Consent to be part of a Research Study
To be conducted at
Children's Medical Center of Dallas and any of its affiliated entities
Texas Health Presbyterian Hospital Dallas – Institute for Exercise and Environmental Medicine

Part 1

Key Information about this Study

The purpose of this research is to explore obesity-related respiratory limitations in 8-12 year old boys and girls at rest, when supine, and during exercise. The study will consist of 4-6 study-test visits (2-3 during pre-testing and 2-3 during post-testing). The subject may also be asked to repeat some tests, which may take up to 2-3 extra visits. Each study visit will be 3-4 hours, visits may run longer than the stated time, but we will make every effort to keep visit length at a minimum.

All the procedures planned for this study are non-invasive, standard cardiopulmonary laboratory tests, which are associated with minimal risks. During the Dual-energy X-ray absorptiometry (DEXA) scan, subjects will be exposed to minimum radiation (0.06 mR) which is less than one-tenth the dose of a standard chest x-ray and less than a day's exposure to the natural radiation. However, the risks of participation are slightly greater than in subjects who do not elect to participate in the study. Nevertheless, the potential benefits from this study are greater than the risks to the subjects of participation. The subjects may directly or indirectly benefit from the results produced by participating in this study.

If you are interested in learning more about this study, please continue to read below.

Information about this form

Enrolling Children
If you are providing consent for someone else, for example your child, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow, the word "you" refers to the person you are providing consent for.

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Tony G. Babb, Ph.D.it, Department of Pulmonary Physiology at The Institute for Exercise and Environmental Medicine.

Funding
The National Institutes of Health (NIH), a federal agency that promotes scientific research, is funding this study. This organization is providing money to the University of Texas Southwestern Medical Center at Dallas so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

This study is being done to explore whether increased body weight (which can vary from individual to individual) reduces lung function in children and whether a reduction in body weight leads to an improvement in lungs.

You are asked to participate in this research study because you are interested in the effect that increased weight has on breathing or to serve as a healthy volunteer for comparisons.

The researchers hope to learn more about the effects of body weight and weight loss on pulmonary function and exercise capacity.

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are interested in the effect that increased weight has on breathing or to serve as a healthy volunteer for comparisons.

How many people are expected to take part in this study?
This study will enroll approximately 142 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 3 pre/post visits with the researchers or study staff.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Many of the procedures are described below as "**standard care**" and would be done even if you do not take part in this research study. You will be told which ones are for "**research only**".

Screening Procedures

Pre-testing:

Screening Visit One (4 hours in duration):

Screening Procedures

To help decide if you qualify to be in this study, the researchers may ask you questions about your health, including medications you take and any surgeries you have had.

You may also have to fill out certain forms or have the following exams, tests or procedures:

- Medical history;
- Pulmonary (Lung) Function Tests;
- Vital signs;
- Electrocardiogram (ECG), a tracing of the electrical activity of the heart; and

These procedures will be done to determine if you qualify for this research and could take up to 4.5 hours to complete.

During the first visit, you will also have the following evaluations:

Review of medical history: (i.e., medications you take for any health problems, and any surgical procedures you have had), filling out a physical activity questionnaire, asthma screening questionnaires, and a sleep questionnaire. You will also complete a self-assessment of your pubertal status using drawings of different stages of breast, genital and pubic hair development. Your Parent/Legal Guardian may be present while you are providing the information to the nurse. The nurse will review the pictures with you. You will be able to complete and seal the form in a private place. Your Parent/Legal Guardian will have the opportunity to review this form. These procedures may be done even if you do not participate in this research.

Pregnancy Test: If you are capable of becoming pregnant, a pregnancy test will also be done prior to testing. If you have started your period, a urine pregnancy test will be done (using a few drops of urine), and it must be negative before we conduct any testing. You cannot be pregnant during your participation in this study. If you become pregnant during the course of the study, you must immediately inform the staff, and withdraw from the investigation. If your parents or guardian asks, we will tell them the results of your pregnancy test or that you are using birth control.

Pulmonary function tests or PFTs: These involve breathing exercises to measure your lung function. You will be asked to sit in a plastic, body box (body plethysmograph) for about 2 – 2.5 h and perform a number of breathing exercises. A body box is best described as an enclosed, clear chamber (you can see through the walls) where pulmonary function testing is performed. In order to screen for asthma you will be asked to inhale 4 puffs [90 mcg per actuation] of a drug (Albuterol) during your lung function tests. You will breathe through a mouthpiece and wear a nose clip during the tests.

Maximal exercise test: The goal of the test is for you to exercise as long as possible. You will start pedaling at a rate that is easy for you. Then, it will get harder at every stage. This will feel like you are riding up a hill. You will breathe through a mouthpiece and wear a nose clip during the test. Your breathing pattern, heart rhythm, blood pressure, and oxygen saturation level (via pulse oximetry) will be monitored during the test. Most children cycle for 8 – 15 minutes; however, there is no set time limit for the test. You will only be asked to work to the best of your abilities. You may stop exercise when you wish, because you are feeling tired or uncomfortable.

Verification test: The goal of this test is for you to exercise as long as possible at a workload that is a little higher than the highest workload achieved during your maximal exercise test described above. We do this test to verify your maximal exercise capacity. You will breathe through a mouthpiece and wear a nose clip during the test. Your breathing pattern, heart rhythm, and oxygen saturation level (via pulse oximetry) will be monitored during the test. Most children

cycle for 2 - 3 minutes at this high workload; however, there is no set time limit for the test. You will only be asked to work to the best of your abilities. You may stop exercise when you wish, because you are feeling tired or uncomfortable.

Study-Test Visit Two (3 hours in duration):

Dual-Energy X-Ray absorptiometry (DEXA): Your body composition (percentage of fat and lean tissue) will be determined by using an FDA-approved bone density measurement machine. The procedure is called Dual-energy X-ray Absorptiometry (DEXA). You will be asked to lie face up, on a padded bed for 7 minutes while the scanner arm of the DEXA machine passes over your entire body. The scanner will not enclose you or touch you, and you can wear my regular clothing (no metal allowed). This test takes about 15 minutes.

Moderate exercise: You will be asked to pedal on a stationary exercise cycle at a constant work rate (pedal resistance) for 10 minutes at the most. The exercise will not be too easy and it will not be too difficult, it will be somewhere in between. You will breathe through a mouthpiece and wear a nose clip during the test. Your breathing pattern, heart rhythm (ECG), blood pressure, and oxygen saturation level (via pulse oximetry) will be monitored during the test. Pulse oximetry is a method of determining the amount of oxygen in the blood by using a sensor placed on the skin. You may stop exercise when you wish, because of personal feelings of fatigue or discomfort.

Postural changes in lung function: You will be asked to perform several different breathing exercises while breathing through a mouthpiece and wearing a nose clip during the test. You will be coached on each breathing maneuvers while seated or lying on your back. We may repeat the supine measurements with a small 10 lb weight placed on your stomach so that we can test how weight on the stomach changes the way you breathe while lying down.

Voluntary Hyperventilation (EVH): The EVH test will be performed in order to estimate the oxygen cost of breathing. We may also ask you to perform a separate EVH test as an “indirect bronchoprovocation” test to rule out asthma, which will not be performed on all children.

During the EVH test to estimate the oxygen cost of breathing, you will be asked to breathe deeper and faster than normal while seated at rest, and while on the mouthpiece with noseclips. The breathing rate will be set by a metronome, where a ticking sound will help you pace your breathing. You will breathe at two different levels (“low” and “high”), each lasting 7 minutes.

The EVH test to rule out asthma will be performed only on obese children with a prior diagnosis of asthma without confirmation by lung function tests if PFTs are negative or borderline. An EVH test to rule out asthma may also be performed on obese children who have respiratory symptoms without the diagnosis of asthma after PFTs have been found to be negative or borderline. The absence of asthma or borderline results in the PFT will be further confirmed by a negative response to a bronchial challenge test (EVH). The PI/co-investigator will have the oversight to determine necessity for this test. If asked to perform this test, you will be asked to breathe deep and fast. You will breathe through a mouthpiece and wear a nose clip during the test. The EVH test to rule out asthma will last approximately 4 to 10 minutes. You may stop the test when you wish if you are feeling tired or uncomfortable. Before and after the voluntary hyperventilation every few minutes, you will be asked to perform a breathing exercise so we can measure how your breathing changes in response to the hyperventilation. If there is a change in your breathing, you will be asked to inhale 4 puffs [90 mcg per actuation] of a drug (Albuterol) and the breathing exercises will be repeated after 10 minutes. While we prefer to complete EVH testing on your last visit, it may be performed on either Visit 1, 2, or 3 as determined on an individual basis at the discretion of the PI/co-investigator.

Gas mixtures: You will be asked to breathe different gas mixtures while seated upright, while lying down, during exercise, and during voluntary hyperventilation. These will include room air, mixture of acetylene, helium, nitrogen and oxygen for several breaths or 3%, 4% or 5% carbon dioxide mixtures with oxygen and nitrogen during the voluntary hyperventilation trials. You may be asked to breathe these gases during the course of this study or a combination of

any of these gases may be used during the experiment. These gases are used to measure lung volumes or to help maintain a normal level of carbon dioxide in your blood.

Weight Loss and Exercise Program:

If you are under the guidance of physicians at the **C**enter for **O**besity **A**nd its **C**onsequences in **H**ealth (COACH) Program at Children's Medical Center. We will keep in touch with you periodically after your pre-testing visits to help answer any questions that might arise during the weight loss and exercise program regarding diet and physical activity recommendations. If needed, we will demonstrate physical activity intensities on multiple exercise devices depending on your preferences (e.g., stationary cycle, treadmill, gaming, etc.). We will not interfere with the dietary and medical recommendations set forth by COACH, but we will provide monitoring and support throughout the study. If you are overweight and not enrolled with COACH, you will receive standard of care information regarding weight loss and regular physical activity and will be monitored and supported throughout the study. The monitoring and support will include periodic follow up phone calls/emails and completing the physical activity questionnaire (same that you filled out during the screening visit). The purpose of these phone calls/emails is to follow up with you to answer any questions that you might have related to weight management or regular physical activity. The phone calls or emails will be every 1- 3 months at your convenience. You will have the option of answering the follow-up survey questions on the phone or via a secure email link to a survey containing the follow-up questions.

Option of three visits

If you prefer to do three short visits rather than two long visits, the tests will be completed in the following order:

Visit One (3-3.5 hrs)	**Visit Two (1.5-2 hrs)**	**Visit Three (2.5-3 hrs)**	**Visit 4 (optional; 1.5-2 hrs)**
Review of medical history	Max test	DEXA	EVH to estimate oxygen cost of breathing
Pregnancy test (if applicable)	Verification	Postural changes in lung function	
Pulmonary function tests of PFT		Moderate Exercise	
		Voluntary hyperventilation - EVH to rule out asthma (if necessary): While we prefer to complete this test on visit 3, it may be performed on Visit 1, 2 or 3 as determined on an individual basis at the discretion of the PI/co-investigator.	
		Standard of care information regarding weight loss and regular physical activity	

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Risks – "What are the risks of participation in the research?"

Risks from the specific research procedures (drug(s), interventions, or procedures)

The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are life threatening or fatal (could cause death). The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

Risks and side effects related to the Albuterol (Ventolin®) include those which are:

Likely, some may be Serious
In 100 people, approximately (1 – 100) may have:

- Palpitations (awareness of rapid or pounding heartbeat)
- Chest pain
- Rapid heart rate
- Shakiness and nervousness
- Nausea
- Increased blood pressure
- Dizziness
- heartburn

Rare and Serious
In 100 people, approximately (less than 1) may have:

- Allergic reaction

<u>Pulmonary Function Test</u>

There are no known risks of performing pulmonary function tests.

<u>Breathing Carbon Dioxide</u>

The risk to you of breathing increased levels of carbon dioxide at rest or during exercise is minimal. You may feel your breathing rate increase, which may cause some feelings of shortness of breath, lightheadedness, and/or temporary headache or feeling hot. We will monitor end-tidal carbon dioxide levels when indicated to maintain concentrations within acceptable limits.

Maximal Exercise

During maximal exercise, you will experience discomforts similar to those associated with any type of heavy exercise. There is the possibility of certain changes occurring during the test. They include abnormal blood pressure, fainting, disorder of heartbeat, and in rare instances, heart attack. The risk of serious complication during maximal exercise testing is estimated to be less than 1 per 40,000 such tests in adults. Every effort will be made to minimize these through the preliminary interview and screening, and by observations during testing. A physician or his/her designee will be immediately available during the exercise test**.**

During sub-maximal (mild) exercise, you will experience discomforts similar to those associated with any type of sub-maximal exercise. Examples of these discomforts may include, but not limited to, shortness of breath, leg fatigue and soreness, and discomfort from sitting on a bike seat. These discomforts have been reported in 2-20% of subjects tested.

Voluntary Hyperventilation

There is a very small possibility of severe breathing problems during this test. If this occurs, you will be immediately treated with a medication (Albuterol) that will reduce your breathlessness. You may experience cough, shortness of breath, chest tightness, wheezing, chest soreness, or headache, however, most people have no symptoms. These symptoms typically disappear after administration of medication (Albuterol). We will monitor your breathing and other vital signs during the test to limit the risks.

Psychological Stress

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

DEXA:

Radiation exposure to a woman's reproductive organs may harm an embryo or fetus. Therefore, on the day of your DEXA scan, a urine pregnancy test will be done (using a few drops of urine) prior to your DEXA appointment. The pregnancy test must be negative in order to continue with your DEXA appointment and in order to remain eligible for participation in the study.

If your parents or guardian asks, we will tell them the results of your pregnancy test or that you are using birth control.

Risks of Radiation – Diagnostic Test

This research study includes exposure to radiation from diagnostic tests in addition to that which you would receive from standard care. The additional radiation dose you will get is about 1% of the average radiation dose from all sources (natural background radiation, consumer appliances, radon gas, medical tests, etc.) that a person in the United States receives each year.

Other Risks

There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers. For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there Risks related to withdrawing from the study?
There are no risks related to withdrawing early from the study. If you decide to withdraw from this study early, please discuss your decision with the principal investigator.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

You may not receive any personal benefits from being in this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

This is not a treatment study. You do not have to be part of it to get treatment for your condition.

Payments – Will there be any payments for participation?

You will be compensated a total of $180 in gift cards for completing all study tests (excluding the optional visit), regardless of whether you choose to complete the study over two long visits or three short visits. In addition, if you choose to visit our laboratory for the optional visit, we will compensate you $60 for that visit, which will total $240 for completing all tests including the optional oxygen cost of breathing test.

Two long visits: You will be paid $120 for visit one ($20 for completing the questionnaires, $40 for pulmonary function testing, and $60 for maximal exercise testing), and $60 for visit two ($20 for the DEXA scan, and $40 for the postural/exercise testing). If you choose to come back for the optional visit, you will be compensated $60 for completing the oxygen cost of breathing test. The two visits after the weight loss and exercise program or control intervention will be paid at the same rates. Your payment will be made in the form of gift cards. Payments will be processed after completion of your visits. You will be paid at the end of each visit.

Three short visits: If you choose to do the three short visits the payment will be $60 for visit one, $60 for visit two, and $60 for visit three. If you choose to come back to our lab for the optional visit, you will be compensated an additional $60.

If you are asked to complete the EVH test to rule out asthma, you will be compensated $40 for completing that test, in addition to all other tests. If you do not complete all visits, you will be paid according to your participation. For example, if you participated in visit one only, you will be paid $60. Furthermore, if you are disqualified from a visit, or if you repeat some testing, you will be paid a pro-rated rate, depending on whether you completed part of the visit or the whole visit.

In order to comply with the safety policies set by Texas Health Resources, you are required to test negative for COVID-19. In addition to the payments described above, you will be compensated $30 for the time required for COVID-19 testing.

We do not pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Your Social Security Number (SSN) will be given to Texas Health Presbyterian Hospital Dallas - Institute for Exercise and Environmental Medicine in order to process your payment as required by law. This information will remain confidential unless you give your permission to share it with others, or if we are required by law to release it.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

How will my information and/or tissue samples be used?

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information or tissue samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Date of Birth (Age)
- Social Security Number (for payment purposes only)
- Adverse Events
- Treatment
- Gender
- Ethnicity
- Height
- Weight
- Body composition
- Body size measurement
- Medical history
- Exercise history
- History of mental illness

- List of current medications
- Heart rate
- Blood pressure
- Electrocardiogram (recording of the electrical activity of the heart)
- Oxygen saturation level (level [percent] of oxygen in the blood)
- Lung function test results
- Exercise test results
- Breathing pattern (breathing rate and size of breaths)
- Breathing mechanics (volumes of air in the lungs and rate of airflow into and out of the lungs)
- Ventilation (amount of air in the lungs and rate of airflow into and out of the lungs)
- Gas exchange (amounts of oxygen used and carbon dioxide in the exhaled air)
- End-tidal carbon dioxide level (level of carbon dioxide exhaled in the air)
- Ratings of perceived breathlessness and ratings of perceived exertion (according to scales
- that will be explained during visit 2) and qualifies of respiratory sensations
- Self-assessment of pubertal status
- Urine pregnancy test (if needed)
- Physical Activity Questionnaire
- Epworth Sleepiness Scale
- Asthma screening questionnaires (ISAAC and ERCHS II)

We will get this information by asking you, and by collecting during testing.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, National Heart, Lung and Blood Institute – National Institutes of Health funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- the members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center, Parkland Health and Hospital System, Children's Medical Center of Dallas and any of its affiliated entities, Texas Scottish Rite, Texas Health Resources.
- the Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of The Institute Exercise and Environmental Medicine for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to *Tony G. Babb, Ph.D., 7232 Greenville Avenue, Dallas, TX, 75231, (214)345-4622*. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:
Primary contact:

Tony G. Babb, Ph.D. can be reached at 214-345-4622, that can be reliably reached during and after normal work hours or 214-534-1898 after hours and on weekends and holidays.

If primary is not available, contact

Research nurse can be reached at 214-345-6574, that can be reliably reached during regular business hours.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Surrogate Signature Section

			AM PM
Printed Name of Participant	Signature of Participant Giving Assent (*If incapable of signing, person obtaining consent should initial here*)	Date	Time
			AM PM
Printed Name of Person Giving Consent for Participant (If applicable)	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM