Study Protocol

Caregiving While Black-LIVE: Empowering Black Dementia Caregivers to Navigate Care

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PROTOCOL TITLE: Caregiving While Black-LIVE: Empowering Black Dementia Caregivers to Navigate Care

EXTERNAL (NON-EMORY) COLLABORATORS

N/A

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REVISION HISTORY

No need to review this section if this is the first version of the protocol you are submitting to the IRB

Revision #	Version Date	Summary of Changes
1	4/12/2023	Removed language of Part 11 validation

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1. Study Summary

Study Title	Caregiving While Black-LIVE: Empowering Black Dementia Caregivers to Navigate Care
Study Design	2-phase project (Phase 1-user centered design and Phase 2- 1-group feasibility design)
Primary Objective	Assess the feasibility and preliminary efficacy of Caregiving while Black: LIVE in enhancing caregivers' sense of caregiving mastery
Secondary Objective(s)	Determine CWB's improvement in health literacy and emotional well-being
Research Intervention(s)/Interactions	facilitator-guided, face-to-face and asynchronous (self-paced) interactive psychoeducation course
Study Population	African American Dementia Family Caregivers
Sample Size	40
Study Duration for individual participants	6 months
Study Specific Abbreviations/ Definitions	PLWD: Person living with dementia CES-D: Center for Epidemiological Studies-Depression PI: Principal investigator HLQ: Health Literacy Questionnaire CWB: Caregiving while Black LIVE: Learning in vital engagement NIA: National Institute on Aging
Funding Source (if any)	National Institute on Aging (pending)

2. Objectives

The proposed psychoeducation course, ***Caregiving while Black-LIVE*** (Learning In Vital Engagement), seeks to equip and empower Black dementia caregivers with the knowledge, skills, and sense of mastery they need to address and cope effectively within their role broadly, not just in the context of the pandemic. The course, tailored and responsive to the needs of Black dementia caregivers, will be offered to these caregivers in a small cohort format (8-10 caregivers) in which online synchronous (facilitator-guided, face-to-face) sessions augment and complement asynchronous (self-paced) interactive components. Video instruction, resource links, and interactive exercises will promote active and engaged learning and interactivity among cohort members.

We seek to strengthen caregiving self-efficacy in Black caregivers while acknowledging the social and cultural realities of this historically minoritized racial and ethnic group. Our premise, based on Social Cognitive Theory[14,15] and the Sociocultural Stress and Coping Model[16], is that our psychoeducational course will enable Black caregivers to understand the racial disparities and inequities that substantially affect their caregiving challenges, acquire self-assessed competence in handling these challenges, and deploy effective, problem-focused coping strategies to address them, all of which, in turn, will lessen emotional distress. We propose the following aims:

Aim 1. Using an iterative, user-centered design approach, reconfigure the *Caregiving while Black* asynchronous program into a manualized and substantially more interactive online synchronous (facilitator-guided, face-to-face) and asynchronous (self-paced) interactive psychoeducation course, Car*egiving while Black-LIVE*.

Aim 2. Assess the feasibility, usability, acceptability, and preliminary efficacy of the *Caregiving while Black-LIVE* course, employing a mixed-methods pre-post no control design to gather formative and evaluative data from four cohorts (n=10 each) of Black caregivers. We will employ established instruments to gather baseline and immediate post-course data on caregiving mastery, health literacy, and emotional well-being (i.e., stress, anxiety, and burden).

Exploratory Aim. Determine sustained effects in engaging in *Caregiving while Black-LIVE* by collecting data 3 months after course completion.

3. Background

Disparities for Black Caregivers. Recently heightened racial tensions, pandemic-related longer days of caregiving, shuttering of community-based care alternatives, and the ongoing challenge of navigating persistent race- and class-based disparities in the healthcare system underscore and add to the challenging and multifaceted roles Black family caregivers normally play.[18,19] Black caregivers typically deal with the complexities of caregiving through the lens of race and health disparities.[2,3,13] Prior work by PI Epps found that Black dementia caregivers felt that the health system they experience is "broken," that being "a person of color" contributed to their difficulties navigating the health system, and being dismissed by providers.[18] Due to the centuries-old disadvantaged social history of Black Americans, a number of unique stressors, vulnerabilities, but also resources, have emerged which could inform and affect Black caregivers' experiences and well-being.[2-5]

Black caregivers and their care recipients experience disparities in care, have lower rates of formal service use, and are generally under-treated.[7,8,20-23] More specifically, disparities in healthcare quality include higher rates of missed or delayed dementia diagnoses among Black older adults,[21,22] and a lower likelihood of receiving dementia medication or care from a dementia specialist.[23,24] Notably, disparities exist for caregivers of persons living with Alzheimer's disease and related dementias (PLWD) as well: Black caregivers report more time spent in caregiving than do White caregivers and use less respite service.[11] Black caregivers also report increased difficulties navigating the healthcare system.[6,8,18,25] Further, racial differences and disparities related to caregiving experiences exist at alarming rates for use of supportive services (33% vs 25%), care hours (54% vs 39%), and living below the federal poverty level (32% vs 12%) among Black caregivers compared to White caregivers.[7] Black families faced with dementia (Medicare beneficiaries) incur 1.7 times more in healthcare cost and higher proportions of preventable hospitalizations than White families.[26] Among PWLD, Black older adults account for nearly a third of preventable hospitalizations.[23] It should be noted that these disparities are not due to biological

or genetic differences between racial or ethnic groups, as race and ethnicity are social constructs. Rather, it is more likely due to lived experience and structural racism leading to disparities in social and structural determinants of health.[9,27] These amplified experiences highlight the importance of this proposal to further develop a course that addresses the cultural and practical reality of supporting a PLWD as a Black in America, as Black caregivers desire better access to culturally relevant caregiving and self-care information.[18] One potential tool to mitigate the aforementioned health disparities is to offer an education tailored and responsive to the needs of Black caregivers.

This project responds to a compound gap in psychoeducation aimed at promoting caregiving mastery. A variety of psychoeducation interventions using a variety of distance delivery methods to engage caregivers in active learning environments have demonstrated benefits in enhancing caregivers' day-to-day caregiving self-efficacy (mastery), with resulting positive outcomes for both caregivers and care recipients.[28-34] Few of these programs have been specifically adapted for or targeted to the development of mastery in Black caregivers, and none have focused principally on care navigation skills (e.g., navigating healthcare and other systems of support, including family support) and mastery development in any caregiving group. The proposed synchronous/asynchronous psychoeducation program, ***Caregiving while Black-LIVE*** (Learning In Vital Engagement), seeks to address this gap. This course aims to enhance Black caregivers' capacity to cope effectively with their caregiving role of navigating care and the world of healthcare in ways that take into consideration the social and cultural context of their unique life experiences.

4. Study Endpoints

The key study outcomes are measures of caregiver psychological well-being and confidence in their ability to provide effective care to the PLWD. The study ends after participants complete the course and the follow-up interviews conducted to gather these study endpoints/outcomes.

5. Study Intervention/Design

We propose a 2-phase project. In the first phase, we will employ an iterative user-centered design approach to review and revise the pilot asynchronous psychoeducation curriculum, Caregiving while Black, and expand it into Caregiving while Black-LIVE, adding a synchronous facilitator-guided cohort-structured component to the original self-paced asynchronous curriculum material. In the second phase, we will conduct a prototype test of the course to assess its preliminary efficacy and its usability, acceptability, and feasibility.

6. Procedures Involved

Aim 1. (Months 0-9) Using an iterative, user-centered design approach, reconfigure the *Caregiving while Black* asynchronous program into a manualized and substantially more interactive online synchronous (facilitator-guided, face-to-face) and asynchronous (self-paced) interactive psychoeducation course, *Caregiving while Black-LIVE*. End-users (n=8-10 Black caregivers per design group) will be engaged in a 3-part iterative process of defining the structure and delivery modalities of the curriculum elements.

Design & Procedures. Aim 1 entails the transformation of the fully asynchronous *Caregiving while Black (CWB)* program into *Caregiving while Black-LIVE (CWB-LIVE), a psychoeducation program* that aims to intensify the development of caregiver mastery by integrating the online learning assets of *CWB* with synchronous, group-based opportunities for interactivity and active learning. Our overall backward integrated design approach to the development of the *CWB-LIVE*

course is one we have used successfully in Co-I Hepburn's work to develop the synchronous/asynchronous Tele-Savvy program.[33] End-users will be engaged throughout in a 3-part iterative process of defining the structure and delivery modalities of curriculum elements, repurposing (as necessary) the considerable existing instructional assets of the prototype *CWB* program, identifying and collaborating in the production of needed new assets, structuring and scripting the synchronous components of *CWB-LIVE*, and crafting the granular elements of course facilitator and caregiver manuals. They will also assist in strategizing how to attract and enroll caregivers who might be skeptical of academic and/or online programs.

Prior to engaging end-users, the investigative team and educational design specialists will establish a preliminary set of learning objectives for *CWB-LIVE* and create a storyboard for the program that builds on the original *CWB* curriculum and feedback from *CWB* participants. The *CWB-LIVE* storyboard will serve as a roadmap of the content and sequence of course materials. The storyboard will describe how the course purposefully interweaves instruction, illustration, practice, and coaching to strengthen mastery and also identify and establish the rationale for the use of synchronous and asynchronous methods for achieving the learning goals. With the storyboard in hand, we will convene the first (recorded) 90-minute videoconference design group composed of 8-10 Black caregivers who are familiar and not familiar with the *CWB* course. The group will be led by PI Epps, supported by a trained doctoral student who will take field notes.

Participants in each group will be given a $40 gift card in appreciation of their contribution to *CWB-LIVE* development. In the first part of the session, caregivers will be asked to describe their caregiving and healthcare navigation experiences and to identify ways their caregiving might be strengthened with education. The intent is to establish a heightened sense of empathy within the group for the experience of the Black caregiving and navigation experience. Then, set against this backdrop of the lived experience of the participants, we will present the preliminary storyboard (Table 1) for *CWB-LIVE* as well as exemplar elements from *CWB* and seek participants' feedback: Is this useful? Needed? Still relevant? What is missing? How can it be strengthened? Are the learning objectives appropriate? Which parts are best delivered in a group setting? Which are well suited to self-paced independent learning?

Table 1. Caregiving while Black Course Topic Outline

Key Sections	Topics Within Sections	Lessons
Course Introduction	Welcome	How to Navigate this Course
	Introduction to the Course	The Purpose
		Dementia in the Black Community
		Dementia and Risk for COVID-19
		Public Health Crisis: COVID-19
Navigating the Healthcare System	Introduction	Introduction
	Effective Communication in Healthcare Settings	Health Literacy
		Talk Like Members of Your Healthcare Team
		Navigating Your Next Doctor's Appointment
	Navigating the Hospital	Entering the Healthcare System
		Pathways of the Healthcare System
		Safe Use of the Emergency Department
		Who are the Key Players
	Understanding Insurance Coverage	Insurance and HIPPA
	Care Coordination	Having a Good Plan of Care
		Discharge Planning
		Home Care vs. Home Health
	Hospice and Palliative Care	Palliative Care vs. Hospice
Managing Home Life Managing Home Life	Introduction	Introduction
	Caregivers as Healthcare Providers Guiding your Person's Day	The Clinical Role of the Caregiver
		The Challenges of Disease Progression
		Planning your Person's Day
	Identifying, Accessing, and Using Resources Daily Management	Reliable information, Fake News, and Scams
		Accessing Resources
		Medication Management
		Safe at Home
	Developing Plans of Care	Life Planning
		Crisis Planning
		Your Emergency Grab and Go Kit
Caregiver Self-Care	Introduction	Introduction
		COVID-19 and Caregiving
	Mental Wellbeing	Assessing for and Combating Isolation
		Assessing Your Feelings
	Deeper Dive Self-Care Strategies	Implementing Self-Care
	Respite Care	What Does Respite Care Mean?
	Religiosity and Spirituality	Feeding Your Spirit
	Dealing with Death and Grief	Dealing with Your Person's Death

The transformation will continue in this fashion, engaging two more design groups of 8-10 Black caregivers in recorded 90-minute videoconferences, led by Dr. Epps. In each design group, following a segment in which participants reflect on their experiences serving as caregiver navigators, they will be presented with a storyboard that had been revised based on the analysis of the prior group and shown exemplar materials. In each group, the design probes will ask: What is missing? Where is emphasis needed? What is irrelevant? What is/are the key takeaway

lesson(s)? Do instructional methods encourage involvement and promote the specific caregiving mastery at which we are aiming? Following the same analysis method described above, the team will, after the third group, go into full production mode.

These design group activities will enable us to refine and finalize *CWB-LIVE* content and synchronous/ asynchronous delivery strategies. We will work with our instructional design specialists to finalize the look, feel, and flow of the course, embed it on the learning management platform (i.e., Canvas), and produce an accompanying caregiver manual and other associated course materials (e.g., workbook, reflective journal, and course completion guide). The instructional design team will record any additional video assets – likely brief (4-8 minute) mini-talks provided by our team and other experts as well as collaborating Black caregivers – that will introduce and reinforce the text and pictorial content of the course that was identified as missing from the original course. Based on previous experience, video production should take no more than three weeks, then editing and integrating these materials into the revised course format should take no more than three weeks.

Aim 2. (Months 10-24) Assess the feasibility, usability, acceptability, and preliminary efficacy of the prototype *Caregiving while Black-LIVE* course. We will employ a mixed-methods pre-post no control design to gather formative and evaluative data from four cohorts (n=10 each) of Black caregivers. We will gather preliminary efficacy data on caregiving mastery, health literacy, and emotional well-being (i.e., stress, anxiety, and burden).

Design & Procedures. Accessing the recruitment resources identified above, we will recruit 40 Black caregivers in four cohorts of 10 each to participate in the prototype test. Caregiver Inclusion Criteria: (a) at least 18 years of age; (b) family member (or friend) who self-identifies as Black American and as the principal caregiver of a community-dwelling PLWD (not in hospice care) and who is the principal companion of that person during healthcare encounters; (c) provides some hands-on care multiple times a week; (d) has access to an electronic device and/or access to broadband internet; and (e) able to speak and understand English. Caregivers are not required to be co-located with the care recipient. Caregiver Exclusion Criteria: (a) has plans to relinquish caring responsibilities for PLWD; or (b) considering moving the PLWD to an institutional setting within the next 6 months.

As individuals are identified, we will contact them, obtain their consent for participation, and gather baseline data. Once we have engaged 10 participants, we will enroll them in the course, provide instructions for accessing the weekly sessions and course online, and mail out supplemental course materials. The Canvas platform will enable the research team to monitor each individual's movement in the cohort through the asynchronous part of the course. Nudges and reminders to view these materials will be sent twice a week via text or email with participant's consent. Synchronous sessions will be conducted on a videoconferencing platform (i.e., Zoom) and facilitated by PI Epps. If participants miss a synchronous session, we will contact them to encourage participation and address any issues they may be having. The course coordinator who will monitor caregivers' participation in the interactive exercises will also contact anyone who appears to be falling behind. We expect participants to remain engaged throughout the course. Within 2 weeks of course completion, we will collect the same quantitative interview data (see below) and an evaluation survey we will develop. To address the **Exploratory Aim** of determining sustained effects in engaging in *Caregiving while Black-LIVE*, we will collect the same quantitative interview data at 3-months after course completion. The same pattern of recruitment, enrollment, and data collection will be followed with the second, third, and fourth cohorts.

After each cohort, we will purposively select 4-6 caregivers to participate in semi-structured phone/video interviews (total n=16-24) based on varying caregiver characteristics and findings from baseline quantitative data. Interviews will last approximately 45 minutes and will pose questions about the overall contribution of the course to their own perceived sense of competence as caregiver navigators. We will also seek their responses to the course and delivery (Acceptable? Usable? Feasible? Relevant? Enough? Too much? What is missing? How to improve?). PI Epps will direct the qualitative component of the study, designing the semi-structured interview protocol, overseeing the interviews, to be conducted by a doctoral student, and analysis procedures. We will provide $40 gift cards for participation in each quantitative and qualitative interview conducted.

Data Collection & Management. Using established instruments, we will collect data on participants' self-efficacy (mastery; 6- scales, 3-6 items , α =.71-.92),[42] stress (14-item; α =.88),[43] depression (20-item; α =.90),[44] anxiety (20-item; α =.95),[45] burden (22-item; α =.91),[46] health literacy (9 subscales; 4-6 items, α =.80),[47] and, at baseline, their reasons for caregiving (10-item, α =.86),[13] and experience of medical discrimination (8-item; α =.89)[48] through 30-minute phone/video interviews. A separate, team-developed evaluation questionnaire, to be administered at week 12 through REDCap, will assess issues of course acceptability and utility and participants' sense of benefit. Aim 2 baseline and follow-up instrument-based quantitative data and Exploratory Aim 3-month quantitative data will be gathered through interviews conducted by phone or videoconference by an interviewer trained and supervised by Co-I Hepburn. At the time of each interview, quantitative data will be entered directly into a dedicated project tablet computer and saved on Emory's secure REDCap platform set up to include, where possible, data delimiters to ensure correctness and minimize missing data. Data will be exported weekly and analyzed for data cleaning and verification. Upon completion of each cohort data-gathering point, all data will be merged for scale computation, aggregation, and analysis.

Data Analysis Plan. Descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of all data. For all multi-item scales, internal consistency will be examined using Cronbach's alpha and associated statistics (e.g., item-total correlations, alpha if item deleted). To determine the feasibility of collecting data on caregiving well-being measures for a subsequent clinical trial, preliminary analyses will examine baseline differences among completers and non-completers using 2-group comparison tests (t-tests and non-parametric equivalent tests for continuous variables (normally or non-normally distributed) and Chi-Square tests for categorical variables). The association of predisposing factors (demographics, caregiver history, relationship and care recipient status at baseline) with changes in outcomes over time will be examined to identify potential covariates. Where significant associations with baseline measures are detected, these potential confounders will be controlled for in subsequent analyses using covariate model adjustments. We will use multilevel longitudinal modeling analysis to test for significant changes over the 3 time points from baseline to 2- and 12-weeks post course completion. Given an expected final sample size of 36 (assuming 10% attrition to reduce threats to validity)[49] with data completed at the 3 time points, we will be powered at 80% power and 5% level of significance to detect a large effect size (Cohen's f = 0.53) for changes from baseline.

The post-course qualitative interviews will be analyzed under the direction of PI Epps and provide information about the feasibility, usability, and acceptability of course material and overall course

synchronous/asynchronous design. Three other sources of information will contribute to our ability to move forward with the preparation of a revised course. The faculty-moderated sessions will enable us to gauge caregivers' understanding of, reactions to, and apparent benefit from individual segments of the course. The Canvas platform allows us to monitor caregivers' course behaviors (e.g., time spent on segments, repeated viewing of segments, extent of participation in interactive components). This information may point to the relative importance of segments as well as the usability of interactive components. Co-Is Hepburn and Clevenger will lead the team's efforts to distill these data strands into practical course revision design activities with the Emory Nursing Experience instructional design team to map the steps needed to produce a final synchronous/asynchronous course version.

Activities	Year 1				Year 2			
Phase 1	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
IRB approval; hire and train staff	X							

7. Data Specimen Banking

De-identified transcriptions of audio-recorded course activities and open-ended interviews will be stored on One Drive, accessible only to the study investigators. De-identified interview-gathered questionnaire data regarding caregivers' psychological well-being and self-assessment of competency will be stored in REDCap for analysis. All study participants will be assigned ID numbers. The file linking identities to IDs will be stored separately on the PI's encrypted work-computer.

The final dataset will include standardized measures of caregiver well-being and competence and will be stored in PI Epps's office in the Emory University Nell Hodgson Woodruff School of Nursing in Atlanta, Georgia. Data from this study will be available to qualified researchers through a data sharing agreement that is fully consistent with UC Davis (funding sponsor) data sharing policies and applicable laws and regulations as well as official policies and practices established by Emory University. Although these data will be de-identified prior to release for sharing, there remains a possibility of deductive disclosure of participants with unusual characteristics. Therefore, this data sharing agreement will require: 1) a commitment only to use the data for research purposes and not to identify any individual participant; 2) a commitment to securing the data using appropriate computer technology; and 3) a commitment to destroy or return the data after analyses are completed.

8. Sharing of Results with Participants

Results of each interactive course activity will be shared with participants as each iteration of the course is developed. At study's end, we will prepare a lay report detailing the results of the study and distribute this report to study participants. **This report will be used to debrief study participants after study participation completion.**

9. Study Timelines

The overall project has a timeline of 2 years. Participants take part in the study for a total of 6 months between years 1 and 2. This will include recruitment, enrollment, interviews, and surveys.

Recruit members for design activity groups	X							
Quarterly meetings with community partners	X	X	X	X	X	X	X	X
Focus Group #1, Analysis, and Course Revision		X						
Focus Group #2, Analysis, and Course Revision		X						
Focus Group #3, Analysis, and Course Revision			X					
Finalizing course revision			X					
Phase 2								
Recruitment			X	X	X	X		
1st Cohort Participation & Data Collection				X	X			
2nd Cohort Participation & Data Collection				X	X			
3rd Cohort Participation & Data Collection					X	X		
4th Cohort Participation & Data Collection					X	X		
Analysis and Dissemination						X	X	X
Revision and Next Steps (grant applications)							X	X

10. Inclusion and Exclusion Criteria

Caregiver Inclusion Criteria: (a) at least 18 years of age; (b) family member (or friend) who self-identifies as Black American and as the principal caregiver of a community-dwelling PLWD (not in hospice care) and who is the principal companion of that person during healthcare encounters; (c) provides some hands-on care multiple times a week; (d) has access to an electronic device and/or access to broadband internet; and (e) able to speak and understand English. Caregivers are not required to be co-located with the care recipient.

Exclusion Criteria: Those who cannot provide consent, are not yet adults (<18 years of age), prisoners, cognitively impaired adults, has plans to relinquish caring responsibilities for PLWD or considering moving the PLWD to an institutional setting within the next 6 months, and who are not able to clearly understand English.

11. Population

We will not include any of the following special populations in our research.

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Cognitively impaired or Individuals with Impaired Decision-Making Capacity
- Individuals who are not able to clearly understand English

Community Participation

We will have participation from four community partners for this study. Community partners will consist of groups that serve and support caregivers. They will meet with the research team monthly to advise on the design of the course/study. Research status updates and preliminary results will also be shared with community partners.

Our study is focused on one race and ethnicity, Black/African American. For the purposes of this research, the following definitions will be used for race and ethnicity. If your research questions involve race and/or ethnicity, please clarify the following:

- Race: any one of the groups that humans are often divided into based on physical traits regarded as common among people of shared ancestry. Race categories generally reflect social definitions in the US and are not an attempt to define race biologically, anthropologically, or genetically.
- Ethnicity: Shared culture, such as language, ancestry, practices, and beliefs.

For the purposes of this research, participants will be asked to identify their race and/ethnicity in this study. Only those individuals identifying as Black and/or African American will be included in this study.

This research does not involve individual who are vulnerable to coercion or undue influence.

12. Local Number of Participants

We plan to recruit 40 participants for the course. All participants will be recruited from networks around the United States. All will be African American with a goal of 32 identifying as female.

13. Recruitment Methods

The investigative team will draw on their multiple involvements and established national networks as recruitment sources to enroll a representative group of Black caregivers. PI Epps's established community advisory board and ongoing work with Black faith communities and organizations will enable broad recruitment possibilities. Co-I Clevenger's clinic has patient panel of >600, more than 40% of whom are Black Americans. Established partnerships with Black community and civic organizations will also be used.

<u>Eligibility Determination</u>

Screening will be conducted by distance means (phone or videoconference) by study team members.

- Is the potential subject providing care for a family member or friend? If so:
    - Does that person have a diagnosis of dementia or exhibiting signs of memory loss/cognitive impairment?
    - Is the person living in the community?
    - Is the caregiver the main caregiver for the person?
- Does the caregiver have an or access to an electronic device with internet access?
- Can the person read and understand English?

The screening calls or videoconferences will not be recorded. No identifying information about the screening calls, including the person's IP address, will be recorded.

14. Withdrawal of Participants

Study participants may request, verbally or via course message or email, to withdraw from the study at any time. Likewise, the study team may also withdraw a participant if their caregiving situation changes (e.g., if the person for whom they are providing care is institutionalized or dies).

15. Risk to Participants

We believe that caregivers taking part in the trial of the *Caregiving while Black* course will be exposed to very low risks. The two main risks are of transient emotional distress and breach of confidentiality. These are described below.

Transient emotional distress. As persons providing care to a person living with dementia and doing so under the strains of the threat and restrictions of a pandemic, subjects in this study are already very likely to be experiencing a higher-than-normal level of stress and distress. The content of the course will draw their attention to their situation in ways that might make them more acutely aware of their distress or cause them to lower the defenses they might have erected to fend off the distress. Likewise, the subject matter raised, and the questions posed in the research interviews, the focus groups, and semi-structured interviews may also call attention to distressing matters and situations.

Based on our research experience with similar study subjects and the same questions and methods, we judge the occurrence of such distress to be relatively infrequent (perhaps in 25% of cases), of low magnitude (perhaps a 2 on a scale of 10, where 10 is the highest), of very brief duration, and fully reversible. The research interviewer will be trained to recognize such events and to provide ways to back away from and calm them. The participating investigators who would conduct the focus groups or semi-structured interviews are experienced in working with dementia caregivers and in managing such transient events in ways that permit the caregiver to work through them in a brief, respectful, and calming manner.

We can see no procedures in the study that might produce currently unforeseeable risks, and we can see no procedures that might put others at risk who are not in the study.

Threats to Confidentiality.

The study will gather personal information on all participants (name, email, address, etc.). This information will not be attached to any research study file. A unique ID number will be assigned to each participant, and all research documents pertaining to that participant (the data stored in REDCap or the transcriptions of the focus groups and individual interviews) will only be stored using that ID number. The file with baseline personal information and the file that links personal identifiers to ID numbers will be stored separately in the Emory encrypted computer in PI Clevenger's office. Any later sharing of data from the study will be done according to a NIA compliant data and resource sharing agreement, and those data will be completely de-identified.

16. Potential Benefits to Participants

Although we are careful not to assert this to potential study participants, we believe the program will provide them with knowledge and skills that will help them to better negotiate the additional dementia caregiving challenges.

In terms of a knowledge contribution to the field: If this trial demonstrates positive preliminary efficacy in reducing caregiver distress and enhancing caregiver mastery, it will add to the evidence that a psychoeducational approach (developing skills, knowledge, and competence through an active and interactive learning strategy) is effective with this important population. This study's approach is aligned with other work by the investigators and with investigators supported by the Emory Roybal Center for Dementia Caregiving Mastery and with clinical practice at the IMCC that developing caregiver competence reduces caregiver distress.

In terms of the caregiver knowledge that would be strengthened: the program aims to increase caregivers' knowledge about ways to manage day-to-day life with a person living with dementia, knowledge about infection control practices to minimize risk of viral infection; and knowledge about navigating the healthcare system.

As noted in an above section, participants will receive a $40.00 gift card (e.g., Amazon card) for each research interview, focus group, and/or semi-structured interview in which they take part.

17. Compensation to Participants

We will provide $40.00 gift cards (e.g., Amazon card) to participants for each interview in which they take part. All trial participants will be asked to take part in a baseline interview and then subsequent interviews 3 and 6 months later. About 20% will be asked to take part in semi-structured interviews following course completion. Thus, the maximum payment for any participant would be $160.00 and tax information will not be required. If participants withdraw early, they will only receive payment for interviews that they participated in.

18. Data Analysis, Management and Confidentiality

All data entry screens are set up in Research Electronic Data Capture (REDCap) and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data. Data will be exported into SPSS monthly, and syntax run for cleaning, further data verification and file concatenation. Descriptive statistics will be computed through SPSS v 24 to examine participant characteristics. In preliminary analyses, descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of merged files.

Descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of all data. For all multi-item scales, internal consistency will be examined using Cronbach's alpha and associated statistics (e.g., item-total correlations, alpha if item deleted). To determine the feasibility of collecting data on caregiving well-being measures for a subsequent clinical trial, preliminary analyses will examine baseline differences among completers and non-completers using 2-group comparison tests (t-tests and non-parametric equivalent tests for

continuous variables (normally or non-normally distributed) and Chi-Square tests for categorical variables). The association of predisposing factors (demographics, caregiver history, relationship and care recipient status at baseline) with changes in outcomes over time will be examined to identify potential covariates. Where significant associations with baseline measures are detected, these potential confounders will be controlled for in subsequent analyses using covariate model adjustments. We will use multilevel longitudinal modeling analysis to test for significant changes over the 3 time points from baseline to 2- and 12-weeks post course completion.

Sample size and power: Given an expected final sample size of 36 (assuming 10% attrition to reduce threats to validity)[49] with data completed at the 3 time points, we will be powered at 80% power and 5% level of significance to detect a large effect size (Cohen's *f* = 0.53) for changes from baseline.

The study team for this study will be comprised of the principal Investigators, study coordinators, and co investigators/research assistants. The coordinator and co-investigators will be responsible for the day-to-day operations of the study including recruitment and data collection management and analysis. The administrative site will be at Emory University, Nell Hodgson Woodruff School of Nursing. All team members have completed CITI training. Study-specific training for staff who will be obtaining data by interview.

Dr. Epps is the primary individual charged with identification and reporting of all adverse events (AE) and serious adverse events (SAE). Dr. Epps will provide systematic routine monitoring for the following central elements: protocol eligibility (direct source documentation of eligibility as defined in the protocol), appropriateness of consent documentation, and timeliness and accuracy of data. Monitoring reports will be conducted on a bi-weekly basis and as needed and will be reviewed at the weekly core team meeting of the investigator team.

All caregiver survey assessment data will be audited upon completion of the study. Each audit will consist of review and evaluation of 1) conformance with informed consent requirements; and 2) individual subject case review to detect low data quality (e.g., inconsistent responses on a data element that should be the same throughout the study period, such as age within 1 year). All data that impact on the interpretation of primary study endpoints will be verified with source documents. Investigator compliance with the protocol also will be evaluated. We will encourage a culture of transparency to encourage self-report of protocol breaches.

19. Provisions to Monitor the Data to Ensure the Safety of Participants

This study does not involve more than minimal risk to study participants and will not require a data safety monitoring board (DSMB). However, we will incorporate a data safety monitoring plan (DSMP)ongoing monitoring of this study will be conducted by the PI Epps and research team throughout the study to ensure the study is conducted according to the approved protocol. In addition, Emory University's IRB will conduct regular reviews of study protocols, changes in study protocols, and adherence to protocols in the field. The PI Epps is required to report any unexpected study-related adverse events to the Emory IRB and NIH. An independent safety monitor or a data and safety monitoring board will not be used.

Plans for Assuring Compliance with Requirements Regarding the Reporting of Adverse Events: The Principal Investigator is responsible for reporting serious adverse events to the Emory's IRB and NIH within 48 hours of the occurrence.

A serious adverse event is defined as one that: is fatal or life-threatening (i.e., results in an immediate risk of death); requires or prolongs hospitalization; results in persistent or significant disability; is a birth defect; or is an important medical event that when based upon appropriate medical judgment, may jeopardize the participant, and may require medical or surgical intervention to prevent one of the outcomes listed above. Serious adverse events are not expected to occur during this study.

If there are instances of severe distress observed during the interviews, we will provide the caregiver with a list of resources that the caregiver may use, such as counseling services or resources offered by Alzheimer's Association. In emergent circumstances, the we will make a referral to the local emergency room.

Plans for Assuring Data Accuracy and Protocol Compliance: Under the direction of PI Epps, all data will be managed in a secure fashion. All of the data will be kept on a secure server. In all of the data files, data will be coded by identification number only. Participants' names will be separated from the data and kept on a secure server or in a locked file cabinet. Access to the secure server and the file cabinet will be strictly controlled by the Principal Investigator.

Data Maintenance: We will use REDCap to minimize data entry errors. All data entry screens are set up in REDCap and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data.

20. Provisions to Protect the Privacy Interest of Participants

Protection of Privacy Interests.

There are very few threats to participants' privacy interests involved in the study, and below we describe how we will minimize and manage those threats:

- Except in the focus groups in which we will ask 20% of subjects to take part, there is no direct contact between and among study subjects. Participation in these focus groups is entirely voluntary; no identification is provided about participants to other participants, and participants can choose to take part without video.
- The only personal information to be obtained will be gathered in baseline interviews; we have described above the measures we will take to remove identifiers from the data stored in REDCap.
- The research interviewer will be trained by investigator Hepburn in techniques designed to make participants feel at ease with the questions being asked in the research interviews. Training will involve simulated research interviews conducted with project

investigators by the research interviewer in which the interviewer will be expected to react effectively to situations in which the interviewee exhibits signs of feeling discomforted or intruded upon.

- The focus groups and semi-structured interviews will be conducted by study investigators, all of whom are experienced in interacting with caregivers and helping them to feel at ease in situations that might feel intrusive or distressing.

As noted above, all confidential data will be separated from REDCap files and transcripts, all of which will use ID numbers, and the confidential material will be stored separately in PI Epps's Emory encrypted computer. None of the data from the study will be entered into participant's medical records. Under the direction of Drs. Epps all data will be managed in a secure fashion. All the data will be kept on a secure server. In all the data files, data will be coded by identification number only. Participants' names will be separated from the data and kept on a secure server or in a locked file cabinet. Access to the secure server and the file cabinet will be strictly controlled by the PI Epps at Emory University. Audio recordings of qualitative interviews will be destroyed after the completion of the study and transcripts are confirmed.

We will follow sponsoring agency policies in retaining and destroying identified study information.

Participants will be informed that their personal information we only be shared with the members of the research team as they will used this data to contact them during business hours to schedule interviews.

We will allow participants to break up interviews to make them feel at ease with research interviews. The research interviewer will be trained to be alert for such moments where the participants may feel uncomfortable and will be able to provide reassurance, offer a break from the interview, and/or reschedule the remaining portion of the interview.

21. Economic Burden to Participants

Participant will be responsible for any cost associated with internet services during their time in this study.

22. Informed Consent

Interested individuals will be contacted by the PI or member of the research team to screen for eligibility using inclusion criteria and to schedule a time to consent prior to data collection. If eligibility criteria are met, individuals will be scheduled to be consented by the study coordinator or investigator on the research team.

We will have 2 options to obtain consents. **Option 1.** We will email the consent document in an encrypted email to participants, discuss the informed consent over the phone or using Emory Zoom videoconference (using log in password), and have the participant email the signed consent

back encouraging them to reply to the encrypted message. **Option 2.** We will email a link to the consent via REDCap to the participant, discuss the informed consent over the phone or using Emory Zoom videoconference (using log in password), and have the participant provide a digital signature via REDCap. The uploaded consent to the IRB application will be used and uploaded to REDCap to obtain digital signature.

Consents will be obtained prior to data collection and investigators and the study coordinator will be responsible for obtaining consent.

The following measures will be implemented to minimize the possibility of coercion or undue influence: explaining the (a) voluntary nature of participation; (b) any alternatives to participating; (c) ability to withdraw at any time; and (d) fact that the decision whether to participate will have no impact on the availability of care through Emory Healthcare System.

All aspects of the study will be communicated to the participant. We will make it clear that this is a feasibility/pilot study. We will also make it clear that individuals will have opportunity to pose questions about the project. Consent will be sought and documented when provided. Consent discussion will take approximately 25 minutes.

In compliance with Emory University policy, the Fully Asynchronous Online Savvy program pilot/feasibility project will be registered with, and information submitted to ClinicalTrials.gov in a timely manner. The informed consent procedure and its documentation will note the registration of the trials in ClinicalTrials.gov.

Non-English-Speaking Participants: N/A

As part of inclusion criteria, participants will be required to read and understand English. The reason for this exclusion of subjects with limited English proficiency is because the education program will only be provided in English.

23. HIPAA

Protected health information will not be collected for this study.

24. Setting

Emory University, School of Nursing will be the main site for this research and remote data collection. Participants will be recruited from multiple in person and virtual platforms such as caregiver support groups, faith-based organizations, social gatherings, and professional/network meetings. All consenting and research interviews will be done via Emory secured zoom platform.

25. Resources Available

This research will have administrative support from the Emory Roybal Dementia Caregiving Mastery Center. It is, as described above, also being conducted within the context of the study team members' several involvements in local, state, and national engagements, all of which are directly related to issues of dementia care and the support and development of the capacity of family caregivers to provide effective care to community-dwelling persons living with Alzheimer's disease and related disorders.

Recruitment of 40 study participants seems very feasible. Within the immediate reach of the study team there are at least 1,000 eligible caregivers, and our extended reach, especially through the NIA-supported network of Alzheimer's Disease Centers (with several which we have worked closely) there are many thousands more.

All study personnel are currently working from home, but in a phase 3 or 4 relaxation of restrictions situation, the Center has designated space in the School of Nursing, and all investigators have private offices and Emory encrypted computers. Under both scenarios, the facilities are appropriate for conducting this fully online study.

We have described above the measures we will take to ensure that any transient emotional distress participants might experience can and will be handled at the time of occurrence, and we do not foresee the need for any additional psychological resources. The study does not involve procedures that might require medical resources.

The procedure for training the interviewer was described above. The PI will train the program coordinator in the conduct of the Eligibility procedure and the Consent Call, should she be the team member to handle either or both.

A protocol from another study will be in place to identify participants whose scores on a set of three questionnaires exceed established limits; in such cases, one of the investigators will contact the individual to check on his/her safety and well-being.

Weekly research team meetings will be held to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

The setting for the project is that of a major research-intensive school of nursing at Emory University. The investigators for this project are all faculty members in the Nell Hodgson Woodruff School of Nursing. In fiscal year 2018, the school received $17.9 million in external sponsored funding and $8.9 million in National Institutes of Health research funding, ranking 3rd nationally in NIH funding among schools of nursing. U.S. News & World Report ranked the school's graduate programs 4th overall. Currently, the school has 443 baccalaureates, more than 269 masters, 30 PhD, and 52 DNP students as well as two postdoctoral fellows. Students who complete their degrees go on to become national and international leaders in patient care, public health, government, research, and education. The school's PhD program is focused on generating

new knowledge to improve health and health care quality and developing the next generation of nurse scientists and educators who will change the face of health care. Emory University is well qualified to lead this project.

Befitting a research-intensive environment, faculty members in the school engage across (and beyond) Emory to pursue a wide variety of scholarly endeavors and innovations, and the activities of the investigators embody these pursuits. In addition to leading their own research and implementation projects, the investigators are engaged in leadership or engagement roles in Emory's NIA-supported Alzheimer's Disease Research Center (Hepburn, Clevenger, Epps), the Georgia state-supported Georgia Memory Net (Hepburn), the HRSA-supported Geriatric Workforce Enhancement Program (Hepburn, Clevenger, Epps), the Integrated Memory Care Clinic (Clevenger; located in the Emory Brain Health Center), and the Emory Roybal Center for Dementia Family Care Mastery (Hepburn, Clevenger, Epps).

Emory is a highly collaborative institution, and multiple collaborative activities have already established the foundation for the proposed project. Within this context, the MPIs have already assembled and have begun working with a group of colleagues from across the health sciences and Emory Healthcare to gather information that will contribute to the content of the Caregiving while Black. Working with infection control and vaccine specialists from Emory Healthcare and Emory's Rollins School of Public Health, we have compiled materials that can be employed in the course to prepare caregivers to assume and maintain their role in infection prevention and risk mitigation. With colleagues from Emory's School of Medicine, we have begun identifying key issues in navigating the health care system.

Emory leverages pre-existing relationships between the investigators at local universities, and a wide array of community partners to successfully implement the proposed project. Emory is in close geographic proximity to historically Black colleges (i.e., Morehouse College, Morehouse School of Medicine, Spellman, and Clark Atlanta) and major research universities (i.e., Georgia State and Georgia Tech). The Morehouse School of Medicine partners with Emory in the Atlanta Clinical and Translational Science Alliance and in the provision of dementia diagnostic and care planning services at Grady Memorial Hospital through the Georgia Memory Net. MPI Epps works closely with Georgia State University to lead a church-based dementia-friendly community program that includes partnerships with several faith communities across Georgia.

26. Multi-Site or Collaborative Research

N/A

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28. Protocol Checklist

Please note that protocol sections with an asterisk (*) should always be included in the protocol; if the section does not have an asterisk, and you have not included the section in the protocol, the IRB will consider it your attestation that the section does not apply to your study.

Protocol Section	Added to the protocol?
External Collaborators- if applicable, add each external collaborator information and indicate whether that institution's IRB will review (or has already reviewed) that individual's engagement in human participants research activities)	☐ **Yes**
Funding Source*: Include the information for the funding entity for this study. Please explain if this study is covered by a sub-award or other pertinent information. Say "department" if you do not have any other funding.	☒ **Yes**
Objectives*: Describe the purpose, specific aims, or objectives and state the hypotheses to be tested	☒ **Yes**
Background*: Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Describe any relevant preliminary data or knowledge to be built upon in this study. Examples of issues to address are cultural expectations, political conditions, economic conditions, disease prevalence/incidence, environmental factors. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Include any other non-research rationale for the work, if this study is a mix of non-research and research	☒ **Yes**
Study Endpoints: Sample: provide some information about the data set that the research team will be analyzing.	☒ **Yes**
Study Intervention/Design*: Describe the study intervention that is being evaluated, and/or the nature of interactions proposed.	☒ **Yes**
Procedures involved*: Describe and explain the study design in more detail. Describe all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks. Procedures performed to lessen the probability or magnitude of risks.	☒ **Yes**
Procedures-Source Records*: The source records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms in the smartform on the "Study-Related Documents" page under "Other Attachments." If unable to attach data collection instruments due to copyright requirements, include a description of the instrument in the protocol document	☒ **Yes**

Procedures-Data collection*: What data, specifically, will be collected during the study, and how that data will be obtained. If audio/video-recordings will be generated, describe processes for transcribing audio/video recordings. Will audio-recordings be destroyed after transcription? If so, how long after transcription? If not, how will they be kept secure? If video-recordings will be used beyond the current research procedures for educational/presentation purposes.	☒ **Yes**
Procedures- Long Term Follow Up*: If there are plans for long-term follow-up (once all research-related procedures are complete), what data will be collected during this period.	☒ **Yes**
Procedures-Deception: Does the research design require subjects to be deceived? Describe and justify the need for deception. Describe the plan to debrief participants after study participation is completed. Will the subjects be exposed to any stress? Describe and justify the need for stress.	☒ **Yes**
Data and Specimen Banking: If data or specimens will be banked for future use, describe where the data or specimens will be stored, how long they will be stored, how the data or specimens will be accessed, and who will have access to the data or specimens. List the data to be stored or associated with each specimen. Describe the procedures to release data or specimens, including the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.	☒ **Yes**
Sharing of Results with Participants*: Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.	☒ **Yes**
Study timelines*: Describe the duration of an individual subject's participation in the study, the duration anticipated to enroll all study participants, and the approximate total duration of the overall study	☒ **Yes**
Population and Inclusion/Exclusion Criteria*: Describe how individuals will be screened for eligibility; the criteria that define who will be included or excluded in your final study sample; and indicate specifically whether you will include or exclude each of the following special populations: • Adults unable to consent • Individuals who are not yet adults (infants, children, teenagers) • Pregnant women • Prisoners	☒ **Yes**

Note: you cannot exclude people with limited English proficiency unless you can demonstrate the scientific need for such exclusion. Community Participation: For studies aimed at addressing issues that affect a certain community or group: How, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community/ies?	
Research with pregnant women, fetuses, or neonates: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research with neonates of uncertain viability: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving prisoners: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving children: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving cognitively impaired adults: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving economically or educationally disadvantaged persons: describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects	☐ **Yes**
Local Number of Participants*: Indicate the total number of participants to be accrued locally. If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.) Provide your projected enrolling goals, including the percentage of participants according to sex and race.	☒ **Yes**
Recruitment Methods*: Describe when, where, and how potential participants will be recruited, who will make initial contact and how, and if physicians or staff refer participants. Describe the source of participants. Describe the methods that will be used to identify potential participants. Describe materials that will be used to recruit participants. (Attach copies of these documents in Smartform on the "Study-Related Documents" page under "Recruitment material templates." with the application. For advertisements, attach the	☒ **Yes**

final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/videotape. You may submit the wording of the advertisement before taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/videotape.) How will eligibility be determined? Provide a detailed description of any eligibility screening done before enrolling the subject (including whether any identifiers will be recorded – note that IP address is an identifier). If recruiting online, describe how potential participants would be directed to your recruitment information and study description. If using contests or raffles as an incentive, you must offer entry to all potential participants, not just those who enroll in the study/complete study-related procedures, per Georgia State Law. If recruiting online, describe how potential participants would be directed to your recruitment information and study description. All research recruitment through social media needs to follow this guidance, which does not allow the use of personal social media accounts for some recruitment activities	
Withdrawal of Participants*: Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.	☒ **Yes**
Risk to Participants*: List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to the participant's participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Include risks of loss of privacy or breach of confidentiality. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not participants. Do not state that there are no risks.	☒ **Yes**
Potential Benefits to Participants*: Describe the potential benefits that individual participants may experience Indicate if there is no direct benefit. Do not include benefits to society or others. Describe areas of knowledge that would be strengthened. Compensation should NOT be stated as a benefit.	☒ **Yes**
Compensation to Participants*: Describe if/how subjects will be compensated for participation in this study. Indicate what method compensation will be delivered (e.g. cash, gift card, school credit).	☒ **Yes**

Describe the amount and timing of any payments to participants. How much? What kind? Is tax information required? (if so, must be reflected in the informed consent form). Will payments be pro-rated if a participant withdraws early?	
Data Analysis, Management and Confidentiality*: Describe the data analysis plan, including any statistical procedures or power analysis. Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for the quality control of collected data.	☒ **Yes**
Describe how data or specimens will be handled study-wide*: What information will be included in that data or associated with the specimens? • Where and how data or specimens will be stored? • How long the data or specimens will be stored? • Who will have access to the data or specimens? • Who is responsible for receipt or transmission of the data or specimens? • How data or specimens will be transported?	☒ **Yes**

Data Monitoring and Participants Safety
(if this study is no more than minimal risk, this section is not required)
• Ensure that you review our Data and Safety Monitoring plan guidance for specific details about this section, and examples of what the IRB will be requiring according to the level of risk.
• If a DSMB is needed, please describe the composition of the board (if not already detailed in the protocol). Review this guidance for more information. If the sponsor protocol does not contain all required information, please in this section.
• Describe the plan to periodically monitor the data at the site level, and if you have international sites.
• Description of the plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the Emory IRB reporting requirements, and if so, a description of the requirements and plan for meeting them.
• Please address the specific details below. If deemed not applicable, please provide rationale:
• Subject safety:
  ○ Specific subject safety parameters
  ○ Frequency of subject safety observations
	☒ **Yes**

○ Individual responsible for safety monitoring ○ Subject stopping rules – under what conditions will a subject be removed from study participation and who will make the decision? ○ Study stopping rules - under what conditions will the study be modified or stopped and who will make the decision? ○ Reporting mechanisms (i.e. Deviations, adverse events, UPs) • Data Integrity: ○ Specific data elements to be reviewed ○ Frequency of monitoring data, points in time, or after a specific number of participants ○ Individual responsible for data monitoring	
Provisions to Protect the Privacy Interests of Participants*: • Describe the steps that will be taken to protect participants' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or whom they provide personal information. • Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures. • Indicate how the research team is permitted to access any sources of information about the participants.	☒ **Yes**
Economic Burden to Participants*: Describe any costs that participants may be responsible for because of participation in the research.	☒ **Yes**
Informed Consent*: Describe where the consent process will take place, any waiting period available between informing the prospective subject and obtaining the consent; and the process to ensure ongoing consent. Describe the role of the individuals listed in the application as being involved in the consent process; the time that will be devoted to the consent discussion; steps that will be taken to minimize the possibility of coercion or undue influence; and steps that will be taken to ensure the participants' understanding. Note: If you are planning to obtain consent via electronic signature, please review this document. Additional guidance on consent documentation and process can be found on our website, under the consent toolkit.	☒ **Yes**

Consent Process-Non-English-Speaking Participants*: Indicate what language(s) other than English are understood by prospective participants or representatives. If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. If you checked N/A, please provide reasoning of why subjects with limited English proficiency are excluded. **Note**: if you stated that subjects with LEP will be enrolled, you are approved for the use of the Emory IRB short forms. Please read the guidance about the use of short forms here.	☒ **Yes**
Consent Process-Children: After determining if the subject is a child per GA law (or if enrolled outside GA, per state/country law), please describe whether parental permission will be obtained from: • Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. • One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care. When assent of children is obtained describe whether and how it will be documented per Emory Policies and Procedures	☐ **Yes**
Consent Process-Cognitively Impaired Adults: describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.	☐ **Yes**
Consent Process-Adults Unable to Consent: List the individuals from whom permission will be obtained in the order of priority. (E.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, and adult child.) For research conducted in the state, review "46 LEGALLY AUTHORIZED REPRESENTATIVES AND SURROGATE CONSENT" to be aware of which individuals in the state meet the definition of "legally authorized representative."	☐ **Yes**

For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. Describe the process for the assent of the participants. Indicate whether: • Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not. • If assent will not be obtained from some or all participants, an explanation of why not. Describe whether the assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents	
Waiver or Alteration of Consent and HIPAA authorization (consent will not be obtained, required information will not be disclosed, or the research involves deception) Review the Emory IRB waiver document to ensure you have provided sufficient information for the IRB to make these determinations. If the research involves a waiver of the consent process for planned emergency research, please review the Emory P&Ps, Chapter 48, WAIVERS OF, AND EXCEPTIONS FROM, INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH to ensure you have provided sufficient information for the IRB to make these determinations.	☐ **Yes**
Setting*: Describe the sites or locations where your research team will conduct the research including where the subject will be identified and recruited, where the research procedures will be performed, and if you will involve a community advisory board. For research conducted outside the organization and its affiliates describe the site-specific regulations or customs affecting the research outside the organization and the local scientific and ethical review structure outside the organization.	☒ **Yes**
Resources Available*: Describe the resources available to conduct the research such us the feasibility of recruiting the required number of suitable participants within the agreed recruitment period; describe the time that you will devote to conducting and completing the research; describe the availability of medical or psychological resources that participants might need as a result of an anticipated consequences of the human research; describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.	☒ **Yes**
Multi-Site Research when Emory is the Lead Site	☐ **Yes**

Study -Wide Number of Participants: indicate the total number of participants to be accrued across all sites.
Study-Wide Recruitment Methods: If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.
Describe when, where, and how potential participants will be recruited.
Describe the methods that will be used to identify potential participants.
Describe materials that will be used to recruit participants.
Describe the processes to ensure communication among sites. See "WORKSHEET: Communication and Responsibilities (HRP-830)." All sites have the most current version of the protocol, consent document, and HIPAA authorization.
All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record).
All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented.
All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy
Describe the method for communicating to engaged participating sites (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):

- Problems (inclusive of reportable events).
- Interim results.
- The closure of a study

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

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