PARTICIPANT INFORMATION LETTER

PROJECT TITLE: Mechanisms responsible for reduced muscle growth when resistance and endurance exercise are performed together
PRINCIPAL INVESTIGATOR: Dr. Donny Camera
ASSOCIATE INVESTIGATORS: Professor John Hawley; Ms. Brooke Devlin; Dr. Ryan Timmins; Mr. Paul Tofari
STUDENT RESEARCHER: Mr. Bobby Shamim
STUDENT’S DEGREE: PhD

Dear Participant,

You are invited to participate in a research project conducted by Australian Catholic University (ACU), ‘Mechanisms responsible for reduced muscle growth when resistance and endurance exercise are performed together’ as you are healthy, aged 18-35 years, have a Body Mass Index (BMI) of 18.5-29.9, and are recreationally active.

This Participant Information Sheet/Consent Form informs you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully and ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project.
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.
What is the project about?
Exercise is well known to induce multiple physical and psychological benefits, although the nature of these benefits is dependent on the type of exercise performed. For instance, resistance training can increase muscle strength and mass, while endurance exercise can enhance the ability and efficiency to use energy so that exercise can be performed at higher intensities or longer durations.

Many individuals who undertake exercise, particularly those involved in team sports, perform a combination of resistance and endurance exercise so that all the physical benefits of exercise can be attained. However, previous research has established that the gains in muscle strength and mass with resistance exercise can be reduced when resistance exercise is performed concurrently with endurance exercise. The mechanisms responsible for this reduced response are not completely understood, but may be related to a combination of factors including fatigue, inadequate exercise intensity and/or duration, and poor diet to facilitate muscle growth. In this regard, it is well established that protein ingestion can enhance muscle growth responses with resistance exercise. Whether protein can similarly enhance muscle growth following combined resistance and endurance exercise is not known. Accordingly, the aims of this research project are to:

1. Determine whether a high protein diet can ‘rescue’ the loss of muscle growth following 12 weeks of combined resistance and endurance exercise compared to resistance exercise only.
2. Characterise the effects of 12 weeks of combined resistance and resistance and endurance exercise on several performance tests measuring strength and power, and compare these responses to resistance or endurance exercise performed in isolation.

Who is undertaking the project?
This project is principally being conducted by Dr. Donny Camera with the assistance of his PhD student, Mr. Bobby Shamim. Bobby is a PhD student at the Australian Catholic University (ACU) and this research project will form part of his thesis. Dr. Camera is a research fellow within Exercise and Nutrition Research Group at ACU and has ten years’ research experience conducting exercise and nutrition studies. Professor John Hawley is the Head of the Exercise and Nutrition Research Group at ACU and possesses over 30 years’ research experience. Ms Brooke Devlin is an Accredited Practising Dietitian (APD) and the research dietitian with Exercise and Nutrition Group at ACU. Dr. Ryan Timmins is a Lecturer within the School of Exercise Science at ACU and has recently graduated from his PhD. Mr. Paul Tofari is a lecturer within the School of Exercise Sciences and will co-ordinate all exercise performance testing. The project has been approved by the ACU Human Research Ethics Committee and is supported and funded by a Collaborative Research Network (CRN) project grant awarded to Dr. Camera.
Are there any risks associated with participating in this project?

As a participant you will be exposed to some risks arising from invasive sampling techniques. Appropriate measures will be taken to provide you with the safest possible testing environment. All invasive procedures (muscle biopsy and blood sampling) will be conducted by a medical doctor under strict sterile conditions by using single use sterile equipment.

While this research does not involve any interventional treatment, you may be receiving medical treatments that can cause potential side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, you are encouraged to talk to the medical doctor who, if required, will discuss the appropriate ways to manage any side effects. In the event of a serious side effect or reaction to any treatment within the research project, the medical doctor may need to advise withdrawal from the study.

Skeletal muscle biopsy
This study involves sampling of muscle tissue. There are very low level risks of swelling/bruising, nerve damage, and infection, which are minimised by the use of sterile equipment and experienced medical doctor. The day following a muscle biopsy, the leg may feel uncomfortable when walking down stairs and to some lesser extent activities that involve forceful movements of the abdomen. However, it is common to exercise in the minutes, hours or days following a biopsy. To allow the incisions to heal properly and minimize any risk of infection, avoid prolonged submersion in water for 4 days. Daily showers are acceptable, but baths, swimming, saunas etc. should be avoided for at least 4 days following the biopsy. Please refer to the section below on muscle tissue biopsy for a detailed explanation of the procedure.

Blood Sampling
A single 10 ml tube of blood through venepuncture will be collected on each of the four occasions when a muscle biopsy is performed during the 12-week exercise and nutrition intervention. This volume (total = 40 ml) is minimal compared to the standard 500ml for a Red Cross donation. The 10 ml of blood collected on the three occasions is a volume close to a level teaspoon, and will be taken via a catheter placed into a forearm or mid-arm vein. There is a very low risk of infection and dizziness which are minimised by the use of sterile equipment and experienced medical doctor.

Physical exercise
While any type of physical exertion involves some possible risk of injury or complication, the exercise sessions in this study will not present any risk other than those experienced during a typical resistance or endurance exercise session. These include, but are not limited to, cardio-respiratory stress and musculoskeletal injuries (e.g. strained muscles, tendons or ligaments).

What will I be asked to do?
If you are interested in participating in the study and meet the selection criteria (are healthy, aged 18-35 years, have a Body Mass Index (BMI) of 18.5-29.9, and recreationally active), you will be
required to complete and sign a consent form, a cardiovascular risk factor questionnaire and a muscle biopsy information form (all attached) for clearance into preliminary strength and performance tests, and the subsequent experimental intervention. It is desirable that your local doctor be advised of your decision to participate in this research project. Factors that may exclude you from taking part in this study include: not meeting selection study inclusion criteria or an inability to consent to the study. Certain medications may also prevent inclusion in the study and the study doctor will advise of this.

**What does participation in this research involve?**

**Exercise and Sports Science Australia’s Adult Pre-exercise Screening Form**
If you are interested in participating in the study, you will be required to complete this screening questionnaire to determine if you are ready to begin light/moderate intensity physical activity or if guidance from a health professional is required prior to commencing.

**Consent Form:**
If you decide to participate in this study, a consent form will be signed prior to any study assessments being performed.

**Muscle Biopsy Form:**
A muscle biopsy form will be signed prior to the experimental trial to ensure this research technique is clearly explained and that you are comfortable and aware of all associated risks.

**Cardiovascular Risk Factor Questionnaire:**
A cardiovascular risk factor questionnaire will be completed prior to any study assessments.

**Body Composition and Urine Sample:**
A dual energy X-ray absorptiometry scan (DXA) is a specialised X-ray technique to provide a measure of body composition. Participants lay facing up on the scanning bed for the duration of the scan. This is just like a normal X-ray, with no pain involved and it will measure total body mass, fat mass and lean mass. The scan lasts for 7-8 minutes and participants will be scanned wearing light clothing at the beginning, four weeks, eight weeks and conclusion of the study (Figure 1). Participants will also be asked to provide a small urine sample when arriving at the laboratory prior to the DXA scan for a measurement of hydration status. Ms. Devlin will co-ordinate all DXA scans.

**Ultrasound**
Two-dimensional ultrasound is the most common technique used for assessing the structure of a muscle. Participants will be required to lie on their back on top of a massage table. Two-dimensional ultrasound will then be used to assess the structure of the quadriceps muscles at three sites along the length of the thigh. Participants will then be asked to move onto their stomach. They will then have the structure of their hamstring muscles assessed. The entire ultrasonography assessment will last approximately 10-15 minutes. Dr. Timmins will co-ordinate all ultrasonography assessment.
**Strength and Power Testing**

Maximum muscular strength will be determined during a series of one repetition maximum (1RM) attempts and during an isometric mid-thigh pull (IMTP). The 1RM attempts will be performed on the leg press, leg extension, and bench press exercises and will be co-ordinated by Mr. Bobby Shamim. The IMTP is a simple test performed on a force platform that assesses lower-body strength. Participants will be shown correct and safe technique for each exercise by a qualified exercise physiologist and will subsequently be provided with appropriate time to safely perform each technique until competent and comfortable. Following an appropriate warm-up for each selected exercise, a single exercise repetition will then be performed with 3 minutes’ recovery periods between each attempt until the repetition load that can be completed once but not a second time is determined.

To assess power output, participants will perform two different jumps on the force platform: a countermovement jump (CMJ) and a squat jump (SJ). During the CMJ, participants will place their hands on their hips and try to jump as high as they can. For the SJ, participants will again place their hands on their hips, squat down to a self-selected height and hold the position for 3 seconds, prior to jumping as high as they can. Participants will have two attempts at each jump separated by 1-min rest. As per the strength testing, participants will receive adequate instruction and demonstration prior to completing the testing. Mr Paul Tofari will co-ordinate all strength and power testing.

**VO₂Peak Test**

The VO₂peak test is an incremental test to exhaustion on a stationary cycle ergometer. The workload increases every 2½ minutes until you can no longer maintain a pedalling rate of 60-70 rpm. This test is expected to last between 10-15 minutes. During the test expired air will be sampled as you breathe into a mouthpiece attached to an automated gas analyser. The results from this test will provide you with a peak oxygen consumption reading and peak power output (PPO) and physiological data regarding your cardiovascular health and fitness. Mr. Shamim and Dr. Camera will administer all VO₂peak testing.

**Dietary Intervention**

For the duration of the 12-week exercise and nutrition intervention, participants will consume a ‘high’ protein diet. A diet is considering high in protein if it consumed above the recommended daily intake of 0.8g/kg/day. In this study, daily protein intake will be set at 2 g/kg/day, with a recommended total daily energy intake of 30 – 40 kcal/kg/day. This level of protein consumption is completely safe with similar, and in many cases, higher quantities used within the research field.

Individual diet counselling as well as personal food and recipe plans will be provided by the study dietician Ms. Brooke Devlin on a fortnightly basis throughout the entire study. Participants will log their food intake using the Easy Diet Diary™ mobile phone App or manually through a ‘food diary’ which will be co-ordinated by Ms. Devlin. Food preferences and allergies will be
discussed at an initial consultation meeting. Certain foods will also be provided to participants as part of the dietary intervention.

Exercise Training Program

For the duration of the 12-week exercise and nutrition intervention, participants will undertake exercise training in one of three groups listed below. Participants will be randomly and equally assigned to one of the groups following preliminary testing and all exercise sessions will occur at the ACU gym under the supervision of Mr. Shamim and Dr. Camera. Both Mr. Shamim and Dr. Camera possess the appropriate Fitness Instruction qualification to safely teach through all the different exercise types

**Group 1: Resistance Exercise Only with High Protein Diet**

Participants in Group 1 will consume a ‘high protein’ diet as described above and perform only resistance exercise three times per week for the duration of the 12-wk training period. Resistance exercise will progressively increase in weight to account for increases in muscle size and strength throughout the program.

The resistance exercise protocol will consist of a whole-body routine including the following types of exercises: chest press, lat pulldown, rows, leg extension, leg press, shoulder press and lunges. The training protocol will be broken down into the following phases:

1) Phase 1 – Familiarization (Week 1): Sessions in this period will introduce main movements and exercises.

2) Phase 2 – Hypertrophy (Weeks 2-6): Sessions in this period will focus primarily on building muscle mass through higher volume of repetitions per session. Load will increase in a linear progression throughout this phase.

3) Phase 3 – Power (Week 7): Sessions in this phase of training will act as a ‘de-loading’ period and aim to improve muscle power in primary movements.

4) Phase 4 – Strength (Weeks 8-10): Sessions in this phase will focus on strength development and consist of a lower volume of repetitions paired with heavier weights. A linear increase in load will also be used during this phase.

5) Phase 5 – Peaking (Weeks 11-12): Sessions in this phase will focus solely on peaking the neuromuscular system and preparing for the main movements performed during the final strength testing.

Participants in the resistance exercise group will be required to training on three occasions per week (Monday, Wednesday, and Friday OR Tuesday, Thursday, and Saturday). These exercise sessions can be completed in the morning between 6 and 9.30am, or the evening between 4.30-9.30pm. Saturday sessions can be completed between 6am and midday.

**Group 2: Endurance Exercise Only with High Protein Diet**

Participants in Group 2 will consume a ‘high protein’ diet as described above and perform only endurance-based exercise three times per week for the duration of the 12-wk training period.

Endurance exercise will consist of variety of diverse exercise sessions including:

- 30-45 minutes of moderate intensity cycling on a stationary ergometer at approximately 50-75% of VO2peak capacity at a speed of approximately 60-70 rpm
- High-intensity interval training involving 5 mins of cycling at approximately 75-85% of each individual’s pre-determined VO2peak capacity with short recovery periods.
- Sprint interval training involving <60 seconds of cycling at approximately 85-100% of each individual’s pre-determined VO2peak capacity with short recovery periods.

Participants in the endurance exercise group will be required to training on three occasions per week (Monday, Wednesday, and Friday OR Tuesday, Thursday, and Saturday). These exercise sessions can be completed in the morning between 6 and 9.30am, or the evening between 4.30-9.30pm. Saturday sessions can be completed between 6am and midday.

**Group 3: Combined Resistance and Endurance Exercise with High Protein Diet**
Participants in Group 3 will consume a ‘high protein’ diet as described above and will perform combined resistance and endurance exercise six times per week for the duration of the 12-week training period. The concurrent training program will incorporate the same resistance and endurance exercise protocols mentioned in Group 1 and Group 2, respectively, on alternate days. Therefore participants in this combined exercise group will be required to perform resistance training on Monday, Wednesday, and Friday, and endurance training on Tuesday, Thursday, and Saturday, each week. These exercise sessions can be completed in the morning between 6 and 9.30am, or the evening between 4.30-9.30pm. Saturday sessions can be completed between 6am and midday.

**Figure 1:** Overview of the 12-week exercise and nutrition intervention including 2 weeks before and after the intervention for testing/measurements including DXA, muscle biopsies, strength and VO2peak testing, and food diary submission.
Muscle Tissue Biopsy
Muscle tissue biopsies will be collected on four occasions (Figure 1) during the study:
(1) Before the commencement of the 12-week training program (Week -2)
(2) 3 days after the completion of the 2nd week of exercise training (Week 3);
(3) 3 days after the completion of the 8th week of exercise training (Week 9); and
(3) 3 days after the completion of the 12-wk training program (Week 13).

Muscle biopsies are necessary in order to measure muscle growth responses to the respective diet and exercise interventions. The muscle biopsy procedure will be conducted by our study doctor Andrew Garnham who possesses extensive experience having conducted over 7,000 muscle biopsies with no adverse effects/reactions. The muscle biopsy sample is obtained from the outer thigh as this muscle site contains few surface sensory nerves. The muscle biopsy is a rapid procedure (approximately 5 seconds) performed to obtain small samples of tissue equivalent to the size of a corn kernel. In preparation for a biopsy, a small amount of local anaesthetic is injected under the skin which may result in a mild burning sensation while the fluid is injected. A small, 4-5 mm incision will then be made into your skin to create an opening for the biopsy needle. There is often a small amount of bleeding from the incision; however this bleeding is generally minimal. The biopsy needle will then be inserted through the incision site. You may feel the sensation of deep pressure in the biopsy site, and on some occasions this is moderately painful. However, the discomfort very quickly passes and you are capable of performing exercise and daily activities within minutes. There may also be some minimal bleeding when the needle is removed which may require the application of pressure for a few minutes.

At the completion of each biopsy, the incision will be closed with sterile tape and wrapped with a bandage. You are advised to refrain from excessive muscle use for the remainder of the day. Once the anaesthetic freezing wears off, your leg may feel tight and often there is the sensation of a deep bruise. Pain killers such as paracetamol (e.g. Panadol) or Ibuprofen (e.g. Advil) are acceptable to use if you experience pain associated with the biopsy. Periodically applying an ice pack to the biopsy site the following day will reduce any local swelling and/or residual soreness. The following day your leg may feel uncomfortable when walking down stairs and to some lesser extent activities that involve forceful movements of the abdomen. However, it is common to exercise in the minutes, hours or days following a biopsy. To allow the incisions to heal properly and minimize any risk of infection, avoid prolonged submersion in water for 4 days. Daily showers are acceptable, but baths, swimming, saunas etc. should be avoided for at least 4 days following the biopsy.

How much time will the project take?
The experimental period lasts a total of 14-16 weeks. The time commitment during each of visits will vary depending on the commitment involved for that day and the training group to which you have been assigned. In general, commitments throughout the 14-16 weeks will range anywhere from a minimum of 30 minutes to a maximum of 90 minutes. Participants will be provided with a protein ‘shake’ after every exercise session. Additionally, participants will also be required for four preliminary visits:
1) Visit 1: Collection of standardized meals and biopsy guidelines (approximately 5 min)
2) Visit 2: Preliminary measurements of body composition (DXA and ultrasound) and muscle biopsies (approximately 90 min). *Meeting with study dietician to discuss habitual food activity, preferences, and allergies (approximately 30 min).
3) Visit 3: Preliminary VO₂PEAK testing (approximately 25 min). Strength and performance testing familiarization (approximately 60 min) *Meeting with study dietician to discuss habitual food activity, preferences, and allergies (approximately 30 min)
4) Visit 4: Performance (approximately 30 min) and strength testing (approximately 45 min). *Meeting with study dietician to discuss habitual food activity, preferences, and allergies (approximately 30 min)

Note: *One visit depending on availability

**Reimbursement and Costs**
There are no costs associated with participating in this research project, nor will you be paid. However, you will be reimbursed a total of $1100 if in the combined resistance and endurance exercise group, and $700 if in the resistance or endurance exercise only groups in the form of a pre-paid Visa credit card for your time involvement over the 12 weeks. Participants will also be provided with a cab-charge card for travel to and from the Australian Catholic University on days of muscle biopsies.

**Local Doctor Notification**
It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project. If you decide to participate in this research project, the study doctor will inform your local doctor. You may also be advised to seek medical clearance from your local GP or allied health professional prior to undertaking physical exercise/ activity in the study.

**What are the benefits of the research project?**
We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include an improved understanding of personal muscular strength, cardiovascular fitness and important body composition measures such as muscle mass and muscle-free mass.

There will be no clear benefit to you from your participation in this research.

**Can I withdraw from the study?**
Participation in this study is completely voluntary and you may withdraw at any time. If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.
Will anyone else know the results of the project?
Information for each participant will be identified by a code so that your name does not appear on any data sheets. Only the principal investigators Mr. Bobby Shamim and Dr. Donny Camera will have access to muscle samples obtained while Dr. Brooke Devlin will only have access to individual dietary records.

Individual information (hard and soft copy where applicable) will be kept for 5 years in a locked cabinet in the office of the research laboratory manager Dr. Orly Lacham-Kaplan at ACU (Daniel Mannix Building, Level 1.32) after which all material containing confidential information will be destroyed. If you wish to gain access to your data, contact one of the principal researchers and it will be provided to you. Please note that no material that could personally identify you will be used in any reports or presentations of this project. Results from the study may be summarised and appear in publications or may be provided to other researchers in a form that does not identify the participants in any way.

Any information that you provide can be disclosed only if (1) it is to protect you or others from harm, (2) a court order is produced, or (3) you provide the researchers with written permission. The results from this study will be presented at scientific conferences and published in peer-reviewed scientific journals.

Will I be able to find out the results of the project?
You will be provided with a report detailing results of preliminary testing. If you wish to gain access to any additional data from the study please contact the principal research and it will be provided to you.

Who do I contact if I have questions about the project?
Please contact Mr. Bobby Shamim (baubak.shamim@myacu.edu.au, ph: 0432 703 424), Dr. Donny Camera (donny.camera@acu.edu.au, ph: 0403 166 127), Ms Brooke Devlin (brooke.devlin@acu.edu.au, ph: 9230 8073) or Professor John Hawley (john.hawley@acu.edu.au) if you have any questions relating to participation in this study.

What if I have a complaint or any concerns?
The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University (2016-54H). If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics Committee care of the Office of the Deputy Vice Chancellor (Research).

Manager, Ethics
C/o Office of the Deputy Vice Chancellor (Research)
Australian Catholic University
North Sydney Campus
PO Box 968
NORTH SYDNEY, NSW 2059
Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?

Please contact Mr. Bobby Shamim (baubak.shamim@myacu.edu.au, ph: 0432 703 424) or Dr. Donny Camera (donny.camera@acu.edu.au, ph: 0403 166 127).

Consent forms and questionnaires need to be returned in person. Please note, both copies of the consent form must be signed by the participant and returned to the investigators.

Yours sincerely,

PRINCIPAL INVESTIGATORS

Dr. Donny Camera PhD

Prof. John Hawley PhD

STUDENT RESEARCHER

Mr. Bobby Shamim
CARDIOVASCULAR RISK FACTOR QUESTIONNAIRE

To be eligible to participate in the experiment you are required to complete the following questionnaire which is designed to assess the risk of you experiencing a harmful cardiovascular event during the course of the trial. A full and honest disclosure of your medical history is vital.

Name: ___________________________ Date of Birth: ____________
Age: _____ years Weight: _____ kg Height: ______ cm

Give a brief description of your average weekly activity pattern:
______________________________________________________________

Circle the appropriate responses for the following questions:

1. Are you overweight? Yes No Don’t Know
2. Do you smoke? Yes No Don’t Know
3. Does your family have a history of premature (<70 years) cardiovascular problems (e.g. heart attack, stroke)? Yes No Don’t Know
4. Are you asthmatic? Yes No Don’t Know
5. Are you diabetic? Yes No Don’t Know
6. Do you have high blood cholesterol levels? Yes No Don’t Know
7. Do you have high blood pressure? Yes No Don’t Know
8. Do you have low blood pressure? Yes No Don’t Know
9. Do you have a heart murmur? Yes No Don’t Know
10. Do you have, or have you ever had, any blood-clots in any of your blood vessels (e.g. deep-vein thrombosis)? Yes No Don’t Know
11. Do you have, or have you ever had, any disease or condition that resulted in reduced or slower than normal blood-clotting? Yes No Don’t Know
12. Do you have, or have you ever had, any tendency to bleed for long periods after cutting yourself? Yes No Don’t Know
13. Do you have varicose veins? Yes No Don’t know

14. Are you currently using any medication? Yes No
   If so, what is the medication? ____________________________

15. Have you ever experienced any of the following during exertion (exercise or physical
   labour) or at rest? (Please circle).
   a. Light headedness or dizziness
   b. Pain in the chest, neck, jaw or arm
   c. Numbness or pins-and-needles in any part of your body
   d. Loss of consciousness

16. Have you suffered any known adverse effects to caffeine ingestion? Y / N

17. Do you have any known allergies? Y / N

18. If you answered yes above please specify if you are allergic to the
   following (Please circle).
   a. Eggs
   b. Soy or any soy containing product
   c. Peanuts
   d. If none of the above please specify ____________________________

18. Do you think you have any medical complaint, allergy or any other reason which you
   know of which you think may prevent you from participating in this trial? Y / N
   If yes, please elaborate. ____________________________

I believe that the answers to these questions are true and correct.

Signed: ___________________ Date: ________________
Biopsy Information Sheet

Exercise Metabolism Laboratory
School of Exercise Science, ACU

You have volunteered to take part in a research study that requires you to undergo several muscle tissue biopsies. This is a commonly performed procedure in research studies and for the medical diagnosis of muscle disease. The procedure will be performed by a medical doctor trained to perform muscle and fat biopsies or a specially trained researcher directly supervised by a medical doctor. The biopsy involves the removal of a small piece of muscle tissue from one of the muscles in your leg using a sterile hollow needle. The area over the outside of your lower thigh muscle (vastus lateralis muscle) will be carefully cleaned. A small amount of local anaesthetic will be injected into and under the skin. You will likely experience a mild burning sensation while the fluid is injected. Then, a small, 4-5 mm incision will be made in your skin in order to create an opening for the biopsy needle. There is often a small amount of bleeding from the incision, but this is usually minimal. The biopsy needle will then be inserted through the incision site and a small piece of muscle (100-200 mg; about the size of a kernel of corn) will be quickly removed and the needle taken out. During the time that the muscle sample is obtained (about 5 seconds), you may feel the sensation of deep pressure in your thigh, and on some occasions this is moderately painful. However, the discomfort passes very quickly and you are quite capable of performing exercise and daily activities. It is completely safe and common for many exercise-related studies to perform exercise in the minutes following a muscle biopsy. There may be some minimal bleeding when the needle is removed which may require application of pressure for a few minutes. The study doctor will always be present through the muscle biopsy procedure and during exercise intervention undertaken thereafter as well as during recovery.

Following the biopsy, the incision will be closed with sterile tape (steri-strips), and wrapped with a tensor bandage. You should refrain from excessive muscle use for the remainder of the day. Once the anaesthetic freezing wears off, your leg may feel tight and often there is the sensation of a deep bruise, “corked thigh” or "charlie horse". Pain killers such as paracetamol (e.g. Panadol) or Ibuprofen (e.g. Advil) are acceptable to use if you experience pain associated with the biopsy. It is also beneficial to periodically apply an ice pack to the biopsy site the following day, as this will help to reduce any local swelling and/or residual soreness. The following day your leg may feel uncomfortable when going down stairs. The tightness usually disappears within 2 days and participants routinely begin exercising at normal capacity within 48 hours. In order to allow the incisions to heal properly and minimize any risk of infection, you should avoid prolonged submersion in water for 4 days. Daily showers are acceptable, but baths, swimming, saunas etc. should be avoided for at least 4 days following the biopsy procedure.
BIOPSY SCREENING FORM

To help us ensure your safety and wellbeing please answer the following questions.

1. Have you ever had a negative or allergic reaction to local anaestheisa (e.g. during dental procedures)? (please circle the appropriate response)
   No / Yes

2. Do you have any tendency toward easy bleeding or bruising (e.g. with minor cuts or shaving)?
   No / Yes

3. Are you currently taking any medications that may increase the chance of bleeding or bruising (e.g. Aspirin, Coumadin, Anti-inflammatory, Plavix)?
   No / Yes
   If yes, please list the medication used (including herbal medication) ______________________________
   ______________________________________________________________________________________

4. Have you ever fainted or do you have a tendency to faint when undergoing or watching medical procedures?
   No / Yes

5. Will you contact the physician who did the biopsy directly if you have any concerns about the biopsy site including: excessive redness, swelling, infection, pain or stiffness of the leg?
   No / Yes

6. Are you willing to visit the physician who did the biopsy 7-10 days following the biopsy for an assessment of the biopsy site?
   No / Yes

Subject Name (print): __________________________

Subject Signature: ____________________________ Date: __________

Signature of Person Conducting Assessment: ____________________________