Document Coversheet

Study Title: Assessment of Medication Optimization in Rural Kentucky Appalachian Patients With Mild Cognitive Impairment or Dementia: The AMOR Kentucky Study

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ASSESSMENT OF MEDICATION OPTIMIZATION IN RURAL KENTUCKY APPALACHIAN PATIENTS WITH MILD COGNITIVE IMPAIRMENT OR DEMENTIA: THE AMOR-KENTUCKY STUDY

We are asking you to choose whether to volunteer for a research study about medications and whether patients are willing to accept medication changes based on recommendations by the study team. We are asking you because you are an adult 60 years or older, with mild cognitive impairment or dementia, that is taking medications that have been identified as potentially not appropriate for someone your age and are seen in the telemedicine clinic at the University of Kentucky. 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 investigators in charge of the study is below.

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

Our study aims to investigate whether patients taking medications that have been identified as potentially not appropriate are willing to change their medication regimens.

By doing this study, in the future we hope to learn the effects of changing any potentially inappropriate medications you currently take on Alzheimer's disease or other disorders of aging. Your participation in this research will last about 6 months.

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

If you decide to participate in this study, you will have a licensed pharmacist and physician specialized in geriatric care evaluate all the medications you are taking and provide recommendations that consider your preferences and desires.

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

You should not participate in this study if you do not wish to consider changing your current medicines.

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 Daniela Moga, MD PhD of the University of Kentucky, Department of Pharmacy Practice and Science at 859-323-9682 or daniela.moga@uky.edu , or Gregory Jicha, MD PhD of the University of Kentucky, Sanders-Brown Center on Aging at 859-323-0885 or gregory.jicha@uky.edu.

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 will not qualify for this study if you are younger than 60 years of age or if you do not take any medications that have been identified as potentially not appropriate for someone your age.

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

The research procedures will be conducted via telemedicine at the end of your scheduled appointments with the UK Telemedicine Cognitive Clinic. In addition to the initial and 6-month follow-up telemedicine appointments as part of the Telemedicine Cognitive Clinic, you will have up to two telemedicine appointment to discuss medication changes with the study pharmacist and clinician. Each of those visits will take about 30 to 90 minutes. The total amount of time you will be asked to volunteer for this study is 3 to 4 hours over the next 6 months.

WHAT WILL YOU BE ASKED TO DO?

You are receiving this information because you have a telemedicine appointment scheduled with the Telemedicine Cognitive Clinic. You can review this information before your appointment. After your appointment, if Dr. Jicha determines that you are eligible for the study, we will ask whether you agree to participate and review this document with you and your caregiver. You will have the opportunity to ask questions and decide whether you are interested in participating. If you agree to participate, we will ask you to confirm your willingness to be in the study and sign the informed consent.

- If you are attending the telemedicine appointment with the Telemedicine Cognitive Clinic at the local clinic/facility, please sign this document and hand it to the clinic personnel. We will contact them to obtain the signed document.
- If you are attending the telemedicine appointment with the Telemedicine Cognitive Clinic from your home and you can mail us the signed document, please mail it at your earliest convenience.
- If you are attending the telemedicine appointment with the Telemedicine Cognitive Clinic from your home and can take a picture or scan the signed document, please email it to us at rosmy.george@uky.edu or daniela.moga@uky.edu
- If none of the options above work, but you agree to receive a text message, we will ask you for you phone number and to respond to the text message you will receive from the study team.
- If none of the options above work, we will ask for your permission to audio record the part of the enrollment visit where you will be asked to provide consent to document your willingness to participate.

After enrollment, the study will involve assessing your medication use and identifying any medicines that may be inappropriate for someone your age. This will be done by a team including a pharmacist with expertise in medication use for the older adults. During the study, you will meet with the study physician and the pharmacist to review any changes they recommend that are needed to eliminate medicines on your list that are not recommended for older adults. These visits are referred to as the Medication Therapy Management visits. You will decide whether to accept the recommendations and work with your primary care provider to implement them. In addition, we will ask you to complete some surveys.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks of being in the study includes the possibility of being recommended a change in your current medications in line with current medical recommendations. Changing your medications could result in worsening or improvement of your medical symptoms for which your current medications are being prescribed. If you experience side effects or worsening of your medical conditions, the study team will work with your primary care doctor to find suitable alternatives or recommend that you return to your previous medicine that was managing your symptoms when you enrolled in the study. Change of medications indicated by the study team will follow standard of care practices and should lead to no more risk of harm than that associated with regular doctor visits and medication changes.

There is always a chance that any medical treatment can harm you. The research treatments/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.

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. Your information will be combined with information from other people

taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, some people have experienced improvement in health due to better medication management. If you take part in this study, 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, you could ask your primary care doctor and pharmacist to have your medications reviewed and adjusted.

WHAT WILL IT COST YOU TO PARTICIPATE?

There will be no cost to participate in this study. All tests and procedure required by the protocol are being done for the sole purpose of the study.

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.

In this study, the study doctor and pharmacist may recommend changes to your medications that could potentially result in higher costs (deductible or other out-of-pocket expenses). The final changes to medications will be made by your primary care provider. The study team will work with you and your primary care provider to find the lowest cost alternatives and if financial issues cannot be resolved, the study team will work with you to continue with your current medications rather than accepting potentially higher cost changes. If you choose to accept a higher cost medication as part of the recommended medication changes that are implemented by the primary care provider, this cost will be your responsibility. These costs 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 at 1-800-635-2570.)

Your insurer, Medicare, or Medicaid may agree to pay for the costs. However, a co-payment or deductible may be needed from you. The amount of this co-payment or deductible may be costly.

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 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. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

Data collected in the study will be stored in the University of Kentucky's medical database that has limited medical personnel access, is password protected, and monitored for abnormal activity. Incidental materials containing subject identifiers will be shredded or incinerated.

You should know that in some cases we may have to show your information to other people because the law may require or permit us to share your information. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child or vulnerable adult being abused or if you pose a danger to yourself or someone else.

To ensure the study is conducted properly, officials of the National Institutes of Health, the University of Kentucky, the Sanders-Brown Center on Aging, Center for Clinical and Translational Science and their agents/representatives, and the College of Pharmacy may look at or copy pertinent portions of records that identify our subject.

We will be using REDCap, a data collection software. It is important to note that any data collection process undertaken through the use of third-party software comes with potential risks. Included among these risks is a

potential breach of confidentiality. The study team will take all available precautions to prevent this from occurring, although we cannot guarantee that your identity will never become known.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

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 data collection, we cannot guarantee the security of data obtained by way of the Internet.

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.

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:

- 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 take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this 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 done during the study, you should call the PI of the study, Dr. Gregory Jicha at (859) 323-5550 or (859) 559-7429 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.

The medical costs related to your care and treatment because of research 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); and 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 from you may be required 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 substantial.

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 $100 at the end of your participation for taking part in this study. If you decide to discontinue your study participation before the end of the study, you will be compensated $50 for your study participation.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

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 YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will provide you with individual information related to the medications you are taking.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by the study Principal Investigators and the Safety Officer to determine if it is in your best interest to contact you.

If so, do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

☐ Yes ☐ No _____Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Daniela Moga, MD PhD 789 S Limestone, room 241, Lexington, KY 40536.

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.

Do you give your permission to be contacted in the future by study investigators and staff regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 50 people to do so.

The National Institute on Aging is providing financial support and/or material for this study.

A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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 information collected during the scheduled appointments with the UK Telemedicine Cognitive Clinic, such as medical history, results from the physical examination, as well as results from the cognitive tests conducted during the visit.

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
- Representatives from the National Institute on Aging
- Center for Clinical and Translational Research
- Sanders-Brown Center on Aging
- College of Pharmacy

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: Dr. Daniela Moga, 789 S Limestone, Room 241, Lexington LY 40536 to inform her 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.

INFORMED CONSENT SIGNATURES

_____ _____ **Signature of research subject** *or, if applicable, *research subject's legal representative* **Date** _____ **Printed name of research subject**
_____ **Printed name of research subject's legal representative* **If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject:* _____ _____
_____ _____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization Date