University of New Hampshire

# CONSENT FORM
# EXERCISE & DIET STUDY IN FIREFIGHTERS- UNH IRB #8242

## RESEARCHER AND TITLE OF STUDY

Hello, my name is Deb Feairheller and I am a researcher at the University of New Hampshire. I am also a firefighter (volunteer) myself, so I understand the work and risk involved with being a firefighter.

This study is called "Effects of Combined Diet & Exercise Intervention on Cardiovascular Risk Factors in Firefighters & Civilians"

## WHAT IS THE PURPOSE OF THIS FORM?

This consent form describes the research study and helps you to decide if you want to participate. It provides important information about what you will be asked to do in the study, about the risks and benefits of participating in the study, and about your rights as a research participant. You should:

-Read the information in this document carefully, and ask me or the research personnel any questions, particularly if you do not understand something.

-Not agree to participate until all your questions have been answered, or until you are sure that you want to.

- Know that if you qualify, you will be enrolled for a total of about 8 weeks. During this time period you will complete the following steps:

1. Orientation and informed consent (15-30 min). This will occur on UNH campus, in NH hall.
2. Diet training (includes a study manual and a 45-minute training session with study personnel)
3. Pre-intervention testing
    a. Morning fasted study (45 min). This will occur on UNH campus, in NH hall.
    b. Fitness test session (45 min). This appointment will be scheduled at your convenience, either in NH Hall or in a firehouse.
    c. Blood pressure monitoring (includes wearing an ambulatory blood pressure monitor for 12-hours and a 30 min appointment to get set-up on the monitor). This will occur in NH Hall.
4. 6-week intervention (includes a circuit workout 3-times per week and following the diet, both done on your own at home, in the fire station, or in a fitness center)
5. Post-intervention health and fitness testing which will be the same as pre-testing (#3).

Each of these steps will be described in detail below.

-Understand the potential risks of participating in this study that are described below in detail. These risks include potential pain or infection at blood draw or finger stick sites, risk of injury during fitness testing or training, discomfort while blood pressure cuffs inflate, potential risk of emotional stress, and risk of unknown dietary allergies.

## WHAT IS THE PURPOSE OF THIS STUDY?

This is a clinical intervention study and you are being asked to join because you are an adult (18 years or older). You report no history of renal disease, diabetes, or cardiovascular incidents; no existing orthopedic issues that could prevent you from exercising; and do not take more than one anti-hypertensive or one cholesterol medication.

This will be a clinical trial including both firefighters and civilians. We anticipate including 30 adults in the study, 15 firefighters and 15 civilians. The purpose of the study is to examine benefits of combining exercise and diet and examine how they can improve health and reduce blood pressure levels. The study involves participation in a circuit exercise program and a Mediterranean diet.

Thank you for your interest and participation.

**WHAT DOES YOUR PARTICIPATION IN THIS STUDY INVOLVE?**

Upon enrollment, you will undergo pre-testing, complete a 6-week intervention, and then undergo post-testing. The pre- and post-testing are the same, and this is how we can measure the improvements in outcomes that relate to cardiovascular and blood vessel health before and after the 6-week intervention period.

During the entire study you will complete an Orientation and Consent meeting, Pre-intervention testing, Diet training session, the 6-week intervention, and Post-intervention health and fitness testing which will be the same as pre-testing.

Each of these steps is described in detail below:

**Orientation & Consent**

Initially, you will meet some of the research personnel, the study will be explained by Dr. Feairheller, and you will be given a copy of this consent form to read. After this, you may ask any questions that you have about participating in the study. After all your questions have been answered, if you choose to participate, you will sign this informed consent form and keep your own copy.

Next, you will be asked to complete a simple 2-page wellness questionnaire. This will be used to determine your current state of health and level of physical activity. This is an intervention study, and we ask that you maintain your normal routines throughout the duration of the study and add on the assigned intervention.

Finally, we will have you complete a short 21-item scale that asks questions related to your feelings over the past week. It is called the Depression, Anxiety, and Stress Scale (DASS-21). We are using this to measure feelings in relation to how high your blood pressure surges when the alarm sound occurs.

**Pre-Intervention Testing Visits**

You will participate in three testing components during pre-intervention. This includes a morning ***fasted study***, a ***blood pressure monitoring***, and a ***fitness test***. We coordinate these appointment times to fit into your schedule.

***Fasted Testing Appointment****:*

The total time for this visit will be around 45 minutes. You will be required to fast for 10 hours before coming into the lab for the testing. For this visit, we ask that you have no food or drink (water is allowed) for at least 10 hours before coming into the lab. We also ask that you avoid alcohol and exercise the night before. Height, weight, and blood pressure will be taken. Body composition will be measured, glucose and cholesterol levels measured, a blood draw collected, and you will have blood vessel ultrasound and pressure studies done. If we find that you have high blood pressure or high lipid/glucose levels, we will inform you and we will offer to give you the data so that you can visit your physician. This is not an exclusion criteria from the study.

> *Body composition test* will tell the investigators what percentage of the body is fat, muscle and bone. The instrument that measures body composition is called bioelectrical impedance (BIA). The machine will cause a very small current to travel through the body for 2-3 seconds, but nothing will be felt. To do this test, you will lie on a table for about on your back with left foot exposed. To collect the measurements, a technician will place two electrodes on the left foot and two electrodes on left hand.
>
> *Blood glucose and cholesterol measurements* will tell the investigators what the levels of fasted plasma glucose and cholesterol are. We will be measuring these with a finger-prick test. Only one finger prick will occur, and a single large drop of blood will be collected.

*Plasma inflammation, oxidative stress, and vasodilation levels*. A blood draw will occur where we collect 2 tubes of blood (equivalent of 7 tsp or 1.2 oz). This will allow us to measure common markers that circulate in the blood which are related to heart health.

*Blood vessel ultrasound and pressure measures.* We will be checking the function of your blood vessels through the use of several machines. No needles will be used for this test. We will collect images of the carotid artery blood vessel in your neck. Separately, we will also use a large cuff device called a pulse wave analysis system, this will allow us to measure your central blood pressure (the actual blood pressure at your heart level and not in your arm). This test allows us to see how stiff blood vessels are. For this, we will take some measurements and the cuff will squeeze quickly to get a measurement. We will place a cuff on the arm for measurement and then next place a cuff separately on the leg for a measurement.

***Blood Pressure Monitoring Appointment**:*

This requires a visit to learn about the ambulatory blood pressure monitor and to get set-up with a cuff and monitor. The total time for this is about 30 minutes. The system is an at-home blood pressure monitor that is about the size of a cell phone. It will take measurements every half hour during a 12-hour period. While wearing the cuff and monitor, when the pager goes off, you will push the monitor's button to force an automatic blood pressure reading. We will show you how to do this during the visit to the lab. If you are a firefighter, we also ask that you remove the monitor device right before donning fire gear and take the monitor to the call on the apparatus. We ask you to remove it while wearing your gear because monitors will not record blood pressure when you move. This method is effective and has been done in the lab during our studies. Once you get back on the apparatus to return to station, we ask you to put the monitor back on and take another manual reading on the way back to station. After that, blood pressure measures will continue to be taken automatically at 30-min intervals.

If you are not a firefighter, we will instruct you how to download a mobile app which we will use to randomly page you 1 or 2 times over the 12-hour period. You will also push the monitor's button to force an automatic blood pressure reading.

***Fitness Testing Appointment**:*

The total time for the fitness testing will be around 45 minutes, and each of the tests will measure a part of fitness. A seated clinical blood pressure measurement will be taken first. The fitness test session includes: plank pose, stairway climb, 12-step climb, right and left single-leg stand, wall sit, and a treadmill test. All tests will be done in civilian fitness clothing.

*Plank pose* test to assess core strength. Hold plank position until exhaustion or when the position is compromised. Data will include total time.

*Stairway climb test* to assess leg endurance/strength. Climb up/down stairs for 2 minutes. Data will include total number of steps.

*12-step climb test* to assess agility and power. Ascend 12 steps as fast as possible. Data will include total time.

*Balance test.* Stand on single leg while holding a 15 lb dumbbell until exhaustion or balance is lost. This will be repeated with the other leg. Data will include total time.

*Wall sit test* to assess functional ability and leg strength. Squat down to sitting position with back flat against the wall, legs at 90-degree angle, and knees over the heels. Hold until exhaustion or when position is compromised. Data will include total time.

*Aerobic fitness* will be measured by the Wellness Fitness Iniative protocol, which is approved by the NFPA 1582 *Standard on Medical Requirements for Firefighters and Information for Fire Department Physicians* and the NFPA 1583 *Standard on Health-Related Fitness Programs for Firefighters*. This submaximal test is completed on a treadmill until a target heart rate is reached. The target heart rate is based on age and is less than 85% of the age-predicted maximal level. Each minute during the test, the treadmill will increase in either speed or incline and the test is stopped when heart rate is reached. The test lasts anywhere from 2 minutes until 20 minutes, depending on current fitness state.

*Functional strength test*. This is a dummy drag (drag a rescue dummy for distance in 30 seconds) which is completed by the firefighters in the study. The civilian population will not complete this test.

## 6-Week Intervention: Mediterranean Diet Component

***Pre-Intervention Diet Training**:*

The total time for this training appointment will be around 45 minutes. We will issue a participant training manual and teach the serving sizes for the food groups in the Mediterranean Diet.

Also, before starting the diet, each participant will write down all the food that is consumed for a 3-day period. This will give us a baseline assessment of how your diet is before you start the study, and this will guide us to the number of serving sizes you will be prescribed.

***Diet Intervention**:*

The Mediterranean diet includes a high consumption of fruits and vegetables, a moderate consumption of fish, nuts, and wine, and a low consumption of red meat and other meat products. Also, olive oil is the principal source of fat instead of other types of oils.

During the study, you will receive the diet information, you will have online access to diet information by our website, http://www.theheartlab.org/#dietexercise, you will receive weekly educational documents and tips through email, you will be provided with informational websites, and receive many lessons on serving size. We also provide all participants with sample serving size containers to get them started.

For the duration of the diet intervention, you will be asked to track your diet and enter serving numbers into our research website each week. The manual and the website have a nice checklist that can be used to track your weekly diet.

Here is a quick summary of the number of servings per week you will target and what you will track during each week of the diet intervention (please know that some serving numbers may be reduced based on your body size though):

Vegetables = more than 28 per week
Low/Non-Fat Dairy = 14-21 per week
Fish = more than 4 per week
Red Meat = less than 2 per week
Nuts/Healthy Oils = less than 8 per week
Sweets/Processed Food = less than 4 per week
Fruits = more than 21 per week
Grains/Potatoes = 42-49 per week
Poultry = less than 3 per week
Beans = more than 3 per week
Other Fats/Oils = less than 8 per week

## 6-Week Intervention: Exercise Training Component

The exercise intervention will be self-report. This means that the exercises will be done at home or in the fire house or in a fitness center. All participants are asked to complete the circuit workout 3 times per week for the 6-week period. For the workout, each station below will be done 3 times within each workout, and it should take around 45 minutes. The workout can be done by going through each station and rotate back around 3 times, or the workout can be done by doing each station 3 times and moving on to the next station. Either way that you choose to complete the workout, the amount of work that you will do is the same, so it gives you flexibility to pick each time.

*Circuit Exercise Stations and Directions*:

1. Unsteady Carry – carry 40 lb or an extrication tool for 100 ft (50 ft over and back)
2. Stairway Run/Walk – ascend and descend a stairway continuously for 3-minutes
3. Plank Pose- hold plank pose for 45 seconds. If cannot hold for 45 seconds, hold for as long as possible.
4. Weighted Carry – carry 20 lb or a fireground tool for 100 ft (50 ft over and back), moving as fast as possible.
5. R/L Single Leg Stands – stand on single leg while holding a 15 lb dumbbell or fireground tool for as long as can maintain balance. Repeat with other leg.
6. Stairway Carry – carry 15 lb dumbbell or fireground tool up and down the equivalent of 30 steps.

**Post-Intervention Testing Visits**

You will complete the exact same tests after the intervention that you did before.

**WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN THIS STUDY?**

*Loss of Confidentiality:* Once others know that you are participating in the study, you may lose some confidentiality. Fire crews work in close quarters and some spend time living together in the fire house, so confidentiality may be lost by your presence at the testing appointments. We will reduce this risk because your name will not be on any documents and your personal data will not be shown to anyone during the test sessions.

*Depression, Anxiety, and Stress Scales (DASS-21)***:** The risk associated with completing this short 21-item survey is that you may feel uncomfortable while answering the questions. If you feel this and your symptoms are severe, we will work with you to refer you to a proper clinician who is part of your health network.

*Blood glucose, cholesterol, and blood draw***:** These measurements will involve a finger prick and a needle stick. The risks associated are slight discomfort in the site. These are routine and conventional procedures used to measure blood levels of metabolites. Minor risks include a small amount of bleeding under the skin (bruising), but this has been reported in <10% of the cases, dizziness, and a very small risk of infection (1 in 1000). The risk of infection will be reduced by proper cleaning and antiseptic techniques by the technician.

*Blood vessel studies***:** The blood vessel ultrasound studies may include discomfort in the arm and leg when the cuff squeezes to take a measurement. This feeling could be similar to what is felt when a foot or leg falls asleep after sitting in certain positions. This is not a risk to your health, but it is a discomfort. To help with this risk, we recommend that you stay very still and as the blood flows back to the arm and the feeling will go away.

*Fitness testing/training***:** The risk of any exercise is injury to muscles, joints, ligaments, and tendons. It has been found that in 1 out of every 70,000 exercise tests, a person could die from heart problems. In medical terms, doctors call this a rare event. Because you are otherwise healthy with no known risk factors, the risks of a medical problem are even lower. You are aware that if any exercise makes you uncomfortable, you should notify us immediately.

*Diet intervention***:** The risk of allergy exists when any special diet is followed. You are asked in your initial Wellness questionnaire if you have any known food allergies and this is documented in the inside of your folder. If you do have allergies, a modified diet will be provided to you. If something arises, please notify HEART lab staff immediately.

**WHAT HAPPENS IF YOU GET SICK OR HURT FROM TAKING PART IN THIS STUDY?**

If you are injured or require medical treatment, you may seek treatment from your primary care provider or, if eligible, from UNH Health & Wellness. The University of New Hampshire is not responsible for the cost of any care required as a result of your participation in this study.

**WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING IN THIS STUDY?**

By participating in this study it is hoped that you will gain information about your health and fitness levels. You also get to participate in a lifestyle intervention and find how the intervention changes your health. Whether these benefits will occur for you cannot be guaranteed.

Also the broader benefit to the community is great by your participation. Firefighters across the world need to be aware of their blood pressure levels and should know that the blood pressure surge can be large with pager alarm. If this research can identify potential relationships between the blood pressure surge and cardiovascular health, the knowledge could save lives. Also, if this study can show that a simple diet and exercise program can reduce the blood pressure surge, we could save lives.

**IF YOU CHOOSE TO PARTICIPATE IN THIS STUDY, WILL IT COST YOU ANYTHING?**

The cost to you will include transportation to the testing appointments and your time. Some cost may be incurred through grocery shopping as you adapt to a different diet. We will reimburse you any cost that is incurred for parking.

**WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATING IN THIS STUDY?**

There will be no compensation for participation, other than the health and wellness benefits you may gain. You also may request your health records upon study completion.

**DO YOU HAVE TO TAKE PART IN THIS STUDY?**

Taking part in this study is completely voluntary. You may choose not to take part at all. If you agree to participate, you may refuse to answer any question or participate in any testing component.

**CAN YOU WITHDRAW FROM THIS STUDY?**

If you agree to participate in this study and you then change your mind, you may stop participating at any time. Your decision to not participate will not affect your current or future relations with the University or the research team. Any data collected as part of your participation will remain part of the study data records.

**HOW WILL THE CONFIDENTIALITY OF YOUR RECORDS BE PROTECTED?**

We plan to maintain confidentiality of all data and records associated with your participation in this study. Any data that is released in publication or presentation will be de-identified. The investigators will use a coding system consisting of a combination of letters and numbers to maintain confidentiality. You understand that the results of this study may be published. If the results are published, you will not be identified by name.
Further, any communication via the internet poses minimal risk of a breach of confidentiality. The information that you send over the website about your diet is only the serving number information and there is nothing personal or identifiable about diet serving numbers.
There are, however, rare instances when I may be required to share individually identifiable information with the following:

- Officials at the University of New Hampshire
- Regulatory and oversight government agencies
- The American Heart Association, who is sponsoring this study.

The only people who would routinely have access to the data are the investigator and students who are affiliated with the project. All data that is presented will be aggregated and reported in publications and presentations. The data will be shared with the American Heart Association at the end of the study. It will be uploaded to the Clinical Trials website, but this data will also be de-identified.

**WHOM TO CONTACT IF YOU HAVE QUESTIONS ABOUT THIS STUDY**

If you have any questions pertaining to the research you can contact the Principle Investigator, Deborah Feairheller at deborah.feairheller@unh.edu, or by phone at 603.862.3282 to discuss them.

If you have questions about your rights as a research subject you can contact Melissa McGee in UNH Research Integrity Services, 603/862-2005 or melissa.mcgee@unh.edu to discuss them.

**STUDY FUNDING DISCLOSURE**

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**CLINICAL TRIAL REGISTRY DISCLOSURE**

This human research study has been registered on https://clinicaltrials.gov/

**STATEMENT OF CONSENT**

This study has been explained to me, questions answered, and I have read all of the above information.

I consent/agree to participate in this research project.

Name (printed) _____

Signature _____ Date _____