

**CONSENT FOR RESEARCH**  
**MEMORIAL HOSPITAL OF RI**  
**BROWN UNIVERSITY**

**Principal Investigators:**

XXXXXXXX  
XXXXXXXX  
XXXXXXXX

APPROVED BY THE COMMITTEE FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

\_\_\_\_\_  
Chairperson, Committee on the Use of  
Human Subjects in Research

\_\_\_\_\_  
Date

You have been asked to take part in a research project described below.

The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, xxxxxx, the person mainly responsible for this study, xxxxxx will discuss them with you.

**1. The Study:**

**You have been asked to take part in the following study:**

This is a research study to talk with people who are at least 65 years of age about their experiences taking their medicines, and talking to their doctors or pharmacist about their medicines. Today, we are only asking you to participate in a 2-hour discussion. You have been asked to take part because you are at least 65 years of age or you are a caregiver for a person who is at least 65 years of age. For this study, approximately 120 people living in Rhode Island will be participating in focus groups. The study is sponsored by Brown University and Memorial Hospital of RI.

**If you decide to participate in the study, here is what will happen:**

You will take part in one 2-hour focus group. This means that you with about 7 other people, will have a discussion with a researcher about the topics of interest to this study. The focus groups will be made up of men and women.

The topics that will be included are the difficulties you have taking your medicines, things you do to make it easier to remember to take your medicines, how your doctor talks to you

about your medicines, and your experiences asking pharmacists questions about your medicines.

The discussion will be recorded with an audiorecorder, and later a typed transcription of the recording will be made.

*You will not be asked to specifically disclose your medical conditions, however you will be asked to talk about your experiences taking medicines. No other sources of your health information will be obtained, and the researchers will not look at your health records. Your name will never be listed as having participated in this focus group. The researchers will not disclose your name, address or telephone number to anyone outside of the study team, and they will not disclose any of the comments you make during the focus group linked with your name. Only the study team will have access to the focus group recordings and transcriptions. Your personal health information will not be disclosed to or used by any other people or organizations, except in the unusual circumstances where it may be required by law.*

We will use the information that you tell us to help us design materials aimed at helping people take their medicines correctly.

You will be given a gift card for Walmart valued at \$30 for your participation in the focus group.

At the end of the focus group, you will be asked if you are interested in being contacted in the future for other possible study activities. Your future participation is completely voluntary.

**The parts of the study that are experimental are:**

We are gathering research data through focus groups.

**2. Risks or Discomforts:**

**These risks or discomforts have been known to happen; they could happen to you:**

You will be asked to express your ideas related to the topics of this study. At times you may feel uncomfortable about a question. If that happens, you may decline to answer some questions.

**3. Benefits:**

**The benefits of this study are:**

There are no direct benefits to participating in this study. However you may find that it is interesting or enjoyable to talk about the study topics with others in the focus group. Your participation in the study will help researchers design better materials to help people take

their medicines correctly.

**4. Alternatives:**

The alternative to participating in this study is to choose not to participate.

**5. Confidentiality:**

Your part in this study is confidential. The findings of the study may be used for scientific publication however none of the information used for publication will identify you by name. All audiorecordings and records for this project will be handled according to Memorial Hospital of RI and Brown University policy for records, Federal guidelines, and Rhode Island Law on confidentiality of health-care information.

**6. Whom to contact:**

If you have any questions pertinent to this study, or this study causes you any injury, you should call Dr. Roberta Goldman (401-729-2924).

If you are not satisfied with the way this study is performed, or if you have any questions about your rights as a research subject, you may report your concerns or questions (anonymously, if you choose) to the Institutional Review Board of Memorial Hospital of Rhode Island at 401-729- 2147 or Susan Toppin of the Brown University Research Protections Office at 863-2777.

**7. Your Decision and Right to Quit at Any Time:**

The decision whether or not to take part in this study is up to you. You do not have to participate. If you decide to take part in the study, you can choose not to answer a particular question. Whatever you decide will not in any way cause a penalty or affect any benefits that you are otherwise entitled to.

*Your authorization for use or disclosure of your personal health information in connection with this study will expire when the entire research study is complete.*

*You may withdraw your authorization for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator identified on the first page of this document. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.*

**8. Your Consent:**

*The decision of whether or not to sign this form is up to you. You do not have to authorize the use and disclosure of your personal health information for research. Whatever you decide will not in any way change your relationship with your doctor or affect your treatment at Memorial Hospital of Rhode Island, except that you will not be permitted to participate in the research study.*

*More information concerning the privacy of patients' protected health information is described in Memorial Hospital of Rhode Island's Notice of Privacy Practices, which is available upon request.*

*Your signature on this form means that you understand the information, and that you have decided to authorize the use and disclosure of your personal health information for the purposes and in the manner described in this document, and that you have decided to participate in the study.*

A copy of this form will go to:

You     Researcher

**I HAVE READ THE CONSENT FORM AND UNDERSTAND IT.  
ALL MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION.  
I AGREE TO TAKE PART IN THE STUDY. I AUTHORIZE THE USE AND  
DISCLOSURE OF MY PERSONAL HEALTH INFORMATION FOR THE  
PURPOSES AND IN THE MANNER DESCRIBED IN THIS DOCUMENT.**

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Signature of Person Explaining Study

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date