Effects of Compassion-Based Resiliency Training (CBRT) on Racism-Based Stress Among African American Adults: A Pilot Study

NCT06146218

Protocol Version: 1.11

Organization: Rockefeller University

Organization ID: RKI-1047
Protocol Date: IRB Approved - 8/22/2025

Public Version for ClinicalTrials.gov Submission

The Rockefeller University
SCIENCE FOR THE BENEFIT OF HUMANITY

Institutional Review Board
Sarah J. Schlesinger, MD, Chair
Dale Miller, BA CIP
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Vanessa Smith, BA MPS, CIM, CIP
Sr. IRB Specialist, (212) 327-8410
Hospital Bldg., Room 201 Box 331

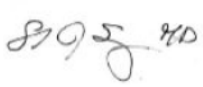
ClinicalTrials.gov
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894

Re: Compassion-Based Resiliency Training (CBRT) Intervention on Racism-based Stress, RKI-1047, NCT06146218

Dear Representative of ClinicalTrials.gov:

This letter is to confirm that the uploaded Study Protocol and Statistical Analysis Plan PDF/A document for the study, Compassion-Based Resiliency Training (CBRT) Intervention on Racism-based Stress, IRB ID: RKI-1047, NCT06146218 is the original, pre-specified Study Protocol and Statistical Analysis Plan document approved by the Rockefeller University Institutional Review Board. Our institution utilizes an IRB application format, rather than a separate Protocol and/or Statistical Analysis Plan. Please do not hesitate to contact me if I may be of further assistance.

Sincerely,



Sarah J. Schlesinger, MD
Chair, Institutional Review Board
Associate Professor of Clinical Investigation
Senior Attending Physician
Laboratory of Chemical Biology and Signal Transduction
The Rockefeller University

Study Application (Version 1.11)

1.0 General Information

***Please enter the full title of your study::**

Effects of Compassion-Based Resiliency Training (CBRT) Intervention on Racism-based Stress among African Americans: A Pilot Study

***Please enter the study short title:**

Compassion-Based Resiliency Training (CBRT) Intervention on Racism-based Stress
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Is this Study using Subject Management?

(•) Yes ( ) No

2.0 Add departments

2.1 List departments associated with this study:

- **Please choose at least two labs/departments. Your main lab/dept. should be the primary lab listed, e.g. your HOL's lab.**
- **All protocols must also list "Rockefeller University Hospital (RUH)" as a secondary lab/dept.**
- **You may also list additional, lab/dept(s) if appropriate to include RU collaborators.**
- **If your lab/department is not listed in the 'Add Department' dropdown menu, please contact RUH IT at hospital_informatics@rockefeller.edu to arrange for the new lab to be added to the listing.**

Is Primary?	Department Name
(•)	**RUH** - Laboratory of Neurogenetics of Language (Jarvis)
( )	**RUH** - Rockefeller University Hospital (RUH)

3.0 ▪ Assign key study personnel(KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

Name	Role	Training Record
Kimani, Rachel Wangari, DNP	**Principal Investigator**	**View Training Record**

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Name	Role	Training Record
No Additional Investigators have been added		

B) Research Support Staff

Name	Role	Training Record
No Research Support Staff have been added		

3.3 *Please add a Study Contact:

Name	Role	Training Record
Kimani, Rachel Wangari, DNP	**Study Contact**	View Training Record

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

4.0 Rockefeller University Conflict of Interest

4.1 Investigator Financial Conflict of Interest All KSP must complete an annual certification of their Significant Financial Interest ("SFI") disclosures in the University's online Research Administration System at https://RAS.rockefeller.edu. Disclosures also must be updated in connection with new human subjects research protocols ("Research Certification"), and within 30 days of discovering or acquiring a new SFI. To avoid delays in the IRB review process, when prompted by an email from rascoi@rockefeller.edu requesting an updated Research Certification, KSP should click on the Research Certification link contained in that email notification, or go to https://RAS. rockefeller.edu, to (a) review and update his or her SFI disclosures or certify that he/she has no updates, as appropriate, and (b) indicate whether any of his/her SFI disclosures are reasonably related to the design, conduct, or reporting of the research protocol. If a KSP discloses a SFI that might constitute a conflict of interest with respect to the proposed protocol, he or she must e-mail a copy of the Lay Summary of the draft protocol to Teresa Solomon, Esq. (solomot@rockefeller.edu). Doing so will facilitate addressing COI issues in step with the development of the study protocol. Non-compliance or tardiness in making or updating COI disclosures will result in a delay in IRB review. Institutional Conflict of Interest:

As early as possible the PI (or a designee) preparing a clinical research protocol must review a list of entities in which The Rockefeller University has an Institutional Financial Interest at https://icoi.rockefeller.edu/account/login.php. If the proposed study involves any entity on that list, the PI (or designee) must notify Teresa Solomon, staff to the FCOI Committee, by e-mail solomot@rockefeller.edu and Sarah Schlesinger, Chair of the IRB, by email: schless@rockefeller.edu, provide the name(s) of the entities and a copy of the Lay Summary. Doing so will facilitate addressing institutional COI issues in step with the development of the study protocol. Failure to take steps to review and address potential institutional conflicts of interest will delay the IRB review process.

5.0 External Personnel

5.1 List external personnel who will be working on the study:

Name	Institution	Telephone	E-mail	Role
No External Personnel has been added to this Study				

6.0 Delegation of Authority

6.1 Enter authorized activities for all Rockefeller University personnel named on the study.

Activity Codes:

1. Informed consent **
2. Inclusion / exclusion criteria
3. Medical/medication history *
4. Perform Physical Exam *

4a. Write / Sign LIP orders *

5. Skin assessments and photos
6. Study drug dispensing *
7. Study drug administration *
11. Participant recruitment
12. Perform assays
13. Specimen / sample analysis
14. Lumbar puncture *
15. Femoral line placement *
16. Central line placement *
17. Insulin clamp procedure *
21. Skin biopsy *
22. Conduct sleep study
23. Diet design and preparation
24. Nutritional assessment and counseling
25. Addition of PABA to food
26. Data analysis
27. Data review

8. Study drug reconciliation
9. Study drug compliance
10. Administer study questionnaire(s)
18. Leukapheresis *
19. Sigmoidoscopy *
20. Fat biopsy *
28. Data management
29. Maintain regulatory documents / files
30. Complete CRF's

Add up to three additional authorized activities specific to this study (do NOT add activities that have previously designated codes):

31:	
32:	
33:	

Activity Codes Continued:

34. Behavioral Testing
35. Bod Pod
36. Bone Marrow Aspiration *
37. Neuropsychological Testing *
38. Conduct Focus Group
39. Conduct Smell Study
40. Genetic Counseling *
41. Apply EEG Electrodes **
42. Olfactometer Test
43. Study Participant Teaching
44. Resting Energy Expenditure
45. Source Document Review & Correction
46. Medical Photography
47. See 4a
48. Adverse Event Assessment
49. Clinical Trial Registration
50. Study Support Drug Dispensary
51. Internal Monitoring
52. Randomization

Enter delegation of authority for Rockefeller University Key Study Personnel:

NOTE:

* Indicates procedures requiring the individual complete specific credentialing **BEFORE** the activity may be added to their delegated activities.

** Indicates procedures requiring the individual complete specific training **BEFORE** the activity may be added to their delegated activities.

Name	Title	Authorized Activities	Start Date	End Date
Kimani, Rachel Wangari, DNP	PI	1,2,3,4,4a, 10,11,12,13,26,28,29,30,43,48,51	09/05 /2023	
Jarvis, Erich, PhD	Co-PI	26,27,28,51	09/05 /2023	08/21 /2025
Dowd, Kathleen, BSN, RN,	Facilitator	29	09/05 /2023	06/30 /2025

CCRC				
Campbell, Ann, RN, MSN, MPH	Co-PI	27,29	02/01 /2024	08/21 /2025
Olufeko, Oluwatobi Temitope, MPH, MA, CCRC	Facilitator	29	02/01 /2024	06/30 /2025

Enter delegation of authority for additional Rockefeller University Key Study Personnel:

Name	Title	Authorized Activities	Start Date	End Date
No results found				

Enter the authorized activities for External Personnel:

Name	Title	Authorized Activities	Start Date	End Date
No results found				

7.0 Study Description

7.1

Study Classification

Full Review

7.2

* Submission Request Category

Note: For each submission, please designate the level of review, or "Submission Request Category" you are requesting. When completing this field, please indicate the level of review you are requesting for the specific submission you are working on.

For example, if you are submitting an Expedited Amendment request to change the Key Study Personnel on your existing Full Board study, you should select "Expedited Review" in both the Amendment Submission Form and Study Application. The IRB will confirm an Expedited review of the Amendment submission is appropriate, and the overall study will remain classified as a full Board review. Please see the help bubble for guidance.

To submit a request for a Not Human Subjects research determination, please exit this form and select the "Not Human Subjects Research Determination" form under Create a New Study.

- ○ Exempt from Review
- ○ Exempt with Limited Review
- ○ Expedited Review
- ◉ Full Review

7.3 * **Lay Summary**

Please provide a summary of your study in lay language that is easily understood by a non-scientist. The summary should be no more than half a page (500 words or less) and should contain a clear statement of the rational for the study.

Please click on the help bubble to get the information on " How to use iRIS text editor."

Please provide a summary of your study in lay language. The summary should be no more than a half page (500 words or less) and should contain a clear statement of the rationale for the study.

Racism and racial discrimination profoundly affect mental and physical health among minoritized ethnic groups, including Black, Indigenous, and People of Color (BIPOC). The negative health impacts are evident in elevated mortality rates, early disease onset, and increased comorbidity burden among BIPOC individuals. This study seeks to address these health disparities by investigating the potential of Contemplative-Based Resilience Training (CBRT) to mitigate the impact of racism-related stress. CBRT holds promise in countering the neurobiological changes attributed to chronic stress, aligning with the "weathering hypothesis" and Allostatic load theory.

The primary aim of this pilot study is to explore the feasibility, acceptability, and preliminary effectiveness of CBRT intervention among African Americans. The specific objectives include assessing feasibility, gathering participant feedback, evaluating CBRT's impact on psychological and biological outcomes, and exploring the mediating role of mindfulness.

The study employs a 1 group design. Participants are recruited from various sources and undergo baseline and follow-up assessments. The intervention involves a 10-week CBRT program focusing on mindfulness, compassion, self-awareness, and stress-reduction techniques. Measures include socio-demographics and psychological measures (race-based stress, depression, perceived stress, quality of life, social connectedness, sleep, and resilience) and biological measures (allostatic load, saliva cortisol, telomere length, and gene expression. Data is collected at baseline and 10 weeks.

Feasibility will be assessed based on recruitment rates, retention, attendance, and qualitative feedback. The impact of CBRT will be evaluated through various statistical analyses, considering intention-to-treat principles and controlling for covariates. Preliminary findings from a pilot investigation with 20 African-American participants suggest associations between psychological measures, mindfulness, sleep, coping, resilience, and racism-induced stress. These results underscore the potential of CBRT in addressing complex relationships among these factors. By investigating the potential benefits of CBRT in alleviating racism-induced stress and associated health disparities, this research aims to contribute insights into mindfulness-based interventions to address racism-related stress and its broader implications for the well-being of BIPOC communities.

7.4

* **Public Health Impact Statement**

Provide a brief plain language statement (100 words or less) of the value of the research proposed and its potential impact on population health. Additional instructions located in Help.

Racism is a public health crisis proven to be a source of stress contributing to health disparities. While dismantling systemic racism is the most effective way to address the health costs of racism-related stress, there is a critical need to address the ongoing racism-related injury. This study aims to explore how racism-induced stress impacts the brain and body and how a culturally

responsive intervention can reduce the mental and physical effects of this stress. This study will provide valuable information to help develop tools to reduce the impact of racism-related injury and improve health outcomes for minority communities.

8.0 Clinical Trial Registration

8.1 Clinical Trial Registration

The types of studies listed below must be registered at **Clinical Trials website** before enrolling the first participant in order to be in compliance with federal regulations and preserve the opportunity to publish the study in journals that adhere to the **ICMJE guidelines**. Please check the answer that best applies.

- ○ Study involves testing of FDA regulated drugs or biologics (See HELP)
- ◉ Study is funded by the NIH, and meets the definition of a "clinical trial" (see HELP)
- ○ Study meets the ICMJE definition of a "clinical trial" (See HELP)
- ○ Additional funding agency or journal requires clinical trial registration
- ○ None of the above

If you selected 1, 2, 3, or 4 you must register your trial with ClinicalTrials.gov through the Rockefeller University institutional account. Please contact the Clinical Research Support Office x7408 for assistance.

9.0 Study Overview/Summary

9.1 * Who initiated this study?

Please specify one:

- ◉ Principal Investigator Initiated
- ○ Industry Initiated
- ○ Other

9.2 *Are other institutions involved in the study?

- ◉ No
- ○ Yes

9.3 * Is this a multi-site trial using a single IRB (sIRB) review arrangement? Please see help bubble for definition.

- ○ Yes ◉ No

9.4 * Who (What) is to be studied?

- ☑ Human Subjects - including coded samples and/or data with links to Identifiers
- ☐ Deidentified Samples - unable to be linked to identifiers by receiver
- ☐ Data Only - unable to be linked to identifiers

☐ Identifiable samples or data for exemptions (per 104 (s)(4))

9.5 *Study Type:

◉ Interventional
○ Observational

9.6 The initial date of IRB approval/determination was:

10/05/2023

9.7 * What is the expected duration of the study?

1 year

9.8 * Are any of the following agents to be used in the study?

Check all that apply:

☐ FDA Approved Drug
☐ FDA Approved Drug for Off-Label Purpose (This might require an IND)
☐ Investigational New Drug
☐ Biologic Agents
☐ Nutritional Supplements
☐ Placebo
☐ Vaccines
☑ No Agents
☐ FDA Exemption to use Study Drug

9.9 * Are investigational devices to be used in the study?

○ Yes ◉ No

9.15 Special Research Procedures

Does the study propose to directly involve participants in the following special research procedures?

☐ Recombinant DNA
☐ Gene Therapy
☐ Fetal Tissue
☐ Embryonic Stem Cells
☐ Induced Pluripotent Stem Cells
☐ CRISPR-Cas9

If any item is checked, please see Help for details.

9.16 * Radioactive Isotopes Involved

Will participants be exposed to any radiation other than routine x-rays solely for clinical care purposes?

○ Yes ◉ No

10.0 Interventional

10.1 *Interventional, please specify:

- (•) Open Label
- ( ) Single Blind
- ( ) Double Blind
- ( ) Other

11.0 Study Phase:

11.1 Study Phase:

Select where applicable

- ( ) Phase 0
- ( ) Phase I
- ( ) Phase I/II
- ( ) Phase II
- ( ) Phase III
- ( ) Phase IA
- ( ) Phase IB
- ( ) Phase IIA
- ( ) Phase IIB
- ( ) Phase IB/IIA
- ( ) Phase IIB/IIIA
- ( ) Phase IIIA
- ( ) Phase IIIB
- (•) N/A

12.0 Objectives and Rationale

12.1 * Overview

Briefly state the ***purpose of this study***. Give enough background and rationale to provide both scientists and lay members of the IRB and ACCTS with the basis for exposing human participants to the risks involved.

Experiences of racism and racial discrimination profoundly affect the mental and physical health of individuals from minoritized ethnic groups (Paradies et al., 2015). This pernicious impact of racism has garnered significant public health support, including the surgeon general office medical and nursing organizations (American Public Health Association, 2021). Research consistently demonstrates that minoritized groups, especially Black, Indigenous, and People of Color (BIPOC), grapple with disproportionately adverse health outcomes characterized by elevated mortality rates, earlier disease onset, heightened disease severity, and increased comorbidity burden(Carter et al., 2017; Harrell et al., 2011). These health disparities are attributed to the cumulative impact of structural racism, manifesting in limited healthcare access, suboptimal quality of care, and persistent experiences of discrimination and identity threats. Although dismantling systemic racism remains the paramount strategy to mitigate the health toll of racism-related stress, addressing the ongoing injuries and the resulting mental and physical health repercussions is equally imperative. Hence, comprehending the intricate interplay between structural racism, chronic health disparities, and the cascading physiological responses is crucial for developing effective interventions to nurture equitable health outcomes and uproot the deeply ingrained inequalities faced by BIPOC communities.

In the context of chronic stress's profound physiological impacts, comprehensive interventions like Contemplative-Based Resilience Training (CBRT) hold significant promise in light of the "weathering hypothesis" and Allostatic load theory. The "weathering hypothesis" suggests that individuals from marginalized communities, particularly those experiencing systemic racism and discrimination, undergo accelerated aging and health deterioration due to the chronic stressors they encounter throughout their lives (Simons et al., 2021). The

physiological toll of chronic exposure to racism, as highlighted by the "weathering hypothesis," accentuates the significance of interventions that can counteract the neurobiological changes contributing to health disparities (Geronimus et al., 2006). This viewpoint aligns with the Allostatic load theory put forth by McEwen (1998), which posits that ongoing exposure to chronic stress triggers maladaptive physiological responses, amplifying vulnerability to diseases (McEwen, 1998). Consequently, the prolonged experience of stress induced by racism and discrimination culminates in the accrual of toxic allostatic load—an embodiment of the body's gradual deterioration under prolonged stress (McEwen, 2012).

The intricate connection between race-based stress and the emergence of conditions characterized by inflammatory underpinnings, including cardiovascular diseases (CVD) and diabetes, is underscored by the manifestation of stress within brain regions like the prefrontal cortex, hippocampus, amygdala, and anterior cingulate cortex (Clark et al., 2018; Berger and Sarnyai, 2015; Saban et al., 2018). Within this context, interventions such as CBRT present a promising "top-down" approach by integrating mindfulness with cognitive education, affect modulation, motivational imagery, breath control, and self-massage. CBRT research into compassion-based meditative therapies, as demonstrated by Loizzo (2009), supports CBRT efficacy in nurturing pro-social attributes and fostering social connections. Individuals possessing elevated mindfulness traits often exhibit improved emotional regulation and reduced emotional reactivity, while mindfulness interventions bolster individual resilience (Fuchs et al., 2013; Zapolski et al., 2019). Scholars like Watson-Singleton (2019) and Hidalgo (2020) have also suggested that heightened mindfulness levels could protect against discrimination and race-related vigilance. In addition, mindfulness therapies have been shown to influence stress-related neural plasticity and allostatic load by modulation of key mediators like glucocorticoids and excitatory amino acids (Daskalakis et al., 2022; McEwen, 2017; Saban et al., 2021). This compelling groundwork substantiates CBRT's potential to address the intricate interplay between systemic racism, chronic stress, and physiological responses. The intervention's capacity to enhance psychological well-being and alleviate the physiological toll of stress warrants further exploration in the quest to address health disparities within BIPOC communities.

While previous research has shown mindfulness interventions' viability and acceptability across different populations, including those facing chronic stress, a notable gap exists in exploring mindfulness's potential to mitigate the specific challenges of racism-based stress and its associated outcomes. Despite the existing evidence suggesting mindfulness's potential to buffer the psychological impact of discrimination, studies targeting racism-related stress and its effects remain limited, primarily focusing on psychological measures. Consequently, we hypothesize that persons who experience racism-based stress and engage in a CBRT program will report substantial enhancements in various domains, including overall stress levels, perceived discrimination, resilience, coping skills, anxiety, depression, mindfulness, sleep quality, allostatic load, and salivary cortisol. Here, we test the feasibility of a CBRT intervention and acceptance, substantiated by factors such as enrollment rates, attendance, engagement, and qualitative feedback. By investigating these multifaceted outcomes, our study aims to contribute essential insights into the potential of mindfulness-based interventions to address racism-based stress and its broad-ranging implications.

Preliminary study

The proposed study builds upon a preliminary pilot investigation (RKI-1036), where a cohort of 20 African-American participants was recruited. This initial endeavor aimed to gather methodological insights, establish a robust protocol, and lay the groundwork for a subsequent Contemplative-Based Resilience Training (CBRT) interventional study to lessen the impact of race-based trauma and stress. This preliminary study employed a mixed-methods approach, incorporating an embedded qualitative inquiry. Initially, the study sought to gauge the feasibility of recruiting 20 African-American participants to measure psychological and physiological indicators of race-based stress. Subsequently, the investigation aimed to validate and expand the assessment of additional physiological variables, exploring how racism is a stressor influencing allostatic load, gene expression, and telomere length. Alongside these efforts, interviews were conducted to capture participants' perspectives and feedback on an intended 12-week mindfulness intervention study designed to mitigate the consequences of race-based stress among African Americans, assessing their willingness to engage in the intervention and undergo further testing such as fMRI.

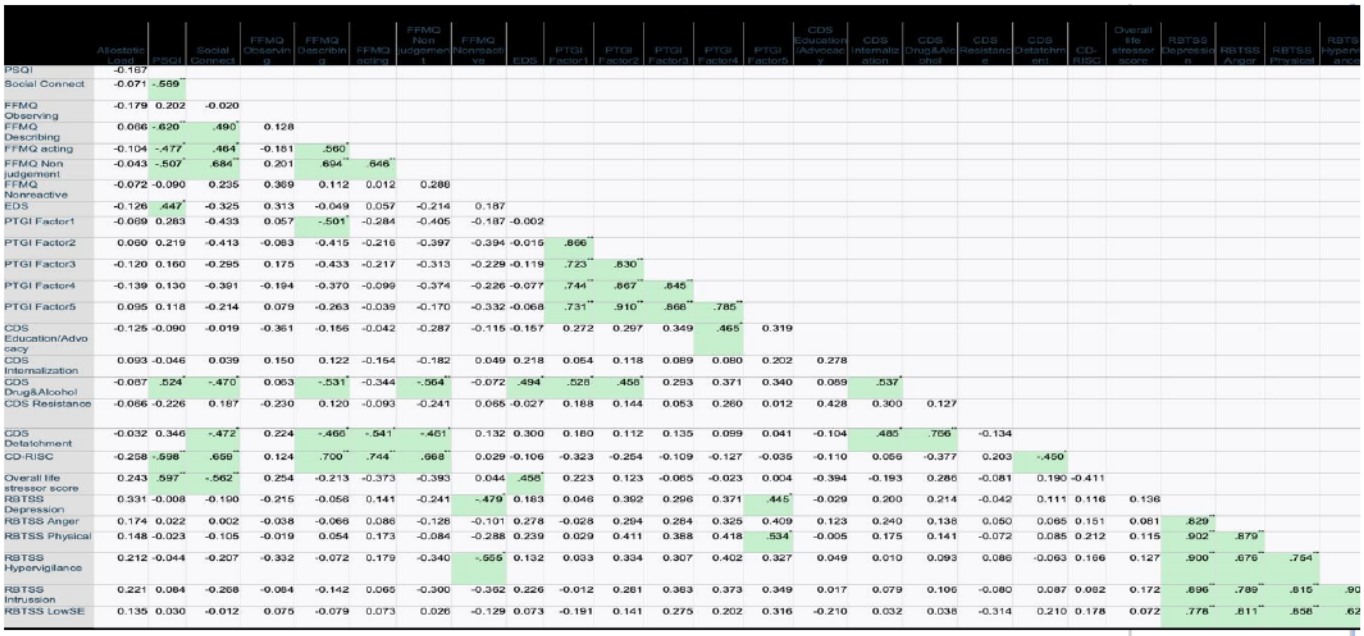
This preliminary pilot study with 20 individuals completing the full assessment shed light on intriguing associations between psychological measures, mindfulness, sleep quality, coping strategies, resilience, and racism-induced stress. For example, individuals reporting lower racism-based stress, quantified using the Everyday Discrimination Scale (EDS), exhibited elevated high-density lipoprotein (HDL) cholesterol levels compared to those reporting high EDS. Furthermore, a significant divergence in the Total cholesterol/HDL

cholesterol ratio emerged between the Low EDS group and the High EDS group. This distinction implies that individuals with elevated EDS scores possess a less favorable lipid profile, as evidenced by a higher Total cholesterol/HDL cholesterol ratio, in contrast to those reporting lower perceived discrimination. The Total cholesterol/HDL cholesterol ratio is a marker of cardiovascular health, with a lower ratio indicating a more favorable lipid profile and a reduced risk of heart disease, as presented in Table 1.

Table 1: Everyday Discrimination and Clinical and Laboratory Data

	Everyday discrimination (EDS)				
	Low EDS		High (EDS)		Total (n=20)
	Mean	SD	Mean	SD	Mean
Systolic BP	115	10	123	13	119
Diastolic BP	73	6	78	9	75
Total cholesterol	183	27	166	20	175
HDL cholesterol	62	9	42	12	52
Total/HDL cholesterol ratio	2.99	.38	4.20	1.24	3.59
LDL	108.4	25.05	111.7	15.01	110.05
HbA1c	5.1	.3	5.3	.4	5.2
Waist(inc)	35.6	5.5	41.8	7.1	38.7
Hip (inc)	42.6	4.0	46.7	6.2	44.6
Waist /Hip ratio	.83	.10	.89	.07	.86
BMI	28.65	5.00	33.03	7.28	30.84
Creatinine clearance	.9	.2	1.2	1.0	1.0
Albumin	4.3	.3	3.9	1.1	4.1
CRP	.60	.20	.54	.12	.57
DHEA	280	138	321	142	301
TNF	.8	.2	1.0	.4	.9
IL-6	3.1	1.3	3.2	1.0	3.2
Allostatic Load	1.8	1.1	2.4	1.2	2.2
Cortisol AM	0.273	0.144	0.369	0.19	0.319
Cortisol T=30m	0.41	0.24	0.457	0.22	0.430
Cortisol -Bedtime	0.177	0.159	0.112	0.069	0.147
Cortisol awakening Response (CAR)	0.133	0.248	0.087	0.155	0.112

Mindfulness trait was linked to improved sleep quality, enhanced coping abilities, increased resilience, and reduced hypervigilance, signifying mindfulness's potential benefits in these domains. See Figure 1. Additionally, the study illuminated a significant relationship between sleep quality and coping mechanisms. Individuals with high racism-induced stress (measured by EDS) reported high life stress scores, poorer sleep quality, and adverse coping strategies involving drug and alcohol use. Additionally, while allostatic load, a comprehensive gauge of physiological stress, did not demonstrate significant correlations with psychological measures, distinct trends were observed. These trends pointed towards positive associations between allostatic load and racism-based stress, counterbalanced by negative associations with mindfulness traits. These preliminary findings provide a robust foundation for exploring the potential of CBRT intervention to address and mitigate the intricate relationships among psychological measures, sleep quality, coping, resilience, and racism-induced stress. Publication is in progress.



	Allostatic Load	PSQI	Social Connect	FFMQ Observing	FFMQ Describing	FFMQ acting	FFMQ Non judgement	FFMQ Nonreactive	EDS	PTGI Factor1	PTGI Factor2	PTGI Factor3	PTGI Factor4	PTGI Factor5	CDS Education/Advocacy	CDS Internalization	CDS Drug&Alcohol	CDS Resistance	CDS Detatchment	CD-RISC	Overall life stressor score	RBTSS Depression	RBTSS Anger	RBTSS Physical	RBTSS Hypervigilance
PSQI	-0.167																								
Social Connect	-0.071	-.569**																							
FFMQ Observing	-0.179	0.202	-0.020																						
FFMQ Describing	0.066	-.620**	.490**	0.128																					
FFMQ acting	-0.104	-.477**	.464**	-0.181	.560**																				
FFMQ Non judgement	-0.043	-.507**	.684**	0.201	.694**	.646**																			
FFMQ Nonreactive	-0.072	-0.090	0.235	0.369	0.112	0.012	0.288																		
EDS	-0.126	.447**	-0.325	0.313	-0.049	0.057	-0.214	0.187																	
PTGI Factor1	-0.089	0.283	-0.433	0.057	-.501**	-0.284	-0.405	-0.187	-0.002																
PTGI Factor2	0.060	0.219	-0.413	-0.083	-0.415**	-0.216	-0.397	-0.394**	-0.016	.866**															
PTGI Factor3	-0.120	0.160	-0.295	0.175	-0.433**	-0.217	-0.313	-0.229	-0.119	.723**	.830**														
PTGI Factor4	-0.139	0.130	-0.391	-0.194	-0.370**	-0.099	-0.374**	-0.226**	-0.077	.744**	.867**	.845**													
PTGI Factor5	0.095	0.118	-0.214	0.079	-0.263**	-0.039	-0.170	-0.332**	-0.068	.731**	.910**	.866**	.785**												
CDS Education/Advocacy	-0.125	-0.090	-0.019	-0.361	-0.156**	-0.042	-0.287**	-0.115	-0.157	0.272**	0.297**	0.349**	.465**	0.319**											
CDS Internalization	0.093	-0.046	0.039	0.150	0.122	-0.164**	-0.182**	0.049	0.218	0.054	0.118	0.089	0.080	0.202**	0.278**										
CDS Drug&Alcohol	-0.087	.524**	-.470**	0.063	-.531**	-0.344**	-.564**	-0.072	.494**	.526**	.458**	0.293**	0.371**	0.340**	0.089	.537**									
CDS Resistance	-0.066	-0.226**	0.187**	-0.230**	0.120**	-0.093	-0.241**	0.065	-0.027	0.188**	0.144**	0.053	0.260**	0.012	0.428**	0.300**	0.127**								
CDS Detatchment	-0.032	0.346**	-.472**	0.224**	-.466**	-.541**	-.461**	0.132**	0.300**	0.180**	0.112**	0.135**	0.099**	0.041	-0.104**	.485**	.766**	-0.134**							
CD-RISC	-0.258**	-.598**	.659**	0.124**	.700**	.744**	.668**	0.029	-0.106**	-0.323**	-0.254**	-0.109**	-0.127**	-0.035	-0.110**	0.056**	-0.377**	0.203**	-.450**						
Overall life stressor score	0.243**	.597**	-.562**	0.254**	-0.213**	-0.373**	-0.393**	0.044**	.458**	0.223**	0.123**	-0.065**	-0.023**	0.004**	-0.394**	-0.193**	0.286**	-0.081**	0.190**	-0.411**					
RBTSS Depression	0.331	-0.008	-0.190	-0.215	-0.056**	0.141	-0.241**	-.479**	0.183	0.048	0.392**	0.296**	0.371**	.445**	-0.029	0.200**	0.214**	-0.042	0.111**	0.116	0.136				
RBTSS Anger	0.174	0.022	0.002	-0.038	-0.066**	0.086	-0.128**	-0.101	0.278	-0.028	0.294**	0.264**	0.325**	0.409**	0.123**	0.240**	0.138**	0.050	0.065**	0.151	0.081	.829**			
RBTSS Physical	0.148	-0.023	-0.105	-0.019	0.054**	0.173	-0.084**	-0.288	0.239	0.029	0.411**	0.388**	0.418**	.534**	-0.005	0.175**	0.141**	-0.072	0.085**	0.212	0.115	.902**	.879**		
RBTSS Hypervigilance	0.212	-0.044	-0.207	-0.332	-0.072**	0.179	-0.340**	-.555**	0.132	0.033	0.334**	0.307**	0.402**	0.327**	0.049	0.010	0.093**	0.086	-0.063**	0.166	0.127	.900**	.676**	.754**	
RBTSS Intrussion	0.221	0.084	-0.268	-0.084	-0.142**	0.065	-0.300**	-0.362**	0.226**	-0.012	0.281**	0.363**	0.373**	0.349**	0.017	0.079	0.106**	-0.080	0.087	0.082	0.172	.896**	.789**	.815**	.90
RBTSS LowSE	0.135	0.030	-0.012	0.075	-0.079**	0.073	0.026	-0.129**	0.073	-0.191**	0.141**	0.275**	0.202**	0.316**	-0.210**	0.032	0.038**	-0.314**	0.210**	0.178	0.072	.778**	.811**	.858**	.62

Figure 1: Correlation Matrix

12.4 * Engaging Stakeholders: Describe any plans to engage other stakeholders (Scientists, practitioners, patients, advocacy groups, etc.) for hypothesis generation, or feasibility purposes.

In developing this protocol, we have had discussions with several stakeholders who have expressed interest and see value in developing an intervention to reduce the effects of systemic and interpersonal racism. Locally we have worked with community core research at Rockefeller University to explore potential community partners and recruitment strategies to enhance the fidelity of this protocol. In conceptualizing the measurement of race-based stress, we consulted with Dr. Robert Carter, who developed a race-based traumatic stress symptom scale designed to assess the psychological and emotional stress reactions to racism and racial discrimination. We have also had multiple meetings with the Pathways project, including scientists and advocates interested in mindfulness practice's social and clinical effects. The Pathways project includes Erich Jarvis, PhD, who serves as the project mentor, Joe Loizzo, MD, Ph.D., founder of Compassion-based Resilience Training (CBRT), academic director of Nalanda Institute and Clinical Assistant Professor of Psychiatry at Weill Cornell Medical College (WCMC); Rahshaana Green, CBRT Teacher, and Teacher Trainer, Co-Director of the New York City and Switzerland Contemplative Psychotherapy Programs and Director of Equity and Inclusion at the Nalanda Institute; Patricia Bloom, MD physician at Mount Sinai and MBSR teacher, Janna Gordon-Elliot, MD, a psychiatrist at WCMC, Nathalie Blachere, Ph.D., immunology expert, Jordan Marrocco, Ph.D., neuroendocrinology expert, Ann Campbell, MSN, MPH, founder of the Pathways project, Nurse Practitioner and mindfulness teacher. We have also discussed using neuroimaging in mindfulness intervention with Dr. Uraina Clark from Mt. Sinai Hospital, an active researcher on race discrimination and specializing in fMRI testing. To develop the CBRT intervention to be used in this study for racism-based stress, we worked with Nalanda Institute Joe Loizzo, MD, Ph.D., and Rahshaana Green, Director of Equity and Contemplative Psychotherapy at Nalanda Institute and CBRT Teacher and Teacher Trainer. We have also consulted Dr. Steve Cole, an expert on molecular pathways by which social environments influence gene expression. Dr. Cole and the UCLA Social Genomics Core offer gene expression profiling through the CTRA (Conserved Transcriptional Response to Adversity) as a paid service.

We also obtained research participants feedback from 20 participants who participated in the RKI-1036 study. In the study, interviews were conducted to capture participants' perspectives and feedback on an intended mindfulness intervention study designed to mitigate the consequences of race-based stress among African Americans, assessing their willingness to engage in the intervention and undergo further testing such as fMRI.

12.5 * Hypothesis

Describe the ***research hypothesis*** in a single sentence.

Persons who experience racism-based stress and engage in a CBRT program will report substantial enhancements in various domains (including overall stress levels, perceived discrimination, resilience, coping skills, anxiety, depression, mindfulness, sleep quality, allostatic load, salivary cortisol, telomere length)and the study contribute essential insights into the potential of mindfulness-based interventions to address racism-based stress and its broad-ranging implications.

12.6 * Aim(s)

Indicate how you will ***address the hypothesis*** (e.g., to compare groups, to estimate a parameter, to ascertain feasibility). Since the sample size determination is usually based on the primary aim only, the primary aim should be sufficient to justify the study.

This study aims to assess the feasibility and acceptability of Compassion-Based Resiliency Training (CBRT) intervention to reduce racism-based stress among African Americans.

The specific aims of this pilot are to:

1. A) Assess the feasibility of CBRT by examining recruitment, retention, and attendance rates in mindfulness sessions to inform the design of future large-scale efficacy trials.

   B) Gather participants' feedback and experiences of the CBRT to refine and enhance the intervention protocol for future implementation. Participants will be asked questions regarding the intervention, experiences of the sessions, features of the intervention, likes and dislikes, and changes experienced.

2. Evaluate the potential effectiveness of the CBRT intervention in improving both psychological outcomes (overall stress, everyday discrimination, resilience, coping, anxiety, depression, mindfulness, and Health-Related Quality of Life (HRQoL) and biological measures (salivary cortisol, allostatic load, CTRA gene expression).

3. Determine if changes in mindfulness mediate psychological (overall stress, everyday discrimination, resilience, coping, anxiety, depression, mindfulness) and biological measures (salivary cortisol, allostatic load, CTRA gene expression).

12.7 * Primary Outcome(s)

Indicate which ***variable(s)*** will be assessed to judge the primary specific aim. Give measurement units, if applicable.

Feasibility and acceptability of CBRT by examining recruitment, retention, and attendance rates in mindfulness sessions and participant feedback regarding the intervention, experiences of the sessions, features of the intervention, likes and dislikes, and changes experienced.

12.8 * Secondary Outcome(s)

Indicate which ***additional variable(s)*** will be assessed to judge the secondary outcome(s). Give measurement units, if applicable.

1. Allostatic load
2. Telomere length
3. Salivary Cortisol
4. C-reactive protein.
5. Gene expression (CTRA)

6. Depressive symptoms
7. Sleep
8. Coping
9. Mindfulness

12.9 * Methods and Procedures

Please provide a description of the laboratory and clinical analyses and procedures that will be performed. Include the role of external collaborators and consultants when appropriate. Please refer to Help text for Guidance.

Study Design and Participants
This study's design is a 1-group design involving 20 participants. We will collect baseline data before and after an intervention.

The study will take place at Rockefeller University Hospital following the approval of the Institutional Review Board, and participants have signed informed consent. Participants will be recruited from a combination of advertisements on Researchmatch.org and Craigslist. Participants who participated in the plenary study on racism and biomarkers of stress (RKI-1036) are eligible to enroll in this study).

Procedures:

Enrollment and screening: Participants will be enrolled at Rockefeller University Hospital and seen in the outpatient research clinic. In the first visit, a clinician will conduct initial screening, and patients who meet the inclusion criteria will be admitted into the study. A full explanation of the study, including study procedures, risks, and benefits, will be explained to each participant, and a clinician will obtain informed consent from all study participants. The original informed consent will be placed in the Rockefeller University Hospital chart.

CBRT intervention
The intervention is based on an established contemplative self-healing program integrating mindfulness with cognitive analysis, affect modulation, motivational imagery, and breathing. The practice is adapted from Indo-Tibetan traditions of mind-body science, reducing cognitive, affective, and behavioral stress. This intervention has been used among women with breast and gynecological cancer and has been shown to improve the quality of life (Loizzo et al., 2009) . The intervention is a 10-week program that will address mindfulness, compassion, social-emotional self-care, exposing stress-reactive habits, self-awareness, visualization, and deep breathing. Our rationale for applying this mindfulness intervention to promote psychological resilience following the development of race-based traumatic symptoms is based on the notion that mindfulness promotes acceptance of complex thoughts and feelings, reduces rumination, and improves psychological function, cognitive flexibility, and coping processes. This will also reduce the effect of stress on the body, as evidenced by a reduced allostatic load.
To develop the CBRT intervention to be used in this study for racism-based stress, we worked with Nalanda Institute Joe Loizzo, MD, Ph.D., and Rahshaana Green, Director of Equity and Contemplative Psychotherapy at Nalanda Institute and CBRT Teacher and Teacher Trainer. Rahshaana Green, who has CBRT experience teaching the CBRT, will deliver the CBRT intervention via Zoom.

Compassion-Based Resilience Training (CBRT) Intervention Plan

Session	Content	Topics	Homework
1	Recognizing the Preciousness of Life – Shifting Gears From Surviving to Thriving	•Discuss 10-week plan •Overview of CBRT •Definitions •How Mindfulness builds resilience	•Review introduction of manual •Practice meditations
2	Embracing Suffering with Body Mindfulness	•Cumulative Impact of Stress and Trauma •Cultivating Self- Acceptance	•Review Module 1 of manual •Practice meditations
3			

	Stopping Reactive Habits with Mindful Sensitivity	•The Cycle of Stress and Trauma and the Habit of Stress- Reactivity •Learning to Self-Soothe	•Review Module 2 of manual •Practice meditations
4	Breaking Free of the Stress Cycle with Mindful Awareness	•Unlearning Stress and Trauma •Learning to Soften and Open	•Review Module 3 of manual •Practice meditations
5	Mindful Insight: The Lifelong Path of Self-Healing	•Making Healthy Behavior Change •Developing a Self-Care practice	•Review Module4 •Practice meditations
6	How Mindfulness and Compassion Build Resilience	•Connection between Mindfulness and Compassion •How Compassion builds resilience	•ReviewInter mezzo •Practice meditations
7	Disarming Social Stress and Bias with Equal Empathy	•How Implicit Social Bias and Reactive Emotions are the Blocks to Common Humanity and empathy •Developing Perceptive Compassion	•Review Module 5 of manual •Practice meditations
8	Healing Reactive Emotions and Beliefs with Self-Compassion	•Learning to Accept and Reparent Yourself •Developing Emotional Compassion	•Review Module 6 of manual •Practice meditations
9	Cultivating Prosocial Emotions with Wise Give and Take	•Balancing Care for Self with Care for others •Developing Intentional Compassion	•Review Module 7 of manual •Practice meditations
10	Embodying a Resilient Self and Life with Caring Imagery	•Developmental Psychology and Role-Modeling Imagery •Developing Embodied Compassion •Wrap-up	•Review Module 8 of manual •Practice meditations

•Participants will receive access to web-based meditations, videos and a manual
•Sessions will include led meditations, embodied practices (like breathwork and gentle movement), and reflection questions

Below is the detailed breakdown of each visit:

Study Visit #1: Screening/Enrollment (approximately 3 hours)

In the first visit, a clinician will conduct initial screening, and patients who meet the inclusion criteria will be admitted into the study. A full explanation of the study, including study procedures, risks, and benefits, will be explained to each participant, and a clinician will obtain informed consent from all study participants. The Original informed consent will be placed in the Rockefeller University Hospital chart. A licensed clinician/nurse practitioner will perform a brief medical examination of the study participants. To screen for psychiatric diagnoses, a nurse practitioner will interview participants using a Structured Interview for DSM-5 (QUICKSCID-5) (First and Williams, 2021). During the first visit, POCT HIV will be used to screen for HIV. In addition, POCT pregnancy will be obtained among women of childbearing age. Clinical data, including Blood pressure, waist, and hip measurements, and BMI, will be obtained.
Participants will also be provided with saliva collection kits and detailed instructions. They will be guided to collect three saliva samples on one chosen day before the next appointment. The three samples will be collected in a single day: upon waking, 30 minutes after waking, and at bedtime. To ensure accurate samples, participants will be instructed not to consume food and beverages, or brush their teeth during the 30 minutes of each collection time. After collection, participants will be requested to properly store and return the samples using the provided home collection kit and bring them to their next appointment at RU Outpatient.

Study Visit #2: (approximately 3 hours) (10 days +/- 2 days)

During this visit, participants' vital signs will be taken. Women of childbearing potential will be given a POCT pregnancy test. Blood donation of 100ml will be collected for analysis of (CBC, CMP creatinine, AST, ALT, Total cholesterol, HDL cholesterol, albumin, CRP Interleuken6, TNF-a, HbA1c, random glucose, telomere, and gene expression). A meal will be provided after the blood draw. In addition, participants will be asked to complete a set of questionnaires.
Participants will also be provided with saliva collection kits and detailed instructions. They will be guided to collect three saliva samples on one chosen day before the 10-week follow-up appointment. The three samples will be collected in a single day: upon waking, 30 minutes after waking, and at bedtime. To ensure accurate samples, participants will be instructed not to consume food, and beverages, or brush their teeth during the 30 minutes of each collection time. After collection, participants will be requested to properly store and return the samples using the provided home collection kit and bring them to their next appointment at RU Outpatient.

Once the participants agree to participate and a cohort of 20 participants has been screened and baseline data collected, participants will participate in a 10 weeks CBRT intervention. Participants will receive a series of 10 weekly 1-hour Compassion-Based Resiliency Training (CBRT) sessions conducted online via a secure Rockefeller University Zoom link. Subsequently, participants will return to the Rockefeller University Outpatient Clinic for bloodwork and surveys.

Study Visit #3: (approximately 3 hours) (after 10 weeks of intervention)

The third visit will be after 10 weeks of receiving the intervention . During this visit, participants' vital signs will be taken. Women of childbearing potential will be given a POCT pregnancy test. Blood donation of 100ml will be collected for analysis of (CBC, CMP creatinine, AST, ALT, Total cholesterol, HDL cholesterol, albumin, CRP Interleuken6, TNF-a, HbA1c, random glucose, telomere, and gene expression). A meal will be provided after the blood draw. In addition, participants will be asked to complete a set of questionnaires.
Participants will be asked to give open and honest accounts of their experiences and opinions of the intervention. Their responses will be recorded and transcribed using nVivo software.

Measures

Structured psychological instruments.
Clinical data, including psychological assessments, will be done by participants on an iPad with the instructions of a clinician. Socio-demographic variables (Age, sex, self-identified AA, marital status, income, education, housing, locality, and chronic conditions) will be collected. The Race-based Traumatic Stress Symptoms Scale (RBTSS) and the Everyday Discrimination Scale are used for race-based stress assessment. In addition, we included psychometric measures to assess depression, perceived stress, health and quality of life, social connectedness, sleep, and resilience. Participants will be assessed a two main time points: Baseline (preintervention) and 10 weeks see Table 1 (Study Assessments Timelines), with selected measures at each time point.

Racism-Based Stress Surveys

1. Race-based Traumatic Stress Symptoms RBTSSS (Carter et al., 2013). The scale is 52 a self-report instrument that assesses reactions resulting from negative racial experiences. Participants identify the most memorable negative racial encounter and complete emotional symptom reaction items. Items are rated along a 5-point Likert scale. RBTSSS comprises of 7 symptom scales: Depression (10 items), Intrusion (8 items), Anger (8 items), hypervigilance (8 items), physical reactions (8 items), Low self-esteem (6 items), and avoidance (4 items). Higher scores indicate a greater presence of reaction symptoms.
2. Everyday discrimination Scale(Williams et al. 1997). An original version of the EDS consists of nine items on a 6-point Likert-type response format, with modified versions of the EDS having different numbers of items. The total possible range of the original EDS is 1 to 54, with higher scores indicating higher levels of perceived discrimination. Items included in the EDS are daily experiences with unfair treatment, such as being treated with less respect, being treated with less courtesy, being called names or insulted, and being threatened or harassed.

Mental health and lifestyle-based surveys

3. Life Stressor Checklist-Revised (LSC-R) (Kimerling et al., 2000). This is a self-report measure that assesses traumatic or stressful life events. The questionnaire includes 30 life events, including experiences with natural disasters, physical or sexual assault, death of a relative, and other events, following a yes/no response format.
4. Depression Anxiety Stress Scale -21 (Henry and Crawford, 2005)- measures self-reported negative emotional states of depression, anxiety, and stress. The DASS-Stress scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset /agitated, irritable/over-reactive, and impatient. Subjects are asked to use a 4-point severity/frequency scale (0 = Did not apply to me at all, 1 = Applied to me to some degree, or some of the time, 2 = Applied to me a considerable degree, or a good part of the time, and 3 = Applied to me very much, or most of the time) to rate the extent to which they have experienced each state over the past week. This scale has been used in clinical research and practice to identify individuals with high stress who may be vulnerable to psychopathologies.
5. Medical Outcomes Study Short Form 12 (SF12) (Ware Jr et al., 1996). The SF-12v2 is a health-related quality-of-life questionnaire consisting of twelve questions that measure eight health domains to assess physical and mental health.
6. Connor-Davidson Resilience Scale (CD-RISC) has 25 items, each rated on a 5-point scale (0–4), with higher scores reflecting greater resilience (Connor and Davidson, 2003). Scale demonstrates that resilience is modifiable and can improve with treatment.
7. Social Connectedness Scale(Lee and Robbins, 1995) 8-item measure scored on a 6-point Likert Scale assessing interpersonal closeness in the social realm.The SCS is a uni-dimensional assessment, with a higher summed rating reflecting an enhanced sense of social connection (# = .93).
8. Pittsburg Sleep Quality Index (PSQI) (Buysse et al., 1989)– 19-item questionnaire to measure sleep quality and disturbances over a 1 month period
9. Coping with Discrimination Scale (CDS)(Wei et al., 2010): 25-item scale that assesses coping strategies with discrimination. Items are answered using a 6-point Likert scale format ranging from strongly agree to strongly disagree. Scores are calculated for 5 subscales: Education/advocacy, Internalization, Drug /alcohol use, Resistance, and Detachment. Mean scores for each subscale range from 1 to 6 with higher scores indicating a higher presence of the attribute measured.
10. Post-traumatic Growth Inventory (PTGI-SF) (Cann et al., 2010). 10-item inventory measuring positive changes trauma recovery by focusing on the beneficial cognitive and personality shifts resulting from grappling with traumatic events (Tedeschi and Calhoun, 1996). It records PTG in five domains: 1) relating to others, 2) perception of new changes 3) Personal strength 4) Spiritual change 5) Appreciation of life.
11. Five-Facet Mindfulness Questionnaire (FFMQ) (Baer et al.,2006)- a 39-item Likert-type scale that measures trait mindfulness with responses ranging from (1) never or very rarely true to (5) very often or always true. The FFMQ consists of five facets: observing, describing, acting with awareness, non-judging, and non-reactivity. Higher scores are indicative of higher levels of trait mindfulness.

Biological measures

1. Allostatic load. This includes biomarkers of cardiovascular and metabolic activity. In addition to BMI, we included parameters that are usually considered in metabolic syndromes, such as waist circumference, waist-to-height ratio (blood pressure, flipid and blood glucose levels, insulin resistance, and salivary cortisol as a neuroendocrine marker of stress. Cholesterol and glucose level labs will require participants to fast 8 hours prior to blood collection. The allostatic load will be determined using the clinically relevant cut-off points determined by pre-established values in clinical medicine.
2. Telomere Length. Genomic DNA will be extracted using a DNA blood kit, ScienCell's Absolute Human Telomere Length Quantification qPCR Assay Kit. Quantitative RT-PCR will be used to determine changes in average telomere length. A reference DNA sample provided with the kit will be used to compare the results from the participants. Telomere-length studies will be conducted at Rockefeller University. Homo sapiens (taxid:9606) sample with known telomere length in kilobases will serve as a reference to calculate samples' telomere length
3. Gene expression conserved transcriptional response to adversity (CTRA). Blood will be collected using PAXgene tubes and stored at -20C until it is shipped on dry ice to the University of California, Los Angeles (UCLA) Social Genomics Core for gene expression profiling by RNA-seq. We consulted Dr. Steve Cole, and the UCLA Social Genomics Core CTRA gene expression profiling is a paid service. Gene expression levels of all genes will be tested for correlations with behavioral and other biological measures.
4. Salivary cortisol. Samples will be collected using the passive drool technique using a Salimetric Salivabio swab and tube. Participants will be instructed to gather saliva samples 3 times in one day: at waking, 30 minutes after waking, and at bedtime. Participants will be instructed not to eat, drink, or

brush their teeth during the 30 min prior to sample collection times. After collection, the participants will be asked to store their samples in a cool area or refrigerator and return them on their next appointment. Samples will be stored at Rockefeller University Laboratory of Neurogenetics of Language at 20C and then shipped to Salimetrics for analysis using the Salimetrics Salivary Cortisol Enzyme Immunoassay Kit.

Measures	**0-Baseline**	**10wks**
Socio-demographic variables.	x	
Allostatic Load *	x	x
Saliva cortisol	x	x
Telomere Length	x	x
Gene Expression CTRA	x	x
Everyday Discrimination (EDS)	x	x
Pittsburg Sleep Quality Index (PSQI)	x	x
Medical Outcomes Study SF 12	x	x
Connor-Davidson Resilience Scale (CD-RISC)	x	x
Depression Anxiety Stress Scale	x	x
Race-based Traumatic stress symptoms RBTSSS	x	
Life stressor Checklist-Revised (LSC-R)	x	
Social Connectedness Scale SCS	x	x
Coping with Discrimination Scale (CDS)	x	x
Post-traumatic Growth Inventory (PTGI-SF)	x	x
Five-Facet Mindfulness Questionnaire (FFMQ	x	x

*Allostatic Load includes blood pressure, lipids, BMI, Glycated hemoglobin, Waist-hip ratio, Albumin, CRP, creatinine

Venipuncture: Participants will have blood work drawn during in-person visits (visits 2,3 and 4) at Rockefeller University Outpatient Department. A nurse or trained technician will perform venipuncture to obtain approximately 100ml of blood/ visit for a total of 300ml for the study, following the outlined blood donation guidelines. A portion of the blood (approximately 80ml) will be sent to MSKCC (CBC, CMP, HDL cholesterol, total cholesterol, HbA1c, glucose, albumin, CRP, and creatinine clearance) and LabCorp (Interleukin-6, TNF-a, DHEA). A portion of the blood specimen (approximately 20ml) DNA will be extracted and stored in the Laboratory of Neurogenetics of Language at Rockefeller University for gene expression analysis and telomere length testing.

Qualitative Interview
Participant feedback and experiences of the CBRT will be assessed using a structured interview. Participants will be asked questions regarding the intervention, experiences of the sessions, features of the intervention, likes and dislikes, and changes experienced. Interviews will be conducted at the end of the 10-week intervention period for each group to assess the acceptability of the CBRT program. We will use a structured interview guide to ask questions regarding the intervention, experiences of the sessions, features of the intervention, likes and dislikes, and changes experienced. The interviews will be recorded using a dedicated digital audio recorder that will be kept securely locked when not in use. The audio will then be uploaded onto NVivo and deleted from the audio recorder. Nvivo will be used to transcribe the audio into text. All audio recordings will be reviewed for accuracy and any identifiers prior to using data analysis software (NVivo desktop version). After all recordings have been transcribed, the audio files will be deleted and files stored in RU Rockefeller University Central File share. Thematic analysis will be conducted to identify recurring themes.

Adverse Event Assessment
In this research study, we have established a comprehensive safety plan to protect the well-being of our participants. Participants will be clearly informed of their right to decline to answer questions or share information that may cause distress or discomfort. We will maintain continuous vigilance over their well-being by closely monitoring their experiences and maintaining open lines of communication. The Investigator and CBRT providers are dedicated to encouraging participants to express any concerns or discomfort they may encounter during the study. If, at any point, a participant exhibits significant distress or requests assistance, they will be immediately referred to our Licensed Social Worker for a thorough evaluation and the necessary support. Subsequently, our dedicated study team will follow up with them to ensure their ongoing well-being and assess

the need for any modifications to their participation. Adverse events will be documented in the RUH chart and reported to the Institutional Review Board (IRB) as required.

Data Storage: Clinical research data will be coded and entered into the Redcap database. Clinical data containing personal identifiers or linked to participants' names will be coded before storage. Paper forms will be stored in a locked cabinet. Qualitative interviews will be audio-recorded, transcribed, coded, and stored on Rockefeller University Central File share, password-protected and encrypted per Rockefeller University IT policy.

Data Protection:
All samples, and associated metadata will undergo a GCP-compliant coding process before sharing with the UCLA Genomic Core. The code key will not be shared with the UCLA genomic Core. The original data and code key will be securely maintained in a password-protected and encrypted computer at Rockefeller University. Access to data at the UCLA Core will be limited to the coded samples and associated metadata, encompassing age, gender, allostatic load, and saliva cortisol. All data, including sequencing data and corresponding metadata, will be transferred via RU secure Dropbox in agreement with the material transfer agreement created for this project and Rockefeller Data Protection guidelines for clinical samples.

12.10 * Data Analysis

Describe method(s) of data analysis.

We will evaluate the recruitment process by analyzing the number of interested participants, those screened, and successful enrollments to assess feasibility. Furthermore, we will calculate the eligibility percentages, dropout rates, and attendance at intervention sessions. The acceptability of the intervention will be evaluated through inductive thematic analysis of the interview responses, identifying recurring themes and insights.

To pursue exploratory aims, we will conduct a 2-tailed, paired sample *t*-test (or paired sample Wilcoxon signed-rank test) and compute Cohen effect size values for variables pre-intervention.

12.11 * Explain the rationale for the choice of statistical measures and the number of participants proposed for the study, including the power calculations when applicable.

A convenience sample of 20 was chosen due to the explorative nature of this study to determine whether variables are measurable with sufficient precision to be studied in later experimental studies and to check the logistics of a proposed experiment.
This is primarily an acceptability and feasibility study so that the analysis will focus on the key parameters necessary for a future RCT. Most of the analysis will be descriptive in nature. Moreover, we are conducting numerous tests on a small population; therefore, we will not apply a restrictive correction for multiple statistical tests to reveal the trends clearly.

12.12 * Will samples be coded?

(•) Yes ( ) No

If Yes, Please describe coding scheme consistent with GCP. If samples will not be coded, please provide justification for this proposed departure from GCP practice.

All samples will be coded with unique identifiers based on the study number assigned to each individual upon enrollment (for example, RKI-1047-001). Study volunteers' HIPAA-protected information will not be associated with any research data. All computers used to store and analyze research data will be password-protected and encrypted. All data will be backed up into the system maintained by the Information Technology Service at Rockefeller University.

The interviews will be recorded using a dedicated digital audio recorder that will be locked securely when not in use. The audio will then be uploaded onto NVivo and deleted from the audio recorder. Nvivo will be used to transcribe the audio into text. All audio recordings will be reviewed for accuracy and any identifiers prior to using data analysis software (NVivo desktop version). After all recordings have been transcribed, the audio files will be deleted, and files stored in RU Rockefeller University Central File share. Thematic analysis will be conducted to identify recurring themes.

If available, upload the Data and Sample Sharing Management Plan approved by RU IT.

Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.					

13.0 Participants of Study

13.1 Specify age range of participants:

* Minimum Age:

18

* Maximum Age:

50

Please note: If the age of participants indicated is less than 18 years old, you will be prompted to attach a Pediatric Assent form later on in the submission process. A link to the Pediatric Assent form can be found in the Help link to the right, or this form can be downloaded later on in the submission process.

13.2 * Indicate the gender(s) of the participants:

- [x] Female
- [x] Male
- [x] Unknown
- [ ] Not Reported

13.3 * Indicate projected enrollment by race and ethnicity. See Help for disease/volunteer population demographics.

13.4 Exclusion of Protected Groups:

***Research involving human participants should be designed/conducted to be as broadly inclusive as possible regarding sex, gender, race, age, and ethnicity. Exclusions regarding these characteristics require an explanation of the rationale and justification.**

Will participants of a specific sex/gender/race/ethnicity/age or other protected group characteristic be excluded from participation?

(•) Yes ( ) No

Please identify the group/characteristic that will be excluded:

- [x] Age
- [ ] Sex

- [ ] Gender
- [x] Race
- [x] Ethnicity
- [ ] Other groups excluded based on an identifiable group characteristic; please specify below, with justification

Please describe the specifics of the exclusion (e.g., "males" or "individuals age 60 and older" or "study includes only persons who self-identify as Black") and the justification for the exclusion:

Age and HIV status - Participants older than 51 years of age and those living with HIV will be excluded from participating in the study. Evidence shows that persons living with HIV have shorter telomeres than the general public (Alejos et al., 2019). Longitudinal studies have also showed that telomere lengths shorten with age (Huang et al., 2021)

13.5 Vulnerable Populations

Indicate whether any of the following populations will be included in the study:

- [ ] Children
- [ ] Pregnant Women
- [ ] Cognitively Impaired Persons
- [ ] RU Employees
- [ ] RU Students
- [ ] Other:

13.6 *What is the total number of evaluable participants you plan to enroll at Rockefeller University Hospital over the course of the entire study?

20

13.7 * What is the total number of participants who will need to sign consent *at Rockefeller University Hospital over the course of the entire study* to result in the desired number of evaluable participants?

30

13.8 * What is the total number of participants you plan to sign consent *at Rockefeller University Hospital in the next year?*

0

13.9 * What will be the total number of evaluable participants *at all sites over the course of the entire study?*

20

13.10 Inclusion Criteria

Please list participant inclusion criteria:

Order Number	Criteria
1	Self Identity as African American or Black
2	18-50 years old
3	Fluent in English
4	Born and or raised in the United States

13.11 Exclusion Criteria

Please list participant exclusion criteria:

Order Number	Criteria
1	History of significant pre-existing brain disease or injury (e.g., dementia, stroke, seizure disorder, and head injury with cognitive sequelae or loss of consciousness >30 min., seizure disorder)
2	Reported history of learning disability/mental retardation
3	Current ADHD, depression, bipolar disorder, post-traumatic stress disorder (PTSD), or psychotic disorder diagnosis
4	Current psychotropic medication (as these medications have known impacts on brain function) eg. antipsychotics, antianxiety
5	Severe/chronic medical illness (e.g., reported HIV+ status, cardiovascular disease, liver disease/cirrhosis, chronic kidney disease,current/past cancer with radiation /chemotherapy treatment, etc.)
6	Current methadone/suboxone/buprenorphine (or similar) maintenance
7	Use of illicit substances other than cannabis within the past 90 days
8	Pregnancy
9	Major life events in the last 30 days (hospitalization, marriage, death in the family of friends, disaster)
10	Any medical, psychological, or social condition that, in the opinion of the Investigator, would jeopardize the health or well-being of the participant during any study procedures or the integrity of the data.

14.0 Schedule of Events/Study Plan

14.1

Instructions:New Studies:

- **A Schedule of Events is required for all new studies involving interactions with human subjects.**
- **The iRIS Study Plan will not be accepted for new protocols.**
- **A template Schedule of Events is available on the IRB Website. For any new study, populate the template with the visits and procedures for the study.**
- **The content of the Schedule of Events should be consistent with any descriptions of study procedures that may be in the protocol text and informed consent.**
- **Attach the completed Schedule of Events document to the Submission Form in the Schedule of Events section.**

Existing Studies: For existing studies, investigators may elect to update the existing Study Plan OR may replace the Study Plan with a Schedule of Events, following the instructions above for new studies.

Attach the Study Plan (an option only for studies with pre-existing Study Plans):

*** What is the total number of outpatient visits for all participants projected for the next year?**

0

*** What is the average length of each outpatient visit (in hours)?**

0

*** What is the total number of Day Patient visits for all participants projected for the next year?**

0

*** What is the average length of each Day Patient visit (in hours)?**

0

*** What is the total number of inpatient days for all participants projected for the next year?**

0

15.0 Consent Procedure

15.1 * This study will use the following types of informed consent:

- ☐ Informed Consent Form Standard - a standard consent form with instructions for adapting it to your study
- ☐ Consent Form Genetic- a consent form designed for a study where genetic testing (as defined by NYS law) is to be done in the CURRENT study
- ☑ Consent for studies including genome wide sequencing
- ☐ Pediatric Assent Form (To be used in addition to Consent) for Pediatric patients
- ☐ Other (e.g., waivers, electronic informed consent)

Links to the **Standard Consent, Genetic Testing Consent** and the **Pediatric Assent** forms can be found in the Help link to the right, or these forms can be downloaded later on in the submission process.

15.2 * Indicate the consent process to be used.
(See Help for CCTS SOP)

Describe how the required information is being presented to participants (consent form, orally, information sheet, etc.). Attach a copy of what is being presented to participants (usually the ICF and Assent forms).

Before initiating any study-related procedures, the potential participants will be given a copy of the most recent IRB-approved and stamped informed consent to read. The PI or study staff member who has been designated to consent will discuss via Zoom or in person the specifics of the study, including but not limited to the purpose of the research, procedures, time commitment, required tasks, test article or device, alternative treatments, benefits, risks, confidentiality, etc. Information will be provided comprehensibly (non-scientific), using language readily understandable by the participant. Participants will be informed that participation is voluntary and that they will not be penalized if they do not consent. Participants will be given ample opportunity to ask questions until satisfied before signing the consent.

Participants who are enrolled remotely may receive the protocol REDCap eConsent via email, following the RU eConsent SOP. Following the consent discussion, the person obtaining consent will email the participant a link to the REDCap eConsent for review and signature. Once the participant signs, the study member will countersign and email a PDF of the fully signed consent form, which will be emailed back to the participant. The research team member obtaining the consent will complete documentation, including the elements of the consent.

Describe the circumstances under which consent will be obtained, where the process will take place and any waiting period between informing the prospective participant and obtaining consent.

Potential participants will be provided with a private, confidential setting to read and discuss the informed consent, free from coercion, undue influence, or time constraints. All participants will be given a chance to ask questions and express concerns. They will be given the option to take the consent home and discuss it with family, friends, and /or healthcare providers. After a participant and the person conducting the consenting signs and dates the consent, the participant will be given a copy of the signed informed consent form. The original consent form will be retained in the Rockefeller University patient chart. An enrollment note will be written in the patient chart as to who obtained consent, how, what were questions asked and answered, and that a copy of the informed consent was given

to the participant.

Describe the experience of the investigators designated for this task in the DOA in obtaining consent from participants.

Rachel Kimani has been trained, demonstrated competency, and has extensive experience with consenting research participants.

How will it be determined that the participants or the participants' authorized representatives understand the information presented?

We will use the 'teach-back' method to assess participant understanding and retention of protocol requirements, adverse event information, risks and benefits, and the participant's rights described in the informed consent process.

If English is not the participants' native language, how will written and/or verbal translation be provided?

Given the inclusion criteria and required English comprehension, we do not anticipate consenting participants whose native language is not English. However, for the isolated participants who need a translator, Pacific Interpreters will be used to facilitate the explanation of the study.

Will any participants be cognitively impaired so that they may not have the capacity to give consent?

○ Yes ◉ No

For participants where it has been determined that they lack the capacity to give consent, describe the provisions for obtaining consent from the participants' legally authorized representative.

Participants who are determined not to have the capacity to consent will not be enrolled in the study.

15.3 * Based on the demographics, will this study's participant population require foreign language consent form?

○ Yes ◉ No

15.4 * This study's consent procedure will require the following waivers:
(See Help for additional information.)

○ Waiver of one or more elements of informed consent, 45 CFR 46.116(f)
○ Waiver of documentation of informed consent, 45 CFR 46.117(c)
◉ No waiver is requested

15.5 Will you obtain a Certificate of Confidentiality (CoC) for this study?

◉ Yes ○ No

☑ A CoC will be provided automatically as part of its funding mechanism with NIH
☐ The PI will apply independently to NIH for a CoC

Note to Investigator: If this study has a CoC, the Informed Consent document must contain CoC template language

15.6 * Does this study include video/audio recording, photography or other electronic recording of human participants?

◉ Yes ○ No

15.7 Please select from following:

☐ Photography (Please see the RU Policy on photography in research)
☐ Video Recording
☑ Audio Recording

☐ Other Electronic Recording

15.8 Describe what will be done:

Interviews will be conducted individually in a private room at Rockefeller University's Outpatient department. Before beginning the interview, the interviewer will explain the purpose of the interview, the format, and the length of time for the interview. Participants will be reminded when the recording begins.
Qualitative interviews using semistructured questions will be conducted to obtain feedback on CBRT intervention

16.0 Recruitment and Advertising

For assistance consult CRSO to create a robust Recruitment Plan see Help.

16.1 * What is the plan for recruitment?

What is the plan for recruitment?
Overview: The CRROSS seeks to prescreen 40 healthy volunteers between the ages of 18- 50 to achieve the overall goal of 20 evaluable participants.

Feasibility and Assessment:
Incentives: 1) Altruism; 2) Interest in study topic 3) Compensation

Challenges: 1) Overall impact of the Covid-19 pandemic may dissuade individuals from voluntarily participating in research studies; 2) Scheduling 20 participants for weekly Zoom meetings for the intervention; 3) all participants must be enrolled before the interventional portion of the study can begin; 4) Retaining participants over the course of 10 weeks; 4) Recruiting and completing study in time for PI's graduation deadline.

Issues relevant to rapid accrual:
Positive: 1) Existing cohort of healthy volunteers in the repository; 2) Many participants from first pilot study conducted last year may be good candidates for the current study; 3) Cash completion bonus for participants who complete the entire study.
Negative: 1) High no-show turnout for healthy participant studies in general.

Projected Time to Accrual Completion (PTAC):
The research team plans to screen up to 2 participants 3 days per week which translates to enrolling up to 6 volunteers a week.

Factors Affecting Predicted Time to Accrual Completion	Weeks
Research team plans to screen 2 participants 3 days per week 20 total / 6/week enrolled = 4 weeks to recruitment	4
Anticipated startup: Miscellaneous delay	2
Add any vacation time when screen/visit capacity will be reduced	-
Recruitment is to occur during August? add 2 weeks due to historical slowing	-
Recruitment to occur across Dec January timeframe; add 2weeks for unit closure	-
Staf for KSP changes– add onboarding time	-
Staff travel for major conferences– add weeks lost capacity	1
Institutional interruptions (graduation, symposium days, etc.) add team estimate	-
Projected Time to Accrual Completion (PTAC)	7

Recruitment Implementation:
Advertising- CRROSS will advertise on Craigslist. Volunteers will also be drawn from the Research Volunteer Repository in Clinical Conductor. Eligible participants from RKI-1036 will be invited to screen for this study.

Centralized Call Management – CRROSS will work with the research team to develop a protocol-specific pre-screening script based on IRB approved protocol eligibility criteria to prescreen volunteers who call 1800RUCARES. Potentially eligible candidates will be scheduled for the study team for further screening. CRROSS staff will also call volunteers based on Repository queries described above. Research teams are responsible to provide timely updates on pre/screening

outcomes by updating volunteers' Study Status in Cerner. The Recruitment team uses screening outcomes to review progress and strategy to keep enrollment on target.

Please describe how the Recruitment Plan addresses recruitment of the volunteers consistent with the demographics of the condition under study: (referenceCensus,Maps, CDCdata)

Healthy, self-identifying Black/African American participants of all genders between the ages 18-50 will be considered for the study. RU EMPLOYEES AND STUDENTS ARE NOT ELIGIBLE TO PARTICIPATE IN THIS STUDY.

16.2 *From the date of final IRB approval, how long will it take to complete enrollment of the study?

- ○ 6 Months
- ◉ 12 Months
- ○ 18 Months
- ○ 24 Months
- ○ More than 2 years (specify in years)

16.3 This Study

- ◉ Involves an intervention or comparison and a defined enrollment target
- ○ Is a natural history study with expected annual enrollment over many years
- ○ Is an exploratory mechanistic study
- ○ Other

16.4 This Study will enroll:

- ◉ Healthy volunteers
- ○ Individuals affected with a specific disease/disorder
- ○ Both

16.5 * Do you plan on using the Research Participant Repository (RKO-0648) ?

◉ Yes ○ No

16.6 * Are you screening or recruiting from or through a record review of an existing patient database of a healthcare provider?

○ Yes ◉ No

16.7 * Please describe how the Recruitment Plan addresses recruitment of the volunteers consistent with the demographics of the condition under study:

Healthy, self-identifying Black/African American participants of all genders between the ages 18-50 will be considered for the study. RU EMPLOYEES AND STUDENTS ARE NOT ELIGIBLE TO PARTICIPATE IN THIS STUDY.

16.8 * Do you plan to advertise directly to potential volunteers? (As opposed to relying on practitioner referrals or flyers to practitioners)

◉ Yes ○ No

16.9 * Do you plan to use the free, web-based volunteer registry, ResearchMatch.org, as a recruitment tool?

◉ Yes ○ No

17.0 Research Participant Repository (RKO-0648)

17.1 This protocol, will be linked with the Research Volunteer Screening/Recruitment Data Repository run by the Recruitment staff and the Clinical Research Support Office (protocol RKO-0648-1008). In order to participate in the generation of the Repository the PI will enter into a Collector/Collaborator agreement regarding the Repository. The role of Collector/Collaborator is to contribute to the Repository the name, contact and demographic information, recruitment referral information, and screening outcome information, as well as appropriate protocol specific screening information, of volunteers who are screened by telephone or in person for entry into the protocol regardless of the screening outcome. In addition to screening volunteers for the PI's current study, verbal consent will be obtained from the volunteers regarding their willingness to be contacted in the future about possible additional research studies. This permission may be obtained by the Recruitment office staff through the central Call Center. If the PI receives calls directly from participants for initial prescreening, then the PI is responsible for collecting the required information and conveying it to the Recruitment staff for data entry. The consent or withholding of permission will be recorded in the Repository as will the name of the person who obtained the permission. A volunteer's permission or declination will not affect their eligibility for my current protocol, or future protocols. The Recruitment staff of the Clinical Research Support Office may gather the Repository information and request the verbal consent of the volunteer for re-contacting on my behalf as part of our recruitment plan. In order to benefit from the Repository, the PI will enter into a Recipient/Collaborator agreement with the Repository. The Recipient/Collaborator may receive from the Repository pre-screened lists of potentially eligible participants for his/her study as a means to facilitate recruitment. The Recruitment staff will prepare the Repository queries according to the protocol eligibility requirements and available Repository information, and may re-affirm permission to re-contact volunteers as necessary. The PI may use the information and names in the list from the Repository only for the current study and may not save the list to use for a future study of his/her own, nor may he/she share the list with colleagues for other studies."

18.0 Utilization of ResearchMatch.org

18.1 Utilization of ResearchMatch.org for Recruitment

Basic information regarding this tool:

- **ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University. There is no cost for researchers at participating institutions in the ResearchMatch.org Network to use ResearchMatch.org. The Vanderbilt IRB provides oversight for ResearchMatch.org as a recruitment tool and this has been documented within the ResearchMatch.org IRB Letter of Understanding which was executed by Dr. Gotschlich in October, 2009. However, individual requests to use ResearchMatch.org as a recruitment tool must be submitted to this institutions' IRB.**

Registration:

- **This recruitment tool may be utilized once the PI or research staff registers for recruitment access through ResearchMatch.org and the Institutional Liaison provides approval.**
- **The ResearchMatch.org Institutional Liaison will review the study information and evidence of IRB approval. He/she will set the researcher's expiration date to mirror that of the study's IRB approval.**

Search Capability:

- **After being granted recruitment access, the researcher can search for appropriate matches amongst the non-identifiable ResearchMatch.org Volunteer profiles in the system. He/she can enter study inclusion/exclusion criteria in the ResearchMatch.org Search Builder which will yield a list of potential matches to the study's criteria.**

Contacting ResearchMatch.org Volunteers:

- **Once yielding a list of potential matches (ResearchMatch.org Volunteers), the researcher will send out IRB-approved content that will be the initial recruitment message that these volunteers receive about the study through ResearchMatch.org. The study's recruitment message will be inserted into the standard ResearchMatch.org electronic notification that informs possible matched Volunteers that he/she has been identified as a potential match for the study. The secure ResearchMatch.org clearinghouse will route this standard ResearchMatch.org email notification. These potential matching volunteers will have the option of replying yes, no, or not respond through a set of quick links available in this notification to the study announcement. THE CONTACT MESSAGE WILL NOT INCLUDE THE STUDY'S DIRECT CONTACT INFORMATION (e.g. EMAIL, PHONE). By responding yes, the Volunteer has authorized ResearchMatch.org to release his/her contact information to the researcher. The researcher will be responsible for managing this contact information as called for by this IRB-approved study protocol.**

Study Management in ResearchMatch.org:

- **Researchers (and the Liaison) can view information regarding his/her study's status in ResearchMatch.org (e.g. number of volunteers contacted for the study via ResearchMatch.org to date, response rate of volunteers, etc.). ResearchMatch.org will also be collecting aggregate data regarding the status of ResearchMatch.org volunteers within the study. Volunteers consent to this within the ResearchMatch.org Volunteer Agreement. This information will allow the researcher to indicate where the**

Volunteer currently stands within the recruitment process and thus will help the researcher monitor the utility and effectiveness of using this resource (e.g. Did not contact, Not eligible, Enrolled, Completed, etc.).

19.0 Potential Benefits to Participants

19.1 * Will participation in this study provide direct benefits to the participant?

(•) Yes ( ) No

19.2 If Yes, describe the potential direct benefits:

CBRT is a contemplative self-healing program that integrates mindfulness with cognitive education, affect modulation, motivational imagery, breath control, and self-massage. Research demonstrates that compassion-based meditative therapies support the development of pro-social attributes and social connections. Individuals with higher mindfulness traits are thought to be more able to regulate their emotions and less emotionally reactive. In addition, mindfulness interventions can also lead to the development of individual resilience, and by focusing on the present moment, negative feelings are less likely to persist, leading to psychological well-being and, consequently, physiological health.

20.0 Potential Risks to Participants

20.1 * Describe any potential risks: physical, psychological, social, legal or other and assess their likelihood and seriousness. Indicate risks both to the participants and to the embryo or fetus if the participant is or may become pregnant. Please provide the potential risks below:

Venipuncture: Possible risks include mild discomfort, pain, possible bleeding, fainting, bruising, and the risk of infection associated with venipuncture.

Psychological: Some of the questions on psychological questionnaires and mindfulness intervention might be considered personal and sensitive to some participants. In addition, they may be triggering and causing psychological distress.
Participants experiencing distress will be referred to the Rockefeller University Licensed social worker for further evaluation.

Confidentiality: There is a risk of a breach of confidential information gained during this study. In addition, the intervention will be held via a secure Zoom with no recording. There will be no recording of sessions; however, it is possible to be exposed through other participants.

21.0 Procedures to Minimize Risks

21.1 * Describe the procedures for protecting against or minimizing any potential risks, and include an assessment of their likely effectiveness. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing medical treatment, if needed.

Venipuncture. Blood is only drawn by experienced technicians, nurses, or licensed clinical practitioners.

Psychological: Participants will be apprised of the potentially sensitive content of the study and will also be apprised of their right not to answer any question posed to them. In addition, participants are informed of their right to withdraw from the study at any time. Participants experiencing distress will be referred to the Rockefeller University Licensed social worker for further evaluation.

Privacy: All research data will be stored in password-protected and computer-encrypted computers. Data collected will also be coded, and no identifying information will be stored in an electronic research database.

CBRT session will be held via a secure Zoom link with no video recording; all participants will be taught to blur their background to prevent exposure to their environment.

Study Safety Plan

In the study safety plan, participants will be fully informed of their right to refrain from answering questions or sharing information they may find distressing or uncomfortable. Throughout the study, the well-being of participants will be closely monitored by the Investigator and CBRT providers, who will maintain open lines of communication, actively encouraging participants to express any concerns or discomfort. Should a participant exhibit significant distress or request assistance, they will be promptly referred to our Licensed Social Worker for immediate evaluation and support. Subsequently, our study team will follow up to ensure their ongoing well-being and assess the need for any modifications to their participation. All incidents of participant distress, referrals, and follow-up actions will be meticulously documented in the RUH chart and, as mandated, reported to the Institutional Review Board (IRB).

22.0 Alternative Methods or Treatments

22.1 * Describe alternative methods or treatments for the disease(s) under study, if any, that were considered and why they will not be used:

None

23.0 Data and Safety Monitoring

This section describes the Data and Safety Monitoring Plan (DSMP) required of each protocol undertaken at the CCTS according to HRPP and NIH policies Notice 98 -084 and Notice 00-038, as cited in Help Sections below. Depending on the level or risk and trial phase, some protocols will need Data and Safety Monitoring Boards.

23.1 * Overall Risk Classification

An estimate of risk is necessary to evaluate the adequacy of the planned monitoring. The HELP section provides guidance in making the risk assessment.

Read the risk definitions and examples of risk in the HELP section and select the risk category that best describes the current study.

If your assessment differs from the definitions the HELP section, describe any factors that modify your judgment of the overall risk in the text box after the risk designation.

- ○ MINIMAL RISK
- ○ LOW RISK
- ◉ MODERATE RISK
- ○ SIGNIFICANT RISK

Please provide any optional description(s):

23.2 Protocols Involving Minors

The chance of direct benefit to the child, or to understanding a disorder not otherwise understood, may be major factors in justifying more than minimal risk in research involving children.

Based on the above definitions, please specify your study's risk classification below:

- ○ NOT GREATER THAN MINIMAL RISK (the risk of daily life to a healthy child living in a safe environment) 45 CFR 46.404
- ○ GREATER THAN MINIMAL RISK WITH DIRECT BENEFIT TO PARTICIPANT; 45 CFR 46.405
- ○ GREATER THAN MINIMAL RISK, NO DIRECT BENEFIT, BUT BENEFIT TO UNDERSTANDING OF PARTICPANT'S DISORDER; 45 CFR 46.406
- ○ RESEARCH NOT OTHERWISE APPROVED PRESENTING OPPORTUNITY TO UNDERSTAND, PREVENT OR ALLEVIATE SERIOUS PROBLEM AFFECTING CHILDREN 45 CFR 46.407 (cannot be approved by IRB; requires public comment)

23.3 DSMB

1. The NIH requires that all SIGNIFICANT RISK protocols have a **Data and Safety Monitoring Board** and provide information about the expertise and independence of that Board
2. Phase III trials require a Data and Safety Monitoring Board,
3. A DSMB may be appropriate for some Phase I and II protocols. (See Help for examples.)
4. It is the investigator's responsibility to report to the IRB, the findings and recommendations of the DSMB as they become available.

Please specify:

- ○ A DSMB is required for this study
- ◉ A DSMB is not required for this study
- ○ Unsure

If a DSMB is not required, but is being constituted for other reasons, please explain:

23.4 * Safety Review

Select one:

- ◉ Safety Review is conducted as follows: Laboratory results for research volunteers will be reviewed in a timely manner, usually within 24 hours of receipt by a licensed practitioner. The potential clinical significance of any abnormal finding will be documented in the medical and research record(s), and an appropriate plan or referral developed. The PI's review of safety issues at research team rounds will be documented in the meeting minutes.
- ○ Protocol Specific

23.5 Monitoring

Monitoring Personnel: See Help Bubble to the right.

Internal Monitoring

The PI or his/her designee shall conduct internal monitoring to assure the safe and proper conduct of the protocol and all the elements list above in monitoring, following the general principles of quality management. The intensity and frequency of internal monitoring will depend on the protocol risk to participants, the experience of the PI and research team, rate of enrollment, and specific details of the protocol.

Internal monitoring of informed consent and eligibility documentation will be conducted by the research team shortly after enrollment begins. Internal monitoring activities will be documented by logs, meeting minutes or other systematic means.

Specify the research team members who will conduct the internal monitoring of the study (see Help for who may monitor):

Internal Monitoring
The PI or his/her designee shall conduct internal monitoring to ensure the safe and proper conduct of the protocol and all the elements listed above in monitoring, following the general principles of quality management. The intensity and frequency of internal monitoring will depend on the protocol risk to participants, the experience of the PI and research team, the rate of enrollment, and specific details of the protocol.

The research team will conduct internal monitoring of informed consent and eligibility documentation shortly after enrollment begins. Logs, meeting minutes, or other systematic means will document internal monitoring activities.

For new investigators: Internal monitoring should be conducted at least monthly by new investigators until there are essentially no findings to correct at each review.

External Monitoring

* Is external monitoring planned for this protocol?

- ○ Yes
- ◉ No
- ○ Unsure

If external monitoring is planned, please specify (see Help for who may monitor):

- ○ (Significant Risk) External monitoring will occur at least every six weeks unless there is no enrollment
- ○ (Moderate Risk) External monitoring will occur at least quarterly
- ○ (Low or Minimal Risk) External monitoring will occur at least annually

If external monitoring is planned, please specify the name of the monitor:

- ☑ Note that copies of external monitoring reports must be supplied to the IRB and the CRSO as soon as they are made available

Additionally, audits of the research records of minimal, moderate or significant-risk protocols may be performed by the CRSO staff on a random basis or as part of a prospectively identified auditing plan.

23.6 Adverse Event Classification

Adverse events are classified by definition, severity, and association with the investigational trial.

Definition of an Adverse Event
Any unfavorable or unintended sign (including abnormal lab findings), symptom or disease temporally associated with the use of a medical treatment or procedure, or protocol, regardless of whether it is considered related to the medical treatment or procedure or protocol.

Definition of a Serious Adverse Event
Any unanticipated event that involves the following:
- o results in death
- o is life-threatening
- o requires hospitalization or prolongs existing hospitalization
- o results in persistent or significant disability/incapacity
- o is any medical event which requires treatment to prevent one of the outcomes listed above

Other events can be classified as "serious adverse events" at the discretion of the PI.

Definition of Anticipated/Expected Adverse Event

Any adverse event, which has been reported in the Investigator's Brochure, package insert, safety reports, clinical protocol, consent form or listed in the NCI agent-specific Expected Adverse Event List[3], is classified as an expected adverse event. The investigator must provide the available data of known adverse events and toxicities that have been associated with the study drug, device, intervention, or procedures. This information helps to define the level of risk of the trial and enables safety monitoring. A minimal risk trial may not have any defined risks and a statement to that effect is sufficient to meet the DSMP requirements.

Definition of an Unanticipated/Unexpected Adverse Event
Any adverse event that is not consistent with the known, predicted possible effects of the research protocol. An unexpected adverse event varies in nature, intensity or frequency from information on the investigational product provided in the Investigator's Brochure, package insert, safety reports, clinical protocol, or listed in the consent form.

Definition of an Unanticipated Problem (UaP)
A UaP is an event or circumstance that meets all the following three criteria: [1] the nature, severity, frequency of the event(s) or information was not expected in the descriptions in the study documents or the characteristics of the participant population being studied; [2] there is a reasonable possibility that the procedures involved in the research caused or are linked in a significant way to the problem; [3]the event or information suggests that the research places particpants or others at a greater risk of harm than was previously known or recognized (including physical, psychological, economic, or social harm.

Grade and Relatedness of Adverse Events:

Adverse Events are graded for severity and scored for relatedness to the protocol, according to a published scale. Several standardized AE Reporting scales are available. (See Help for links to these scales.)

* Please indicate the scale you intend to use:

- ○ CTC v2.0 (http://ctep.info.nih.gov/reporting/ctc.html)
- ○ CTCAE v3.0 (http://ctep.info.nih.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf)
- ◉ CTCAE v4.0 (http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf)
- ○ CTCAE v5.0 (https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf)
- ○ AIDS Clinical Trials Group (http://aactg.s-3.com/)
- ○ Other

23.7 Reporting Adverse Events

All AEs will be reported to the IRB at least annually.

Reporting Serious AEs

☑ Serious Adverse Events, (SAEs) will be reported to the IRB according to policy, within two working days of identification of the SAE.

Select all that apply:

☐ SAEs will be reported to the Sponsor and or ESCROW

SAEs will be reported to the sponsor within how many days of the event?

☐ SAEs will be reported directly to the FDA, per 21 CFR 312

SAEs must be reported directly to the FDA within 7 days of the event by the investigator/sponsor.

☐ SAEs will be reported to another entity

Describe:

Reporting Unanticipated AEs:

Select all that apply:

☑ UAEs will be reported to the IRB

UAEs that are related and greater than moderate severity must be reported to the IRB according to policy, within two working days of identification of the UAE.

☐ UAEs will be reported to the Sponsor

UAE will be reported to the sponsor within how many days of the event?

☐ UAEs will be reported to the FDA, per 21 CRF 312

UAEs will be reported to the FDA, per 21 CRF 312, within 15 days.

☐ UAEs will be reported to another entity

Describe:

23.8 Reporting Unanticipated Problems

☑ Unanticipated problems involving risks to participants or others will be reported to the IRB and the CRSO within five working days.

23.9 CLIA/CLEP

Only laboratory and research tests that are CLIA/CLEP certified or waived may be used to determine eligibility, shared with research volunteers, and used in clinical decision making.

Select if applicable:

☑ This study includes tests that are not CLIA/CLEP certified; the results of such tests will not be used in clinical decision making, or to determine eligibility, or shared with participants or their health care providers.

23.10 Tissue Repository
Human Tissue and Data Repositories collect, store, and distribute human tissue materials and or data for research purposes. Repository activities involve three components: (i) the collectors of tissue samples\data; (ii) the repository storage and data management center; and (iii) the recipient investigators.

* Select one:

◉ I DO NOT intend to collect, store, and distribute human tissue materials for research purposes

○ I DO intend to collect, store, and distribute human tissue materials for research purposes, therefore this protocol entails the Operation of a Tissue Repository. The IRB requires that the protocol specify the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to protect the privacy of participants and maintain the confidentiality of data.

If you do intend to collect, store, and distribute human tissue materials, you will be asked to upload the following documents later on in the submission:

- A Sample collection protocol (for tissue collector collaborators to follow) and informed consent document for distribution to tissue collectors and their local IRBs.
- A Certificate of Confidentiality (to protect confidentiality of repository specimens and data).
- A Recipients Agreement describing the commitment of the recipient to preserve the anonymity of the samples shared.

24.0 Toxicity Management and Stopping Rules

24.1 * Describe any drug toxicity or other conditions under which the participation of a participant or the conduct of the study would be stopped in order to maximize safety (e.g., toxicity management and stopping rules):

1.Participants may withdraw at any time.
2.Participants may be withdrawn from the study at the discretion of the PI for noncompliance, psychological evaluation, laboratory abnormalities, substance use, unwillingness to continue the study, or disruptive behavior during intervention sessions
3.We will stop the interview if the participant experiences any distress during the interview, and the interview will be discontinued. The steps in the mitigation plan will be followed to refer them to a follow-up Rockefeller University licensed Social worker for further evaluation.

4.The study will also be stopped if unanticipated problems place participants at greater risk of psychological and social harm than previously known or recognized.

*** Indicate withdrawal criteria and procedures below:**

1. Participants may be withdrawn from the study at the discretion of compliance with fasting, psychological evaluation as noted on the psychological instruments, laboratory abnormalities, and substance use.
2. The interview will be stopped if a participant experiences any distress during the interview and intervention, and the interview will be discontinued. The steps in the mitigation plan will be followed to refer them to a follow-up Rockefeller University Licensed Social worker for evaluation

25.0 Compensation/Costs

25.1 *Will any compensation be offered to participants in return for their participation, e.g., direct payment, medical care, tests, etc.?

- ○ No
- ◉ Yes (Please describe)

Please Describe

Participants will receive compensation of $100 for each visit numbered 2 and 3. Additionally, participants will be eligible to receive $20 for every Compassion-Based Resiliency Training (CBRT) class, with an additional $50 bonus for those attending at least 8 out of the 10 CBRT classes. Compensation will be issued in cash at the end of in-person visits 2 and 3 according to the completed activities). Participants who complete all the activities will be paid a total of $450.

Payment will be made to participants who are eligible for and want to receive payment and who fill out a brief form with tax identification information from The Rockefeller University Finance Office.

25.2 * Will there be any costs to participants associated with their participation in research?

- ○ Yes
- ◉ No

26.0 Bibliography

26.1 Enter your bibliography below:

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27.0 Appendices

27.1 Enter your appendices below:

28.0 Funding

28.1 * Do you have sufficient financial resources to support your study?

(•) Yes ( ) No

28.2
If this study is/was pilot funded, please specify dates of funding:

From date:

To date:

28.3 Source of investigational agents:

- ( ) N/A (no investigational agents)
- ( ) Provided by a pharmaceutical sponsor/partner with funding as described below
- ( ) Provided by a pharmaceutical sponsor/partner without additional funding
- ( ) Provided by investigator, participants, or other

28.4 Specify funding by Rockefeller University, industry sponsor and/or grant:

28.5 List grants in which this study is named:

PHS or Non-PHS	Program	Grant Number	Grant Name	From Date	To Date
No results found					

29.0 Clinical Services

29.1

- [x] Well/Minimally Ill
- [ ] Moderately Ill
- [ ] Severely Ill
- [ ] Other
- [ ] Not Applicable

If other than Well/Minimally Ill, please describe:

29.2 * **Does your study group have special care needs?**

○ Yes ◉ No

29.3 * **Does your study have special equipment needs?**

○ Yes ◉ No

29.4 * **Will you require storage space on the clinical units for supplies to conduct this study?**

○ Yes ◉ No

29.5 * **Is special training of hospital staff required?**

○ Yes ◉ No

30.0 Pharmacy Services

30.1 * **Does the study require Pharmacy Services?**

○ Yes ◉ No

31.0 Bionutrition

31.1 * **Will study require patient meals?**

○ Yes ◉ No

If Yes, please specify:

Type of Diet	In/Outpatient	Pack Meal
Standard	☐ Inpatient ☐ Outpatient	◉ Pack Meal
Therapeutic	☐ Inpatient ☐ Outpatient	○ Pack Meal
Research Diet	☐ Inpatient ☐ Outpatient	○ Pack Meal
Formula Diet	☐ Inpatient ☐ Outpatient	○ Pack Meal

Nutrient(s) to be controlled (specify):

31.2 **Will meal times be altered?**

○ Yes ◉ No

If Yes, please explain:

31.3 Does the protocol require any of the following activities?

- ☐ Food Frequency Questionnaire
- ☐ Bod Pod/ Anthropometric Measurements
- ☐ Diet History/ Food Records
- ☐ Diet/ Nutrition Education

31.4 Will food be provided to caregiver, parent or significant other?

○ Yes ◉ No

31.5 For metabolic diets, is diet homogenization required for nutrient analysis by independent lab?

- ○ Yes
- ○ No
- ◉ N/A

32.0 Clinical and Translational Research Facilitation Office

32.1 Indicate navigation assistance requested and/or received in the development of the study:

	Requested	Received
Protocol Development	☑	☑
Protocol Implementation	☑	☑
Protocol Conduct	☐	☐
ACCTS/IRB Submission	☑	☑

32.2 Indicate additional education assistance requested and/or received in the development of the study:

	Requested	Received
IND	☐	☐
IDE	☐	☐
Team Science Education	☐	☐

Study Progress Meeting	☑	☑
Investigator Responsibilities	☐	☐
Regulatory Binder/Folder	☐	☐
Source Documentation	☐	☐
Participant Involvement in Research	☐	☐

33.0 Clinical Research Support Office Resources (CRSO)

33.1 Indicate regulatory input assistance requested and/or received in the development of the study:

Regulatory Support/Design	Requested	Received
General, Vulnerable Populations, Minors, Group Harms	☐	☐
IND/IDE advice, assistance, and referral	☐	☐
Informed Consent/Assent	☐	☐
Data Safety Monitoring Plan	☑	☐
Clinical Trial Registration	☑	☑
Plan For Return of Research Results	☐	☐
Audit/Monitoring Service, Referrals, SOPs	☑	☐

33.2 Indicate recruitment assistance requested and/or received in the development of the study:

Recruitment of Participants	Requested	Received
Recruitment Planning and/or written Plan	☑	☑

Advertising Strategy, Content, Placement	☑	☐
Repository/Research Match Queries	☑	☐
Call Center/Prescreening /Scheduling	☑	☐
Cost Sharing for Advertising	☑	☐

33.3 Indicate community engaging assistance requested and/or received in the development of the study:

Community Engagement	Requested	Received
PHI Statement/Engaging Stakeholders Section	☑	☐
CEnR Navigation – fostering pt /community partnership	☑	☐
Outreach to community/partner /advocacy group/CE Studio	☑	☐

33.4 Indicate other assistance requested and/or received in the development of the study:

Other	Requested	Received
Survey design, fielding, validation	☑	☐
Data transfer and security planning	☑	☐

34.0

BERD: Biostatistics, Epidemiology and Research Design Resource

34.1 Indicate the Biostatistical assistance requested and/or received in the development of this study:

	Requested	Received
Development of experimental design	☑	☑

Power analysis/Sample size determination (# of subjects)	☑	☑
Navigation (Did Statistician participate in a navigation meeting)	☐	☐
Randomization schedule	☐	☐
Data analysis	☑	☐
Development of new statistical techniques for data analysis (Statistical research)	☐	☐
Protocol implementation	☐	☐
Other	☐	☐

34.2 If you are/will be using data analysis specify:

- ☑ Exploratory
- ☑ Descriptive
- ☐ Hypothesis testing
- ☐ Statistical modeling
- ☐ Other

34.3 If you are/will be assisted with protocol implementation, specify:

- ☐ Publication
- ☐ Conference
- ☐ Other (type of dissemination)
- ☑ Grant(s)

34.4 Please select the Biostatistician on this Protocol:

- ☐ Roger Vaughan, DrPH
- ☑ Caroline Jiang, MS
- ☐ Sandra Garcet, PhD
- ☐ Adam Qureshi, MA
- ☐ Other

35.0 Biomedical Informatics Resources

35.1 Indicate Bioinformatics assistance requested and/or received in the development of this study:

	Requested	Received

Microarray analysis	☐	☐
Pathway analysis	☐	☐
RNA-seq analysis	☐	☐
Bioinformatics training and consultation	☐	☐
Bioinformatics experimental design	☐	☐
HPC computing	☐	☐
Other	☐	☐

35.2 If you are/will be using pathway analysis software, specify:

- ☐ Ingenuity IPA
- ☐ David
- ☐ GSEA
- ☐ Other

35.3 If you are/will be using RNAseq analysis software, specify:

- ☐ Tophat
- ☐ Cufflinks
- ☐ Cuffdiff
- ☐ CummRbund
- ☐ STAR
- ☐ featureCounts
- ☐ DESeq2
- ☐ VOOM
- ☐ RNA-SeQC

If other, specify:

35.4 Indicate Medical Informatics assistance requested and/or received in the development of this study:

	Requested	Received
Data storage inside of iRIS	☐	☐
Redcap Database	☑	☑

Custom or Ad Hoc reports	☑	☐
Study plan creation	☐	☐
Specialize database or custom software	☑	☐
Other	☐	☐

36.0 HIPAA Form

36.1 A study's specific HIPAA form signed by the volunteer is required for institutions that are HIPAA covered entities so that they may communicate Private Health Information (PHI) to the Investigator.

Below, Memorial Sloan Kettering Cancer Center, New York-Presbyterian Hospital and Weill Medical College of Cornell University are listed so that that they may report laboratory results and X-ray readings respectively. If you foresee that any other entity may need to provide PHI then add them to the field highlighted in green.

36.2 Name of Study:

Effects of Compassion-Based Resiliency Training (CBRT) Intervention on Racism-based Stress among African Americans: A Pilot Study

36.3 Principal Investigator:

Rachel Wangari Kimani, DNP

36.4 Industry Sponsor:

If the funding source is industry please type in the sponsor here

Who may obtain, use, and/or disclose your health information?

The following persons and organizations may obtain, use, or disclose health information about you.

- The Principal Investigator(s) listed at the top of this form, and persons who assist the Investigator(s) in carrying out the research
- Each research site for this study, including The Rockefeller University, and the research management and support staff and the medical staff at each site
- Health care providers who have provided in the past, or currently provide, health care services to you
- Laboratories and other persons and organizations that will analyze your health information and/or biological samples as part of this study, including Memorial Sloan Kettering Cancer Center, New York-Presbyterian Hospital and Weill Medical College of Cornell University

Other entities that may need to provide PHI:

- UCLA Genomic Core
- Labcorp

- Members and staff of the Institutional Review Board and other boards and committees that watch over research at The Rockefeller University
- Members and staff of The Rockefeller University's Office of Sponsored Research

- The sponsor(s) of the research, named above, and persons who watch over the research for the sponsor (s)
- The United States Food and Drug Administration, other government agencies, regulatory entities and Rockefeller University consultants that watch over the safety, effectiveness, and quality of research and /or fund The Rockefeller University Hospital
- Others (as described here):

What information will be obtained, used, or disclosed?

The persons and organizations listed above may obtain, use, and disclose:

- Information about you that is created or collected during the research study (but not including any HIV-related information)
- Health information in your medical records that is relevant to the research study (but not including any HIV-related information)
- **And**, if checked below:

___ HIV-related information (this includes any information indicating that you have had an HIV-related test or have HIV infection, HIV-related illness, or AIDS, as well as information that could indicate you may have been exposed to HIV)
___ Other information (as described here):
_____
_____
_____
_____

- Other information (as described here):

By signing this form, you give permission to the persons and organizations listed above to obtain, use and disclose your health information noted above.

How will your health information be used?

The health information noted above, as well as information shown by the boxes checked above (if any), may be obtained, used, and disclosed:

- to conduct the research study explained to you during the informed consent process; and
- to assure the quality, safety, and effectiveness of the research study

Please note that the persons and organizations listed above may re-use or further disclose your information if they are permitted by law to do so.

What are your rights?

It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study. Your health care outside the study will not be affected. The payment for your health care and your health care benefits will not be affected.
If you sign this authorization form, you will have the right to withdraw it at any time except to the extent that the persons and organizations listed above:

- have already taken action based upon your authorization;
- need the previously collected information to complete analysis and reports of data for this research; or
- will continue to use and disclose previously collected information as permitted by the informed consent form signed by you (except as to HIV-related information, for which disclosure to new persons or organizations will not occur unless permitted by federal or state law).

If you withdraw the authorization, you will not be permitted to continue taking part in the research study. This authorization form will not expire unless you withdraw it. If you want to withdraw this authorization, please write to the above named investigators.
You have a right to see and copy your health information described in this authorization form in accordance with The Rockefeller University's policies; in certain circumstances where the integrity of the study will be affected, you will not be able to obtain your health records in this study until the study has been completed.
You will receive a copy of this form after you have signed it.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that such information may not be shared without your approval unless permitted by federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

Your signature

I have read this form, and all of my questions have been answered. By signing below, I acknowledge that I have read and accept all of the information above.

_____
Signature of participant or participant's legal representative

_____
Date

_____
Printed name of participant

_____
Printed name of legal representative (if applicable)

_____
Representative's relationship to participant

THE STUDY PARTICIPANT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.

37.0 End of Application Form

37.1 The study application form is complete.

The next step in the submission process is to gather attachments before proceeding to the submission form.

The following submission reports are generated in the Lab/Dept Reports menu, Submission Reports section:

- **Delegation of Authority** (if applicable, and if not previously generated)
- **HIPAA form** (if applicable)
- **CCTS Utilization Report** (required for all submissions)
- **Study Progress Report** (if the study has been managed in iRIS for a minimum of one year, generate the Progress Report from the report menu in iRIS. if the study has not been managed in iRIS for one year, complete the Progress Report located on the IRB website.)

All other required forms can be downloaded from the corresponding sections' help links above or from the IRB website.