UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, 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 other doctors) 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.*

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

Identification of phenotypic factors that predict success for weight loss and long-term weight maintenance. (Consent for metabolomic, metabolic profiling including biopsies.)

1.2 Company or agency sponsoring the study:

Atkin's Foundation; Investigator's discretionary funds

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Charles Burant, M.D., Ph.D.
Amy Rothberg, M.D., Ph.D.
William Herman, M.D., M.P.H.
Jeffrey Horowitz, Ph.D.
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Andrzej Galecki, M.D., Ph.D.

2. PURPOSE OF THIS STUDY

The goal of the study is to identify individual characteristics that may predict successful weight loss and long-term maintenance of weight loss in people. Our measure of success is at least a 10% decrease from your initial weight at 2 years' time. Secondarily, we will measure the ability of weight loss to change your blood fat profile such as reductions in triglycerides, LDL-c, (bad fraction) and an increase in HDL-c (good fraction). We will measure changes in glucose (blood sugar) and insulin as well as the change in your body's composition (how much fat and muscle you have). We will see how well weight loss improves your fitness by measuring how well you can exercise. We will also try to find genes and metabolites (small molecules that are in your blood) that may make it harder or easier for you to lose weight and keep it off. Finally, we will ask you questions that will describe how your weight has impacted your physical and emotional health and how you feel when you are losing weight.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. You can still participate in the weight loss program even if you do not want to participate in this study.

3.1 Who can take part in this study?

Overweight and moderately obese men and women aged 18-85 years old with a body mass index (BMI) measured as a ratio of weight (in kilograms) divided by height (in meters squared) of greater than 28 kg/m^2 will be recruited for this study. We will also recruit lean people who have a BMI >17 but <28. We will not include people with significant heart, kidney, liver, gastrointestinal tract, neurological, psychiatric or endocrine disorders, HIV/AIDS and cancers other than minor skin cancers. We will also not include people who have stopped smoking within the previous 6 months and anyone with weight changes greater than 5 kg (about 11 pounds) within the previous 3 months, a history of eating disorder, or a history of or current substance abuse. Patients who have had bariatric surgery for weight loss will be excluded. Other exclusion criteria include women who are pregnant; women of childbearing age who wish to conceive within two years of starting the diet should not participate in this study. Women of childbearing age must be willing to use a reliable form of contraception. Those who plan to move within 2 years should also not participate in this study.

3.2 How many people (subjects) are expected to take part in this study?

800 individuals are expected to participate (700 obese or overweight persons and 100 lean persons).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you are overweight or obese, you are participating in a weight loss and maintenance of weight loss program as part of your clinical care. You will be prescribed a diet low in calories and be expected to exercise for at least 150 minutes per week done at intervals at your convenience.

As part of your clinical care, you will meet with a nutritionist to assess your goals and barriers to weight loss. Prior to any measurements, a 4 day calendar of consumption, meal times, location of meals (restaurant or at home) and physical activity will be reviewed. The dietician will assess your caloric requirements at baseline and meet with you once you start to lose weight to determine your dietary understanding and adherence (your ability to stick with a diet). One measure of adherence and to verify absolute intake is to review food diaries (you will record all the food you ate for a precise period of time, e.g. for 4 days).

At the start of the diet, the dietician will follow you weekly during the first 4 weeks, monthly for a period of 3 months and then every 3 months during the rest of year one (1) and during year two (2). We may request that you come in for additional individual or group meetings if you have difficulty losing weight. Weight loss goals will be reviewed at these intervals. At these visits, measurements of blood pressure, heart rate, weight, waist and hip circumference and skinfold thickness will be obtained. If weight loss goals are not met, a new plan, i.e. a further change in diet composition, further caloric restriction and/or medication will be started. You may be asked to use meal substitutes in the form of HMR shakes) for a total of 12 weeks to help you lose weight and then transition to a program of meal replacement 4-14 times weekly for a period of one to two months or longer if desired to achieve optimum weight loss and thereafter maintain loss of weight. There will be an initial emphasis on calories and the elimination of food dense in calories. You will be encouraged to use portion control plates at meals.

As part of standard care within the clinic (**not** research related), you will routinely have measurements of blood pressure, heart rate, temperature, and anthropometric measurements: (one time measurement of height), weight, calculation of BMI, waist circumference, hip circumference and waist/hip ratio, skin fold thickness and have blood drawn to measure blood electrolytes, glucose, cholesterol and other lipid levels as well as any additional laboratory tests that in the judgment of the doctors are necessary for taking good care of you with respect to your other medical conditions, (e.g. measure of HbA1c, urine for protein and liver tests in patients with Type 2 diabetes). You will be asked about your physical activity with respect to time spent daily/weekly and what

activities you perform. Your response will be captured as part of the research record. Please tell us if you do not want this information recorded in our research record.

For the research part of the study, we will measure your physical fitness by testing your exercise capacity and your body composition. Biochemical measurements of your blood will be performed, and blood will be taken to isolate your DNA to test for variations that may predict a person's ability to lose weight. We will attempt to coordinate blood draws as part of study with any blood draws for your standard care.

The following are the procedures (tests) in which we invite you to participate <u>in as part of the research</u>. If you are an overweight or obese subject, these tests will be done at the beginning of your treatment, and between 3 and 6 months and 2 years afterwards. If you are a healthy, lean person, you will be asked to complete these tests only once. You can agree to participate in none, some or all of the procedures outlined below. We would also like your permission to contact you for future studies related to obesity.

<u>Please initial next to the specific test(s) in which you agree to participate.</u>

_____Please contact me for future studies related to obesity.

_____Completion of questionnaires: The questionnaires you will be asked to complete should not take more than 15 to 20 minutes. The questionnaires ask questions related to your present mood and deal with how being overweight/obese has impacted your physical and emotional health.

_____Iowa Gambling Task. In the Iowa Gambling Task you have the opportunity to win or lose hypothetical money and the overall goal of the game is to maximize profit. You will start with $2000, and can win or lose money each time you select a card from one of 4 decks. The task consists of 100 card selections and takes approximately 15 minutes. The Iowa Gambling Tasks allows us to examine how people make complex decisions.

_____Food Healthfulness Questionnaire and 3 pass dietary recalls. We would also like you to give us your opinion on the healthfulness of 24 food items by ranking them and providing an estimate of their calorie content. We would like to contact you 3 times in the period when you are first seen by the physician and the start of your

diet to review what, how much and when you eat. Each call takes about 20 minutes in duration to collect this information.

We would also like to collect this information in those who have already lost weight and well into the weight maintenance phase to determine whether weight loss and maintenance of weight loss has affected your perceptions (characterizations) of food.

_____75 g Oral glucose tolerance test (oGTT). An oGTT requires a blood sample after you have fasted overnight (time = 0) after which you will be given a sugared drink to consume, which is then followed by repeat venous blood draws obtained at 30, 60, 90 and 120 minutes. The oGTT will be obtained at the beginning of the study, at 6 months and at the end of two years. Please note that if you have diabetes, you will not need to have this test. If you do NOT have diabetes, but on testing have an elevated blood sugar, you will be referred to get this test done as part of standard care.

_____Blood and urine samples for lipomic and metabolomic measurements (measurements of the small molecules in your blood that represent a kind of fingerprint of your current metabolic state) and inflammatory markers.

_____ ___One of the primary goals of the study is to assess the neurobehavioral response to dietary restriction and weight loss and relate mood, hunger, anxiety and other psychological parameters to changes in metabolite levels in the plasma. It has become clear that some individuals who are on a very low calorie, liquid diet (VLCD), find that they are unable to continue VLCD for the entire 3 month period. Because these individuals may have different psychological make-up or rapid and significant changes in metabolites, we would like to reassess your psychological profile and metabolite levels prior to supplementing the liquid diet with other food. We would like to obtain 10 ml of plasma and repeat metabolomic/lipomic profiling prior to dietary change from VLCD (liquid diet) to incorporation of other food.

_____Genetic analysis. We would like to obtain an extra sample of blood for DNA in order to examine candidate genes related to obesity and to further explore genetic variations associated with obesity. The results of the DNA analysis of the genes done for this study are unlikely to have direct clinical implications at this time, but may provide useful information for the treatment of overweight and obesity in the future. You will not be told the results of this genetic testing.

_____We believe that certain hormones, metabolites and amino acids affect hunger and satiety (sense of fullness). We have observed that patients on liquid meal replacement have decreased hunger and cravings. In a subset of individuals (~10-15 patients), we would like to obtain blood for glucose, insulin and amino acids and

other small metabolites after you have completed one month of very low calorie diet (VLCD) in the form of meal replacement shakes in order to characterize changes in these levels that may be related to consumption of these shakes. After an overnight 12-hour fast, we will give you a meal replacement shake (HMR® Boston, MA) to drink. A catheter will be placed in the antecubital vein (the vein near your elbow) prior to drinking the shake. Blood is drawn before (time = 0) and then at 15 mins., 30 mins., 60 mins., and 120 mins. (for a total of 2 hours). A total of about 10 ml (2 tablespoons) of blood will be taken. If you participate in this test, you will NOT to participate in the Three-hour mixed meal test (see below) or in the muscle or adipose tissue biopsies."

_____*Three-hour mixed meal test*. After a 12 hour fast, you will be asked to drink one can of 'Boost High Protein' over 10 minutes along with taking 650 mg of acetaminophen (commonly known as Tylenol®). This test stimulates your pancreatic beta cells to secrete insulin in response to an ordinary meal and measures the time it takes for the food to pass through your stomach. You are being given the acetaminophen to study how quickly it is absorbed through the stomach, giving us an indication of how quickly food passes through it. A catheter will be placed in the antecubital vein (the vein near your elbow) prior to drinking the Boost High Protein. Blood is drawn before (time 0) and every 15 minutes for acetaminophen and glucose for a period of 3 hours. A total of about 60 ml (6 tablespoons) of blood will be taken.

_____Dual Energy X-ray Absorptiometry (DXA). 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.

_____The BodPod is used to measure body composition. It is designed to accommodate a wide variety of human shapes and sizes. Because of its generous-sized interior and oversized window, the BodPod can accommodate subjects up to 7 feet tall and 550 pounds. We will make every accommodation to make sure you are comfortable and to reassure you while in the vessel. Clothing, hair, jewelry, and eyeglasses can have a significant impact on the volume and mass measurements performed during a BodPod test. Therefore, it is EXTREMELY IMPORTANT that all subjects tested in the BodPod remove all jewelry and eyeglasses, and wear minimal, form-fitting clothing such as a Lycra® or Spandex® swimsuit during testing. Single-layer compression shorts and/or lightweight bras without padding or wires are also acceptable clothing. A swim cap must also be worn to compress any air pockets within the hair. You will be asked to sit comfortably and quietly inside the BODPOD for the brief measurement period (no talking). Sounds relating to valves opening and closing may be heard, but most people are unaware of the slight pressure changes that take place during a BODPOD test. A few people have noted a feeling similar to that of moving from the first to second floor in an elevator. The BodPod measurements take ≤ 5 minutes.

_____VO2 peak is a measure of physical fitness obtained by having you walk or run on a treadmill or pedal on a cycle and breathe through a mask connected to a tube. Accurately measuring VO_2peak involves a physical effort sufficient in duration and intensity to fully test your exercise ability. This involves a graded exercise test (either on a treadmill or cycle ergometer) in which exercise intensity is progressively increased while measuring ventilation (breathing) and oxygen and carbon dioxide concentration of the inhaled and exhaled air. Your test will be monitored by a trained professional, either physician, physician's assistant or exercise physiologist. If you have underlying heart and/or lung problems, the test may be at a reduced intensity (sub-maximal) test to ensure your safety. With all

subjects, the test will be individualized and based on overally health, sex, weight, and previous activity level.

_____RQ (Respiratory quotient) is the ratio of the volume of carbon dioxide released to the volume of oxygen consumed by a body tissue in a given period of time; it provides a measure of the composition and utilization of carbohydrates, fats and proteins as they are converted to smaller molecules and used by the body as energy. Resting metabolic rate (RMR) is measured by gas analysis through a process called indirect calorimetry, though a rough estimation can be acquired through an equation using age, sex, height, and weight.

_____SenseWear. The SenseWear Armband system acts as a versatile monitor allowing us to conveniently collect and analyze information about your activity and sleep habits. The sensor is lightweight and worn on the arm. The SenseWear device is a 3 axis accelerometer that also can measure changes in skin temperature. You will wear the armband for 7 consecutive days other than when bathing or swimming. You will be asked to wear the armband before you get started on diet, and periodically at certain milestones: 5% weight loss from baseline (BL), 10% weight loss (BL), 15% weight loss (BL), (and 20% if you achieve that percentage of weight loss), then at 6, 12 and 24 months (at the end of program).

_____Fat Biopsy. This procedure involves numbing a small region of skin near your belly button and using a needle and syringe to aspirate a small amount of fat tissue from beneath your skin.

_____Muscle Biopsy. This muscle biopsy procedure involves numbing a nickel-sized portion of the skin of your thigh with a local anesthetic, making a small incision (1/4 inch), and removing a small piece of muscle (approximately the size of 2-3 grains of rice). The incision will then be closed with a piece of sterile tape.

4.2 How much of my time will be needed to take part in this study?

2 years.

4.3 When will my participation in the study be over?

At the end of 2 years.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Questionnaires: Some participants could find the information sensitive, however, it is not anticipated to be disturbing or traumatic. The risk of discomfort is minimized because you have the option of not answering any questions you prefer not to answer.

Blood draws: blood drawing is mildly painful from the insertion of the needle and can cause bruising and very rarely, fainting, blood clots or an infection at the needle stick site. Blood drawing will be done by experienced personnel in the MCRU. All care will be taken to minimize any discomfort. Approximately 90 mL (about 9 tablespoons) will be drawn.

Genetic studies: Since we are keeping identifying information, it is possible that someone could learn about your genetic information. However, we have put a number of things in place to prevent someone from linking the research data to you. See the breach of confidentiality section below.

Mixed meal test: The risk of blood draws (see above description), and you may experience some nausea after drinking the food supplement. Acetaminophen at high doses (much higher than given in this study) can cause liver damage.

DXA scan: This scan gives you a very small amount of radiation that is less than the background radiation you would get living at high altitude (such as in Denver, Colorado).

BodPod: Even with its ample size, you may still feel claustrophobic. Although measurements take only a few minutes, if you are unable to tolerate being in the BodPod, we will simply stop the test and have you step out.

RQ is measured while you rest comfortably on a bed in a softly lit and quiet room. Gas exchange is measured via a soft and large canopy placed over your head. Although most people find this test relaxing, there is a chance that the canopy might make you feel claustrophobic. If you experience that feeling, we will simply remove the canopy and stop that test.

VO2 Peak (exercise test): During the testing, it is possible that you may experience abnormal blood pressure, fainting, problems with your heart beat, and in very rare instances, persons may have a heart attack. You may also experience chest discomfort, nausea, difficulty breathing, and joint or muscle pain or injury. To decrease these risks, your doctor will determine whether you have health problems that may make it more likely that you may have these symptoms during the test, and decrease the intensity of the exercise if you have risk factors that may make it more likely for you to experience any symptoms during the exercise test. In addition, you will be monitored during the exercise testing to make sure you are alright.

Biopsies: The needle sticks during the biopsies may cause some discomfort or pain. During the biopsies, you may experience some bleeding and bruising, and there is a small risk of infection.

Breach of confidentiality. As with any study collecting information that can be traced back to the participants, there is a risk that the information we collect from you may be seen by persons other than the study team. We are taking careful measures to prevent this from happening. For example, we will use coded identifying numbers rather than your medical record number. Further, we will store all data that we collect in password protected files and only the study team will have the passwords to these files. Collaborators both inside and outside the University of Michigan may only have access to samples that have been coded but do not contain any of your personal information.

As with any research study, there may be additional risks that are unknown or unexpected.

There may be a risk of inconvenience to you in the event that you are found to be not eligible for the study.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:, • Health insurance companies and group health plans may not request your genetic information that we get from this research., • Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums., • Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment., All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009., Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. However, there will be ongoing metabolism of obesity studies that may interest you. Please contact the investigators if you wish to participate in those.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, we believe the information obtained from this study will help us understand how individual differences in genes and other factors influence a person's response to treatment for overweight and obesity, which may help improve the treatment of overweight and obesity in the future.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information. Any findings from the genetic analysis are considered research and are not the same as "genetic testing" results performed in clinical diagnostic laboratories and therefore will not be shared with you.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

You may continue to participate in the standard weight loss program as part of your clinical care without participating in the research. You may decide to try to lose weight on your own or through an alternative program.

6.2 If I participate in the study, do I have to give blood for future studies?

No. You can participate in the study but choose to not give blood for future studies (see above under 4.0 "What will happen to me in this study.")

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

Since some of your samples or information will be de-indentified, it may not be possible to identify samples that are yours should you decide to withdraw from the study before the research is completed. However, you may request to have any stored samples that still contain your unique subject identification to not be used. Please contact the investigators listed under section 10.0 of this consent if you wish to withdraw your samples.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

As this is a study that simply involves gathering your medical information, samples, and test data from you, there should be no harm to you if you leave the study early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples 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 suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Treatment of complications
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's **medical reviewer.**

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid $50 for your participation in all of the following three (3) parts of this study as mentioned above (DXA or BodPod or both, V02 peak, and RQ). Total compensation for completing all three measures at the three time periods (at baseline (time = 0), between 3 and 6 months and at the end of study at 2 years) is $150. You will be mailed a check after the completion of each set of procedures. For example, you will be paid after you complete baseline procedures, again after you complete the 2nd set between 3-6 months and again at the end of 2 years after you have completed the 3rd set of procedures.

You will be paid $100 for your participation in the adipose (fat) and muscle biopsies. Total compensation will be $300 for both biopsies done at baseline (time = 0), between 3 and 6 months and at the end of study at 2 years. You will be paid at the time frames stated above.

If you are lean subject, you will also be paid $150 for participating in the metabolic component (DXA, V02 peak and RQ) and one time muscle and fat biopsies. You will be paid following the completion of all of the procedures.

You will be issued a check sent to you by US mail. If you are a University of Michigan employee, your compensation will be directly deposited into your paycheck.

8.3 Who could profit or financially benefit from the study results?

The company whose product is being studied: None.

No one will directly profit financially from this study.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

University of Michigan policies require that private information about you be protected. This is especially true for your personal health information.

On the other hand, sometimes the law allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.

- The researchers may need the information to check your test results or look for side effects.

- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.

- If you receive payment of greater than $100 for taking part in this study, the University of Michigan accounting department will collect your name, address, social security number, payment amount and related information. The information collected may be used for tax reporting purposes. If you receive greater than $600 in compensation from the University of Michigan in a calendar year, the accounting department will for tax reporting purposes submit this information to the Internal Revenue Service (IRS).

- The researchers may need to use the information to create a databank of information about your condition or its treatment.

Information about your study participation may be included in your regular UMHS medical record.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.

- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

- Results of genetic analysis examining candidate genes related to obesity will be stored in a password protected database. These files do not contain any personal information about you, but are stored under a unique identification number to which only study staff have access.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University Of Michigan Notice Of Privacy Practices. This information is also available on the web at

http://www.med.umich.edu/hipaa/npp.htm. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Amy Rothberg, M.D., Ph.D.

Mailing Address: 24 Frank Lloyd Wright Dr., Lobby C, MEND

Telephone: (734) 647-5871

Co-investigator: Charles Burant, M.D., Ph.D.

Mailing Address: 1000 Wall St. Rm 6309 48105 SPC 5714

Telephone: (734) 615-3481

Email: burantc@med.umich.edu

Study Coordinator: Christine Fowler, RD, MS

Mailing Address: 24 Frank Lloyd Wright Dr., Lobby C, MEND

Telephone: (734) 232-3593

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

University of Michigan Medical School Institutional Review Board (IRBMED)

2800 Plymouth Road Building 200, Room 2086

Ann Arbor, MI 48109-2800
Telephone: 734-763-4768

Fax: 734-615-1622

e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

☐ This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

☐ Other (specify):_____

12. SIGNATURES

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____

Witness (optional):

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Name: _____

Signature: _____ Date of Signature: _____