INFORMED CONSENT DOCUMENT

Project Title: **Personal Health Record Prototype Development: Participatory Design**

Principal Investigator: X

Research Team Contact: X

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; you report taking at least one medication regularly; you can read a computer screen and use a computer keyboard and mouse; and you have an email account.

The purpose of this research study is to develop, with a group of older adults, a model of an electronic Personal Health Record (PHR). The PHR we are developing will be used in other research activities with older adults, so we want input from older adults to help design it.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 10 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 a series of 12-16 one-hour group meetings over the course of several weeks.

WHAT WILL HAPPEN DURING THIS STUDY?

During the study, you will attend 12-16 one-hour group meetings. The meetings will occur in a private room that is close to where you live. A research team member will take attendance at the start of each session by asking you for your name when you arrive.
At the study sessions, a research team member will ask you and other the other attendees for input in sketching designs for a model electronic Personal Health Record. We will ask you for your opinions

about what should be included in a Personal Health Record and how it should look and function. We will present different options on paper and on computer screens for you to comment on.

We will also ask you for your opinions about messages that we are developing. These messages are related to medication management, and they would be eventually used in the Personal Health Record you help design. For this study, you would only give your opinions about these messages by telling us if the messages make sense to you, what can be improved, and what you think you would do if you received the message while using an real electronic Personal Health Record.

After the first session, we will present you with updated PHR design models and messages for you to review again. These updated models and messages would be based on discussions from past meetings.

We will continue this process for a total of 12-16 one-hour sessions, until we have worked out as many of the problems with the PHR model and messages as best we can.

Between sessions, we will call you to remind you of the next session to and to see if you plan on attending.

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.

There is a risk that your participation in the study would be released to someone outside the research team. Also, as with any group activity, other subjects attending the study meetings may disclose information about you with persons outside the meeting.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the feedback we receive from you in designing the PHR may be beneficial in creating a PHR that other older adults can use to help maintain records of their health and medications.

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 may also need to provide your address if a check

will be mailed to you.

You will be reimbursed $8.00 for every study session you attend. Since there will be 12-16 study sessions, you can be compensated a total of $96.00 - $126.00, depending on how many sessions you attend. Payments will be provided in increments of $24 or less.

WHO IS FUNDING THIS STUDY?

The Agency for Healthcare Research and Quality (AHRQ) is funding this research study. This means that the University of Iowa is receiving payments from AHRQ 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 AHRQ 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)
- the sponsor, AHRQ

To help protect your confidentiality, we will store all paper records in a locked drawer or file cabinet in a locked office on the University of Iowa campus. We will store any electronic files we create on a password protected computer.

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: X at XXX-XXX-XXXX. If you experience a research-related injury, please contact: at XXX-XXX-XXXX.

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: 07/01/10.

_____ _____

(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)