SITE SPECIFIC CONSENT INFORMATION

Site Name: AdventHealth Translational Research Institute

Study Title: Investigating the effects of aerobic and resistance training in vivo on skeletal muscle metabolism in vitro in primary human muscle cells (MoTrMyo)

IRB Application Number: IRB00097197

Consent Version: v2.0

Site Principal Investigator: Lauren Sparks, PhD

Site Principal Investigator Contact Information:
301 East Princeton Street
Orlando, FL 32804
407-303-7352

Emergency Contact: Medical Investigator: Richard Pratley, MD
407-303-7100

Other Study Contact(s): Research Coordinator: Brandon Hernandez, EMT
407-303-1342

Introduction:
This study is being done at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

Payment for Study Participation:

If you agree to take part in this research study, we will pay you up to $200.00 for your time and effort. Upon completion of each extra needle insertion for the companion study MoTrMyo during the MoTrPAC biopsy, you will be paid $100.00. Participants in the exercise or non-exercise groups can earn up to $200.00, and participants in the athlete group can earn up to $100.00. You will be provided a Mastercard® as a means to receive payments in this study. Payment may take about 3 business days to be processed, once requested. The Terms and Conditions for this card will be provided to you for review. Study payments that reach/exceed IRS limits of $600.00 in a calendar year will be reported to the IRS as required by law. Your social security number will be needed for IRS reporting purposes.

For participants who are not AdventHealth Orlando Employees
If you receive more than $600 in payments in a calendar year from AdventHealth Orlando, this income will be reported to the IRS. You may be required to pay tax on this income.

For participants who are AdventHealth Orlando or AdventHealth Medical Group Employees
All payments will be reported as added income to your base salary and will be taxed on a future paycheck.

Compensation for Research-Related Injury:

If you experience a research related injury or are injured as a result of this study, the study doctor will review the situation and, if necessary, provide treatment or refer you for treatment. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not a research related injury. Generally, this care will be billed to you, your insurance, or other third party. AdventHealth Translational Research Institute for Metabolism and Diabetes (TRI) has no program to pay for medical care for non-research related injury or illness. There are no plans to offer you payment for such things as lost wages, expenses other than medical care, or pain and suffering. If you have questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury, contact:

Richard Pratley, MD
Medical Investigator,
AdventHealth Translational Research Institute
301 E. Princeton St.
Orlando, FL 32804
407-303-7100
Or
Lauren Sparks, PhD
Principal Investigator
AdventHealth Translational Research Institute
301 East Princeton Street, Orlando FL 32804
(407) 303-7100

To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

Employee language:

If you are an employee of AdventHealth Orlando, you should know that your participation or lack of participation in this study will not affect your employment or relationship with AdventHealth Orlando.

Additional information about your local site:

HIPAA Authorization for Disclosure of Protected Health Information:

If you have not received a copy of the AdventHealth Orlando Privacy Notice, please request one. If you have questions about your privacy rights, you may contact AdventHealth Orlando Privacy Officer at PH: (407) 200-2961.

Privacy laws, including the Health Insurance Portability & Accountability Act (HIPAA) and other federal and state laws, rules, and regulations, protect your individually identifiable health information (also called Protected Health Information or PHI). If you agree to be in this study, privacy laws require you to sign this Authorization that describes your rights and explains how your Protected Health Information (PHI) will be used and disclosed for this research study.

By signing this informed consent/HIPAA Authorization, you will be authorizing the principal investigator, his/her research staff (see top of the "Site Specific Consent Information" section) and the sponsor) to use (which includes reviewing your medical records as necessary to conduct the study) and disclose your PHI for the purposes described below. By signing this form, you will also be authorizing your doctors, AdventHealth Orlando personnel, and individuals who provide health care services at AdventHealth Orlando to disclose your PHI for the purposes described below. This includes information from your past, present, and future medical records.

This Authorization does not have an expiration date. This means the researchers and others associated with this study may use and disclose your protected health information for as long as necessary to complete the study. If you volunteer to take part in this research study, others may learn your identity. Study information may identify you in the following ways:

- Name
- Address
- Telephone number
- Social Security Number (No study information will be linked to your SSN)

This study includes a number of researchers, businesses and government agencies. They may use your health information and share it with others. We want you to know who may use this information and how they may use it.

Who may use and give out information about you?

The Investigator (study doctor) and research staff will have information about your health that tells us your identity. They may give this information to others during and after the study.

Who may see this information?

The study sponsor may see your health information and know your identity. "Sponsor" includes people or companies working for or with the sponsor or owned by the sponsor.

The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people in the

MoTrMyo study, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join may be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of the MoTrMyo study. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

In addition to the study sponsor and its agents, the following people, agencies and businesses may get information from us that identify who you are.

- Doctors and healthcare professionals taking part in the study;
- U.S. Department of Health and Human Services (DHHS), which includes:
    - U.S. Food and Drug Administration (FDA)
    - U.S. Office of Human Research Protections (OHRP)
- Government agencies that must receive reports, including reports about certain diseases
- Government agencies in other countries
- AdventHealth Orlando representatives
- Institutional Review Board (IRB)
- Accreditation organizations

What information may be used and shared?

If you decide to be in this study, medical information that identifies you and relates to your participation will be created, used, and/or shared. This may include the following types of medical information.

- Information obtained from procedures used to find out if you are eligible to take part in this study. This may include physical examinations, blood and urine tests, x-rays and other procedures or tests, and any other information that you may release to us, including information about your health history.
- Information from your medical chart.

- Information obtained in the course of the study including information about your response to any study treatments you receive, information related to study visits and phone calls, physical examinations, blood and urine tests, x-rays and other tests or procedures that may be performed, and other medical information relating to your participation in this study.

By signing this document, you agree that your health care providers may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Why will this information be used and/or shared?

Information about you and your health, that might identify you, may be given to others to carry out the research study. The sponsor and/or the investigator will analyze and evaluate the results of the study. In addition, if this is a sponsored study (see page one) people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?

If you sign this consent form, you will be giving permission to use and give out the health information listed above for the purposes described above. If you decide not to give permission, you will not be able to be in this research. However, this will not change your relationship with your doctor or with AdventHealth Orlando and you will still be able to receive all benefits to which you are entitled.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this authorization (permission) will never expire (end) unless you revoke (cancel) it in writing. Additionally, you agree that your information may be used for similar or related future research studies. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study. If you want to withdraw your permission and not have your information shared beyond what has already been shared, please send the written notice to:

Lauren Sparks, PhD
301 East Princeton Street
Orlando, FL 32804

When you withdraw your permission, no new health information that might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

If you give permission for the hospital or the investigator to share your identifiable health information to other people or businesses, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Your personal information may be disclosed if required by law. Your records for this study may be sent by facsimile transmission (FAX machine) or over the Internet. It is possible that your records could be sent to the wrong person.

How long is my information kept?

Research with private health information must be maintained for seven years after the research study has been closed at the AdventHealth Orlando site. The Sponsor may require a longer period of time.

Documentation of Consent/Signatures
Your signature on this form means that:
You understand the information given to you in this form, you accept the provisions in the form, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS CONSENT FORM

Signature of Participant	Print Name	Date
Signature of Person Obtaining Consent	Print Name	Date