Combining Testosterone Therapy and Exercise to Improve Function Post Hip Fracture

STEP-HI Project
Starting a **T**estosterone and **E**xercise **P**rogram after **H**ip **I**njury

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INFORMED CONSENT DOCUMENT

Project Title: **STEP-HI Study: Combining Testosterone Therapy and Exercise to Improve Function Post Hip Fracture**

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form, you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks, and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are female, 65 years old or older, and you recently had surgery to repair a hip fracture.

Decreased muscle strength, muscle mass (amount of muscle), and bone are common in women over the age of 65 years following a hip fracture. Low testosterone ("male" hormone) levels occur with aging in both men and women, and are associated with a decline in muscle strength.

The purpose of this research study is to see if 6 months of testosterone gel therapy combined with resistance (weight) training exercise improves physical function after a hip fracture more effectively than resistance training alone, or an independent home exercise program.

Testosterone gel is approved by the U.S. Food and Drug Administration to increase

testosterone levels in men who do not produce enough of the hormone naturally. However, the use of testosterone gel is considered investigational in this research study. Testosterone gel is being compared to a placebo, which is an inactive substance containing no active study drug.

WHAT WILL HAPPEN DURING THIS STUDY?

The study staff will review all the requirements and restrictions of the study with you to determine if you qualify for the study and to answer your questions. You may be able to complete a portion of the activities with research staff from your home, either over the phone or through video call. However, some parts of the screening, baseline, month 3, and month 6 visit must be completed at the research center. Transportation will be provided to you for all study-related visits to the research center.

SCREENING VISIT (Expected to last about 2.5 hours)

You must complete the screening visits prior to study entry to determine whether you are eligible to continue in the study. The screening visit may take up to two sessions, depending on staff availability and your preference. Transportation will be provided for any visits occurring at the research center.

- We will ask you questions about your medical history, any current illnesses, and any medications you are taking. During your participation, you should tell the study team before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- We will collect information about your primary care physician, orthopedic surgeon, and oncologist (if applicable) so we can notify them of your interest in the study and confirm that participation is safe for you.
- You will be asked to complete questionnaires about your mood and about angina (chest pain). We will also ask questions to check your memory and thinking abilities. You do not have to answer any question you do not want to answer.
- Your heart rate, blood pressure, and weight will be measured.
- You will have a physical examination performed by a study physician or Advanced Practice provider. The physical exam will include a neurological and musculoskeletal evaluation.
- A blood sample will be collected for some laboratory tests to make sure it is safe for you to participate in the study. About 3 teaspoons (13.5 ml) of blood will be collected into about 4 small tubes. It may also be necessary to re-draw a portion of the blood sample.
- An electrocardiogram (ECG) will be done. An ECG painlessly measures the

electrical action of your heart and helps evaluate the health of your heart. It involves placing electrodes (sticky patches) on your chest, arms, and legs. It takes less than 10 minutes to complete.

- If you are found to be at higher risk of having heart complications from exercise training, you will be referred to your primary care doctor for clearance to be part of this study. Your doctor may order a stress test or other tests that are part of the standard of care for people with heart conditions or cardiac risk.
- You will complete a Modified Physical Performance Test (mPPT) to measure your strength, walking speed, and balance. You will only be required to perform activities that you are capable of doing on your own. The mPPT is made up of 9 tasks. Some of the tasks will be timed.
    - Book lift
    - Putting on a lab coat
    - Picking up a penny from the floor
    - Standing balance
    - Standing up 5 times from a chair
    - 50 foot walk, including a turn
    - Climb 10 stairs
    - 360 degree turn
    - Climbing 2 flights of stairs.

BASELINE VISIT (Expected to last about 6 hours)

If you fulfill all screening criteria and choose to participate in the study, you will be asked to complete more procedures and tests that may be scheduled on several days in a 2 week period. When coming to the research center, transportation will be provided to you. The following activities will be completed during the baseline visits:

- Your walking endurance will be measured using a 6-Minute Walk Test (6MWD). You will be asked to walk for 6 minutes along a marked path. The goal is to walk as far as possible. You may set your own pace and rest as needed. The distance you cover will be measured.
- You will complete the same Modified Physical Performance Test (mPPT) to measure your strength, walking speed, and balance that you completed at the Screening visit.
- You will complete a 4 meter timed walk at your usual pace and at a fast pace.

- You will perform a 1-Repetition Max (1-RM) test to measure the muscle strength of your legs. 1-RM is the maximal amount of weight that you can lift one time. For the test, you will perform a leg press exercise on a weight machine that has been chosen specifically to accommodate patients who have undergone hip fracture repair.
- You will be asked to grip a tool called a dynamometer to measure the strength of your hand and forearm.
- You will be asked to complete questionnaires that include questions about your ability to perform activities of daily living (ADLs), your perceptions of your health, pain symptoms, your mood, and your physical activities. You do not have to answer any questions you do not want to answer.
- You will have a physical exam performed by a study physician or Advanced Practice provider to update any changes since the screening physical exam and check for hair growth patterns to compare with later changes that might occur as a result of taking testosterone.
- You will have blood drawn for laboratory testing so the study team knows where your levels are at the beginning of the study. A total of about 2 teaspoons (10.5 ml) of blood will be collected - usually 2 tubes. In order to get an accurate reading, a portion of the blood sample may have to be re-drawn.
- You will have a Dual X-ray Absorptiometry (DXA) Scan: DXA is a type of x-ray that measures bone density and total body mass (muscle and fat). This test will take approximately 30 minutes to perform, and will require that you lie on a table for about 15 minutes. There is a small chance you will be asked to repeat the scan to obtain the best possible image.
- You will have a mammogram if you haven't had one in the past 6 months. A mammogram is an x-ray of the breast. The breast is briefly compressed while the x-ray images are taken. The total examination takes 10-15 minutes. If you have had a mammogram in the past 6 months, you will need to provide the report or give your permission for the study to get the report. If you have not had a mammogram in the past 6 months you will be required to have one.
- A dietician will meet with you to assess your nutrition. The dietician may make recommendations to improve your diet.
- A physical therapist will complete an evaluation with you to find any physical limitations or impairments that may limit your ability to perform specific exercises or require modifications.

RANDOMIZATION (Expected to last about 1 hour)

If you are eligible for the study, you will be randomly assigned to one of three groups after completion of the baseline visits. By "random", we mean that neither you nor any of the study research members can select the group you will be in. Using a procedure, like rolling dice, a computer program assigns you to one of the three study groups:

1. **Enhanced Usual Care**
2. **Supervised Exercise Program with Inactive Gel (Placebo)**
3. **Supervised Exercise Program with Active Gel (Testosterone)**

Even though the assignment is random, you do not have an equal chance of being assigned to each group. Only 1 out of 9 participants will be assigned to the Enhanced Usual Care group. 4 of the 9 will be assigned to the Supervised Exercise Training Program with Inactive Gel (Placebo) and the remaining 4 will be assigned to the Supervised Exercise Training Program with Active Gel (Testosterone).

INTERVENTIONS

1-Enhanced Usual Care

You will receive a home exercise program that consists of a set of 9 exercises focused on joint range of motion and flexibility. Each month an exercise trainer will review the exercises with you. All exercises are similar to standard care (regular care you would receive if you chose not to participate in this study) you would receive after being discharged from physical therapy after a hip fracture repair. You will be given an illustrated guide to the exercises and written instructions. You are encouraged to perform the exercises 3 times per week over the 6 month period. You will maintain a log of your exercise sessions on a form. The study forms will be turned in to the study team on a monthly basis. The study team will also check in with you by phone or email to ask if you have questions and offer encouragement.

You will participate in a monthly follow-up visit where study staff will review any symptoms you are having, review the assigned exercises, collect your exercise log, and provide a health education session. The monthly sessions will typically last about 60 minutes. The month 3 and 6 visits will be longer for follow-up assessments. Transportation will be provided to all visits at the research center.

Study procedure	M1	M2	M3	M4	M5	M6
Home based exercise program	x	x	x	x	x	x
Health Education session	x	x	x	x	x	x
Calcium & Vitamin D	x	x	x	x	x	x
Dietary Assessment			x			

2-Supervised Exercise Program and Inactive Gel (Placebo)
3-Supervised Exercise Program and Active Gel (Testosterone)

Exercise Intervention:

The supervised exercise program will be led by a physical therapist, exercise physiologist, certified personal trainer, or a qualified exercise professional directly supervised by a physical therapist. Exercise sessions will be conducted at an outpatient exercise or rehabilitation facility. You will be expected to attend an average of two exercise sessions per week for 6 months. Each session will last about 1 hour. Transportation will be provided to all the exercise sessions. Your first exercise session will take place within one week of your randomization visit.

The exercise program will be advanced gradually and conducted in two phases. Phase 1 is light resistance, flexibility, and balance training. This phase is meant to improve balance, range-of-motion, muscular endurance, and to prepare you for Phase 2 of the program. Phase 1 will last about one month. Phase 2 consists of progressive resistance training. You will exercise using weight machines and free-weights. Phase 2 will last about five months.

In the event of increased COVID restrictions, a remotely supervised exercise program will be provided. If possible, exercise sessions will be conducted by the exercise trainer remotely through a secure video call using a tablet or laptop with a camera. You will be able to borrow a tablet and stand from the study, if you do not have one.

You will also be encouraged to walk for about 20 minutes and perform a standardized set of exercises at home about 3 other days of the week. You will be provided with a form to track your home exercise activities. Upon completion of the 6 months of training, you will be given a set of exercises to continue exercising safely on you own.

Topical Gel Intervention:

You will receive a **topical gel** that must be placed on the skin daily. The study gel is in a pump bottle to make it easy for you to use. The gel will be either testosterone or placebo. You will not know which gel is prescribed for you. The gel containers will look identical.

At randomization, you will receive a bottle of testosterone gel or placebo gel and detailed instructions on how to use it properly. A study staff member will observe while you apply the first dose of gel. You are expected to apply the gel on your own, as directed during the 6-month intervention period (Randomization to Month 6). You will receive a log that you will use to record the amount of gel applied each day, the location on the skin, and the time of day. During the first month, you will receive a weekly phone call to discuss any questions you have about applying the gel.

It is important that no one else be exposed to the gel. To prevent this you should always:

1. Wash your hands immediately with soap and water after applying the gel.
2. Allow the gel to fully dry.
3. Cover the part of your skin where gel was applied if coming in direct contact with others (for example, holding children) within 2 hours of application.
4. Wash the part of the skin where gel was applied well with soap and water before there is skin-to-skin contact with another person.

Each month, the study staff will ensure you have enough gel for the next month. The study staff member will review your gel use logs and review any symptoms you have experienced.

To make sure that the topical gel is at the target dose, the study team will draw a tube of blood (1 teaspoon or 6 ml) 2 weeks after you start applying the gel to test the hormone levels. The study team will let you know if you need to use more or less of the topical gel. This change will be made for both women who are using the testosterone and the placebo. The blood tests to check your hormone levels will be repeated monthly. Each month, you will apply the gel and have your blood drawn 2 hours after the gel application to make sure it is done consistently each time. There is a small chance the blood sample will need to be re-drawn after a visit.

Study procedure	**M1**	**M2**	**M3**	**M4**	**M5**	**M6**
Center based exercise program	2 times a week	2 times a week	2 times a week	2 times a week	2 times a week	2 times a week
Home maintenance exercises	x	x	x	x	x	x
Apply Gel	x	x	x	x	x	x
Calcium & Vitamin D	x	x	x	x	x	x
Dietary Assessment			x			

All Study Participants:

All study participants will be provided with a daily vitamin D supplement, which is 2000 units per day in one capsule. You will also be given a daily 500 mg calcium supplement that would be taken twice a day, unless it is determined that you should not take calcium. The tablets will be provided to you by the study team.

In addition, you will receive a nutrition assessment to ensure sufficient nutrient intake during the study. You will visit with the study dietician at baseline and again at Month 3 to receive feedback on your nutrition. Also, if you lose more than 5% of your body weight in a month, the dietician will follow up with you.

FOLLOW-UP VISITS
(Expected to last about 1-2 hours for months 1, 2, 4, & 5 and about 3-5 hours at months 3 & 6)

Each month during the intervention period (Randomization to Month 6), you will have a study follow-up visit. After the 6 month intervention period, you will have your final study visit. You may receive a telephone call 9 months after randomization to answer a brief questionnaire about how you have been since the intervention period ended. The table below lists the schedule of the assessments for follow-up.

Schedule of Study Assessments for Follow-up W=Week and M=Month

Follow-up visits	**W2**	**M1**	**M2**	**M3**	**M4**	**M5**	**M6**	**M9**
Physical and Questionnaire Measures								
Height, Weight, Vital signs		x	x	x	x	x	x	
Physical exam				x			x	
Questionnaires				x			x	x
Adverse Event Assessment		x	x	x	x	x	x	
Physical Performance Measures								
Modified Physical Performance Test (mPPT)				x			x	
Six Minute Walk Distance (6MWD)				x			x	
1-RM				x			x	
4 Meter Walk				x			x	
Hand Grip Strength				x			x	
Procedures								
DXA Scan							x	
Mammogram (Exercise Group only)							x	
Transvaginal Ultrasound (Exercise Group only if uterus present)							x	
Laboratory Blood Draw								
Testosterone Level (Exercise Group) 1 tsp	x	x	x	x	x	x	x	
Testosterone Level (Usual Care Group) 1 tsp				x			x	
Safety Labs (1 – 2.5 teaspoons)				x			x	

Transvaginal ultrasound. This procedure will only be done once at the end of month 6 ONLY if you participated in the supervised exercise training groups and have a uterus. The purpose of this test is to measure the thickness of the lining of your uterus (called the endometrium).

- An instrument, which is smaller than a speculum (normally used to look at the cervix), is inserted into the vagina that causes sound waves to bounce off organs inside the pelvis. These sound waves create echoes that are sent to a computer, which creates a picture called a sonogram.
- If the ultrasound measurement of the lining of the uterus is greater than 4 millimeters thick, you will be referred to your gynecologist or PCP to evaluate the cause of the thickened tissue.

WILL YOU SAVE MY BLOOD SAMPLES OR RESEARCH DATA TO USE IN FUTURE RESEARCH STUDIES?

As part of this study, we are obtaining blood samples from you. We would like to use this blood for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding hip fracture recovery, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood you give up any property rights you may have in the blood.

We might remove identifiers from your blood sample and then use the biospecimens for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information and blood.

We will share your blood and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, other sites participating in the STEP-HI study, other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.
If you change your mind and do not want us to store and use your blood for future

research you should contact the research team member identified at the top of this document. The blood will no longer be used for research purposes. However, if some research with your blood has already been completed, the information from that research may still be used. Also, if the blood has been shared with other researchers it might not be possible to withdraw the blood to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood & data may be stored and used for future research as described above.

_____Yes _____No
Initials Initials

My blood & data may be shared with other researchers and used by these researchers for the future research as described above.

_____Yes _____ No
Initials Initials

VIDEO RECORDING

One aspect of this study involves making video recordings of you during your center-based exercise program. For a selection of participants, videos will be taken to make sure that all of the exercise professionals are completing the exercises in the same way. Only the exercise professionals at the site and physical therapy supervisors working with the study have access to the videos. The videos will be uploaded to a secure location for viewing and will be destroyed at the end of the study. You can choose not to be video recorded and still participate in the study.

I give you permission to make video recordings of me during this study.

_____Yes _____No
Initials Initials

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 people will take part in this study conducted by investigators at Washington University. A total of approximately 200 people are expected to participate across the United States.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for about 10 months. There will be visits for screening and baseline. You will have monthly research visits for about 6 months after randomization. The timing of study visits may be modified to accommodate you and the schedule of the study team. You may also receive a brief telephone follow-up 9 months after randomization.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

You should report any injuries or illnesses you experience while you are in the study, even if you do not think they are related.

Medications:

Testosterone gel

Less Likely / Less Common (Occurring in less than 5% of women)

- Mild swelling of the ankles from fluid retention
- Hair growth

Rare (Occurring in less than 1% of women)

- Facial acne
- Scalp hair loss
- Enlarged clitoris
- The effects of testosterone on blood lipids (triglycerides and cholesterol) have been both positive and negative. High levels of these can cause heart disease and stroke.
- For women with a uterus, there is a possibility that testosterone therapy could cause a buildup of the lining of the uterus, and rarely, cause vaginal bleeding. If you develop vaginal bleeding during the study, it will be necessary to evaluate your uterus with a vaginal ultrasound at that time (as discussed in the section about the vaginal ultrasound).

During the intervention, the study team will be monitoring you for these symptoms. These symptoms are typically reversible with prompt discontinuation of the drug. Very rarely, some of these side effects may not be reversible. Occasionally, people have allergic reactions to medications which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include: a rash; shortness of breath; wheezing; difficulty breathing; sudden drop in blood pressure; swelling around the mouth, throat, or eye; fast pulse; and sweating. You should get immediate medical help and contact the study doctor if you have any of these or any other side effects during the study.

Women with a history of breast or gynecological cancers may experience disease recurrence or occurrence of a new primary malignancy. If you have experienced these types of cancers, we encourage you to discuss this study with your primary care physician and/or oncologist and consider whether you should have any additional follow-up with your physicians during or after study participation.

Calcium supplements
Less Likely/Less Common

- Mild constipation

Vitamin D supplements
Vitamin D toxicity has not been observed with doses below 10,000 units per day, which is much higher than the dose of 2000 units per day that will be administered in this study. Although we do not anticipate toxicity from the vitamin D supplement, the following are rare side effects:
Rare

- Elevated calcium level in the blood
- Kidney stones
- Frequent urination
- Irregular heart beat

Strength testing, physical assessments, and exercise sessions:
Likely/Common

- Strength testing may cause minor and temporary muscle soreness or joint stiffness. The soreness typically begins 1-3 days after exercise begins, does not last more than 2-3 days and does not damage the muscle. You may also experience minor fatigue following exercise sessions or visits.

- Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue.

Less Likely/Less Common

- You may fall during one of the intervention sessions or clinical assessment visits. This risk is minimal and is no different than the risk that is normally present during walking. A study staff member will be beside you during all activities, which will reduce the risk of falling.

Rare

- You may fall and fracture a bone during the tests of your walking and balance. This risk will be minimized through the use of a safety belt during testing procedures.
- With any exercise, there is always a risk something abnormal could occur with the heart.
- You may fall during performance of the home exercises. In order to reduce this risk, you will be instructed in proper technique.

Safety Assessments:

Mammogram and transvaginal ultrasound

Likely/Common

- You may experience some discomfort from the mammogram and/or transvaginal ultrasound.

Less Likely/Less Common

- The transvaginal ultrasound (for women with a uterus) may be uncomfortable due to abdominal pressure and/or positioning of the legs. These tests will be done in a modified fashion for comfort and to maintain any hip restrictions that you may have.

Blood draws

Likely/Common

- Bleeding, bruising, or discomfort at the blood draw site

Less Likely/Less Common

- Pain at the blood draw site
- Dizziness or feeling faint

Rare

- Infection

ECG

Less Likely/Less Common

- Patches used during the ECG may cause a skin reaction such as redness or itching
- Patches may also cause skin discomfort and/or hair loss

Radiation

This study will expose you to radiation from DXA scans and mammograms. The amount of radiation from this, when averaged over your entire body, is 4% of the amount of radiation exposure all people in St. Louis receive each year from naturally occurring radiation sources. The risk from the radiation exposure in this study is too small to be measured. It is not a big risk when compared with other risks you take every day. If you want to know more about radiation exposure, please see the "Radiation Fact Sheet" located at https://hrpo.wustl.edu/participants/radiation-fact-sheet or ask the study staff for a copy.

Interviews

Less Likely/Less Common

- Fatigue, embarrassment, and possibly nervousness

Fatigue will be kept to a minimum by keeping the interview sessions brief and taking frequent breaks. You do not have to answer any question you do not want to answer.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because this study may identify effective interventions for recovery of function in people after they have broken a hip. By knowing this information, we may be able to help people get back to their prior level of function after a hip fracture.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, you can consult your doctor about the other options that are available to you. Instead of being in this study, you could choose not to participate in this study. You could obtain health screening evaluations and health education from your own healthcare provider. You could also choose to increase your activity level without enrolling in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The National Institute on Aging (NIA) is funding this research study. This means that Washington University is receiving payments from NIA to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIA for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314-286-2707 and/or the Human Research Protection Office at 1-800-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration (FDA)
- The National Institute on Aging (NIA)
- The sponsor (NIA) may also inspect any part of your medical record for the

purposes of auditing the conduct of the study
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Staff at the University of Colorado in order to review the exercise intervention videos and DXA scans for quality control.
- A data safety monitoring board
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, completed questionnaires and study forms will be kept in participant binders and stored in locked offices. No unauthorized person will be allowed to see the binders or forms. You will be identified only by a unique identification number on data collection forms. Names will only be used to make sure that the recorded information is for the person to whom it refers. All electronic data and computer files will be kept secure with multiple levels of password protection. Blood samples, video recordings, and DXA scans will be labeled with your study identification number.

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.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make

sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- Your treatment or the care given by your health provider.
- Your insurance payment or enrollment in any health plans.
- Any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
        - The research team may only use and share information already collected for the study.
        - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
        - You will not be allowed to continue to participate in the study.

Can we contact you by email?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Appointment scheduling and reminders
- Answer questions you may have

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____Yes _____No
Initials Initials

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain a part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu/participants/ under Withdrawing from a Research Study.

If you decide to leave the study early, we will ask you to return for one study visit to provide 6-month data. If you decline the 6-month visit, we will request that you complete an early discontinuation visit. This visit would be shorter and include less tests than the 6-month assessment.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator or the study sponsor might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue, because your condition has become worse, or because the sponsor has decided to stop the research.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Ellen Binder at 314-286-2707. If you experience a research-related injury, please contact: Dr. Ellen Binder at 314-286-2707.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-800-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant, you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 06/11/24.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)