, disaster, physical assault, abuse, war, homicide or suicide. Then, you will write about it and then read or describe it aloud. I can also take notes for you if you prefer to do it that way. You can face whatever direction you want and you can have your eyes open or closed. However, I ask that you try to recall each part of the event in as much detail as you can in your mind's eye. Think of the actions, events, thoughts, feelings, smells, and sensations. Try to remember how you felt and what was happening in your body. Do you have any questions?

I am going to give you a few minutes to imagine the event and write some notes. Here is a pen and some paper. Anything you write will be destroyed after the task.

***NOTE TO RA**: Give the participant some time to write. Re-iterate any of the instructions if they ask or seem stuck. **Stop the procedure if the participant is extremely distressed and contact a Prototypes site staff and Dr. Garfin**. Remind them they can still be in the study if they don't want to complete this part of the procedures.*

RA: Now please read what you wrote aloud and vividly imagine it in your mind's eye. (*Time ~ 5 minutes*).

NOTE TO RA**:** *20 minutes after completion, collect saliva samples in an identical manner to the first sample. Participants will then passively drool into a collection vial for three minutes or until 0.80 milliliters of fluid is collected. Instruct to lean forward, and allow saliva to pool at the bottom of your mouth. Instruct to use tongue to slowly push the saliva into a straw-like collection tool that leads into a tube until you have collected roughly 1 teaspoon of saliva. Immediately put saliva in cooler!*

POST-TASK DEBRIEFING

Thanks so much for your participation. I know that might have been difficult for you to recall this event. I want to thank you and let you know that we think your participation in this task will help other women who have experienced adversity. While feeling a little distressed might be expected, we want to make sure you are not experiencing a lot of distress. Right now are you are experiencing a lot of distress?

If yes, ask if they want you to get a site staff from Prototypes/Serenity House ***AND*** contact the Principal Investigator, Dr. Dana Rose Garfin ***immediately AND*** provide Dr. Garfin's contact information to them).

If no, thank them for their time and remind them if anything comes up they can call the Principal Investigator, Dr. Dana Rose Garfin and/or talk to any of the Prototypes/Serenity House site staff. (Provide Dr. Garfin's contact information to them).

Provide water and snacks at this time and pay close attention to any noticeable changes in mood until they are released to the care of the Prototypes/Serenity House site staff. ***Immediately inform Dr. Garfin AND Prototypes/Serenity House site staff of any potential issues***.

NOTE TO RA**:** *Please provide the following to the participant (note: can also remind the participant this is also included in the informed consent).*

CONTACT INFORMATION

If you have any concerns please contact the Principal Investigator, Dr. Dana Rose Garfin at dgarfin@uci.edu or (657) 251-9219. You can also call the University of California, Irvine Institutional Review Board at Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

APPENDIX III: Data Safety and Monitoring Plan

UCI Office of Research	**Institutional Review Board** **Human Research Protections** **Appendix S – DESCRIPTION OF DATA SAFETY MONITORING PLAN (DSMP) FOR CLINICAL/ BIOMEDICAL RESEARCH** *Version 09-19-2018*
Researchers: • All studies involving greater than minimal risk to participants are, at a minimum, required to develop a detailed plan to ensure that there is appropriate safety oversight. • For clinical studies involving a test article, it is common to have an independent Data Safety Monitoring Board (DSMB). • Please read the applicable HRP webpage for further guidance.	**HS#:** *(to be completed by the IRB)*
Lead Researcher/Investigator Name: Dana Rose Garfin	

Researchers may *cut and paste into Appendix S from the following sources*, as applicable.
Please remember to submit the following documents with your IRB APP:

- For NIH-sponsored clinical trials, the DSMP should be part of the grant application.
- For industry sponsor-initiated clinical trials, a FDA-approved DSMP should be part of the Master Protocol or the Data Safety Monitoring Committee/Board Charter.
- For studies conducted at the Institute for Clinical and Translational Science (ICTS) or Cancer Center (PRMC), the DSMP information approved by one of these committees should be inserted into this appendix.

Please answer all of the following:

1. Provide details of those individuals who will be responsible for the safety oversight of your study, including the relevant experience/expertise of each individual (for UCI investigator initiated studies conducted only at UCI, provide the names and titles as well).

   The study will have a Data Safety and Monitoring Board (DSMB)

   1. **Dana Rose Garfin, PhD** (Assistant Adjunct Professor and Lead Investigator, Sue & Bill Gross School of Nursing). Dr. Garfin has over 12 years of experience researching stress and trauma in both epidemiological and community-based samples. She has conducted prior studies with vulnerable populations (e.g., homeless women, trauma-exposed children; post-disaster survivors, demographically diverse samples). Dr. Garfin's recent work has explored the efficacy of community-based interventions on high risk samples (i.e., HIV-positive women in India). Dr. Garfin has recently completed a qualitative study exploring the acceptability and feasibility of a mindfulness-based intervention for trauma-exposed, homeless women. Dr. Garfin has an MA in Social Ecology and a PhD in Psychology.
   2. **Adeline M. Nyamathi, PhD, ANP, FAAN** (Founding Dean and Distinguished Professor, Sue & Bill Gross School of Nursing). Dr. Nyamathi has been Principal Investigator of more than

one dozen NIH-funded intervention studies with high risk groups that have resulted in significant reductions in drug and/or alcohol use and risky sexual behaviors, high rates of HBV vaccine completion, latent TB treatment completion, and improvement in emotional health and substance use outcomes. She has worked with homeless adults for over 32 years as well as other vulnerable populations both domestically and internationally.

3. **E. Alison Holman, PhD, FNP** (Associate Professor, Sue & Bill Gross School of Nursing).) Dr. Holman is a health psychologist and family nurse practitioner with over 20 years of clinical experience working with sick children and their families as well as survivors of a variety of traumatic life events. Over the past 20 years, she has served as Principal Investigator and/or co-PI on several studies of individuals coping with trauma (e.g., 9/11, incest, war, and natural disaster). She has also served as the data manager and analyst for several studies including her prospective longitudinal study of coping with the September 11th terrorist attacks. She is PI of an ongoing epidemiological study of American's responses to traumatic events and an NIH-funded R01 studying the acute stress response in stroke survivors.
4. **Sanghuk S. Shin, PhD** (Assistant Professor, Sue & Bill Gross School of Nursing) Dr. Shin is an epidemiologist and biostatistician with expertise in data management, biostatistics, and protocol development and adherence. He has been PI or co-I and lead statistician for numerous NIH-funded intervention studies with high risk samples including homeless individuals and those with infectious diseases including TB and HIV.
5. **Jung-Ah Lee, PhD, BSM, MN** (Associate Professor, Sue & Bill Gross School of Nursing) Dr. Lee's expertise is in healthcare systems and how the structure and processes of a healthcare system affects patient safety and clinical and organizational outcomes. She has investigated quality improvement techniques, patient safety issues, effective healthcare delivery models, and cost-effectiveness of care. She has expertise working with vulnerable populations including older adults and those with chronic diseases. Dr. Lee is is not a member of the research team and will provide independent oversight.
6. **Yuqing Guo, PhD, MN** (Associate Professor, Sue & Bill Gross School of Nursing). Dr. Guo has expertise in women's health and health disparities. She has run numerous family-centered interventions in community settings. She is PI of a study examining maternal care for underserved communities and is well equipped to provide consult and oversight on potential problems with the population of interest. Dr. Guo is not a member of the research team and will provide independent oversight.

2. Indicate how frequently accumulated study data will be reviewed and evaluated for participant safety, study conduct and progress, and, when appropriate, efficacy.

   They will meet face-to-face at least once a year and maintain and approve minutes of meetings. Every 30 participants.

3. Describe the events that would trigger an unscheduled review. Also include stopping guidelines and un-blinding rules if applicable.

   Events where the participant became extremely distressed as part of the research procedure or expressed suicidality or if they were a harm/threat to self or others. The Data Safety and Monitoring Plan (attached, submitted in the NIH grant that funded this application), we provide specific guidelines to assess suicidality or harm to others. The research staff would follow all

procedures to ensure the safety of the participant. And the DSMB would be

4. List who will be *locally* monitoring and collecting information on adverse events and/or unanticipated problems (e.g., UCI Lead Researcher, Research Coordinator, etc.). Include the name, title and experience of the individual(s) and further describe each individual's role in the oversight of subject participating in the study.

   The Principal Investigator (Dr. Dana Rose Garfin) will be responsible for locally monitoring and collecting information on adverse events and unanticipated problems. Dr. Garfin will be onsite during participant recruitment and during the administration of intervention procedures. In the event that Dr. Garfin is not able to be onsite, a senior staff will be in contact directly with Dr. Garfin should any problems arise. Moreover, when Dr. Garfin is not onsite, staff will report daily on study progress and any potential issues. Dr. Garfin will monitor all data weekly.

5. Describe the plan for annual reporting of the participants' safety, and the study's conduct, progress, and efficacy, when appropriate. *Note: At the Continuing Review, please provide all relevant documentation related to the review of the accumulated data for safety. For the case your submission includes a DSMB charged with the oversight of data safety, include all available DSMB reports as part of your submission.*

   Annual reporting will occur at the DSMB meeting. The Principal Investigator will keep detailed notes from the meeting and evaluate the study's conduct (e.g., any unanticipated problems), progress (e.g., recruitment, retention), and efficacy (e.g., results of any preliminary data analyses).

DATA SAFETY AND MONITORING PLAN

Possible Serious Adverse Events or Adverse Events

Serious adverse events

- Suicide attempt, severe violence to another person

Other adverse events

- Inadvertent disclosure of illegal immigrant status
- Adverse reaction to stress task

Risk Management Protocols in Place to Deal with Adverse Events

- Date Safety and Monitoring (DSM) issues are raised at quarterly meetings with all research staff
- Events will be reported as they occur
- A certificate of confidentiality will be secured.
- Research staff will administer the questionnaires individually.
- Participants will be cautioned not to disclose any confidential information within the group sessions.
- Unique identifiers are used on all data. Access to identifiers is restricted to the study PI, lead mentors and data manager by a combination lock.

Data and Safety Monitoring Procedures

- Serious adverse events (SAE) must be reported to the NIH Project Officer (PO) by email or telephone within 24 hours of the SAE. A more complete written report documenting the event must occur within 72 hours of the event.
- All adverse events will be reported by email to the NIH PO twice a year: six months after the Notice of Grant Award (NGA) and at the end of the budget year.

Data Safety and Monitoring Board (DSMB)

The board will be composed of six members, including the PI, mentors (Nyamathi, Shin, Holman) and two mid-level to senior investigators from our institution with psychological expertise (Dr. Yuqing Guo and Dr. Jung-Ah Lee). They will meet face-to-face at least once a year and maintain and approve minutes of meetings. The NIH PO will be kept informed regarding changes to the membership of the DSM board. Data will be reviewed as every 30 participants enter the study.

Training for all staff

During the orientation prior to start of the grant, all research staff and research assistants will be trained on recognizing all types of potential crises, how to make a thorough assessment, and role play protocols that are featured below and in the DSMB section. During these meetings, in services that address mental health crises and associated symptomatology will be provided to enhance the staffs' ability to confidently engage in the protocols for participants who may be experience psychiatric or psychological distress. All research assistants will also meet weekly with the PI to review challenging interactions, circumstances, or situations that may have arisen with the participants. Discussions will focus on how the incident could have been handled differently and what the ideal outcome for that situation might have been.

Training in Red Flag Procedures

Research staff will be trained to assess and react as follows:

RED FLAG – SUICIDE

During your work as a research staff, you may encounter a respondent who expresses suicidal intentions, or you may suspect that a respondent may be suicidal. Be sure to document all the information in sections I and II as you will need to provide that information to the treatment program counselor or on-call clinician.

I. Is this person a suicide risk?

____ The individual is currently thinking about suicide.
____ The individual has a plan and the means to commit suicide.
____ The individual has attempted suicide in the past.

If any of the above are true or if you suspect the client is suicidal, also note if:

____ The individual is currently exhibiting serious depression/anxiety.

____ The individual is experiencing stressful life events.

II. Assessment of support system:

a) Is the individual under professional care (i.e., psychologist, psychiatrist, counselor)?

b) Does the individual have a social support network (i.e., friends, family, sponsor)?

c) Has the individual talked with any of the members of his or her social support network in the last 30 days?

d) Is the individual able to talk about this issue with his or her support system?

e) Is the individual aware of available social service programs?

III. If the person appears to be suicidal or has attempted suicide since the last interview:

a) Let the respondent know that you are concerned, and that you need to inform a clinician and your supervisor.

b) If you are not at a treatment program, have the client wait with you or hold on the line while you take the following steps:
   1) If the client has indicated that he/she is under professional care, ask the client for permission to contact his/her clinician and, if permission is granted, obtain the clinician's contact information. Be sure to document the client's permission and clinician contact information, you will need to provide it to the on-call clinician who will confirm client permission and make the contact.
   2) Contact the on-call clinician at the Los Angeles County Mobile Crisis Response Team (MCRT); _____. A clinician is on call 24 hours a day. Provide the clinician with all the suicidality information you have gathered. Facilitate phone contact between your client and the MCRT clinicians. The clinician will make the decision about what steps to take with this client. Document the details of the clinician call.

d) Report back to the PI immediately.

- Your Principal Investigator Dana Rose Garfin Ph.D., 415-407-9498

The situation will be evaluated by the group and a decision will be made if it should be reported to the LAC MCRT; they will advise us on how we need to proceed.

e) If the person attempts to harm himself or herself in your presence, contact the police (911). The police may place the person in a psychiatric facility for a 72-hour observational hold. Get the police report number.

f) Complete an Incident Report detailing the problem and action taken. Be sure that the Incident Report is placed in the respondent's file.

g) Make arrangements to follow-up on your client's status with the treatment program counselor, supervising counselor, or on-call clinician within the next seven days.

If the MCRT is called, an assessment will be done by the MCRT staff at the location of the participant. Based on the assessment of the MCRT, the participant may be transported to a hospital for inpatient treatment. If it is determined that the person does not need to be hospitalized, the participant will be referred to the outpatient services at the neighborhood clinic. If the participant is at the same location as the staff, the staff will find out if the participant has taken any active steps such as already having taken pills, etc. If the participant is not in immediate danger, the staff will find out the following: history of drug and alcohol abuse; history of familial suicide; history of familial mental illness. The staff will find out if the participant has a plan for how he would commit suicide. If she does have a plan, the staff will find out if she/he has any weapons, pills, etc, and remove all weapons from her possession, and explore the nature of her various plans. The PI, once they have arrived, will continue to focus on the reasons the participant wants to live and build on his support system. The staff will get phone numbers from the participant of those of his outside support system with whom he wishes to be in contact, for future use in case of another emergency. The research staff will collaborate with the treating psychiatrist to facilitate referral and follow through with a counseling psychiatrist/psychotherapist after discharge from the hospital. The staff/PC will document each step of this process.

If it is determined that the person does not need to be hospitalized, any additional treatment will be facilitated with Prototypes staff. To facilitate communication the participant will be asked to sign a Release of Information. If the participant provides a Release of Information, the PC will follow-up to ensure that the participant is receiving the necessary treatment. Depending on the outcome of the event, the PI may recommend that the participant withdraw from study participation. The staff/PC will document each step of this process in an adverse event log.

In addition, the DSMB will be informed of reports of suicidal ideation and current or recent abuse, reported by the staff to the proper authorities. Further, the DSMB will monitor that these reports are made expeditiously and with the full knowledge of the respondent. Monitoring information is also provided in the HSPC segment of this application.

Harm to others

I. Is this respondent dangerous to others?
The individual expressed intent to harm or kill a specified person.
The individual has the means (gun, knife, etc.) to harm that person.
The individual has a thought-out plan.

II. If you feel that the person is dangerous to others, and is likely to follow through with his/her plans:

Assess the situation. If it is safe, complete the study protocol is the participant desires. Report the information to your supervisor, the PI and the licensed clinician on staff at Prototypes. If you

feel unsafe or are not sure about it, complete the research procedures; only if possible. But if the situation is volatile, terminate immediately. Try to be as graceful and subtle as possible. For example, complete the specific task you are on or make up some reason for leaving, and say you will have to reschedule the rest of the procedures. Pay the subject in full, or leave immediately if you don't feel safe to do so. Trust your sense of the situation, and act accordingly.

Report back to your supervisor or call in immediately. If something takes place outside of the work hours, call your supervisor at home. The supervisor should then immediately contact the project's PI. Supervisors are:

Your Principal Investigator Dana Rose Garfin, Ph.D., 415-407-9498

The situation will be evaluated quickly by the group and a decision will be made if the LAC MCRT needs to be called; they will advise us on how we need to proceed. If the situation is reported to the police, get the report number from the police.

III. Complete an Incident Report. Be sure to put a copy of the Incident Report in the respondent's file so that those working with the file in the future know an incident occurred. Aside from the DSMB, the PI will carefully monitor the data weekly.

APPENDIX IV: Citations for Study Measures

Primary Outcome:

PTSD Checklist for DSM-5 (PCL-5; Weathers, Litz, Keane, Palmieri, Marx, & Schnurr, 2013). Responses will be scored continuously and according to diagnostic criteria as implemented in previous research.(143) The PCL-5 initially starts with the identification of the presence of exposure to a DSM-V traumatic event (i.e., "Briefly identify the worst event (if you feel comfortable doing so)") and then assesses whether it involved actual or threatened death, serious injury or sexual violence; whether the person directly experienced it (through direct exposure, witness to the event, occurred to a close friend or family member, or exposed as part of job). There are then twenty-items that assess all four B-E criterion (re-experiencing, avoidance, negative thoughts or cognitions, hyperarousal), assessed on a Likert-type scale 0 "not at all", 1 "a little bit", 2 "moderately", 3 "quite a bit", 4 "extremely".

Secondary outcomes:

Substance use:
Self-report drug use: Texas Christian University (TCU) Screen at Baseline and 6-month follow up. Yes/No to each drug will be assessed for use vs dependency. The total score ranges from 0 - 9; higher scores (> 3) correspond to the DSM drug dependence diagnosis. This will be assessed at baseline, immediately following 9th/final intervention session, and 6-month follow-u (Institute of Behavioral Research, 2017).

Objective drug use assessment: A 5-panel FDA-approved urine test cup will be used in this study. The test cup screens for metabolites of the following drugs of abuse at the established cut-off levels and is used for qualitative purposes: Amphetamines (1000 ng/mL), Cocaine (300 ng/mL), Methamphetamines/ MDMA (500 ng/mL), Opiates (2000 ng/mL), and THC (50 ng/mL). Urine sample validity checks will be provided by temperature and adulterant monitoring strips built into the test cup. Participants whose urine does not pass validity checks will be counted as positive for drugs. Results will be coded qualitatively (above or below threshold). All positive results will be interpreted as positive, regardless of self-report.

Depression: will be assessed using the PROMIS measure for depression (Emotional Distress). The 8-tem form will be used. It assesses negative mood, views of self (e.g., worthlessness), decreased positive affect and anhedonia. In self-report when all participants are given the same questions, it is desirable to use the 8-item short form, which has reliability and validity comparable to the 28-item computer adaptive form (PROMIS Health Organization, 2019).

Cortisol reactivity: Saliva samples will be collected via passive drool before and after a modified script driven imagery task. Saliva All saliva will be assayed in duplicate using standard manufacturers protocol (Salimetrics). The concentration of CRP in saliva will be determined using a Salivary C-Reactive Protein ELISA kit, an enzyme-linked immunoassay. The standard curve is run on every assay plate and must have an R2 value of > 0.99. The

replicates must have a %CV < 15 or an absolute difference <0.030 between the replicates. The mean values across saliva duplicates will be computed for each sample and used in the statistical analyses.

C-reactive protein (CRP) All saliva will be assayed in duplicate using standard manufacturers protocol (Salimetrics). The concentration of CRP in saliva will be determined using a Salivary C-Reactive Protein ELISA kit, an enzyme-linked immunoassay. The standard curve is run on every assay plate and must have an R2 value of > 0.99. The replicates must have a %CV < 15 or an absolute difference <0.030 between the replicates. The mean values across saliva duplicates will be computed for each sample and used in the statistical analyses.

Perceived stress scale: 10-item Perceived Stress Scale (PSS) will be used to measure participant's perception of stress (Cohen, 1993).

Quality of life: will be measured using the 10-item short form of the Quality of Life Enjoyment and Satisfaction Questionnaire. Participants indicate their satisfaction with health, finances, and other life domains during the past week on a scale of 0 (very unsatisfied) to 3 (very satisfied) (Endicottt, Nee, Harrison, & Blumenthal, 1993).

Satisfaction with life scale: A 5-item scale designed to measure global cognitive judgments of one's life satisfaction (not a measure of either positive or negative affect) (Diener, Emmons, Larsen, & Griffin, 1985).

Mindful awareness attention scale (MAAS): is a 15-item scale designed to assess a core characteristic of mindfulness, namely, a receptive state of mind in which attention, informed by a sensitive awareness of what is occurring in the present, simply observes what is taking place (Brown & Ryan, 2003; Carlson & Brown, 2005).

Five facet Mindfulness Questionnaire (FFMQ) is a 39 item questionnaire that assesses five independent sub-scales: observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience (Baer et al., 2008).

Life event history: Life events history will be assessed by asking respondents whether they ever experienced each of 40 specific negative life events (NLEs; will include both trauma and stressors), and, if so, at what age(s) this occurred. This will also be updated with respect to recent events upon immediate completion of the 9 week courses as well as at the 6-month follow up. The measure was modified from the Diagnostic Interview Schedule trauma section (Robins, Helzer,
Croughan, & Ratcliff, 1981) by including several stressful or traumatic events reported by primary care patients (Holman, Silver, & Waitzkin, 2000) and has provided rates of events comparable to other community-based studies (e.g., Seery et al., 2010).

Emotion regulation: will be assessed with the Difficulties in Emotion-Regulation Scale (DERS; Gratz & Roemer, 2004; Kaufman et al., 2016), short form. DERS is a 18- item questionnaire that aims to measure how much one is able to regulate/deregulate their emotions. The 41 questions are based off of six factors including acceptance of emotions, impulsiveness, ability to work towards goals, awareness of own emotions, clarity of emotions, and accessibility to emotion-regulation strategies

Social support will be assessed using the MOS Social Support scale (Sherbourne & Stewart, 1993) This 19 item measure assesses social support.

Anxiety: will be assessed using the PROMIS measure for anxiety (Emotional Distress). The 8-tem form will be used. It assesses symptoms of Generalized Anxiety Disorder. it is desirable to use the 8-item short form, which has reliability and validity comparable to the 28-item computer adaptive form (PROMIS Health Organization, 2019).

General Self-efficacy scale: This 10-item scale was created to assess a general sense of perceived self-efficacy (Schwarzer & Jerusalem, 1995).

Demographics: Age, ethnicity, sexual orientation, incarceration history, religion, income, education, number of children, pregnancy status, mental health history (previous diagnosis) employment history.

Prior Doctor-diagnosed Health Conditions. This survey, modified from the CDC's National Center for Health Statistics Annual National Health Interview Survey, asks respondents to report doctor diagnosed health ailments. This will be assessed at baseline, immediately following 9th/final intervention session, and 6-month follow-up.

Adherence. Measured by class attendance and self-reported time in mindfulness meditation and doing at-home assignment.

Short self-compassion scale. This 12-item scale assesses self-compassion (Raes, Pommier, Neff, & Van Gucht, 2011).

Free Response: Participants will be given the opportunity to provide written feedback regarding their experiences that may not have been captured with these quantitative measures. Prompt will include: We will ask: "Do you have any other thoughts and/or feelings about your participation in this program? Is there anything that you wish to share with us regarding your experience?"

APPENDIX V: Salivary Data Collection During COVID-19

UCI Institute for Interdisciplinary Salivary Bioscience Research

Collection Procedure*

*Please keep a roster of all samples collected from October 2019 onwards. Samples may contain SARS- CoV-2, and this will ensure safe handling in the future as labs may take extra precautions when handling samples collected during this time.

1. Participants wash hands for 20 seconds prior to collecting the saliva sample(s).
2. Collect saliva sample as normal (follow typical passive drool or swab collection protocols). Tubes should be labeled prior to providing them to participants.
3. Sample tubes should be immediately capped and sealed. Outsides of tubes should be disinfected following collection. Disinfectants are listed on the CDC website (https://www.epa.gov/pesticide- registration/list-n-disinfectants-use-against-sars-cov-2). Ensure no disinfectants leak into the tube via an unsealed or partially sealed tube.
4. Samples should be placed in a secondary container (sealed plastic bag with absorbent material, freezer box, etc.) that is labeled, then placed in a freezer (-20°C) as soon as possible. See below for more guidelines.
5. Participants should wash hands for at least 20 seconds after collecting the saliva sample(s).

Sample Storage and Shipping

Always check with your EHS and IRB groups at your institution before collecting and/or shipping saliva samples to ensure you have received proper training and are following appropriate rules/regulations. Additionally, please refer to the following link for CDC guidelines prior to shipping samples: https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html

Sample storage:

1. Once collected, samples should be stored in a freezer between -20°C (home freezer) or -80°C (ultra-cold lab grade freezer) when possible
2. Samples should be placed inside sample storage boxes (or biohazard Ziploc bags + absorbent material for home collections)
3. The sample storage box should be placed inside a large biohazard Ziploc bag (or Ziploc bag with a biohazard sticker on it)
4. A piece of absorbent material (paper towel, etc.) should be placed inside the Ziploc bag to absorb any potential spillageSample Pickup/Shipping:

1. Samples in bags or boxes should be placed inside cooler or in a bioshipper on dry ice.
2. Bioshipper should be labeled with the following:
    a. Hazard labeled with UN Identification Number already on label – UN 3373
    b. Biological Substance, Category B
    c. Hazard Labeled with UN Identification Number- UN 1845
    d. Dry Ice along with the net weight (kg) of the dry ice
    e. Shipper's name and address
    f. Receiver's name and address
    g. Name and phone number of a responsible person.

Receiving samples:

1. Lab personnel receiving samples should wear appropriate PPE before handling samples.
2. Ensure samples are labelled, are frozen, and tubes are in good condition (no cracks or leaks).
3. Sample collection tubes should be disinfected once received by the lab. Disinfectants are listed on the CDC website (https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against- sars-cov-2).
4. Boxes with samples can be marked with date received, and a label noting if the samples were collected during the COVID-19 pandemic. This can act as an indicator to use extra safety precautions while handling those samples in the future. Samples should be stored in -80°C as soon as possible.
5. Sample processing should be performed in a biological safety cabinet.

APPENDIX VII: RECap for Screener (Section 1) and Baseline, Immediate-follow-up, and 6-months (Section 2)

Statistical Analysis Plan

All analyses were conducted using STATA 18. First, descriptive statistics were calculated for the total sample. Next, a series of multilevel models were conducted for each primary and secondary outcomes using a multilevel, random-intercept mixed. Participants were entered as random effects to nest observations within participants, allowing for correlations within each individual over time. Group assignment (i.e., MBSR vs. HP Control), time (i.e., T1, T2, and T3), and group-by-time interactions were entered as fixed effects. Site was also included as a fixed-effect, given the low number (i.e., two) of sites[1]. Covariates were screened for inclusion in bivariate analyses and included if statistically significant and theoretically meaningful. An independent covariance pattern was specified as our final models were random-intercept (nested within participant) only[2]. Results are presented using restricted maximum likelihood for optimal control of Type 1 error[3]. An intention-to-treat analysis was conducted, where every participant was included in the final analyses, regardless of whether they completed all of the sessions.

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