Permission to Take Part in a Human Research Study

AdventHealth
Translational Research Institute for Metabolism and Diabetes

Title of research study: BAT as a therapeutic for the metabolic and cardiac dysfunction with senescence (BATS) Pilot

Investigator: Paul Coen, PhD

Sponsor: TRI-MD

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are between the ages of 20-40 or 60-80; and have a BMI between 19.0 and 34.9 kg/m2.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- 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.

Why is this research being done?

Aging results in impaired metabolism and cardiac health. A third of the population over 60 years of age has diabetes (elderly-onset diabetes), and an additional third of this population has prediabetes. There is also a higher prevalence of cardiovascular mortality in older adults with impaired glucose metabolism compared to those with normal glucose metabolism.

An important tissue that combats metabolic disease and is cardioprotective is brown adipose tissue (BAT). BAT is a tissue found between a person's shoulder blades and is able to dissipate energy as heat. When activated BAT increases energy expenditure and can improve glucose metabolism.

BAT has great potential as a therapeutic target to combat both metabolic and cardiovascular disease, but BAT mass decreases with age.

The objective of this study is to determine the role of BAT in aging-induced impairments in

metabolism and cardiac function. This study could have a transformative effect in identifying both a unique role for BAT in aging and as a potential therapeutic target to reduce mortality from senescence. Studying the role of BAT will potentially help us understand and prevent an accelerated aging process, which will help researchers better understand metabolic and cardiac health in the elderly.

How long will the research last?

We expect that you will be in this research study for up to 5 weeks.

How many people will be studied?

We expect about 30 people will take part in the entire study.

What happens if I agree to be in this research?

Visit 1 Screening (~3.5 hours)

Participants will arrive to the TRI-MD, for this outpatient visit, after a 10 hour overnight fast. After obtaining informed consent, data collection for assessing eligibility will begin. The screening visit will include:

- Demographics
- Complete medical history (including, but not limited to, alcohol use, concomitant medications, supplements, health conditions, allergies and exercise habits)
- Physical exam, including health history
- Height, weight and waist circumference measurements
- BMI, which is a measurement of the body fat on height and weight that applies to adult men and women
- Vital signs (respiratory rate, temperature, heart rate, blood pressure)
- Electrocardiogram (ECG)
- ~~Serum~~ Urine pregnancy test, for women of childbearing potential
- Urinalysis
- Screening blood work will consist of a Complete Metabolic Panel (CMP) which includes electrolytes, glucose, kidney and liver function; lipid profile which includes cholesterol, HDL, LDL, VLDL and triglycerides; Complete blood count with platelet and differential (CBC); TSH and HbA1c. Approximately 14 milliliters (about 1 tablespoon) of blood will be drawn at this visit.
- Physical activity and mental health questionnaires.

You will also complete the following exercise related test:

- **Hand-Grip Strength:** You will be required to squeeze a hand-held instrument as forcefully as possible for three to five seconds. You will be asked to do this three times using your dominant hand.
- **Short Physical Performance Battery Test:** You will be asked to perform a SPPB test. SPPB has been developed specifically for older individuals, therefore will only be

performed for those who are 60-80 years of age.
The SPPB consists of:
  - Balance Test. This test assesses your ability to balance yourself in a standing position.
  - Gait speed test. This test assesses your ability to walk 4 meters at a normal pace.
  - Chair stand test. This test assesses your ability to rise from a seated position without the use of your arms.

The score from each of these tests will be summed to give an overall assessment of function.
- **Step Test: If you are between the ages of 60-80,** you will be asked to complete a timed step test.

Screening tests may be repeated if the Investigator deems necessary.

Visit 2 (~3 hours):
To occur no more than 28 days after Visit 1.

Participants will arrive to the TRI-MD for this outpatient visit, after a 10 hour overnight fast. This visit will include a urine pregnancy test which will be performed before proceeding with any activities on all women of child bearing potential. Activities for this visit include a:
- **Vital signs (respiratory rate, temperature, heart rate, blood pressure)**
- **Body Weight**
- **1 Day Food Record:** You will be asked to record what foods and drinks you have consumed over the last 24 hours prior to the visit. Food records will be reviewed with you for accuracy. You will be asked to eat these same foods and drinks prior to Visit 3.
- **Blood draw:** You will be required to be fasting (no food or drink except water) for 10 hours prior to this visit. You are encouraged to drink water (no other food or other beverages may be consumed) freely the night before and morning of your study visits because proper hydration increases blood volume and makes it easier for the phlebotomist/nurse to collect the blood sample. This sample will be stored for future use as described in the section below titled, “What happens to the information collected for this research?” Approximately 10 milliliters (less than 1 tablespoon) of blood will be drawn at this visit.
- **DEXA (Dual Energy X-ray Absorptiometry)**: You may be asked to change into a hospital gown. Your weight will be collected prior to the DEXA scan. For the test you will be asked to lie on a table called a DEXA scanner. During the scan, an electronic arm will pass over your body, using low dose x-rays to record the amount of bone, fat and muscle in your body.
- **Magnetic Resonance Imaging (MRI):** This test will measure the size and location of muscle, bone, organs and different types of fat in your body. For this test, you will be required to be fasting (no food or drink except water) for at least 8 hours and up to overnight prior to the imaging, depending on your appointment time. The fasting helps

minimize the amount of motion in your belly due to food digestion. You may be asked to change into a hospital gown. If you have previously been instructed to wear comfortable, clothes without zippers or rivets, you may be allowed to remain in your clothes. You can also request to wear a hospital gown. During the data acquisition, the magnet will make loud knocking noises. You will be given hearing protection (ear plugs and ear phones) for the MR scans. You will lie on a table in the MR scanner and lie as still as possible. Once positioned on the table, you will be moved into the magnet. When the imaging begins, you will hear loud knocking noises. For several of the images, you will be asked to hold your breath for up to 20seconds for several of the images. For the remainder of the images, you can breathe normally, but need to stay lying still. The entire MR procedure, including positioning on the table, preliminary guidance images and quantification of fat, will take approximately ~30 minutes.

- **Electrocardiogram (ECG): If you are between the ages of 60-80,** a standard 12-lead ECG will be performed. A recording of the electrical activity of the heart, which involves placement of painless sticky pads (or electrodes) onto your chest, arms and legs, to assess the electrical activity of your heart; you will be required to remove or lift your clothing out of the way, to allow placement of the electrodes on your chest area and this will be done behind a closed curtain for your privacy.
- **Exercise Testing (VO2max):** (The time involved with this test depends on your exercise capacity.) ECG electrodes will be placed on your chest for heart monitoring during the test. Following a warm-up, you will pedal at a comfortable pace and resistance that will progressively get harder until you are winded and unable to continue. During the test, you will breathe through a mouthpiece and wear a nose clip. The volume of oxygen intake and carbon dioxide (CO_2) production will be measured. Your heart rate will also be monitored continuously using a heart rate monitor.
- **Activity Monitor:** You will also have two activity monitors placed around your left upper arm and wrist. You will be asked to wear the monitors for ~7 days, except while showering/bathing. They are tri-axial accelerometers that measure your activity and uses those values to estimate the number of calories you burn based on your height, weight, age and gender. The monitors also evaluate physical effort and the body's response to different activities using body position, skin temperature, heat flux and galvanic skin response. You must return the monitors on your next visit, Visit 3.

<u>Visit 3 (~3 hours)</u>
To occur 6-9 days after visit 2.

Participants will arrive to the TRI-MD, for this outpatient visit after a 10 hour overnight fast. Activities for this visit include a:

- **Vital signs (respiratory rate, temperature, heart rate, blood pressure)**
- **Body Weight**
- **Collection of Activity Monitors**
- **1 Day Food Record:** You will be asked to record what foods and drinks you have

consumed over the last 24 hours prior to the visit. Food records will be reviewed with you for accuracy. You will be asked to eat these same foods and drinks prior to Visit 3.

- **Blood draw:** You will be required to be fasting (no food or drink except water) for 10 hours prior to this visit. You are encouraged to drink water (no other food or other beverages may be consumed) freely the night before and morning of your study visits because proper hydration increases blood volume and makes it easier for the phlebotomist/nurse to collect the blood sample. This sample will be stored for future use as described in the section below titled, "What happens to the information collected for this research?" Approximately 10 milliliters (less than 1 tablespoon) of blood will be drawn at this visit.
- **Magnetic Resonance Imaging (MRI):** This test will measure the size and location of muscle, bone, organs and different types of fat in your body. For this test, you will be required to be fasting (no food or drink except water) for at least 10 hours and up to overnight prior to the imaging, depending on your appointment time. The fasting helps minimize the amount of motion in your belly due to food digestion. You may be asked to change into a hospital gown. If you have previously been instructed to wear comfortable, clothes without zippers of rivets, you may be allowed to remain in your clothes. You can also request to wear a hospital gown. During the data acquisition, the magnet will make loud knocking noises. You will be given hearing protection (ear plugs and ear phones) for the MR scans. You will lie on a table in the MR scanner and lie as still as possible. Once positioned on the table, you will be moved into the magnet. When the imaging begins, you will hear loud knocking noises. For several of the images, you will be asked to hold your breath for up to 20seconds for several of the images. For the remainder of the images, you can breathe normally, but need to stay lying still. The entire MR procedure, including positioning on the table, preliminary guidance images and quantification of fat, will take approximately ~30 minutes.
- **Muscle Testing**: You will be tested to determine the strength and power of your muscles (how quickly and forcefully you can exert your muscles). These tests will be done on a machine called a Biodex and Leg Extension. We will measure the speed at which you can move resistance at different percentages of your peak strength. You will warm-up for about one minute by doing light exercise before testing. After the warm-up, the testing procedures will be explained to you and the tester will explain how the test will be done. You will have a very low resistance practice trial with each leg to familiarize you to the test. Testing on these machines will consist of testing one leg at a time. There will be up to three attempts with each leg at each percentage, followed by a rest period before the next series of tests at the next percentage is done. Although we don't expect that you will experience any discomfort from doing this test, you will be able to give feedback about any pain or discomfort that you might experience during the test. The tester will describe the pain/discomfort scale (0-6 scale) to you.

Permission to Take Part in a Human Research Study

What are my responsibilities if I take part in this research?

The success of this research study depends, in part, on collecting all of the data from all of the subjects who agree to be in the study. If there is missing data, then this can negatively affect the conclusions from the study. Before you sign this Informed Consent Form to take part in this research, it is very important that you understand that you will not be able to change your mind about giving the biospecimens for research after they have been collected. You will only be able to change your mind before the biospecimens are collected. Please take as much time as you need to think about this before agreeing to participate in this study.

If you take part in this research, you will be responsible to:

- Provide truthful information about your medical history, current medical conditions, and drugs that you are taking.
- Do not take any new prescription or over-the-counter medications that are prohibited in the study without prior approval from the Principal Investigator or study doctor.
- Do not begin a diet or weight loss program.
- Fast overnight for at least 10 hours prior to scheduled visit as indicated, i.e., no food or beverage except water and no more than one glass of water within 2 hours before the indicated visit.
- Do not donate blood or plasma during the study.

Tell the Principal Investigator or study doctor about any problems you have during the study.

Is there any way being in this study could be bad for me?

Vital Signs/Blood Pressure Testing: You may experience temporary discomfort during blood pressure recordings due to the pressure of the cuff on your arm.

ECG (Electrocardiogram): There are no risks associated with this test. There is a small possibility there may be some redness or itching if you happen to be allergic to the electrodes' adhesive.

DEXA (Dual Energy X-ray Absorptiometry): The risks associated with having a DEXA scan include exposure to radiation from the scan. The amount of radiation that you will be exposed to is very small, less than half the amount you receive each day, or less than a chest X-ray. Such doses of radiation may be potentially harmful, but the risks are so small that they are difficult to measure. If you are still concerned with the radiation exposure, you can discuss this with your physician. If you are pregnant, you should not have a DEXA scan performed, as the risks posed by these procedures to the fetus is unknown. Therefore, if you are a woman of childbearing potential, a urine pregnancy test will be done prior to the DEXA.

Muscle Testing: The exercise test may cause muscle soreness or fatigue (common). If an abnormal rise in blood pressure or changes in the electrical pattern of the heart is detected, or if you develop chest pain, the exercise should be stopped immediately. Other changes include shortness of breath, abnormal blood pressure, fainting (common) and heart attack, stroke, or

sudden death (rare). Rarely, exercise may cause moderate to extreme pain, which could be due to muscle sprains, muscle strains, broken bones, or chest pain.

Exercise Testing (VO_2max): There is a possibility of certain changes that may occur during maximal or sub-maximal exercise testing. They include abnormal blood pressure, fainting, irregular, fast or slow heart rhythm, and in rare instances, heart attack, stroke or death (about a 2 in 10,000 chance). This risk is very low and similar to when you exercise during your daily life. You may experience shortness of breath or become dizzy or lightheaded during maximal exercise testing and high intensity cardiovascular exercise. These feelings are normal and transient in nature. If these feelings are prolonged and increase in intensity after the end of exercise, notify the study doctor and/or study staff immediately. A Medical Provider will be present during exercise testing for subjects who are at risk according to the American College of Sports Medicine (ACSM) guidelines.

Exercise that is not commonplace or routine may also cause muscle soreness and stiffness, muscle injury, ligament and/or tendon injury, as well as skeletal injury. This is normal at the beginning of an exercise program and should subside with time. However, if undue soreness or stiffness continues, or if more than slight swelling occurs, please notify the study doctor/study staff.

Blood Draws (venipuncture): You will undergo needle sticks during visits where blood samples are collected. You may have pain, light-headedness, fainting, infection, bleeding or bruising at the site of injection; however the staff will use proper technique while taking blood samples in order to reduce the risk of these unwanted effects. You may feel hungry or weak during the times you are required to fast. The total amount of blood drawn during the study will be about 30 milliliters (less than 3 tablespoons). In comparison, the typical amount collected during a blood bank donation is 540 milliliters (2 ¼ cups).

Activity Monitor: There are no anticipated risks with the activity monitors However it is possible you may experience some minor skin irritation from the monitor strap. If you have allergies to metal (especially nickel) you will not be required to wear the Bodymedia monitor.

You should not be or become pregnant while in this research study. Women who are pregnant or nursing a child, or those who have been in the last 6 weeks, may not participate in this research study. If you are a female, a pregnancy test will be performed before you begin the research. If at any point during the research you believe there is any possibility that you may be pregnant, you must notify the investigator immediately.

Questionnaires: The questionnaires used in this research will ask you about your physical and emotional well-being. Completed questionnaires may not be reviewed immediately. If you have concerns about your well-being, please let the study doctor or team know.
As with any investigational study, there may be adverse events or side effects that are currently unknown and it is possible that these unknown risks could be permanent, serious or life-threatening.

Permission to Take Part in a Human Research Study

Will being in this study help me in any way?

There is no direct benefit for study participation. The study is not a treatment for you specifically. In the future, others may benefit from the information learned from this study.

Are there any costs in this study?

The TRI-MD will provide the supplies free of charge during this study. Tests and procedures will not be billed to you or your insurance company.

You or your insurance company may be billed for any follow-up regarding incidental findings. These costs are not covered by this research study.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask your Study Coordinator or Principal Investigator to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

Will there be compensation for injury?

In the event of research-related injury or illness, medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The TRI MD and AdventHealth Orlando does not have a program to pay for medical care for research-related injury or illness.

What happens to the information collected for the research?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Aging. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about

yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

To the extent allowed by law, we limit your personal information to people who need to review it. We cannot promise complete secrecy. The Institutional Review Board (IRB) and other representatives of this organization may inspect and copy your information for the purpose of providing research oversight.

To help protect your confidentiality, your samples will be labeled with a coded number that is different from your clinic number. This number is used instead of your name to help protect your identity. The samples are then stored in a secure location in the TRI-MD laboratory until a scientist is ready to study them.

For the purposes of this study, we may need to send some of your biospecimens and information to outside laboratories for analysis/testing that cannot be done at AdventHealth Orlando. If this is needed, provisions will be put in place to protect the confidentiality of your information.

After the purpose and aims of this study have been met, we will store any left-over or remaining biospecimens samples for additional or future testing that may be needed that could not be predicted at the time you signed the Informed Consent. It is often the case in the process of scientific discovery, we realize that an additional test(s) may help advance the answers we may find.

Also, we will store biospecimens for future research, testing, or experiments. The biospecimens will be stored indefinitely until a research need for them is identified. Because these biospecimens would be used for future research at AdventHealth Orlando and other research institutions, we cannot be sure exactly how they will be used. It is possible that biospecimen samples may be used for chemical, DNA, RNA or protein testing that help us understand the function of the body. Cells from the biospecimens may be separated and treated in various ways to better study them and how they work. Scientists are learning new things every day that may suggest future research directions. Although we cannot predict the exact types of future research, testing, or experiments that may be performed with your samples, there are measures in place to make sure that the research has scientific merit. Biospecimens may be used for commercial profit. Study participants will not be eligible to share in that profit.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. Federal law provides additional protections of your medical records and health information. See the HIPAA section below.

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.

Can I be removed from the research without my OK?

Your participation in this study may be stopped at any time by the Principal Investigator, study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you; you have not followed study instructions;
- the sponsor has stopped the study;
- AdventHealth IRB Orlando or other administrative area of AdventHealth Orlando has decided to stop the study; or
- administrative reasons require your withdrawal

What else do I need to know?

It is important that you tell your Principal Investigator or study doctor if you feel that you have been injured because of taking part in this study. You can tell the them in person or call them. You should contact your Principal Investigator or study doctor at their office number, which is a 24-hour number, call 911, or go directly to an Emergency Room. If you have additional questions or concerns, call the Principal Investigator listed on page one of this document.

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

This research is being funded by National Institute on Aging. If you agree to take part in this research study and you complete all study visits, you will paid $400.00 for your time and effort. Reimbursement checks will be requested upon completion of the study or following withdrawal from the study. Payment may take about 2 weeks to be processed, once requested.

If all study visits are not completed, you will receive the following prorated amount for the visits you have completed.

- Visit 2 $200.00
- Visit 3 $200.00
  Total $400.00

Permission to Take Part in a Human Research Study

HIPAA Authorization to Release Information for Research

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's 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, and the sponsor (see top of page one) 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

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 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.

Permission to Take Part in a Human Research Study

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
- Publications, medical meetings, or scientific journals (individual patients will not be identified).

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, 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.

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.

Permission to Take Part in a Human Research Study

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.

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 Principal Investigator. 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:

Paul Coen, 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.

What happens if I agree to be in research, but later change my mind?

If you change your mind and decide that you no longer want to participate in this research study, you are free to do so at any time by informing the Principal Investigator or Study Coordinator. Any information from the analysis/testing of biospecimens obtained before you contacted the study team will continue to be used in the research study and any remaining biospecimens will **continue to be used** for analysis/testing. It is important for you to know that if you choose to no longer directly participate and you want to request that your

biospecimens no longer be used, that is not an option for this study. Already collected data may not be removed from the study database.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Paul Coen, Ph.D.
301 E. Princeton Street, Orlando, FL 32804
(407) 303-7100
Or
Research Study Coordinator
301 E. Princeton Street, Orlando, FL 32804
(407) 303-7124

This research is being overseen by an Institutional Review Board ("IRB"). The IRB is a group of people who review and approved research studies to be conducted at AdventHealth Orlando. You may talk to them at (407) 200-2677 or FH.IRB.General@adventhealth.com if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Permission to Take Part in a Human Research Study

Signature Block for Adult Subject Able to Consent

Your signature documents your permission to take part in this research.

Subject:

Printed: Name of Subject

Signature: Name of Subject | Date

Person Obtaining Consent:

Printed: Name of Person Obtaining Consent

Signature: Name of Person Obtaining Consent | Date

Witness to Consent Process:

(Use the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.)

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Printed: Name of Witness to Consent Process

Signature: Name of Witness to Consent Process | Date

If "Witness to Consent Process" NOT signed, indicate why:

❑ Subject can understand and read the English language