

## RESEARCH CONSENT FORM

**Title of Project:** Living in Fitness Together (LIFT): Testing an Innovative Fall Prevention Program

**Principal Investigator:** Christine M. McDonough, PT, MS, PhD

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### **Background**

Exercise can improve balance and walking and help people to avoid falling. However, often people have difficulty doing the right kinds of exercise on their own over the long-term. We need to learn the most effective ways for physical therapists to help older adults to become more active and exercise regularly at the right level to make them much less likely to fall as they get older.

This study is funded by a grant from The Foundation for Physical Therapy. It is conducted by a research team at Mount Ascutney Hospital and Health Center (Mt. Ascutney) and at Boston University.

Ms. Linda Hazard, PT, is an investigator of this research study and a physical therapist at Mt. Ascutney. As an investigator, she is interested both in your clinical welfare and in conducting this study. You do not have to participate in any research study offered by your physical therapist. Feel free to ask for a second opinion about your care from another therapist or doctor who is not an investigator in this study before you decide whether to participate.

### **Purpose**

The purpose of this study is to compare the benefits of 2 different physical therapy programs to help older adults at risk for falls to exercise regularly in ways that make them much less likely to fall as they get older.

### **What Happens In This Research Study**

Please read this form carefully and ask any questions you may have before agreeing to participate in this study. We encourage you to talk to family members about the study and to take your time making your decision. If you decide to be in this study, you will sign a copy of this form and we will give you a copy to take home with you.

You are being asked to participate in this study because your primary care doctor or physical therapist has found that you have balance or walking problems that might put you at risk for falls. You will be one of about 48 people to be asked to participate in this study, all at Mt. Ascutney Hospital and Health Center.

### **Random Assignment to Study Group**

If you agree to participate in this study and sign this consent form, you will be randomly assigned to one of 2 different types of physical therapy treatment that include physical

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therapy exercise and group activities. Random assignment is like flipping a coin and is important to do to test which type of treatment is better. This means that you won't be choosing which program you are in.

### One-on-One Physical Therapy and Group Healthy Living Sessions

One type of treatment is to continue with your one-on-one physical therapy and to participate in group sessions to provide valuable information about ways to stay healthy, including healthy eating, activity, relaxation and stress management. Group activity sessions will meet for a half hour, one per week for 6 weeks, and one final one hour session three months later.

For both groups, an Occupational Therapist will assess whether you would benefit from a home safety visit. You will be offered a home visit by a licensed Occupational Therapist at no charge to you or your insurance company if a visit is recommended.

### Group Physical Therapist-led Exercise and Coaching

The other type of treatment is a group session that will include physical therapist-led exercise and education and experimental coaching activities to teach group members ways to help each other to meet their exercise goals during and after the classes are over. Your sessions will be led by Mt. Ascutney physical therapy, occupational therapy and recreational therapy clinical providers who are members of the research team. You will be given materials to help you participate in a home exercise program that include similar exercises to those you will learn in your group class, along with an exercise diary to record your walking and home exercise activity. Group sessions will meet for an hour, twice per week for the first 2 weeks, then once per week for 4 weeks. There will be one final one hour session three months later.

### Evaluation Sessions

You will also come to Mt. Ascutney for 4 evaluation sessions:

#### Pre-Group

You will come to Mt. Ascutney for a 1 hour group session. During this session you will meet the study team and the other people in your group, and receive your study materials. One of the study team will ask you to answer surveys about your mobility and walking, and you will do some balance and mobility tests.

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### Post-Group

At the last session you will be asked to complete the balance and mobility tests and surveys. This will take an approximately 30 -45 minutes.

### 3-Month Follow-up

You will come for a one hour group session. You will be asked to complete the balance and mobility tests and surveys during that time.

### 6-month Follow-up

You will come for a final evaluation session. At that time you will complete the balance and mobility tests and the surveys. This will take approximately 30 -45 minutes.

### Phone Contact After the 6-week Group Sessions

Over the 6-month period after the group sessions, a member of the research team will call you every 2 weeks to see if you are having any difficulty with exercise, activity tracker, falls or other aspects of the program.

### Risks and Discomforts

There are some minor risks and potential discomforts if you decide to participate in this study. The balance and mobility tests are standard tests used by physical therapists and will be conducted a licensed health care provider or trained staff under the direct supervision of the licensed provider. There is a small risk that you could feel some fatigue, muscle soreness or other discomfort or experience a fall or injury during tests and exercise. This risk is similar to that associated with usual physical therapy and exercise. You can decrease risk of injury by communicating with the physical therapist if you are experiencing difficulty or concerns, and by following the group instructions for appropriate shoes and exercise progression. We want to know if your health changes during the study or follow-up period. We will make every effort to insure your confidentiality, but even with these measures, there is a slight possibility that information may be released or disclosed in a way that it will no longer remain confidential. There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

### Potential Benefits

The benefits of participating in this study may be: increased strength, balance, mobility and function. In addition, benefits may include increased confidence with exercise,

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increased physical activity, additional social contacts, increased knowledge about healthy activities and exercise, increased home safety, and satisfaction from contributing to our understanding of how to help older adults improve balance and mobility as they age. You will also receive an Activity Tracker that you will be able to keep after the study, and training in how to use it. You will be offered a home safety evaluation from an Occupational Therapist free of charge. However, you may not receive any benefit from participating in this study.

### Alternatives

Your alternative is to not participate in the study, and to continue with physical therapy as usual. Your treatment will not be affected by your choice.

### Subject Costs and Payments

There are no costs to you for participating in this research study. However, if you are assigned to continue with your usual one-on-one physical therapy sessions, these sessions will be charged to you and your insurance carrier as they would be if you did not participate in the study. You will be responsible for your physical therapy co-pay. There is no cost for the group sessions. You will not be paid to participate in this research study. You will receive free parking for all evaluation and group class sessions in the parking lot at Mt. Ascutney Hospital and Health Center. You will be responsible for your own transportation to and from Mt. Ascutney Hospital and Health Center. Costs for these sessions will be supported by the study, so no charges will be made to you or your insurance company for these sessions. If you are assigned to group physical therapist-led exercise we will provide adjustable weights for you to use in the first 6 weeks of the program, and then if you do not have access to weights to use, we will recommend that you purchase them to progress on your own. The adjustable leg weights cost between \$20 and \$40.

### Confidentiality

Any information you provide for this study will be confidential. All of the information will be kept in a locked cabinet in a locked office or on a secured password-protected computer or a secure online database. Information collected from you and each participant will be given a unique code so that your name will not be used. We will keep a master list matching your name to the unique code. This list be kept secured, and only select study investigators will have access to this list. When the study is reported, participant names will not be used.

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Information from this study may be viewed by Mt. Ascutney Hospital and Health Center, state and/or federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Your information may also be used by non-research staff within Mt. Ascutney Hospital and Health Center and Boston University and by people or groups who we hire to do work for us, who need this information to do their jobs, such as data storage companies, insurers, and lawyers.

### **Subject's Rights**

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. You have the right to refuse to answer questions asked during the study.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at 617-638-7207.

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [\(Linda Hazard, PT\)](#) at [\(\(802\)674-7295 at Mt. Ascutney\)](#) during the day and [\(Christine McDonough, PT, PhD at Boston University\)](#) at [\(\(781\)771-5479\)](#) after hours.

### **Compensation for Research Related Injury**

If you think that you have been injured by being in this study, please let the investigator at Mt. Ascutney know right away [\[Linda Hazard\]](#). Treatment for injury would be available at Mt. Ascutney Hospital and Health Center or elsewhere locally. Boston University Medical Center, Mt. Ascutney Hospital and Health Center, and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

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### **Right to Refuse or Withdraw**

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at Mt. Ascutney Hospital and Health Center, or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

**Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.**

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**Subject (Signature and Printed Name)**

**Date**

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**Person Obtaining Consent (Signature and Printed Name)**

**Date**