College of Health Sciences
DEPARTMENT OF EPIDEMIOLOGY

August 22, 2024

Re: Cover Letter for Clinical Trials.gov NCT05594264

The purpose of this cover letter is to accompany the protocol for NCT05594264, the title of the study is Developing and Implementing a Storytelling Intervention for African Americans Living with Hypertension. The date of approval for the accompanying protocol is March 27, 2023. The study ended in June 2024. The cover letter and protocol are being submitted for PRS Review on August 22, 2024.

Sincerely,

Yendelela L. Cuffee

Yendelela L. Cuffee, PhD, MPH
Assistant Professor, Department of Epidemiology
University of Delaware College of Health Sciences

HUMAN SUBJECTS PROTOCOL
University of Delaware

Protocol Title: Developing and Implementing a Storytelling Intervention for African Americans Living with Hypertension

Principal Investigator
Name: Yendelela L. Cuffee
Department/Center: Program in Epidemiology
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Advisor (if student PI):
Name:
Contact Phone Number:
Email Address:

Other Investigators:

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects occur during this project, including breaches of guaranteed confidentiality or departures from any procedures specified in approved study documents, I will report such events to the Chair, Institutional Review Board immediately.

1. **Is this project externally funded?** **X** YES ☐ NO

If so, please list the funding source: Submitting for funding through Center for Biomedical Research Excellence (COBRE) in Cardiovascular Health Pilot Project

**2. Research Site(s)**

☐ University of Delaware

**X** Other (please list external study sites): Westside Family Health Center (various sites in New Castle County) and recruitment using Research Match.

Is UD the study lead? **X**YES ☐ NO (If no, list the institution that is serving as the study lead)

3. **Project Staff**
Please list all personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

| NAME | ROLE | HS TRAINING COMPLETE? |
|---|---|---|
| Asli McCullers | Research Assistant | Yes |
| Christiana Oyekanmi | Research Assistant | Yes |
| Ermiyas Woldeamanuel | Research Assistant | Yes |
| Elena Lynn | Research Assistant | Yes |
| Suzanne Akuley | Postdoctoral Fellow | Yes |
| | | |
| | | |

4. **Special Populations**
Does this project involve any of the following:

Research on Children? No

Research with Prisoners? No

If yes, complete the Prisoners in Research Form and upload to IRBNet as supporting documentation

Research with Pregnant Women? No

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe

Yes, participants will be recruited from Westside Family Health Center locations across New Castle County. Westside Family Health Center, is a Federally Qualified Health Center, which serves a racially, ethnically, linguistically, and socioeconomically diverse population.

5. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an 8th grade student) of the aims of this project.

The objective of this study is to conduct a pilot study of a storytelling intervention for African Americans with hypertension. We will recruit 30 African Americans with hypertension to view six-eight patient stories and provide feedback on their effectiveness, usefulness, and satisfaction with the stories. Dr. Cuffee was awarded a Penn State Clinical and Translational Science Institute KL2 to develop a hypertension storytelling intervention, HBPStories. For the HBPStories project nine African Americans were filmed sharing their experiences living with and managing hypertension; including, diet and exercise tips, suggestions for locating healthy foods, and motivational stories about successfully controlling hypertension.

We will also elicit feedback from the participants about the best approaches for

delivering a storytelling intervention, and to obtain feedback on the resources and health information that would be helpful to an individual participating in a storytelling intervention.

6. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

**Phase I:** We will recruit 30 African Americans with hypertension from Westside Family Health Center, which has multiple sites in New Castle County, using Google ads and Research Match. The participants will watch the stories and provide feedback on their engagement and satisfaction with the stories, the website, and recommendations for incorporating the stories into a future intervention. We will collect self-reported demographic data including age, gender/gender-identity, income, education, years since hypertension diagnosis, and participants will complete a health literacy screening using the Short-form Health Literacy Survey. The participants will watch the stories on the study website and complete a survey in REDCap. Participants will be asked to watch the eight patient videos (each 2-3 minutes in length) and complete a short 3-5-minute survey after each video. The same survey will be administered after each story (Table 1). We will use a Williams Latin Square to determine the order in which participants will watch the videos. This approach will be used to ensure that videos are not watched in the exact same order by the participants. After providing feedback on the individual stories, the participants will complete a 10-minute survey to gauge overall satisfaction with the stories, engagement, usefulness of the website, and potential uses for future studies. We will use the feedback from the survey to rank which stories were most informative and engaging and select the top six for phase II of the study. Participants will be invited to participate in a 30-minute exit interview to discuss their opinions on the stories, to discuss preferences for a hypertension study, how the stories could be used most effectively, and what type of study would be helpful for them and others managing hypertension. If participants report lack of engagement or satisfaction with the stories, we will ask for their feedback on how we might use the stories to be more helpful and what type of study design would be of interest to them. The study visit will take 1-1.5 hours to complete, and participants will receive a $20 gift card upon completion of the surveys and an additional $10 gift card for participating in the exit interview. The study visit will take place in person or via Zoom depending on the preference of the study participants. **Community Advisory Board:** We will invite Phase I participants to volunteer to participate in a community advisory board, we will meet with the community advisory board 2-3 times to request feedback on the findings of the first phase of the study, advice on how to incorporate the feedback from participants into the design of phase 2, and to provide suggestions for the design of Phase II of the study. We will meet with the community-advisory board at the close of the study and develop presentations to summarize the preliminary findings of the study and determine an approach for disseminating the findings of both phases of the study throughout the community. Community Advisory Board Meetings will be held in person and via Zoom . **Phase II:** Twenty participants will engage in a 6-week online storytelling intervention and provide feedback on the effectiveness, engagement, and recommendations for improving the intervention. Participants will complete a 10-item survey in REDCap after viewing the weekly story. The participants will also review the study website and access health materials from the American Heart Association covering topics such as using an electronic pill bottle to manage medication, working out at home, and cooking healthy meals. A list of the survey topics are listed in Table 1. Participants will be expected to spend 30-minutes to an hour each week viewing the stories and study material. Participants will complete a pre- and post-study survey to assess changes in diet, physical activity, and medication adherence during the study.

Participants will receive $5 dollars for each week for a total of $30 dollars and will receive a free blood pressure monitor. We will complete exit surveys with Phase 2 Study participants to ask about engagement, reasons for not participating/dropping out, satisfaction with the intervention, and approaches for improving the intervention.

## 7. **STUDY POPULATION AND RECRUITMENT**

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.

Study recruitment will be conducted at Westside Family Health Center sites in New Castle County, using Google ads and Research Match. Westside serves a racially, ethnically, and socioeconomically disadvantaged population of over 27,000 patients. Flyers and handouts will be provided to community organizations, social organizations, and shared at community events. In Phase 1 we will enroll 30 study participants, we anticipate 30-40 people will be screened to identify 30 that meet the inclusion and exclusion criteria. For Phase II we will recruit 30 participants, we anticipate screening 30-40 participants to identify participants that meet the inclusion and exclusion criteria. Westside Family Healthcare will be the primary recruiting site.

Attach all recruitment fliers, letters, or other recruitment materials to be used. If verbal recruitment will be used, please attach a script.

Not Applicable

Describe what exclusionary criteria, if any will be applied.

The study inclusion criteria are as follows: 1) self-reported hypertension; 2) prescribed antihypertensive medication; and 3) age ≥ 18 years. The exclusion criteria are: 1) cognitive limitations that limit the ability to provide informed consent; 2) unable to speak or read English and 3) are planning to move during the study period .

Describe what (if any) conditions will result in PI termination of subject participation.

Study subjects will participate in one study visit and will be asked to commit to spending 1-hour viewing the stories and providing feedback. If the participant is unable to spend an hour viewing the stories and providing feedback they will be withdrawn from the study. Participants that are withdrawn from the study will be replaced with new study participants.

## 8. **RISKS AND BENEFITS**

List all potential physical, psychological, social, financial or legal risks to subjects (risks listed here should be included on the consent form).

Potential risk to the subject includes psychological discomfort while watching the videos and self-reflection. Loss of confidentiality is also a risk.

In your opinion, are risks listed above minimal* or more than minimal? If more than minimal, please justify why risks are reasonable in relation to anticipated direct or future benefits.

This is a minimal risk study.

What steps will be taken to minimize risks?

Provide participants with an overview of what topics will be covered and the study process during the consenting progress. Participants will be invited to withdraw if the topics discussed in the videos are upsetting to them.

Describe any potential direct benefits to participants.

There are no direct benefits to the participants.

Describe any potential future benefits to this class of participants, others, or society.

The information obtained from the study participants will be useful in developing other programs and projects for African Americans living with hypertension. We anticipate the participants recruited from this arm of the study will be representative of the Harrisburg community and their experiences may be similar to other patients living with hypertension in other areas in the United States.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

No

9. **COMPENSATION**

Will participants be compensated for participation?

Yes. Participants in Phase 1 will receive a $20 gift card to thank them for their time and their participation and a $10 gift card for participating in the exit interview. Phase 2, participants will receive up to $30 in gift cards for their participation. Gift cards will be distributed after the participant has finished viewing the studies and providing feedback. If the participant does not receive the gift card during the study visit and after participating in the study, it will be mailed to them.

If so, please include details.

10. **DATA**

Will subjects be anonymous to the researcher?

No

If subjects are identifiable, will their identities be kept confidential? (If yes, please specify how)

Participant's data will be entered into the database by using participant ID numbers.

How will data be stored and kept secure (specify data storage plans for both paper and electronic files. For guidance see http://www.udel.edu/research/preparing/datastorage.html )

How long will data be stored?
The de-identified data will be stored indefinitely to allow for data cleaning, analysis, and publication of the study findings. Paper data files will be stored securely in a safe or locked file cabinet in a locked office at the University of Delaware Electronic files will be stored on a password protected computer owned by the University of Delaware. Data with personal identifiers will be destroyed three years after study completion. Any paper records will be shredded and cross shredded. The PI will work with IT to delete any electronic files from personal computers.

Will data be destroyed? ☐ YES **X** NO (if yes, please specify how the data will be destroyed)

Will the data be shared with anyone outside of the research team? ☐ YES **X** NO (if yes, please list the person(s), organization(s) and/or institution(s) and specify plans for secure data transfer)

How will data be analyzed and reported?

The data will be analyzed using NVIVO and STATA software, the combined findings will be presented in a mixed-methods paper and published in scientific journals or presented at scientific conferences.

11. **CONFIDENTIALITY**
Will participants be audiotaped, photographed or videotaped during this study?

No

How will subject identity be protected?

We will use patient ID numbers.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).

No

12. **CONFLICT OF INTEREST**
(For information on disclosure reporting see: http://www.udel.edu/research/preparing/conflict.html )

Do you have a current conflict of interest disclosure form on file through UD Web forms?

Yes

Does this project involve a potential conflict of interest*?

No

* As defined in the University of Delaware's Policies and Procedures ,a potential conflict of interest (COI) occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional judgment, commitment, actions, or decisions could be influenced by considerations of personal gain, financial or otherwise.

If yes, please describe the nature of the interest:

13. **CONSENT and ASSENT**

X Consent forms will be used and are attached for review (see Consent Template under Forms and Templates in IRBNet)

____ Additionally, child assent forms will be used and are attached.

____ Waiver of Documentation of Consent (attach a consent script/information sheet with the signature block removed).

____ Waiver of Consent (Justify request for waiver)

14. **Other IRB Approval**
Has this protocol been submitted to any other IRBs?

No

If so, please list along with protocol title, number, and expiration date.

15. **Supporting Documentation**
Please list all additional documents uploaded to IRBNet in support of this application.

- Phase 1 Participant Survey (clean and edited version)
- Phase 2 Participant Survey (clean and edited version)
- e-Heals Health Literacy Questionnaire (clean and edited version)
- Consent Form Phase 1 (clean and edit version)
- Consent Form Phase 2 (clean and edited version)
- Cover letter to the IRB
- Recruitment Letter
- Letter of Support Westside Family Health Center
- Storytelling Feasibility Study Protocol (clean and edited version)