CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: ACL Falls Prevention Innovation Lab

PRINCIPAL INVESTIGATOR:	**Reena Sethi, DrPH, MHS** Senior Director, Research + Evaluation National Council on Aging 251 18th Street South, Suite 500 Arlington, VA 22202
CO-INVESTIGATORS:	**Emily Nabors, MSG** Associate Director of Innovation National Council on Aging 251 18th Street South, Suite 500 Arlington, VA 22202
	Brian Ezeonu, PhD Senior Research Associate National Council on Aging 251 18th Street South, Suite 500 Arlington, VA 22202
	Angelica Herrera-Venson, DrPH, MPH National Council on Aging

SOURCE OF SUPPORT: United States Department of Health and Human Services (HHS)

Why is this research being done?
The overall goal of this study is to test different falls prevention activities to ultimately reduce falls among older adults in community dwellings.

Who is being asked to take part in this research?
Adults aged 60 years or older, who live in or near this community, do not have plans to leave the area for an extended period of time, who have not participated in a falls prevention program in the past 12 months are being asked to participate.

What procedures will be performed for research purposes?

If you consent to participate in the study, the organization providing the falls prevention program will collect information that is based on your participation in the program through surveys and physical assessments. The approximate time to complete these surveys is indicated in parentheses.

<u>If you consent to participate, we will collect the following information:</u>
A set of questions before you begin the program (15 minutes), which will include:

- Basic information about your age, race, location and chronic conditions
- A review of your health history and information related to your experiences and thoughts about falls, including your fear of falling, history of falls, self-rated health, questions about loneliness and isolation, ability to carry out routine activities in your life, and physical activity

An assessment of your physical functioning, (15 minutes, 4 times per year)), which will include:

- 30-Second Chair Stand Test
- 4-Stage Balance Test
- Timed Up and Go (TUG) Test
- Orthostatic Blood Pressure Measure

Questions after you complete the program (5 minutes), which will include:

- Your satisfaction with the program you participated in
- Whether you would recommend this program to others

What are the possible risks, side effects, and discomforts of this research study?

The risks of participating in the falls prevention program are minimal. Although the falls prevention activities may be delivered ways that are new or unique, the activities within the program are based on previous research. The possible risks participating in this research study are likely similar to those of other falls prevention programs. However, you should be aware of certain risks and discomforts, described below:

<u>The possible risks are:</u>

1.) You may get tired during falls prevention program. If you become tired, you can stop and resume when you are rested.

2.) There is a rare risk that you may fall during the program. However, members of the grantee staff who are delivering the program will be present and stop you from continuing if you appear to be having difficulty or will try to help steady you if you appear to be falling.

3.) There is a rare risk that your confidentiality could be broken. All of the records involving your participation in this study will be kept in locked file cabinets and/or password-protected files. All of the investigators listed on the first page of this form and any additional staff that assist with management of your files are trained in the privacy and confidentiality regulations that govern research.

4.) Because this is a research study, it is also possible that there are risks of participation in this study that are not currently known.

What are the possible benefits from taking part in this research study?

There is the potential for you to benefit from participating in falls prevention program. The potential benefits include: gaining more balance, being less fearful of falling, and having fewer falls. However, there is no guarantee that you will receive such a benefit. There is also the potential that information learned from this study may benefit individuals in the future to help them reduce falls.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if any new information develops during the conduct of this research study which may cause you to change your mind about continuing to participate.

Will I be paid if I take part in this research study?

You will not be paid to take part in this research study unless the organization that is conducting the falls prevention program you are participating in provides a stipend or small incentive.

Who will pay if I am injured as a result of taking part in this research study?

The organization delivering your program will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of the falls prevention program. If you believe that you are injured as a result of the program, please immediately contact the Principal Investigator listed on the first page of this

form.

Who will know about my participation in this research study?
The organization delivering this program and study investigators will know about your participation in this study.

Individuals at the place that is offering the program may see you and know about your participation in this study. Any information about you obtained from or for this research study will be kept as confidential (private) as possible. Study investigators will not know your name. The data collected from you, about you, will be entered into a computer file by the organization conducting the falls prevention program that you are participating in. Colleagues outside of the organization providing the training may be involved in data analysis and data without your name may be shared with them.

Is my participation in this research study voluntary?
Your participation in this study is voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the organization delivering the falls prevention program or the National Council on Aging.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in the falls prevention program (and the research study), to include the use and disclosure of your information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

Your decision to withdraw your consent for participation in the falls prevention program (and research study) will have no effect on your current or future relationship with the organization delivering the falls prevention program or the National Council on Aging.

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VOLUNTARY CONSENT

All of the above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions I have about my rights as a research participant will be answered by the Principal Investigator, Dr. Reena Sethi on 571-527-3972 or the Heartland IRB on 866-618-HIRB (4472).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature **Date**

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Participant's Printed Name

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CERTIFICATION of INFORMED CONSENT
(to be signed only if someone helped you fill out this form)

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date