Optimizing Medication Management by Older Adults through the Med Wise Rx Community-based Program

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# University of Wisconsin-Madison
# Consent to Participate in Research
# and
# Authorization to Use Protected Health Information for Research

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**Study Title:** Optimizing Medication Management by Older Adults through the *Med Wise Rx* Community-based Program

**Lead Researchers:** Beth Martin, PhD, RPh (608 265-4667)
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**Institution:** ***University of Wisconsin-Madison***

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## Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

### Why are researchers doing this study?

The purpose of this research study is to evaluate and improve an online program called *Med Wise Rx*. This research is being done because inappropriate medicine use can cause problems that place people at risk of falls or other health problems. The *Med Wise Rx* program was developed to help older adults talk with their pharmacists and other health care professionals to manage their medicines more effectively. This study is being done at several Aging and Disability Resource Centers (ADRCs) and public health departments in Wisconsin.

We invite you to take part in this research study because you are an older adult taking four or more medications on a regular basis. Participation is voluntary.

### What will I need to do in this study?

The research team will ask you to join the online *Med Wise Rx* program and participate in three telephone interviews and complete a program satisfaction survey.

You will be assigned to attend either the first or second *Med Wise Rx* session. The sessions are the same. The session you get will be chosen by chance, like flipping a coin. Neither you nor the person enrolling you will choose which session you attend. You will have an equal chance of being assigned to the first or second session by a computer.

We expect that you will be in this research study for a total of 7-9 months, until you complete the final interview 6 months after your *Med Wise Rx* session.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

## What are some reasons I might – or might not – want to be in this study?

| You may want to be in this study if you are: | You may NOT want to be in this study if you: |
|---|---|
| • Comfortable having researchers ask questions about your health and medicines<br><br>Willing to participate in the study for several months<br><br>Interested in contributing to scientific knowledge even though you may not benefit directly from the study | Want to be in a study that might help improve your own health<br><br>May not have time to complete study interviews |

## Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect any services you receive from your ADRC or health department. There will be no penalty to you. You will not lose any legal rights. You can ask all the questions you want before you decide.

# Detailed Information

The following is more detailed information about this study in addition to the information listed above.

## How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

## Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to Beth Martin at 608-265-4667 or another lead researcher listed at the top of this form.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

## If I take part in the study, what will I do?

The research team will ask you to:

- Join your scheduled online *Med Wise Rx* program from a device at home, library or ADRC. There will be two 120-minute classes, two weeks apart. If needed, staff at your ADRC or health department will help you learn to use Webex or Zoom to connect to the online classes.
- Participate in a 40-60 minute phone interview within a week or two before the first *Med Wise Rx* class.
- Complete the program satisfaction survey (either electronically (on computer) or paper) at the end of the second class. It will take about 10-15 minutes to complete.
- Participate in a 20-30 minute phone interview eight weeks after the second *Med Wise Rx* class.
- Participate in a 30-45 minute phone interview six months after the second *Med Wise Rx* class.
- Allow us to possibly contact your pharmacy to verify the type of service you received.

A UW interviewer will contact you by phone to conduct the interviews. We also ask for an email address that we would use only to contact you to schedule or confirm interview appointments.

The phone interviews will be scheduled at your convenience and will be done confidentially (in a private setting). We will send the questions to you ahead of time so you will know what to expect. The interviewer will ask questions about your general health, medicines and pharmacy use. You may skip any question in the interviews that you do not wish to answer.

Overall, you will spend about seven hours on this study across seven months. This includes the two Med Wise Rx classes (120 minutes each), the satisfaction survey (10-15 minutes) and the three phone interviews (30-60 minutes each).

If we ask permission to contact your pharmacy, we will only ask them to verify the type of service you received.

### Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your health that includes your name or other information that can identify you, like your age or email. To do this study, we will use the following kinds of PHI:

Your name, phone numbers, address and email address so we can contact you to schedule and conduct the interviews and mail materials and thank you gift cards.

Things you tell the researchers about your health and medications.

If we ask you for permission to contact your pharmacy, we will only request verification of services they provided to you.

## What happens if I say yes, but I change my mind later?

You can leave the research study at any time. If you choose to leave the study, your choice will not affect any services you receive from your ADRC or health department. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights.

If you withdraw from the study, we will no longer contact you to collect new information, but we will retain the information you provided, to help us evaluate *Med Wise Rx*. We will not keep any contact information that could identify you.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done, which will be around December 2024. However:

You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.

If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.

If you take back your authorization, you will not be able to take part in the research study.

To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Beth Martin, at UW School of Pharmacy, 777 Highland Avenue, Madison WI 53705.

## Will being in this study help me in any way?

Being in this study may help you manage your medicines and work with your pharmacist more effectively. However, we cannot promise this will happen. Even if the study does not help you directly, your evaluation of the program may help improve the education sessions for people who participate in future *Med Wise Rx* programs.

## What are the study risks?

There is a risk that your information could become known to someone not involved in this study, which might make you uncomfortable.

## What happens to the information collected for the research?

We have strict rules to protect your personal information and PHI. We will limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We will limit who has access to your name, address, phone number and other information that can identify you. Only members of the research team will have access to your information. We will also store this information securely.

Your name and other information that could identify you will be removed from all records we keep. We will use only a study ID number to identify your project records. Once the study is complete, we will destroy your contact information.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program.

We may also have to tell appropriate authorities, such as health care providers, if we learn during the study that you or others are at risk of harm (for example, due to elder abuse or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison it may not be protected by privacy laws and might be shared with others.

# What else do I need to know?

**Will I receive anything for participating?**
If you agree to take part in this research study, we will pay you up to $125 in thank you gift cards for your time and effort. We will give you a $25 gift card after you complete each of the first two phone interviews and program satisfaction survey and a $50 gift card after you complete the final interview.

## Permission to communicate about the study by email

We will contact you by phone to conduct the interviews. We also ask for an email address that we would use only to contact you to schedule or confirm interview appointments or to send an electronic thank you gift card.

Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Beth Martin, Lead Investigator at 608 265-4667. You do not have to provide your email address to participate in this study.

**How many people will be in this study?**
We expect about 160 people will be in this research study

**Who is funding this study?**
This research is being funded by UW Institute for Clinical and Translational Research Dissemination & Implementation Launchpad.

**What will happen to my data after my participation ends?**
We will keep your deidentified data for an indefinite period of time, meaning we have no plans of ever destroying it. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers. The banked data will not allow anyone, even to the members of this research team, to identify you.