RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Keep It Movin' Trial
Sponsor(s): NIH

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

This study is being conducted to test if a church-based program with physical activity and learning about movement helps people to become more active and to move better. You will be encouraged to participate in walking groups being held at your church, and learn about ways to safely and comfortably increase daily physical activity.

You may benefit from taking part in this study, but there is no guarantee that it will help you.

Instead of participating in this study, you may choose another form of treatment such as a physical activity program at a gym, community center, or park.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?
Adults over the age of 40 who are members of churches in the ALIVE Faith Network are being invited to participate in this study. Specifically, you are being asked to participate because you have reported some difficulty with movements like walking, and you have at least two of the following chronic illnesses: Heart Disease, High Blood Pressure, Stroke, Diabetes, High cholesterol, Arthritis, or overweight.

How many participants will take part in this study?
Approximately 360 participants are expected to take part in this study.

What are the activities you will be doing if you participate in this study?
If you are eligible and choose to be in the study, you will be asked to complete three measurements. The first will be a baseline exam, before the program starts. The second will be in six months, after you have completed the program of education. The last will occur in twelve months, when the church walking program is over.

- The baseline visit will occur before the program begins. At the baseline visit, your blood pressure, weight and height will be measured similar to how it is done at your doctor's office. You will be asked to complete some questionnaires either on paper or using a tablet computer that the study will provide. The questionnaires will ask about your health, any medicines you take regularly, your ability to do different activities, and physical activity. You will also wear an accelerometer—a small device that detects movement—for up to a week in order to measure your activity levels. This visit will take about 45 minutes.
- At the two follow-up visits, we may ask you some questions about what you think about the program and we will repeat many of the measurements you performed at the baseline visit.

The Keep It Movin' study has two study groups. Participants in both groups will be encouraged to participate in walking groups taking place at your church, and will receive education about ways to increase daily physical activity so that you avoid pain or help to prevent falls, including ways to make your home environment safer to prevent falls, and other related topics. The two groups will receive that education in two different ways.

Your church will be "randomized" (chosen by chance or like a roll of dice) into one of these two groups. Neither you nor the research team will be able to ask to be in a specific group. A computer will assign the groups so your church will have an equal chance of being placed in either group.

One group will get training through the GetFit4Life Everyday Guide. This program includes an exercise guide and motivational tips to help older adults start and keep on with a safe exercise program. Members of churches in the GetFit4Life group will complete the guidebook independently, and will control the activities you do in the comfort of your home and community. The self-directed program provides step-by-step instructions on increasing daily movements in a time and place that is most convenient for you. GetFit4Life was developed by scientists at the National Institutes for Health.

The other group will get the Stronger4Longer program. Members of churches in the Stronger4Longer group will get training through 90-minute classes at your church. Classes will be held weekly for 24 weeks. All classes will include education about how to do physical activity safely, social support and problem-solving, along with structured physical activity. The classes are led by teachers with a background in exercise science, who will provide instructions on how to increase your daily activity, along with social support for that activity. In this group, we will start with some indoor walking, then do muscle strengthening exercises, balance exercises, and finish by stretching. During these sessions trained leaders will help you decide the amount of walking to do and will teach you how to properly do each of the exercises. The muscle strengthening portion will be done using adjustable ankle weights, and we will give you a pair of ankle weights so that you can do these exercises at home. This group was developed based on the Lifestyle Interventions & Independence For Elders (LIFE) Study.

Will you be contacted about participating in future research?

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?

Risks from participation in this study may include:

- *Risks of Increasing Physical Activity:* Risks involved with increasing your physical activity include, but are not limited to, injuries to the muscles, ligaments, tendons and joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will follow guidelines and safety recommendations for physical activity set forth by the American College of Sports Medicine and by your doctor. The study will provide you with information and recommendations for safely increasing your physical activity and will make modifications to your program if you experience any of the above problems. This may include requiring you to obtain the consent of your physician to participate in physical activity.
- *Risk of Breach of Confidentiality:* Because you will be asked to attend group meetings, research staff cannot guarantee confidentiality of your identity, or information discussed during group sessions. However, although there is a slight risk that your confidentiality will be breached, all study volunteers are strongly encouraged to maintain strict confidentiality.

There may be other risks that may happen that we cannot predict.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You don't follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Elizabeth Lynch, Dr. Steven Rothschild, their study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, the team working under the direction of Dr. Lynch and Dr. Rothschild will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. The health information that Rush may use or disclose for this research includes:

- Measured blood pressure, height and weight from study assessments
- Self-reported health information from answering questionnaires.

Dr. Lynch and Dr. Rothschild and their study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

Your church coordinator will be informed of your enrollment status, contact information, and attendance at study visits and assessments, but will not be provided with access to any study data.

While you participate in the study you will have access to your medical record, but Drs, Lynch and Rothschild are not required to release to you any study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your

medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Drs. Lynch and Rothschild at 1700 West Van Buren St. Suite 470, Chicago IL 60612.
If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon your completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. In order to keep your information confidential, records will be kept in a locked cabinet in the Department of Family and Preventive Medicine at Rush University Medical Center or on a secure server than is encrypted and password protected. Your name will be removed from interview results, and you will only be identified by an identification number without any identifying information. Only the researchers will be able to link your identification number to your name.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

What are the costs to participate in this study?
There are no costs to you for participating in this research.

Will you be paid for your participation in this study?
You will be paid $25 for completing the Baseline Assessment. You will be paid $50 for the Six-month Assessment, and another $50 for when you complete the Twelve-Month follow-up Assessment.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Amber

Deckard at telephone number (312) 942-3303.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call the project director, Amber Deckard at 312-942-3303 or email her at amber_deckard@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Rothschild or Dr. Lynch in writing at the address on the first page. They may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

_____	_____	_____
Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

_____	_____
Signature of Individual Obtaining Consent	Date of Signature