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: The impact of intensive dietary intervention on weight and health outcomes

1.2 Company or agency sponsoring the study: None

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.
   - Andrew Kraftson, M.D.
   - Nevin Ajluni, M.D.
   - Laura McEwen, Ph.D.
   - Nicole Miller, M.P.H., R.D.
   - Christine Fowler, M.S., R.D.
   - Catherine Nay, M.Ed., R.D., C.H.E.S.
   - Carol Catalano, PA-C
   - Anna Wong, M.P.H., R.D.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The goal of this study is to examine how weight, body mass index (BMI), risk factor assessment based on clinical laboratory parameters, mood (for example, depression), pain and health related quality of life scores change throughout a two year weight management program.

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 management program even if you do not want to participate in this study.

3.1 Who can take part in this study?

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 ≥ 30 kg/m² who will be receiving their care at the University of Michigan Weight Management Program (MWMP) will be recruited for this study. We will
not include women who are pregnant or currently lactating. Women of childbearing age who wish to conceive within two years of starting the clinical program 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?

1,000

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

As part of standard care within the clinic, you will meet with a physician for an initial assessment who will take a health and weight history, perform a physical examination and determine whether you are eligible and that you wish to enroll in the 2 year clinical program. If you enroll, you will meet with a nutritionist to assess your goals and barriers to weight loss. 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) and to offer continued counseling and education. 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, and then monthly for the 2 year clinical program. You will be seen by the physician for an assessment visit (as above), monthly for the first three months and then every 12 weeks thereafter for the 2 year program. We may request that you come in for additional individual meetings if you have difficulty losing weight. Weight loss goals will be reviewed at these intervals. At these visits, one time measurement of height, measurements of weight, measurements of blood pressure, heart rate, waist and hip circumference 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 will be asked to use meal substitutes in the form of meal replacements (for example, Optifast® shakes) for a total of 12 weeks to help you lose weight after which you will gradually be transitioned to regular foods. Some of our participants continue to use meal replacements 2-14 times weekly for longer periods of time to achieve optimum weight loss and thereafter maintain loss of weight. There will be an emphasis on calories and the elimination of food dense in calories. You will be encouraged to use portion control plates at meals.

You will routinely have measurements of weight, one-time measurement of height, blood pressure, heart rate, waist and hip measurements. Also, you will have blood drawn to measure blood electrolytes, glucose, 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, (for example, 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.

For the research part of the study, we would like your permission to review your clinical and laboratory data as mentioned above. In addition, we will assess quality of life, mood (for example, whether you are depressed), level of physical activity, any pain you might have and where you have it, how confident you feel in managing your diet under certain situations (such as eating out with friends), your preference to manage your weight medically v. surgically and your work life (such as how productive you feel at your job or how much time you have had to take off for illness) by asking you to fill out some questionnaires both before you get started on diet and as you lose weight.
The following are the tests in which we invite you to participate as part of the research. Review and analysis of the clinical and laboratory data that will be obtained as part of your clinical care throughout the 2 year program. These data will be compared to other participants in the program. Questionnaires will be given at the beginning of your treatment, between 1 and 12 months and 2 years afterwards. You can agree to participate in none, some or all of the procedures outlined below.

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

_______ 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. You will also be asked about your level of physical activity, any pain you have and where you have it, how confident you feel in managing your diet under certain situations (such as eating out with friends), your preference to manage your weight medically v. surgically and your work life (such as how productive you feel at your job or how much time you have had to take off for illness). In addition, we will have one short questionnaire asking you to evaluate the program at one year and upon completion.

_______ Permission for the research team to access clinical parameters including blood pressure, heart rate, anthropometric measurements (weight, BMI, waist and hip circumference) and laboratory measurements (blood electrolytes, glucose, HbA1C, cholesterol and other lipid levels).

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.

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.

The researchers will try to minimize these risks by:

We are taking careful measures to prevent this from happening. We will store all data that we collect in password protected files and only the study team will have the passwords to these files. However, your clinical data will be part of the University of Michigan Hospital and Health Systems medical record.

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

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.* You should not take part in more than one study without approval from the researchers involved in each study.

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.

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.

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.

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).

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, 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?

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?

There is no compensation for participating in this study.

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.)
- 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.
- 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.
- 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.

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.uofmhealth.org/patient+and+visitor+guide/hipaa. 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: Nicole Miller, RD, MPH
Mailing Address: 24 Frank Lloyd Wright Dr., Lobby G, MEND
Telephone: (734) 232-3587

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

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

Consent/Assent to Participate in the Research Study

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 or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: ______________________________________________________________________

Signature: _________________________________________________________________________

Date of Signature (mm/dd/yy): ________________________

For use only if required by sponsor:

Date of Birth (mm/dd/yy): ____________________________

ID Number: ________________________________________

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: ______________________________________________________________________

Title: ____________________________________________________________________________

Signature: _________________________________________________________________________

Date of Signature (mm/dd/yy): ________________________