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REDCAP Script for Obtaining Informed Consent
The Ohio State University Consent to Participate in Research

Hello, my name is Dr. Kathy Wright. I am an Assistant Professor at The Ohio State University in the College of Nursing, and I am undertaking research-titled, "Addressing the double jeopardy of stress and hypertension among African American female caregivers of persons living with Alzheimer's disease and related dementias."

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Purpose: Taking care of a family member or friend with living with Alzheimer's disease or other dementias can be challenging. In 2019, informal caregivers provided 18.6 billion hours of unpaid care to people living with Alzheimer's disease and related dementias with African American women providing 60% of this type of care. The purpose of this study is to determine the feasibility of a group delivered intervention for stress and blood pressure in African American women caregivers.

Procedures/Tasks:
There will be three study visits for data collection. Each study visit will take about 2 hours to complete. You will have the choice of where the study visit is done. For example, data collection visits can be done at College of Nursing office at 760 Kinnear Road Columbus, Ohio 43212, your home, or private room at a local library. To accommodate your schedule, we will have the option for the study visits to be broken up into smaller 1 hour visits. Additionally, data collection items that do not require an in-person visit, such as questionnaires/surveys, may be completed via phone or Zoom.

At enrollment, we will ask you to provide us with your phone number so we can add it to our participant communication platform, Mosio. For the duration of your participation in the study, we will use Mosio to communicate with you via text messaging. Please note that you will not incur any additional charges for this service, over and above what you normally are charged by your mobile network provider for sending and receiving any text messages or transmitting/receiving any data. Only your name, email, and phone number will be added to the Mosio platform; no other information will be entered. None of your information will be kept past the time required to complete the study.

The restricted website associated with Mosio will contain your first name, last name, email, and phone number. The system will also store any messages that you respond with. This information might be seen by:

- Our study team: in order to send you text message reminders and/or to communicate with you.
- Mosio, its service representatives and companies that work with Mosio.
- Mosio: in order to provide the service Mosio and its service representatives will not share your contact details with other third parties unless required by law or allowed by this form. They will not contact you except for sending the study related messages.
- Mosio may have access to de-identifiable data solely to improve and maintain their platform. The terms of the agreement with Mosio do include that some data (e.g. cell number) will travel through a third party infrastructure for example a cell phone tower which is not under Mosio's control.
- When you are no longer in the study, Mosio will stop sending you text messages. At any point, if you reply to a message with STOP or QUIT, you will no longer receive messages from the system. Study staff are also able to help you "opt out" of the messaging service through the system.

There are no costs to you related to participation. You will not incur any additional charges related to text messages to and from Mosio, over and above what you have normally.

You will complete questions about stress, eating habits, quality of life, and caregiving. You will be asked to report your blood pressure using the automatic monitor that will be provided to you.

You will complete a 7-day stress questionnaire sent to your cell phone through Mosio.

Participants who have enrolled prior to any changes that have taken effect such as the use of Mosio will be re-consented

You will complete questions about stress, eating habits, quality of life, and caregiving. To measure changes in your blood pressure, we will have you complete a computer task viewing words and colors, tracing a simple drawing like a star, and some math in your head. We will take your blood pressure with an automatic blood pressure machine after each computer task. With permission, we will cut a small hair sample equal to about the same amount of hair you get after combing or brushing. The hair sample allows us to measure a stress hormone. The site for the hair sample is covered by hair from the crown of your head and, thus, is not visible following the sample collection. Hair samples are only collected twice, in the beginning and at 9 months. The questions and computer test will be done three times, at the first visit, after you complete the group delivered intervention sessions, and at 9 months.

You may be advised, for informational purposes only, to contact a health provider if your blood pressure is above a certain threshold at any time during the study.

At the end of the first study visit (baseline), you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither

you nor study staff will select the group to which you will be assigned. However, this information can be obtained if you have a medical emergency. You will be randomly assigned to the mindfulness/healthy eating education group or caregiving education group. All group sessions are held on Zoom, not in person. Only the data collection visits are done in person. The group sessions will be held weekly for 8 weeks and last approximately one hour each.

Once we have enrolled the first 6-8 people, you will begin the group online classes held by a trained facilitator.

In the group sessions on Zoom, if you do not want to disclose your identity please let the study team know. The study team will show you how to attend the sessions without showing your face on the video or using your actual name for your privacy. You will also have the option of creating an avatar. You will need a telephone, SmartPhone, or a computer with internet access to get into the classes. Devices that have a larger screen such as a laptop or IPad, are preferred to access Zoom but it is not required.

The class will be held in the morning or evening, once a week for 8 weeks. There may be a weekend option based upon the participants' and research staffs' availability. Depending upon your group assignment, mindfulness/healthy eating or caregiver education, you will learn the following:

- Taking blood pressure;
- Mindful awareness;
- Restful sleep;
- Physical activity;
- Healthy eating;
- Diary to keep track of self-care practices;
- Understanding and responding to dementia-related behaviors; and
- Tips from the latest research in Alzheimer's disease.

When you have completed the 8-week group sessions, we will schedule the *second study visit* (approximately 1-3 weeks after you complete the Zoom group classes.) We will repeat all of the same questions, computer test, and blood pressure measurements. We will not take a hair sample at that time.

After you have completed the 8 week group sessions, we will call you to do a brief check-in (approximately 5-10 minutes) by eight weekly and then four monthly coaching calls. This is to answer questions and reinforce what you learned in your group sessions.

At the *final study visit*, we will repeat the same questionnaires, computer test, and blood pressure measurements. We will also collect a hair sample. Participants will also receive mindfulness/healthy eating or caregiver education materials.

Duration:

The study is projected to last 9-12 months . This is because there may be a wait time from when you consent to be in the study and when you start the group classes on Zoom. Your active participation in the study will be approximately 20 hours over 9 months. However, we might like to contact you for up to one year after you start the study, in case we have questions.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or The Ohio State University Wexner Medical Center.

Risks and Benefits:

There may be no direct benefit to you. However, your participation may provide data which will provide insight into ways African American women can reduce their blood pressure and improve their overall health.

What risks, side effects or discomforts can I expect from being in the study?

You will be asked about topics such as your stress, emotions, socioeconomic status, and your feelings which might create awkwardness or discomfort for you. Some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question. Wearing the inflated blood pressure cuff may cause some temporary numbness and tingling in your hands.

As we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. While data may be coded, it will exist for an extended period of time, which could be affected if there is a data breach. Your data will be stored on a password protected database.
While we ask other group participants to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.

Confidentiality:

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

Would you like to be contacted for future research opportunities related to health and aging?

- ❑ Yes, I want to be contacted about future research studies.
- ❑ No, I do not want to be contacted about future research studies.

Incentives:

Each data collection visit will take approximately 2 hours to complete, and it can be done over two separate days if desired. You will not receive incentives for attending groups sessions or for participating in the check-in calls from study staff. You will receive a home blood pressure monitor at the beginning or the end of the study. The incentives schedule is as follows:

After completion of the 1st study visit for baseline data, you will receive $50.00 in cash.

After completion of the 2nd study visit at 3 months, you will receive $50.00 in cash.

After completion of the 3rd visit at 9 months, you will receive $50.00 in cash.

By law, monetary incentives are considered taxable income.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By agreeing to participate in the study, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact the principal investigator Kathy D. Wright at 614-292-0309 or email wright.2104@osu.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Do you have any questions about this research?

Do you agree to participate?

☐**Yes** ☐**No**