UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

The ENRGISE Pilot Study

3. Who do you call if you have questions about this research study?

Principal Investigator: Dr. Todd Manini at 352-273-9212

Other research staff:

Gainesville Study Coordinator or Research Manager at 352-273-9212

Jacksonville Study Coordinator or Research Manager at 904-244-9620

4. Who is paying for this research study?

The sponsor of this study is the National Institutes of Health (NIH).

Abbott Nutrition is providing funding for the purchase of the fish oil and its matching placebo.

5. Why is this research study being done?

You are being asked to be in this research study because you are over the age of 70 and may have a slow walking speed and high levels of markers of inflammation in your blood and have met eligibility requirements for this study.

The purpose of this ENRGISE Pilot Study is to look at the effect of anti-inflammatory drugs on physical functioning in older adults. This study will see if two study drugs (fish oil and Losartan, a commonly used blood pressure medicine) affect your ability to walk.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

No part of this research study will be done as part of your normal clinical care. The study does not interfere with your normal clinical care and your normal clinical care will not be interrupted whether you participate in the study or not. Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future health care you receive.

7. What will be done only because you are in this research study?

The following are tests that will be completed as a part of the ENRGISE Pilot study.

Walking Test

You will be asked to walk 400 meters at a normal pace. This will be done at the3, 6, 9 and 12 month visits.

Short Physical Performance Battery (SPPB)
The physical ability test has three parts. You will be asked to:

1. Stand in 3 different positions while keeping your balance
2. Walk a short distance (about 13 feet)
3. Stand up from a chair 5 times without using your arms

This will be done at the baseline, 3, 6, 9 and 12 month visits.

Hand Grip Strength
Grip strength will measured in the both hands using a grip strength instrument. This will be done at baseline and the 3, 6, 9 and 12 month visits.

Leg Strength
We will ask you to complete tests that will measure the strength of your leg muscles. This will be done on a muscle strength machine and ask you to push as hard as you can against the weight, but only in a pain free range of motion. This test will be completed at the baseline and 12 month visits.

Questionnaires
We will ask you to complete questionnaires about your level of activity, your mood, your level of fatigue, and your overall health and functioning.

Blood Tests
You will be asked to fast before visits that require blood tests. Please do not eat any food or drink anything except water for 8 hours before these appointments. Please do make sure to drink plenty of water. After we draw your blood, we will provide a snack to you before you continue with the rest of your visit procedures.

Medical Records Release Authorization
The study team will ask you to sign the Medical Records Release Authorization. We would like to have this form signed by you if we need to request your health records when you are hospitalized or if your health problems worsen and the study team has to report details of these events to regulatory authorities (Institutional Review Board, the study sponsor, etc.) to ensure your safety during participation in this research study. Health information collected using this authorization will be applied only to your health events that occurred during your participation in this research.

Below is a description of the visits that will be completed as part of your participation in the ENRGISE Pilot Study.

Screening Visits 1 & 2

You have already completed these screening visits.

Baseline Visit

At the Baseline Visit we will ask to you to do the following:

- Review and sign this informed consent if you agree to take part in this study.

- Review your medical history and medications.
- Measure blood pressure, pulse, temperature, height, weight, and waist circumference.
- Collection of blood for lab tests. About 3 tablespoonfuls of blood will be collected at this visit.
- Complete physical tests (SPPB, grip and leg strength).
- Complete questionnaires about your activity, mood, fatigue and health.
- Sign Medical Records Release Authorization.

You will be asked for your contact information at this time, which will include information for a proxy (a person that can provide information and answer questions for you in the event that you were unable to answer for yourself). In addition to the proxy, we will also ask you to provide us with the contact information of two close friends or relatives who do not live with you and who would know how to reach you in case you move and that know about you and your health. We will ask these people about your ability to walk and if, for any reason, you are not able to answer questions for yourself we will ask these people about any serious health problems you might have experienced.

Group Assignment

If you are eligible for this study, you will be randomly assigned (much like the flip of a coin) to different groups.

- If you are eligible for the fish oil part of the study, you will be randomized to receive either fish oil or placebo. The initial dose of either the fish oil or placebo will be dispensed at 1400mg per day. Based on your inflammation measures at your 3-Month and 6-Month Visits, it is also possible that the dose may increase to 2800mg per day. One capsule of fish oil or placebo is 700mg. The possible dose range is 1400 – 2800mg per day.

- If you are eligible for the Losartan part of the study, you will be randomized to receive either Losartan or placebo. The initial dose of the Losartan or placebo will be dispensed at 25mg per day. Based on the safety information gathered after the baseline visit the dose may increase to 50mg per day. Furthermore, based on the inflammation measures at your 3-Month and 6-Month Visits, it is also possible that the dose will increase to 100mg per day. The capsules of Losartan or placebo are available in 25mg and 50mg doses. The possible dose range is 25 – 100mg per day.

- If you are eligible for both the fish oil and Losartan parts of the study, you will be randomized to receive a combination of fish oil, Losartan, and/or placebo. The dosing scheduling is as described above for both the fish oil or placebo and losartan or placebo groups.

A placebo is a substance that looks like and is given in the same way as an experimental treatment but contains no medicine, for example a sugar pill. A placebo is used in research studies to show what effect a treatment has compared with taking

nothing at all. If you are assigned to receive placebo, you will not receive the benefits of the fish oil or Losartan, if there are any, nor will you be exposed to its risks, which are described below under Section 10. "What are the possible discomforts and risks?" Studies have shown, however, that about 1 in 3 persons who take a placebo do improve, if only for a short time. You and the physician and other persons doing the study will not know which group you are assigned to, but that information is available if it is needed.

At the Baseline visit, you will be given study drug based on which group of the study you are eligible for. It is important to take the study drug exactly as instructed by the study staff. Any unused study drug and any empty bottles will be returned at your next study visit.

The Baseline Visit will take about 3-4 hours.

3, 6, 9, and 12 Month Visit

You will be asked to come back for four follow up visits at 3 month intervals. At these visits, we will ask you to do the following. Not all of the tests will be completed at all follow-up visits.

- Review any changes in your health and medications.
- Measure blood pressure, pulse, temperature, weight, and waist circumference.
- Collect blood for lab tests. Below are estimates of how much blood will be collected at these visits:
    - 3 Month Visit: About 1 tablespoonful
    - 6 Month Visit: About 3 tablespoonfuls
    - 9 Month Visit: About 1 tablespoonful
    - 12 Month Visit: About 3 tablespoonfuls
- Complete physical tests (400 m walk, SPPB, grip and leg strength).
- Complete questionnaires about your activity, mood, fatigue and health at the 12 month visit.

At each follow-up visit you will return all unused study drug as well as return any empty bottles. You will be given study drug to last until your next visit.

Follow-up visits will last about 2-3 hours.

Safety Check Visits

For those people that are eligible to take part in the Losartan group of the study, we will ask you to return for safety check visits about 1 week after you first start Losartan and after changes in your Losartan dosage. At these safety check visits, we will measure your blood pressure and pulse and collect blood for lab testing. Less than one tablespoonful of blood will be collected at safety check visit.

We will ask you about any changes in your health and medicines you are taking.

Safety check visits will take about 30 minutes.

If needed, any study visits can be completed over multiple days.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Reading Exception

All study services and testing are being done for research purposes only and might not be evaluated or used to diagnose/treat your medical problems. The results might not be entered into your medical record. These tests may need to be repeated by your primary care doctor if required for your medical care in the future.

8. How long will you be in this research study?

Your participation is expected to last about 12 months.

9. How many people are expected to take part in this research study?

University of Florida site is planning to screen up to 2500 people and expects that approximately 60 older persons will participate in the study. In addition, approximately 240 people will participate at 4 other sites.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

There are some potential discomforts and risks associated with participating in this study.

Fish oil is considered very safe and only a few mildly adverse side effects such as stomach upset and fishy after taste are associated with its use. Fish oil may rarely cause mild increase in bleeding, increased blood sugar, rise in LDL or “bad” cholesterol, and possibly low blood pressure when combined with treatment for high blood pressure.

Drugs such as losartan have reported side effects similar to that of placebo, but side effects do occur, albeit rarely. Losartan has been safely used in large long-term studies in older persons with congestive heart failure and diabetes. Some side effects of losartan use are as follows:

- Higher level of potassium in your blood, which can affect your heart health. This is rare. For example, in people with diabetes, 7 out of 751 (0.9%) taking lostartan and 3 out of 762 (0.3%) taking a placebo had high potassium in their blood. There was no difference between the groups. This risk is greater if you have kidney

problems. Your lab tests tell us about your kidney health. The ENRGISE study will only enroll people with good kidney health.

- Decrease in kidney function. In people with heart failure, 5 out of 352 taking losartan showed kidney problems (1.4%). This risk can increase in people who are taking a non-steroidal anti-inflammatory drug (NSAID) such as aspirin or ibuprofen. Your lab tests tell us about your kidney health. The ENRGISE study will only enroll people with good kidney health.
- Dizziness and passing out due to a decrease in blood pressure. In people with diabetes, 7 out of 751 (0.9%) taking losartan showed low blood pressure. This was similar to people taking placebo (3 out of 762 or 0.3%).
- Allergic reaction causing rapid swelling of parts of your skin. This is very rare and is often experienced in people who have a history of allergies to blood pressures medication similar to losartan. We ask about your allergies to medications to minimize this risk.

The risks of drawing blood either from a vein or a finger stick include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

The risks of placing a blood pressure cuff on a participant are that it may cause pinching or slight bruising.

There is a risk of losing your balance and falling associated with the physical performance-based testing (walk test and SPPB). We will minimize this risk by: (1) safely escorting you to chairs located along the walking course should you become unsteady; (2) following you at a close distance; and, (3) being at your side should you need assistance.

Questionnaires: Some questions ask about mood. There is a risk that you will find these questions stressful or you might feel tired or sad after answering the questions. There is no right or wrong answer on these questions, and test scores by themselves do not mean that you have any problems; they are used for research purposes only.

Measuring strength may rarely cause pain or muscle sprain. In our experience of thousands of measures the testing has demonstrated to be safe.

Participation includes a risk of loss of confidentiality of personal health information. Several precautions are taken to prevent loss of confidential information including using secure spaces to collect questionnaire data where the interview cannot be overheard. In addition, only study investigators and key research staff (i.e. study programmers and biostatisticians) have access to the study data. Participants are assigned a unique study identifier and individual names are removed from the database. All collected data are maintained in locked computer files and file cabinets to which only study investigators have access. Collected data are used only for research purposes. Published data will not contain any individual identifiers.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

You will receive health and medical screening examinations and the results will be shared with you. These tests are similar to what your physician uses. We will tell you if we find any abnormal values and you'll be asked to seek consultation from your physician. You might find the results from these tests as a benefit to you.

11b. How could others possibly benefit from this study?

The study could impact clinical practice, and may, therefore, benefit individuals and society. However, the study staff will not know if there will be benefits to other people until all of the information obtained from this research has been collected and analyzed.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, Dr. Manini may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Fish oil is available over the counter and losartan is available by prescription from your primary care doctor. If you do not want to be in this study, but are interested in these options, discuss these with your primary care provider.

The other option that you have if you do not want to participate in this study is to do nothing. If you do not want to take part in this study, tell the Principal Investigator or the study team member and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw, no further information will be collected. The information already collected will still be used and stored securely.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

At the discretion of the Principal Investigator, participants may be discontinued early from this study due to unanticipated circumstances. The investigator and the sponsor reserve the right to terminate the study and discontinue your participation at any time in order to ensure your safety.

Some possible reasons for withdrawing a participant from the study:

- failure to follow study instructions
- the investigator decides that continuation could be harmful to you
- you need treatment not allowed in the study
- the study is canceled
- other administrative reason

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Drugs

Losartan, Fish Oil, or placebo will be provided at no cost to you while you are participating in this study.

Study Services

The Sponsor will pay for or provide all services and activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Dr. Manini at 352-273-5914 or study coordinator at 352-273-9212.

Items/Services Not Paid for by the Sponsor

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

15. Will you be paid for taking part in this study?

You will receive $25 for the baseline visit and the 3, 6, 9, and 12 month follow-up visits. No compensation is available for the Safety Check visits.

A $20 gift card will also be provided if you travel more than 20 miles (one way) from your home to the assessment clinic. You may also qualify for travel reimbursement to assessment visits based on the following criteria:

1. No longer having transportation to attend assessment visits at the clinic.
2. Medical condition which prohibits driving and other forms of transportation not available.
3. Financial issues associated with cost of transportation.

Unique situation (these will be discussed with the study team prior to status determination). If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida

Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or

psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Name
- Contact information
- Date of Birth
- Socio-economic status
- Social Security Number for payment and medical release purposes
- Information about your past and current medical history
- Information about medications you are taking

- Information about your vital signs and body measurements
- Information about your physical abilities
- Laboratory results to determine your eligibility
- Information about your level of activity
- Information about your memory and concentration
- Information about your mood
- Information about your level of energy
- Hospital/Physician Medical Records

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of, such as abuse and neglect, or harm to self or others.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To determine how drugs such as fish oil and Losartan may impact or be related to walking speed and chronic inflammation in older adults.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor - NIH.
- United States governmental agencies that are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The Data Safety Monitoring Board, a committee of experts who are not investigators in the study. These experts are appointed by the NIH to monitor all aspects of the study. They will meet regularly to monitor the safety and progress of the study, and to make sure that results are reliable and complete.
- Professionals at the other study centers in the United States also conducting this study.

- Laboratories selected to perform specimen analysis
- Other professionals at other institutions who are involved in this research

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator, Dr. Todd Manini at University of Florida PO Box 112610, Gainesville, FL 32610.

I agree to grant permission for the study team to share results from study, including blood pressure measurements, lab reports, and results from other tests with my primary care doctor.

____ Yes, please share my results with my primary care doctor.

____ No, please do not share my results with my primary care doctor.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

CONSENT TO COLLECT AND STORE TISSUE FOR FUTURE RESEARCH WHEN IDENTITY OF SUBJECT IS CODED AND THE CODES ARE KEPT IN LOCKED FILES BY THE PERSON CONDUCTING THE RESEARCH

As part of the research project, The ENRGISE Pilot Study, Todd Manini, PhD would like to store some of your blood sample that is not needed for your medical treatment or that was not needed for the research study. If you agree, Dr. Manini will keep the samples in a specimen bank at the University of Vermont so that they may be used in future research to learn more about the impact inflammation has on mobility and other medical problems. Researchers are trying to learn more about inflammation, such as what causes inflammation, how to prevent it, how to treat it better, and how, hopefully, to cure it. Even if the research that is done on your tissue cannot be used to help you, it might help other people who have inflammation or other medical problems.

Many medical problems may arise due to the environment or from genetic factors. Your inflammation may come from one or both of these causes. Genetic factors are those that people are born with and that can affect other family members. There may be genetic testing done in the future that would provide information about traits that were passed on to you from your parents or from you to your children. A Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at: http://irb.ufl.edu/gina.html or calling 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

Dr. Manini or his successor will be responsible for making sure that your samples are protected in the specimen bank and that your medical information is kept confidential. Your samples will not be stored with your name or other identifying information but instead will be given a code number to protect your identity. The samples and this code number will only be given to researchers whose research is approved by the Institutional Review Board (IRB). (An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). The researchers will not be told who you are. Because the nature and value of any future research cannot be known at this time, any results obtained from using your tissue will not be given to you or your doctor.

The people who use your samples to do research may need to know more about your health. If researchers ask for reports about your health (information from your medical records), Dr. Manini will not give them or anyone else your name, address, or phone number (unless you are willing to be contacted in the future to take part in more research). Although every effort will be made to keep your information confidential, there is a small risk that an unauthorized person may review your information. Therefore, there is a very slight risk that a test result could be linked to your identity and inadvertently disclosed to you or to a third party. If you were to receive the result of a genetic test that indicated a problem, it could cause anxiety or other psychological

distress. In addition, you might have to decide whether or not to discuss the findings with members of your family. If a third party learned the results, there is a risk of discrimination that could result in stigma and of the unpredicted disclosure of this information to others. You can discuss these issues further with your doctor or nurse and you can request a consultation with a genetic counselor if you wish to discuss these possible risks. In addition, there are laws that require that research records that have your name on them may be shown to people who make sure that the research is being done correctly. As mentioned in the accompanying consent form, the NIH, FDA, and the Institutional Review Board have the legal right to review and copy your medical records related to this research.

There will be no cost to you for any specimens collected and stored in the tissue specimen storage bank. Your tissue will be used only for research. Your blood sample may be shared with other research centers or private companies, in which case the University of Vermont may charge the research center or private company a fee in order to recover the University of Vermont's costs of sharing your blood sample. Some new products might be made because of the results of the research that uses your samples. These products might be sold sometime in the future, but, should this occur, you will not get paid.

The choice to let Dr. Manini keep your tissue for doing research is entirely up to you. No matter what you decide to do, it will not affect your care. If you decide that your tissue can be kept for research but you later change your mind, tell Dr. Manini who will remove and destroy any of your tissue that is still stored. Otherwise, the samples may be kept until they are used up, or until Dr. Manini decides to destroy them.

Please review statements 1 through 6 and then circle the answer that is right for you. If you have questions, please talk to the study team member.

1. I agree that my samples may be stored, coded to protect my identity, and that my identity will not be disclosed to anyone without my permission, except when required by law.

   YES NO Initials_____

2. I agree that some excess blood may be kept by the ENRGISE Study for use in future research related to the aims of the ENRGISE Study.

   YES NO Initials_____

3. I agree that my blood may be used for research to answer other questions that are not necessarily related to the aims of the ENRGISE Study.

   YES NO Initials_____

4. I agree that my DNA samples may be stored, coded to protect my identity, and that my identity will not be disclosed to anyone without my permission, except when required by law.

   YES NO Initials_____

5. I agree that some excess DNA sample may be kept by the ENRGISE Study for use in future research related to the aims of the ENRGISE Study.

   YES NO Initials_____

6. I agree that my DNA sample may be used for research to answer other questions that are not necessarily related to the aims of the ENRGISE Study.

   YES NO Initials_____

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