

Study Title: Electronic Strategies for Tailored Exercise to Prevent Falls  
NCT Number: NCT04993781

Document: IRB Approved Verbal Consent Script for Study Subsample  
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Script for Obtaining Verbal Consent to Participate in the eSTEPS Study via Phone (this script is for the subsample of participants who will participate in 3 phone interviews; baseline, six months and twelve months):

Hello Ms./Mr. {insert study participant name},

My name is NAME. I am calling from the eSTEPS research study. Your primary care practice is participating in the eSTEPS study. I am talking to you from the eSTEPS Assessment Center at Mass General Brigham, which is coordinating recruitment for this study. We are recruiting a subset of patients to participate in answering surveys on topics such as your health, exercise patterns, and recent falls.

CENTRAL SCREEN: You may recall that we sent you a packet of information about the eSTEPS study a few weeks ago.

Is this something you would like to hear more about? Would you be willing to answer questions about your health and medical history to find out if you might qualify for the study? Some of the questions may make you feel uncomfortable. You can stop at any time. This call should take around 30 minutes.

Today, I would like to tell you more about eSTEPS. The name stands for electronic Strategies for Tailored Exercise to Prevent Falls. As the introductory letter you received in the mail described, the eSTEPS study is testing better ways to care for people at risk for fall-related injuries through personalized exercise plans. We are inviting you to participate based on the fact that you are 65 or older, have had a Medicare Wellness Visit, and live independently. At this time, we are conducting a study to test our approach to prescribing safe exercise to prevent fall injuries. This part of the study will enroll about 660 participants. It is being conducted in the Mass General Brigham health system. The study is expected to last about 12 months.

#### Why are we conducting this study?

The purpose of the study will be to learn better ways to encourage patients to exercise who are at risk for fall-related injuries. We will test our approach to prescribing safe exercises that can prevent falls and related injuries. It will also help us set up the processes of caring for patients at increased risk for falls.

#### What does the study involve?

Whether or not you choose to participate in this study, you will continue to receive care from your regular physician and his/her team. This includes care to prevent falls. The

clinics participating in this study are providing an evaluation and exercise plan at a regularly scheduled primary care office visit.

Before I tell you more about the study, I would like to ask you a few questions to test your memory. This is to be sure you're able to understand the benefits and risks of participating in the study. May I ask you a few questions? [IF YES, CONTINUE; IF NO, THANK THE PARTICIPANT AND END THE CONVERSATION].

{INSERT COGNITIVE ASSESSMENT QUESTIONS – the Callahan 6-item screener} – {IF ABLE, CONT' WITH CONSENT, IF QUESTIONABLE OR UNABLE, ASK IF THERE IS ANOTHER PERSON IN THE HOME WHOM YOU COULD TALK TO; SEE SCRIPT FOR SURROGATE CONSENT}

[DOES NOT PASS COGNITIVE SCREEN]

You are not eligible to participate in the study. Thank you for your interest; [End interview]

[PASSES COGNITIVE SCREEN]

Based on your testing, I would like to tell you more about the study. If you agree to participate, you'll be asked to complete this phone interview and two additional phone interviews—one in 6 months and a second in 12 months. The interviews will take about 45 minutes. You will be asked some questions about your health, your ability to care for yourself and to accomplish daily tasks. In addition, you will be asked about your exercise patterns and any recent falls, and concerns that you may have about falling. You will also be asked to provide contact information.

After today, if you agree to participate, we will ask you to keep track of any falls and injuries on a monthly calendar that we will send to you. You will also receive a call in 6 months and 12 months to obtain additional information about your health and to ask you if you have had any falls. We will report this information collectively about people who participate at the end of our study in our study reports and publications.

The information you share with us is private. We are required by law to protect the privacy of health information obtained for research. During this study, information about you and your health will be collected and shared with researchers conducting the study. We share your health information only when we must, for example for quality control and public health. We ask anyone who receives it from us to protect your privacy.

Following the completion of the study, we hope to share our research findings with patients by providing a report that communicates major findings, interpretations, and

next steps to study participants and input from other patient stakeholders. We believe that sharing our results with participants is a beneficial educational opportunity for patients and their family members.

Would you like more information about our privacy policy? I can provide you with more information in writing or online if you would like.

[IF PARTICIPANT WANTS MORE INFORMATION: \*MGB Notice for Use and Sharing of Protected Health Information

[http://www.partners.org/Assets/Documents/Notices/Partners\\_Privacy\\_Policy\\_English.pdf](http://www.partners.org/Assets/Documents/Notices/Partners_Privacy_Policy_English.pdf)  
f.]

Your participation by completing surveys and keeping a falls calendar in this study is completely voluntary. You can drop out at any time. Please feel free to contact us with any questions or concerns. If you do not wish to participate and do not want us to contact you in the future, please let us know. You can contact us by phone (1-xxx-xxx-xxxx), email (eSTEPS@BWH.harvard.edu) or postal mail (Attn: Dr. Patricia Dykes, eSTEPS Study, Brigham and Women's Hospital, 1620 Tremont St, 3<sup>rd</sup>, Floor, Boston, MA 02120).

The Institutional Review Board (IRB) is a group of people who review research to protect your rights. They have approved this study and the procedures for collecting information. If you would like to speak with someone not involved in this research about your rights as a research subject, or complaints you may have about the research, contact the Partners Human Research committee (or IRB) at (617) 424-4100.

### **Questions**

Do you have any questions about the study or what you'll need to do? Any questions about the risks and benefits?

Have all your questions been answered? Would you like to take part?

Do I have your consent to enroll you in the eSTEPS Study?

Yes                    No

Name of Participant:

Name and signature of person obtaining consent:

Date

By signing this form, the person obtaining consent verifies that the form was read aloud in its entirety, the subject passed the cognitive screen, and all questions were answered.