

VERBAL CONSENT SCRIPT FOR PARTICIPATION IN NH-PRIDE STUDY

Aim I: Qualitative Interview with Patients and Proxies to develop the Injury Liaison Service

Co-PIs: Dr. Sarah Berry and Dr. Cathleen Colón-Emeric

OVERVIEW AND KEY INFORMATION

My name is Dr. Cathleen Colón-Emeric. I am a Geriatrician and Clinical Investigator from Duke University School of Medicine. I am calling to invite you to participate in my research study about patients' views on preventing falls with injury in the nursing home setting. You are eligible to be in this study because you (or your loved one) has recently experienced a fall. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

PURPOSE

The purpose of this research is to develop a consistent approach to prevent falls with injury in nursing home residents. Your interview responses may help our study team improve a plan to prevent injury in four nursing home facilities.

RESEARCH FUNDING

The National Institute of Health is sponsoring this study, and provides salary support for some study staff. None of the researchers have a financial conflict of interest related to this study.

DURATION

Your participation in this study will take approximately 60 minutes to complete. You may elect to complete this interview over one or two sessions, depending on your schedule.

PROCEDURES

If you agree to participate in this research study, you will be interviewed by our study team. The interview will be conducted in a private location, and it will be audiorecorded and transcribed. You will be asked to tell the story of a recent fall and attempts to prevent additional falls. You will also be asked about your experience with withdrawing medications and medications to treat osteoporosis. We may contact you in the future to see if you would be willing to participate in a follow-up interview. Participation in the follow-up interview is entirely optional.

COMPENSATION

If you participate in the research study, you will receive \$50.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS

Because we will be audiorecording your stories, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some questions asked as part of this study may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time. You can call the study team at any time if you experience any discomfort related to the research.

REASONABLY EXPECTED BENEFITS TO PARTICIPANTS OR OTHERS

You may not personally benefit from taking part in this study, but your participation may lead to knowledge that will help other people in the future.

CONFIDENTIALITY

The information collected for this study will be kept confidential. We may share your records with Dr. Sarah Berry, a co-principal investigator for this study, at Hebrew SeniorLife. Your research records may be reviewed by other Hebrew SeniorLife staff, who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies that review research information, such as the Office for Human Research Protections (OHRP). **The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information may be destroyed or information identifying you will be removed from such study results.**

RESEARCH RELATED INJURY

We will offer you the care needed to treat any injury that directly results from taking part in this research study. If we cannot provide the care directly, we will arrange for the care to be provided to you at a nearby institution. We (and/or the treating provider, as appropriate) reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

CONTACT INFORMATION

If you have questions about the study or need to talk to the study team, you can contact myself (Cathleen Colón-Emeric) at (919) 660-6932. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the Director of IRB Operations and Research Compliance at Hebrew SeniorLife, 617-971-5415.

Thank you