

<b>MEDICAL RECORD</b>	<b>CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY</b> • Adult Patient or • Parent, for Minor Patient
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INSTITUTE: National Institute of Diabetes, Digestive and Kidney Diseases

STUDY NUMBER: 07-DK-0077 PRINCIPAL INVESTIGATOR: Monica C. Skarulis, M.D.

STUDY TITLE: Study of the Phenotype of Overweight and Obese Adults

Continuing Review Approved by the IRB on 10/30/07

Amendment approved by the IRB on 12/3/07 (E)

Date Posted to the Web: 12/29/07

Standard

### INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

#### **Purpose of the Study**

Obesity is a common medical condition affecting one-third of the American population. It is associated with diabetes, hypertension, heart disease, and depression. Many factors under our control and some that are not, contribute to weight gain over time. Factors considered to be under our control include habits and preferences regarding eating, sleeping and exercising. An example of a factor beyond our control is the internal codes that we inherit in our genes. The purpose of this study is to comprehensively describe the phenotype (the physical and behavioral traits) of individuals that are overweight or obese. This is not a weight loss study. The study will focus on characterizing the hormones, metabolism, food preferences, fitness and physical activity levels, sleep patterns and thought processes in individuals with and without weight problems. Using specialized techniques, the amounts of body fat and muscle and the amount and type of fuel your body burns to support bodily functions and physical activity will be measured. Because we are interested in how these measurements change over time, you will be invited to repeat the evaluations in this study whether you intend to lose weight or not. Genetic material will be collected for studies of the internal codes that influence body weight.

PATIENT IDENTIFICATION

#### **CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (4-97)

P.A.: 09-25-0099

File in Section 4: Protocol Consent (1)

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**Who is Eligible for Enrollment in this Study**

Patients over the age of 18 years are eligible to participate. Patients from all weight categories including lean, overweight, or obese people may be eligible providing you are reasonably healthy. Lean individuals are studied to develop the specialized techniques on the metabolic unit and to serve as a group for comparison with overweight or obese participants.

**Study Outline**

The procedures and testing will be conducted in the clinic and the inpatient Metabolic Units at the Clinical Center. For some of the research studies, weight stability is important; therefore participants undergoing the full testing must not have significant weight fluctuations during the month preceding the testing. We also may ask you to repeat a few of the studies to establish the reproducibility of the specialized methods used. If all of the studies described are performed, the evaluation can be completed in 5 days as an inpatient on the metabolic unit. We invite you to participate in the studies indicated by the check marks and you are encouraged to indicate your willingness to participate by placing your initials in the space next to the study checked. If you have significant physical limitations that may keep you from completing most of the tests in this study, or we find any medical conditions that may put you at risk, you will be excluded from the study.

**Screening Visit**

Potential participants will visit the 5/7 SW unit for a tour. After informed consent is obtained by a member of the research team, a limited physical exam including height and weight will be performed. The nutritionist will provide instructions for collecting food records for seven days. An electrocardiogram, a test of your heart's electrical signals and rhythm will be obtained. There are no risks associated with this test. Blood will be drawn for routine clinical test to assess your health and nutrition status. A urine sample will also be collected to measure proteins.

**Outpatient visit**

You will return for a visit in ~ 30 days to see if your weight is stable and review the food records that you collected. The results of the laboratory testing will be reviewed. If nutritional deficiencies are discovered, recommendations will be given. If your weight is stable (within 3% of initial body weight) an inpatient admission date will be scheduled and an individualized calendar of studies constructed. Some of the testing can be performed as an outpatient; however, some specialized studies require control of your diet and an inpatient evaluation. The types and quantity of food you will be provided on the Metabolic Unit will be similar to the food you ate and recorded in your food record. Menstruating females will be scheduled for metabolic studies on the days right after bleeding stops (the so-called follicular phase of the menstrual cycle).

**Testing and procedures requiring admission to the Metabolic Unit**

- Resting Metabolic Rate:* This test will enable us to study how many calories your body burns at rest. The measurement will be performed in the morning after a 12-hour fast. We will place a plastic transparent hood over your head to collect the air that you exhale for 30 to 40 minutes while you are resting comfortably lying down. The test is non-invasive, but the ventilation hood may cause some minimal discomfort in claustrophobic subjects.
- Mixed meal stimulated C-peptide test with Acetaminophen:* This test is performed in the morning after a 12-hour fast. This test is being done to simulate the response of your beta cells to an ordinary meal and to measure the time it takes for the food to pass through your stomach. You will receive a food supplement, called 'Boost High Protein', which you have to drink within 10 minutes and you have to take acetaminophen (commonly known as Tylenol®). You are being given acetaminophen to evaluate how quickly it is absorbed through the stomach, giving us an indication of how quickly food passes through it. Blood will be collected through an intravenous catheter placed in your arm. This study lasts for

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about 3 hours. A catheter will be placed in one of your arm veins before the study and blood will be drawn every 15 to 30 minutes over 3 hours during the study. We will measure several hormones in your blood stream (e.g. insulin) as well as the concentration of acetaminophen. You may experience some nausea after drinking the food supplement. Acetaminophen at high doses (much higher than given in this study) is known to cause liver damage. The risks related to blood collection include feelings of faintness, nausea, and bruising at the site of injection. Rarely, infection, and/or thrombophlebitis (inflammation of the vein due to blood drawing) may occur.

       *Frequently sampled intravenous glucose tolerance test*: This test will help us find out how sensitive your body is to insulin. If you take diabetic medications, it may be necessary to hold them for this test. The test is performed in the morning after a 12-hour overnight fast, two intravenous catheters will be placed, one in each arm. At the start of the test, glucose will be given to you through your vein over one to two minutes. After 20 minutes, a small dose of insulin is given in your vein. You will be monitored very carefully while blood samples are taken for the next three hours. The risks from this test include the possibility of slight arm tenderness during the glucose infusion, flushing and mild nausea during the glucose infusion and low blood glucose after the insulin is given. With low blood glucose, people may get hungry, have a headache, feel shaky or dizzy or may become drowsy or sweat. If low blood glucose does occur, the test will be stopped and you will be given juice or glucose by vein to raise the blood glucose to normal.

       *24h Energy Expenditure (metabolic room)*: You will be asked to spend a continuous 24 hours in a specialized room that measures the amount of oxygen that you breathe in and the amount of carbon dioxide you breathe out. This is a small but comfortable room equipped with its own toilet and sink with privacy screen, treadmill, bed, desk, telephone and computer with access to television, internet and other forms of entertainment. For the proper measurements to occur, the door to the room must remain shut for the duration of the study. Food and drink will be delivered through a drawer. You can communicate through the intercom and see the nursing staff through a window. There is a device to measure your movement in the room and a camera linked to the nursing station to assure your safety. Members of the nursing staff will be present outside the room for the duration of the study. There are no risks involved in spending time in this metabolic room. If you become uncomfortable or anxious during your stay in the room, you can stop at any time by walking out because the door will remain unlocked at all times. For your safety, your heart rhythm (EKG) will be monitored continuously through a wireless monitor by the nurses during this test.

       *Repeat 24h Energy Expenditure*

       *Diurnal blood sampling and temperature assessment*: In order to study your body's internal clock, we will assess the natural rise and fall of hormones in the blood during daylight and at night. We will also ask you to swallow a small capsule that contains a temperature sensor to establish if the normal changes in body temperature occur over 24 hours. The probe is an FDA approved device. The capsule will be eliminated unchanged from your body in a day or two. During this time, you are advised not to have a study called a magnetic resonance imaging scan (MRI) because the sensor contains small quantities of metal. Skin surface temperature pads may be used at the same time. The diurnal assessment is not risky but may be inconvenient.

### **Testing and procedures *not requiring admission to the Metabolic Unit***

       *Air-Displacement Plethysmography (Bod Pod®)*: To measure your body composition, we will ask you to wear close-fitting clothing and enter a small capsule where you will sit for ~10 minutes. Suggested clothing to wear: For women: An everyday bra (without underwire) and underwear, sports bra and tight-fitting short shorts, "biking shorts", or either a one or two piece bathing suit with little padding. For men: brief or boxer-brief type underwear, Speedo style bathing suit, or tight-fitting short shorts (ex: biking shorts). We will then ask you to breathe normally through a

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disposable tube. This will enable us to study the fat composition of your body by air displacement. Although there is a window some patients may find this test uncomfortable because of the small space.

       *Dual Energy X-ray Absortimetry (DEXA)*: This instrument is used to measure body fat and bone density using low dose x-ray. You will lie on your back for approximately 10 minutes while the x-ray machine is positioned over areas of your body. Depending on your size, we may need to scan half of your body at a time. This scan gives you a small amount radiation. It must be noted that this radiation exposure is **not** necessary for your medical care and is for research purposes only. The total amount of radiation you will receive from this study is from 1-4 DEXA *scans*. The NIH Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving minimal risk and necessary to obtain the research information desired. The DEXA follows the Bod Pod, described above. You will need to wear the same close-fitting clothing for this procedure also.

Using the standard way of describing radiation exposure, you will receive an effective dose of less than one thousandth of one rem from each *DEXA scan*. By comparison the average person in the United States receives approximately this much radiation every day from natural background sources, such as the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. In this scan the only part of the body exposed is the skin, which is less vulnerable to radiation than most other parts of the body. The chance anyone has of eventually dying of cancer in their lifetime is 1 in 4. After receiving this study, for all practical purposes, the chance will remain 1 in 4. *If you are pregnant you may not participate in this aspect of the study.* It is best to avoid radiation to the human embryo. The use of DEXA scan apparatus may also cause some minimal discomfort in claustrophobic subjects and minimal back pain in a small number of the individuals.

       *Repeat Bod Pod<sup>®</sup> and DEXA*: The repeat *DEXA scan* will result in the radiation exposure noted above.

       *Anthropometric measurements and bioelectrical impedance*: Height, weight, and circumferences will be obtained. There are no risks associated with measuring your skinfold thickness with a calipers or waist, thigh and hip size with a tape measure. When the caliper is measuring the skinfold thickness, you may feel a mild pinch which is not painful. Bioelectric impedance analysis (BIA) testing will be used to assess fluid status and percentage body fat. You will be asked to remove socks, shoes, and any metal jewelry before measurement. You are measured while lying supine on a nonconductive surface. There are no risks involved with these measurements.

       *Bromide dilution*: We can measure the amount of water not in cells in your body by assessing the quantity of bromide in your blood after drinking a known amount of sodium bromide in water. Bromide is a chemical frequently used in the formulation of medications. At the dose administered, there are no known toxicities, although the salty taste may be unpleasant.

       *Doubly Labeled Water*: We can measure the amount of calories (how much energy) you burn in a 7-day period by asking you to drink a special type of water. This water does not taste or act differently from tap water, but contains safe and non-radioactive hydrogen and oxygen, which will allow us to measure how much oxygen you use over the study period and tell us how many calories you burn. We will collect urine, saliva and blood prior to and for a few hours after drinking the water. You will collect urine and saliva samples for the next week. When you return the samples, we will obtain your body weight. The doubly labeled water has no known risks.

       *Random 24h diet recalls*: We will place a few unscheduled calls to you during the week after you drink doubly labeled water that will help us interpret the results of the test. We will inquire what you have eaten in the last 24 hours. Some may find the calls from the nutrition staff inconvenient but there are no risks associated with these interactions.

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**Collection of single or 24-hour urine studies:** We will collect all of your urine for 24 hours for hormone measurements. We may ask you to collect a single daily urine specimen for 7 days as part of the doubly labeled water study. Collection of body fluids poses no risk although it may be inconvenient.

**Endothelial Reactivity:** This test is designed to measure the way your blood vessels stretch or dilate and is one way to assess cardiovascular health. You will be asked to rest for 30 minutes before this procedure. An ultrasound picture of your forearm vessels will be taken using sound waves and a blood pressure cuff will be inflated around your arm for 5 minutes. Measurements of the way your blood vessel responds to release of the blood pressure cuff will be carried out for a few minutes. There is transient discomfort including numbness and tingling and pain with the inflation of the blood pressure cuff and the chance that the blood pressure cuff may leave a temporary mark on your skin.

**Exercise capacity:** Based on your history, physical exam and screening electrocardiogram (ECG), we will assess if it is safe to perform an exercise test to determine your level of physical fitness by observing your heart rate and the oxygen you breathe. You will be asked to walk/run on a treadmill or use a reclining bicycle. During the test we will record the electric activity of your heart (EKG). If you are unable to use the exercise equipment, a less strenuous test will be performed. The test will be stopped when you experience exhaustion, muscle cramps, or shortness of breath. If you should have chest pain or a change in your heart activity on ECG, the test will be stopped and a cardiology consultation will be obtained. This testing will help assess your physical fitness level. Exercise testing may precipitate chest pain, abnormal blood pressure, heart rhythm abnormalities, passing out, a heart attack or death in subjects affected by previously unknown coronary artery disease or other forms of heart disease. The chances of these adverse events are reported to occur in less than 1:10,000 studies performed. The risk is reduced but not eliminated by excluding from testing those with a history, signs, or symptoms of heart disease."

**Physical activity monitor:** We will use small portable pager-type devices to measure your physical activity. The devices will be attached at the wrist and hip. There are no risks associated with the monitor, but you may find it to be inconvenient.

**Unicorder:** We will give you an instrument called the Unicorder to wear while you sleep for one night. This device allows us to detect if you have difficulties breathing that may interfere with your sleep. This condition is called obstructive sleep apnea. The instrument is about the size of your fist and you will wear it strapped to your forehead with a soft elastic band. You will have a soft plastic tube (cannula) that fits in your nostrils to measure your breathing. There are no risks or hazards in wearing the Unicorder. You may find the elastic strap or the plastic tube in your nose somewhat uncomfortable, but most people find they can wear it comfortably during sleep. This study may uncover important information about your breathing during sleep and we will share the information with you and discuss proper follow-up should it be needed.

**Subcutaneous Fat and Muscle Biopsy:** To find out the variations in gene expression in fat tissue and muscle, small samples will be taken from under the skin of your abdomen or the thigh after looking at the area with an ultrasound machine (uses sound waves to see the muscle underneath) and numbing the area with a local anesthetic. If the muscle is too deep to reach, the muscle biopsy will not be attempted. We will give you some mild pain medication such as Tylenol or stronger medication if needed. Pain at the biopsy site is usually minimal; bleeding and infection are rare. Biopsy wounds usually heal with a very small, nearly unnoticeable scar, but sometimes a raised scar (keloid) or visible lump may result. The biopsy will be taken from a place on your body that is normally covered and not easily seen. Lidocaine, a numbing medicine, is used to reduce the discomfort of the biopsies. However, the injection of Lidocaine itself causes some mild burning before the numbing takes effect. It is possible that you may experience a sore muscle or ache for up to 3 weeks after the procedure. Other risks of the procedure include minor bleeding in the

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area of the biopsy and, rarely, infection. Some medications may increase the amount of bleeding from the biopsy. If you are taking medications such as coumadin or Plavix or aspirin to thin your blood, you may not have a biopsy. If you are taking aspirin or non-steroidal medications such as Advil for pain and would like to participate in the biopsy portion of this study, you will need to stop taking these medicines for 10 days before the biopsy is performed. You can expect a bruise to develop around the biopsy site, which usually disappears in 1 to 2 weeks. In rare cases, allergic reactions to the numbing medication have been reported; if you know you are allergic to Lidocaine, we will change to another medication.

     *Neurocognitive Testing:* This testing will check memory, decision making, hand-eye coordination, and reasoning. Some of the tests check the function of the frontal lobe of the brain, an area that is important in eating behavior. There are no risks to this test. It will be conducted in two sessions lasting no more than two hours each to avoid undue fatigue and minimize frustration or anxiety.

     *Psychiatric evaluation:* Research has shown that depression and mood disorders are common in people with weight problems. This evaluation will review past and present mood problems and assess your personality type. It is possible that through this evaluation, we may find that you have problems that require the attention of a mental health care professional. We will share with you the results of our evaluation and make recommendations for follow-up should it be needed.

     *Pain evaluation:* We will assess the quantity and quality of pain you may experience through physical examination and questionnaire. There are no risks associated with this evaluation.

     *Taste testing:* We will determine whether you can detect the taste of a bitter substance, propylthiouracil (PROP) placed on your tongue. We will also assess your response to salty, sweet and sour substances. We will photograph your tongue to assess the number of taste organs on your tongue. There are no risks associated with this procedure.

     *Occupational therapy evaluation:* In this evaluation, the manner in which you have made adaptations, if any, to perform activities on a personal, social or professional level will be explored. Your views on your weight and strategies to control weight will be explored in an interview. We will audiotape this interview and study its content. In another evaluation your views on your body size and shape will be examined. There are no risks associated with this type of evaluation, although some participants may not feel comfortable sharing personal information with the examiners, if this is the case, you may decline from answering. The duration of the evaluation is approximately 3 hours and will be done over two separate visits.

     *Physiatry (physical medicine and rehabilitation) evaluation:* This evaluation will assess functional impairment and disability. You will have a thorough musculoskeletal examination consisting of joint and soft tissue assessment, strength, gait, ability to perform activities of daily living, mobility, and self report questionnaires. The evaluation will take about 90 minutes. Filling out the questionnaires will take approximately 30 extra minutes. There are no risks associated with this evaluation.

**Risks not covered under individual procedures listed above**

*Blood sampling and intravenous catheter placement:* Adverse events related to blood collection and intravenous catheter placements include feelings of faintness, nausea, and bruising at the site of injection. Rarely, infection, and/or thrombophlebitis (inflammation of the vein due to blood drawing) may occur. The quantity of blood drawn will not exceed NIH guidelines

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*Research involving study of genes and genetic material:* Some of the blood drawn for this study and some of the adipose and muscle tissue collected at the biopsy will be used to analyze genes that may be important in obesity and its related traits. Family studies are not conducted under this protocol. The results of the testing are likely not to have direct clinical relevance and thus, we will not provide you with the results of such testing. By agreeing to participate in this study, you do not waive any right that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Skarulis at (301) 496-6087. However, if our testing leads us to discover information important to your health or the health of your offspring, we will share it with you and recommend appropriate follow-up which may include genetic counseling. Possible risks of knowing such results include: anxiety or other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. Donation of tissues (blood, fat and muscle) for these research purposes is not included in your medical record.

*Other Research studies:* In addition, studies conducted during this study may uncover a medical condition that could affect your health in the future. Any illness that we detect during these tests will be discussed with you. If a condition is discovered that prevents your participation in this study, you will not be eligible for treatment of that condition under this protocol. However, records of tests obtained during the screening may be forwarded to a physician of your choice to help further evaluation and treatment.

**Storage and disposition of research samples and research test results**

Your genetic material and blood samples will be stored in freezers in NIH laboratories indefinitely for future analysis in the study of obesity and its related traits. All samples will be identified by a study code linked to your name and the code and the results of all analyses will be kept strictly confidential. Likewise, your private health information will be stored indefinitely in the medical record and other secured databases for research in obesity and its related traits.

**Benefits**

Study subjects will receive treatment of nutritional deficiencies found as part of this study. Participants will learn many things about their body, eating habits, physical fitness level and sleep. Participants will have opportunities to attend informational sessions about diet and exercise. Since no specific weight loss treatment is given to participants in this study, we will let you know about other studies that you may be eligible for at the Clinical Center.

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**MEDICAL RECORD****CONTINUATION SHEET for either:  
NIH 2514-1, Consent to Participate in A Clinical Research Study  
NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study**

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**Remuneration**

You will receive the following payments for the time and effort connected with Outpatient Visits, procedures, and Inpatient Hospital Admissions participation according to the following schedule:

1. Daily payment for inpatient and /or outpatient visits. \$40/day X 5 maximum paid visits	\$200.00
2. Indirect calorimetry (1 unit)	\$25.00
3. Mixed meal test (1 unit)	\$25.00
4. Frequently sampled IVGTT	\$25.00
5. Neurocognitive tests (2 units)	\$50.00
6. Endothelial activity test (2 units)	\$50.00
7. Exercise testing (2 units)	\$50.00
8. Fat and muscle biopsy (4 units)	\$100.00
9. Doubly labeled water (1 unit)	\$25.00
10. Respiratory chamber (1 unit)	\$25.00
11. Body composition (1 unit)	\$25.00
12. Week of food logs and activity monitoring	\$70.00
13. Completion of questionnaires	\$30.00
14. Psychiatric Evaluation	\$50.00
15. Occupational Therapy Evaluation	\$75.00
16. Pain Evaluation	\$25.00
17. Physiatrist Evaluation	\$25.00
18. Unicorder	\$25.00
19. Diurnal Evaluation	\$25.00
20. Metabolic Suite	<u>\$100.00</u>
	\$1025.00
Bonus for repeat assessments	\$100.00

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**PATIENT IDENTIFICATION****CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

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**OTHER PERTINENT INFORMATION**

**1. Confidentiality.** When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

**2. Policy Regarding Research-Related Injuries.** The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

**3. Payments.** The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health.

**4. Problems or Questions.** If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Monica C. Skarulis, M.D. Building: 10 CRC, Room 6-3940, Telephone: 301 496-6087.

You may also call the Clinical Center Patient Representative at 301-496-2626.

**5. Consent Document.** Please keep a copy of this document in case you want to read it again.

<b>COMPLETE APPROPRIATE ITEM(S) BELOW:</b>			
<p><b>A. Adult Patient's Consent</b> I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.</p> <p>_____ Signature of Adult Patient/Legal Representative                      Date</p>	<p><b>B. Parent's Permission for Minor Patient.</b> I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)</p> <p>_____ Signature of Parent(s)/Guardian    Date</p>		
<p><b>C. Child's Verbal Assent (If Applicable)</b> The information in the above consent was described to my child and my child agrees to participate in the study.</p> <p>_____ Signature of Parent(s)/Guardian    Date</p>			
<p><b>THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM OCTOBER 30, 2007 THROUGH OCTOBER 29, 2008.</b></p>			
<p>_____ Signature of Investigator    Date</p>	<p>_____ Signature of Witness    Date</p>		