Research Informed Consent Document

Department of Veterans Affairs
VA Western New York Healthcare System, Buffalo, New York

PARTICIPANT NAME:	**DATE:**
PRINCIPAL INVESTIGATOR:	*Bruce R. Troen*
TITLE OF RESEARCH STUDY:	Enhancing functional capacity in older adults with short session high intensity interval training

Informed Consent to Participate in Research

Sponsor: *None*

The investigators have been approved to complete this study by the Facility Financial Conflict of Interest Administrator.

We are asking you to volunteer for a research study at the VA Western New York Healthcare System [VAWNYHS].

The purpose of this study is to assess the feasibility and utility of high intensity interval training in older adults.

Should you take part in this study?

This form tells you about this research study. This form explains:

- Why this study is being done.
- What will happen during this study and what you will need to do?
- Whether there is any chance you might experience potential benefits from being in the study.
- The risks of having problems because you are in this study.

Before you decide:

- Read this form.
- Have a friend or family member read it.
- Talk about this study with the person in charge of the study or the person explaining the study. You can have someone with you when you talk about the study.
- Talk it over with someone you trust.
- You may have questions this form does not answer. You do not have to guess at things you don't understand. If you have questions ask the person in charge of the study or study staff as you go along. Ask them to explain things in a way you can understand.
- Take your time to think about it.

It is up to you. If you choose to take part in this study, you will need to sign this consent form. If you **do not** want to take part in this study, you should **not** sign the form.

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Are you in any other research studies? ____Yes ____No

Why is this research being done?

Exercise is important to maintain health as we age. However, inactivity is common and few people between the ages of 60 and 85 meet the recommended 30 minutes of daily moderate intensity exercise. High intensity interval training (HIIT) may be an attractive alternative to standard exercise as health benefits can be achieved in less time. This in turn may increase participation and be useful in maintaining health during aging. The purpose of this research is to determine if a short session of HIIT (about 10 minutes in length) is workable for older adults, if this exercise improves health, and to gauge the enjoyment of HIIT and explore any changes that occur in fitness, physical activity habits, and function, after stopping a 12-week HIIT program.

How long will you be in the study?

You will be in this research study initially for approximately 13 to 14 weeks. This includes a baseline assessment that will occur over 2 visits (approximately 2 hours), 3 sessions a week of approximately 20-30 minutes each (~11.5 minutes exercise plus assessments) for 12 weeks, and a final endpoint assessment of approximately 2 hours. Following the 12 week HIIT sessions, you may be contacted to return for 1 additional follow-up visit.

What will be done if you agree to be in this study?

Our study will require participation for roughly 13-14 weeks. This includes a baseline measurement, a 12-week exercise program, and an endpoint measurement. Our measurements include the following:

Frailty measurement: Frailty is determined by grip strength (using a Jamar hand grip meter, gait speed (time to walk 15 feet), body weight change, and surveys to assess endurance and activity levels.

Short physical performance battery (SPPB): The SPPB is a performance test that includes gait speed (as done for frailty), chair rise test (participant is instructed to rise from a chair as many times as possible within 30 seconds), and balance and coordination (participant is asked to stand, stand with one foot in front of another, and stand with feet in an offset position).

Function capacity and quality of life surveys: To assess functional capacity we survey participants regarding ability to perform daily living tasks, their feelings on their quality of life, and enjoyment of the exercise protocol. After the post-HIIT follow-up visit, free-living physical activity will be assessed using a Fitbit activity monitor over the course of 7 days. Sleep quality will also be determined using the Pittsburgh Sleep Quality Index (PSQI).

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Physiologic status: We will assess body weight, pulse rate and blood pressure (before and after exercise sessions), leg muscle strength (a measuring device is placed on leg of participant as the individual is asked to lift leg), and maximal oxygen uptake (VO2max). The VO2max test is an exercise test performed on an upright exercise bike. After a warm-up, the difficulty is increased until the participant is too tired to continue. This allows for us to tailor the exercise program to the participant.

Exercise protocol: The high intensity interval training (HIIT) regimen will be a 11.5-minute program featuring a 30 second warm-up, followed by a 3-min continued warm up, followed by 3 intervals of 1 min high intensity, then a 1 min low intensity rest period, and then ending with a 1-min interval at highest intensity and 1 final minute for cool down. The programs will be given 3 days a week for 12 weeks total, with overall difficulty increasing every 4 weeks based upon the participants improvement. HIIT regimen will be performed on a Matrix R3x recumbent exercise bikes. (This component will not be done as a part of the post-HIIT follow-up assessment visits)

Leg muscle blood flow during exercise: We will measure blood flow in your exercising quadriceps muscle during each exercise session using functional near infrared spectroscopy (fNIRS). This will be done with a small, light, non-invasive device about the size of a deck of cards. It will be strapped to your quadriceps muscle using a stretchy, neoprene sleeve. (This component will not be done as a part of the post-HIIT follow-up assessment visits)

Serum collection: We will collect 10 ml of serum at the beginning and the end of the experiment, to be stored by the VA Western New York research service. Serum will allow measurement of inflammatory biomarkers (IL-6, IL-10, and C-reactive Protein), vitamin D, and testosterone levels, blood cell metabolism, and serum microRNA sequence analysis to assess changes in circulating biomarkers due to the HIIT exercise. For participants that return for the post-HIIT follow-up visit, we will collect 80mL total at that visit in two separate blood draws (40mL each).

Post-HIIT Follow-up Visits
Participants that complete the 12-week HIIT program may be asked to return for 1 additional visit ranging from between 16-20 months following their participation on the HIIT component of the study. The post-HIIT follow-up visit will include all of the assessments described above, except the HIIT exercise protocol and V02max test. This will allow us to evaluate any changes that may have occurred in fitness, physical activity habits, and function, after stopping a 12-week HIIT program.

At the post-HIIT follow up visit the following assessment will also be done:
A graded cycle exercise test will be done to look at changes in pulse rate and skeletal muscle response to an acute exercise challenge. Each test will begin and end with a 10-minute rest phase for baseline measurement purposes. A blood draw will be done before and immediately after each graded exercise test. Additionally, cognition will be assessed using the Cognivue Clarity, an FDA-cleared technology that facilitates a 10-minute self-

administered computerized assessment of 6 cognitive domains: visuospatial, executive function/attention, naming/language, memory, delayed recall and abstraction. Cognivue Clarity also measures two speed performance parameters: reaction time and speed processing.

How many other people will be in this study?

Up to 45 people will be in this study at this location.

What are the possible risks?

This study involves both exercise and exercise based assessments. As with any exercise there exists a possibility of adverse chances including, but not limited to, abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and in very rare instances heart attack, stroke, and even death. Furthermore, risk of bodily injury may occur that include, but are not limited to, injuries to muscles, ligaments, tendons, and joints of the body.

Every effort will be made to minimize these occurrences by assessments of your condition before and after each exercise session by our research staff and the participant's own self-assessment of their health. Additionally, the participant should also be aware that this exercise regimen may or may not benefit the participant's physical fitness or general health.

There also exists risk associated with the collection of blood at the beginning and end of the experiment, including momentary pain due to the collection needle, risk of bruising and fainting, and a rare risk of infection. In addition to these health risks, there may be additional risk in the unlikely event of loss of confidentiality.

Taking part in this research study may lead to added costs to you that include travel expenses. Patient remuneration will be provided to offset some of these cost.

What are the possible benefits to you or to others if you are in this study?

You may or may not be helped by being in this study. However, exercise has the potential to improve fitness, functional capacity general health. This study also introduces participants to a maintainable exercise strategy for older individuals, who previously may not have considered exercise to be a viable option to maintain health. If you return to be evaluated for the post-HIIT follow-up visits, it may help you determine how your activity, fitness, and function have changed over the past 12- 16 months following your HIIT sessions.

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Will it cost me anything to be in this study?

Although there are no costs associated with the study, participants will be responsible for arranging travel to the VA medical center for all assessments and exercise sessions over the 13-14 week period (~38 sessions in total) and the 2 post-HIIT follow-up visits.

Will you be paid for taking part in this study?

If you agree to take part in this study and complete in full, you will receive a total of $400. Payment of $100 will be provided for completion of all baseline assessments and $300 will be provided at the end of the study. If you are not eligible for the study after the first visit you will receive $50. If you are unable to complete the study you will receive a pro-rated amount of $5.56 per exercise session attended. After your participation has ended in the HIIT session component of the study, if you return for the post-HIIT follow-up visit, you will receive an additional $250 and a FitBit activity monitor. An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

What happens if you decide NOT to take part in this study?

You should only be in this study if you want to volunteer. You do not need to be in the study to please the study doctor or the research staff.

If you decide NOT to take part:

- You will not be in trouble or lose any rights you normally have.
- You will still have the same services you would normally have.
- You can still get your regular medical care from your regular health care practitioner.

What if you join the study and decide you want to stop later on?

You can decide after signing this informed consent document that you no longer want to be in this study. **We will tell you about any new developments which might affect your willingness to continue to participate in the study.** However, you can decide you want to stop taking part in the study for any reason, at any time. If you decide you want to stop being in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.
- If you decide to stop, you can continue getting care from your regular health care practitioner.

Are there reasons we might take you out of the study later on?

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Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen.
- You are not coming for your study visits when scheduled or completing study tasks as needed.
- The funding for the study is stopped.

What if you are injured while you are on the study?

The VA Western New York Healthcare System will provide necessary medical treatment to you if you are injured by being in a research study. This does not apply to treatment for injuries that occur because you did not follow study procedures. Except in limited circumstances, the necessary care will be provided in VA medical facilities. Any expenses not covered by your insurance may be covered by the VA, consistent with applicable law, regulation, and policy.

Privacy and Confidentiality

Any information obtained about you in this study will be treated as confidential and will be stored as stated in the Privacy Act of 1974. In order to follow federal regulations, records identifying you may be inspected by sponsors of this study and others including, but not limited to:

- **The VAWNYHS Medical Center Research and Development Committee and its Subcommittees**
- **VAWNYHS Research Staff and Research Compliance Officer**
- **The Office for Human Research Protections (OHRP)**
- **VA Office of Research Oversight (ORO)**
- **Office of the Inspector General (OIG)**

How will your information be used?
The ways your study doctor will use your study-related health information and the people who may receive it are identified in a separate form entitled, "Department of Veterans Affairs HIPAA Authorization for Release of Protected Health Information for Research Purposes". You will be asked to sign that form to show that you give permission for these uses and sharing of your information. You do not have to sign the authorization form. However, if you do not sign, you will not be able to participate in the study.

How will your information be stored?
Information will be stored on password protected computers that reside in locked offices. Study information will also be held separately from participant contact information.

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How will your information be kept or destroyed?
Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

How will your information be described to others?
We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

How do you withdraw permission to use your information?

You can revoke this form at any time. This means you can tell the research team to stop using and sharing your information. If you revoke this form:

- **You will no longer be a participant in this research study.**
- **We will stop collecting information about you.**
- **The information that we have collected before you tell us to stop may already have been used or shared, or we may need it to complete the research, so you cannot withdraw that information.**
- **Staff may follow-up with you if there is a medical reason to do so.**

To revoke this form, you must tell us in writing. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study.

If you revoke this authorization, your research doctor or staff can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

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Your Rights:

You can refuse to sign this form. If you do not sign this form:

- You will not be able to be in this research. However, you can receive other procedures that are currently available for your condition as part of your regular medical treatment.
- This will not change your health care outside of this study.
- This will not change your health care benefits.
- This will not change the costs of your health care.

There will be no costs to you for any treatment or testing done as part of this study.

Eligibility for medical care is based on the usual VA eligibility policy. It is not guaranteed by being in a study. If you get medical care by the VA that is not part of the study, you may be charged co-pay for that medical care based on your VA eligibility.

You can get answers to your questions, concerns, complaints or issues about this study.

Bruce R. Troen or his designee has explained the study to you and answered all of your questions. If you have questions, concerns or complaints about the research, you have been told you can call Bruce Troen at _____ . The Study Coordinator, Ayesha Rahman may be reached at _____ . You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. If you have questions about your rights as a research participant, or if you think you have a research-related injury, you may contact the Chair of the Research & Development Committee at _____ or the Patient Advocate at _____. You may also contact the Research Compliance Officer at _____ if you have concerns, questions, or complaints and cannot reach the research team, or if you wish to talk to someone else.

You have been told that if you receive care from non-VA providers, you should tell your other healthcare providers about your participation in this study. If your provider knows of information that may be useful to this study, you will tell them to contact the Principal Investigator (PI).

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Statement of Participation in Research:

You have read or have had read to you all of the above. It is up to you to decide whether you want to take part in this study. If you want to take part, please read the statements below and sign the form if the statements are true.

I freely give my consent to take part in this study and authorize that my health information, as agreed above, be collected and disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

I understand that I do not have to be in this study. My refusal to take part will involve no penalty or loss of rights to which I am entitled. I may leave this study whenever I wish without penalty or loss of VA or other benefits to which I am entitled.

_____
Participant's Signature

_____ _____
Printed Name of Participant Date

_____ _____
Signature of Individual Obtaining Participant's Consent Date

_____
Printed Name of Individual Obtaining Participant's Consent