Document Coversheet

Study Title: Intervention to Improve Medication Adherence Among Stroke Survivors in Rural Kentucky

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Consent and Authorization to Participate in a Research Study
KEY INFORMATION FOR "INTERVENTION TO IMPROVE MEDICATION TAKING BEHAVIOR AMONG STROKE SURVIVORS"

We are asking you to choose whether or not to volunteer for a research study about whether a community health worker working with a pharmacist might help you to take your medications as directed. We are asking you because you are being seen in the Vascular Neurology Clinic as a follow-up visit for a past stroke. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how useful a program which involves a community health worker working collaboratively with a pharmacy technician and pharmacist is for identifying areas where we better understand barriers to taking your medications as directed. The pharmacy technician will ask you a few questions to understand if there are any barriers to taking your medications. This conversation will last about 60 minutes. We will also provide you with a blood pressure monitor to measure your blood pressure at home and an electronic pill box to help arrange your medications. The community health worker will show you how to use both. After this, the pharmacy technician will create a plan to solve the identified barriers to taking your medications with a pharmacist. The pharmacy technician will contact you within 15 days to discuss the plan with you. The pharmacy technician will follow-up with you every 30 days for the following 3 months to check if the barriers were solved and to review your blood pressure recordings. Each online or virtual call will last about 15 minutes. All the activities for this study take place during approximately 4 months and require less than 2 hours of your time. For a complete description of the study and what you will be asked to do, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Participating in the study will give you an opportunity to work with a community health worker, pharmacy technician, and a pharmacist to evaluate your medications to ensure that the clinical team is doing everything they can to prevent a future stroke. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to volunteer for this study if you do not want to visit with a community health worker, pharmacy technician or a pharmacist to review your medicines and stroke risk factors after completing your clinic visit in Neurology, if it is too difficult to receive the calls from the pharmacy technician, or if you will not be able to participate in the study for 4 months. For a complete description of risks, refer to the Detailed Consent. There are no other options other than simply choosing to not participate in the study.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Hend Mansoor, PharmD, PhD of the University of Kentucky, College of Pharmacy at (859) 218-1607.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You are not eligible to participate in this study if you had a stroke because of brain bleed, blood clot in the veins of your brain, inflammation of the blood vessels of the brain, blood clotting disorder, or if you do not take any medications that lower your risk for another stroke.

Other reasons you would not qualify for this study are: (1) if you are less than 30 years of age; (2) if you do not speak and understand English; (3) if you cannot participate in the study during the next 4 months; (4) if you do not have access to internet service; or (5) if you have a severe disability limiting your communication.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

Some of the research procedures will be conducted at the neurology clinic where you are having your clinical visit, but most of the activity will be conducted online using Zoom. You will be provided with a tablet if you do not currently own one to attend your Zoom visits with the pharmacy technician. The study will last for approximately 4 months. Your first meeting with the community health worker will be done at the clinic but your subsequent visits with the pharmacy technician can be conducted virtually and will last for about 60 minutes. You will then have 3-4 virtual calls with the pharmacy technician, each lasting for about 15 minutes. The total amount of time you will be asked to volunteer for this study is about 2 hours over the next 4 months.

WHAT WILL YOU BE ASKED TO DO?

Your clinic visit will be the same whether you participate in the research study or not. If you decide to participate, a study team member will review this consent with you to answer all your questions and have you sign the consent form if you decide to participate.

After you have consented you will visit with the pharmacy technician and will spend some time with them (about 60 minutes) to review your stroke risk factors and medications as well as lifestyle factors (diet, exercise, smoking, and others). The pharmacy technician will also ask questions regarding your medication taking behavior. After your meeting, the pharmacy technician will identify any potential barriers for your medication taking behavior and make a plan that he/she will discuss with a clinical pharmacist. The pharmacy technician will call you within 2 weeks of the first visit to review the plan with you. In addition, the pharmacy technician will contact you monthly for about 15 minutes to review your blood pressure recordings and to check if the barriers were solved. At the final virtual call, the pharmacy technician will review your blood pressure recordings and medication taking behavior. All these virtual calls will not be recorded. We will collect data 4 times during the study, after your initial visit with the community health worker, during the monthly virtual call, and the end of the study. At baseline, we will access data about your health condition and medical history from your electronic health record (EHR). All activities will take place during a period of approximately 4 months and require about 2 hours of your time. Upon the completion of the study, we will request that you return the tablet using the provided return envelope to receive a $100 VISA card.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Discussing your stroke risk with the community health worker and pharmacy technician may be uncomfortable, or cause anxiety or other emotional responses. Your neurologist will be available to you as usual should you experience a significant emotional reaction that requires further medical care.

There is always a chance that any research participation may harm you. The research procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

During this study, you will be provided with a blood pressure monitor and an electronic pill box to help you arrange your medications. You will also learn how to better manage your stroke risks and medications that lower your stroke risk, and sharing this with your primary care doctor may help you lower your future stroke risk. In addition, if you take part in this study, the information learned may help others with your condition.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. There is no cost to you to participate in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will need to collect your social security number if you wish to be paid for your time participating in the research project.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All information we collect in hard copy form (on paper) will be kept locked file cabinets that are in a locked office. Electronic data with identifying information (name, social security number) will be stored on a secure server behind a secure firewall maintained by the University of Kentucky and/or on a University computer that is encrypted and password protected.

You should know that in some cases we may have to show your information to other people. For example, if we discover any life-threatening health conditions or your blood pressure recordings are extremely abnormal, we will talk to you about speaking with your health professional and if you do not have one, we will refer to one. We will then provide you with health-related information to share with the health professional so that he or she can participate in your care.

Other examples, are when the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

To ensure the study Is conducted properly, officials of the University of Kentucky and the National Institutes of Health may look at or copy pertinent portions of records that identify you.

Among web-based programs, we will use the REDCap system. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

Regarding the use of Zoom for providing the virtual sessions, we will be using the HIPAA-approved and secure University of Kentucky Zoom program for all sessions.

Certificates of Confidentiality (CoC):

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study. By signing this consent you agree that your healthcare providers and associated staff affiliated, contracted with, or with access to records of the University of Kentucky (UK) may see your information from research studies and consider and use that information in the course of medical care and related activities.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study about medication taking behavior among stroke survivors. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study. It is important to let the investigator/your doctor know if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Kevin O'Connor, MD at (859) 323-5661 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility; ***or***

- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); ***or***
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive a $100 VISA card for taking part in this study at the end of the study ($25 for each visit or virtual visit). If you choose to withdraw early, you will be compensated at a rate of $25 for each visit or virtual visit that you completed prior to withdrawing from the study. You will receive an additional $100 VISA card upon returning the tablet at the end of the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 2 times per year.

Will your information be used for future research?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- The following protected health information will be collected: name, birth date, zip code, visit date, sex, race, medical history including: cancer, atrial fibrillation, dementia, diabetes, hypertension, high cholesterol, obesity, substance use disorder, sleep disorder, prior stroke, smoking, and alcohol use, blood pressure value, height, weight, and laboratory values.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK HealthCare and their representatives
- National Institutes of Health

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws. You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Hend Mansoor, PharmD, PhD at 789 S. Limestone Street, Suite 237, College of Pharmacy, University of Kentucky, Lexington, KY 40536 to inform them of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.