INFORMED CONSENT DOCUMENT

Project Title: **Personal Health Records and Elder Medication Use Quality: Older Adult/Caregiver Focus Groups**

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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are age 65 or older, a volunteer in the Seniors Together in Aging Research (STAR) registry, and either 1) you reported that you were a caregiver of a family member or friend in the STAR Registry Information Form you completed, or 2) you reported having two or more health conditions, not including difficulty thinking, vision, or hearing problems in the STAR Registry Information Form you completed.

The purpose of this research study is to better understand how older adults, and caregivers of older adults, manage their medications or the medications of persons they care for, and to explore the views and experiences of older adults and their caregivers in managing medications and using personal health records.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for about 90 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to take part in this study, you would first complete a brief questionnaire that asks questions about you and/or the person(s) you care(ed) for. After you complete the questionnaire, you will attend a meeting (called a "focus group") with about 10 other persons. The focus group will be led by a researcher and his/her assistant from the University of Iowa. S/he will ask for your opinions and experiences with medication management and personal health records. You are free to skip any questions you prefer not to answer both on the questionnaire and during the focus group discussion.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making audio recordings of you. We are making audio recordings so that we can review what was discussed at the focus groups in detail. Only members of the research team will have access to these recordings. They will be erased at the end of this study.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

It is possible that someone participating in the focus group session with you would disclose something you discussed in the focus group. It is also possible that your participation or something you said in the focus group would be disclosed to someone outside of the research team.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will receive a $20 gift card to Hy-Vee for your participation in this study.

WHO IS FUNDING THIS STUDY?

The Agency for Healthcare Research and Quality is funding this research study. This means that the University of Iowa is receiving payments from the Agency for Healthcare Research and Quality to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the Agency for Healthcare Research and Quality for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will not write any personal identifying information (like your name) on any notes we take during the focus group. We will store copies of these notes and questionnaires in a locked file cabinet in a locked office at the University of Iowa. Audio recordings that we make will be in the possession of research team members during the course of the focus group, and the device containing the recordings will be stored in a locked file cabinet in a locked office. Any electronic data we create will be stored on a password-protected computer which is located in a locked office at the University of Iowa. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Karen Farris, PhD at 319-384-4516**.** If you experience a research-related injury, please contact Karen Farris, PhD at 319-384-4516**.**

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 200803709
APPROVAL DATE: 05/22/08
EXPIRATION DATE: 03/16/09

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 340 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 03/16/09.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)