CONSENT FOR RESEARCH
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Integrating patient-centered exercise coaching into primary care to reduce fragility fracture

Principal Investigator: Christopher Sciamanna, MD, MPH

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Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 4:30 p.m. (717) 531-7754.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

We are asking you to be in this research because you are at least 65 years old and have had a fragility fracture in the past 10 years. The research is being done to find out whether a coached exercise program can help decrease the risk of a fragility fracture or fall-related injury. This coached exercise program uses resistance bands and includes strength training, balance, and aerobic activity. Approximately 1380 people will take part in this research study across Pennsylvania.

2. What will happen in this research study?

1. **We will ask a few things about you and your health.** Before your first visit with us, we will ask you to complete a 20-minute survey about contact and demographic information, medications, and how your health and well-being affect your daily life. You're free to skip any questions that you prefer not to answer.

2. **We will ask you to complete a study visit.** We will do one final screening step to check your blood pressure and heart rate. If you are eligible to continue, we'll measure your height, weight, blood pressure, and body strength. This visit will be completed at Penn State Hershey Medical Center and should take about 60 minutes.

3. **You may have a DXA scan(s).** If your doctor orders a bone density test, you'll have that done after the visit. The scan uses two x-ray beams to measure your bone density and will take about 20 minutes. You'll also have the option to have a total body composition scan to measure your muscle and fat, which would take another 10 minutes.

4. **You will be assigned to one of two groups.** Both groups will receive information about preventing falls – one will be asked to continue their normal activities, and one will have access to the coached exercise program. Neither you nor the study staff will choose your group. Rather, a computer will randomly assign you to one or the other so everyone has an equal chance of being in either group. We use chance because we don't know which group might be best for you and to help us compare the two groups at the end.

5. **You could be asked to work with a coach.** If you're assigned to the coached exercise group, you will have a coach that works individually with you. They will check your progress regularly by phone and in person and help you find ways to increase your strength and balance. As part of the coached exercise, the coach can provide you with resistance bands and a DVD to use at home and help you find a group exercise session at a community location convenient to you. The group exercise sessions meet three times a week for 50 minutes and include strength training, balance, and aerobic activities led by trained group leaders.

6. **We will ask you to complete brief phone calls.** We will call you every 4 months to see whether you've fallen, had any injuries, and received any medical care. These calls will take about 10 minutes and can be scheduled at your convenience. At 12 and 24 months, we'll also ask some additional questions about your overall health and physical activity.

7. **We will get some information from other places.** To be sure we get a complete picture of any major medical event you report, we will request your medical records from wherever you were treated. We will ask you to sign a Medical Release Form saying it is okay for us to review all relevant radiology reports, emergency department and hospital discharge summaries, and notes from outpatient visits, consultations, and physical exams. We may also ask for your insurance claims number.

8. **We will ask you to complete a second study visit.** At 36 months, we will ask you to come back to Penn State Hershey Medical Center for a visit. Before your visit, we will ask you to complete a 20-minute survey about medications and how your health and well-being affect your daily life. You're free to skip any questions that you prefer not to

answer. The visit will last about 30 minutes and consist of measuring your height, weight, blood pressure, and body strength.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

- Completing visits at baseline and 36 months
- Completing questionnaires once a year
- Completing phone calls every 4 months
- If you are assigned to the exercise group, participating in regular phone calls with coach

3. What are the risks and possible discomforts from being in this research study?
Possible risks for this study include:

- **Loss of confidentiality:** There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your data stored electronically will be maintained to the degree permitted by the technology used. The exercise groups will be encouraged to keep any personal information shared during group discussions confidential. Absolute confidentiality cannot be guaranteed.

- **Questionnaires:** If you are uncomfortable answering questions on the surveys, you are free to skip any questions that you would prefer not to answer.

- **Exercise:** Our exercise program follows recommended guidelines for physical activity, but there is always the possibility that any increase in physical activity may result in an injury. The exercise program could cause: muscle and joint soreness and strain, fracture (such as a spine compression fracture), shortness of breath, dizziness, undue fatigue, chest pain, low blood glucose, heart attack, abnormal heart rhythm, or a fatal event. Your coach will help you start at an appropriate level and individualize the exercises to best fit your needs and capabilities. Each site is led by group leaders trained by our coaches and has an emergency kit.

4. What are the possible benefits from being in this research study?
4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include increasing strength and balance, and decreasing risk of falls and injuries.

4b. What are the possible benefits to others?

The results of this research may help researchers learn how to prevent falls and injuries – the results might benefit people like you in the future.

5. What other options are available instead of being in this research study?

You may choose not to be in this research study.

6. How long will I take part in this research study?

If you agree to take part, it will take you about 36 months (3 years) to complete this research study. You will be asked to return to the research site 1 time and complete 8 brief phone calls.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include these identifiers: your name, address, phone number, email address, date of birth, medical record number, a code number, and possibly your health insurance claim number.

- A list that matches your name with your code number will be kept electronically in REDCap (a password-protected and encrypted electronic research data program). Research staff will use REDCap to both collect and store data.
- Staff will have paper copies of some research documents and data that will be stored in a locked cabinet in Dr. Sciamanna's research office; all personal health information (PHI) will be separated from data collected.

We will communicate the results of any critical values of blood pressure, heart rate, anxiety or depression to both you and your primary care doctor. For research records shared with our partnering institutions (University of Pittsburgh, Temple University and Johns Hopkins), you will be identified only by code number.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

The research team may use the following health information:

- Past, present, and future medical records
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- HMC/PSU research staff involved in this study
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office
- Other researchers and medical centers that are part of this study and their IRBs
- The Research Data Assistance Center (ResDAC), which collects information on patients enrolled in Medicare
- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- Our funder, the Patient-Centered Outcomes Research Institute (PCORI)
- Organizations that provide independent accreditation and oversight of hospitals and research
- The clinical trial monitoring group in the Department of Public Health Sciences at PSU that oversees the data (study information) and safety of this research

These groups may also review and/or copy your original PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address

on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.

- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The Total Body Dual-energy X-ray Absorptiometry (DXA) scan will be provided by Patient-Centered Outcomes Research Institute (PCORI) at no cost to you while you take part in this study.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be billed for the costs of the Bone Density Dual-energy X-ray Absorptiometry (DXA) scan in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility.

HMC/PSU compensation for injury

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.

- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will receive a $25 gift card for completing your first visit and 12-month and 24-month phone calls. You will receive a $75 gift card for completing your 36-month visit. If you complete the study, you will receive a total of $150 in gift cards. If you do not complete the study for any reason, you will be paid for the parts you have completed.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the Patient-Centered Outcomes Research Institute (PCORI) to support this research.

This research study is designed to test a product made by Dr. Christopher Sciamanna (Principal Investigator at Penn State University). Dr. Sciamanna has an investment in a company, Band Up, Inc., such as stock, which has begun to investigate the possibility of creating an exercise service for older adults. The amount of money the investment is worth might be affected by the results of this study. This means that Dr. Sciamanna could gain or lose money depending on the results of this study. This financial interest has been reviewed by the PSU Institutional Review Board and Conflict of Interest Review Committee. If you would like more information, please contact the Conflict of Interest Program at (717) 531-0003, extension 283526.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

Your research doctor [or the sponsor] may take you out of the research study without your permission.

- Some possible reasons for this are: continuing the research would be harmful, your condition has become worse, you did not follow the instructions of the study doctor, or you experience serious side effects.
- Also, the sponsor of the research may end the research study early.
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

During the course of the research, you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Christopher Sciamanna at 717-531-8161 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to talk to someone else about any concerns related to the research.

You may visit the HSPO's web site at http://pennstatehershey.org/irb under research subject information for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Optional DXA Scan

If you take part in this research, you will have one or more medical imaging studies which use radiation. The tests or treatments you will have include a total body composition measurement. The radiation exposure from this research is about 30 microsievert. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 4 extra days' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may have received or will receive from other tests.

You may have a number of x-rays that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These studies will not add to the risk of the research. However, if you have concerns about the overall radiation exposure, you should discuss them with your physician.

This test is an optional portion of the study. If you agree, this test will last about 10 minutes and will be performed at the Penn State Hershey Medical Center during the baseline visit and/or the 36 month assessment visit. During the session, the following procedures will be done:

Your total/whole body and tissue composition will be evaluated using a machine called a DXA bone densitometer. It requires only that you lie still on the padded measurement table for about 10 minutes. All measurements will be conducted by a trained operator.

You should initial below to indicate what you want regarding the DXA scan.

You may have a total body DXA scan performed.
_____ Yes _____ No

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the optional part(s) to the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

Signature of Person Giving Informed Consent

Signature of Subject

By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part(s) of the research study.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name