Cover Page for ClinicalTrials.gov

Document:
Informed Consent Form

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Official Study Title:
The WISE (Weightloss Intervention Surgical Effects) Brain Study (WISEBrain)

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UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Short Title: The WISE Brain Study (**W**eight loss **I**ntervention **S**urgical **E**ffects on Brain Function)

Grant Title: Obesity and Type 2 Diabetes: Bariatric Surgery Effects on Brain Function

3. Who do you call if you have questions about this research study?

Principal Investigator: Dr. Ronald Cohen, office phone number 352-294-5840

Research Coordinator: 352-294-5818

4. Who is paying for this research study?

The funding for research is being supplied by the National Diabetes and Digestive and Kidney Diseases Advisory Council, and National Institutes of Health.

5. Why is this research study being done?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved? The WISE Brain Study is designed to compare the thinking and brain function of people who have had weight loss surgery, and people who have not had weight loss surgery. Participants may or may not have diabetes. You will be considered enrolled in this study for a total of approximately 18 months, or until you have finished the 18 month time point visits.

b) What is involved with your participation, and what are the procedures to be followed in the research? You will have three sets of visits at different time points; baseline, 12-weeks (post-surgery), and 18 months. You will participant in a cognitive assessment, blood draw and MRI brain scan at each of this time points.

c) What are the likely risks or discomforts to you? Psychological frustrations from cognitive assessments and computer tasks. Discomforts from blood draw and Magnetic Resonance Imaging (MRI) scan. Risk of breaching Personal Health Information.

d) What are the likely benefits to you or to others from the research? There are not any direct benefits to you from participating in this study.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you? No clinical care is provided. All of your participation is for research purposes only, and not to treat or diagnose any disease.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Some people participating in this study will do so in combination with their choice for bariatric weight loss surgery. Some people will participate in this research study who will NOT be having surgery for weight loss as a control subject. It is important to understand that the surgery and all clinical care resulting from that surgery is **NOT** part of this research study.

No clinical care is provided. All of your participation is for research purposes only, and not to treat or diagnose any disease. All clinical care is provided by your own doctor or surgeon and unrelated to this research study in any way. Any decisions you make concerning surgery for weight loss are private and between you and your doctor, and not part of this study at all. Your participation in the study or ending participation in the study, will not have any effect on your health care at UFHealth and Shands.

7. What will be done only because you are in this research study?

All research participants will receive the same research study procedures, whether they are planning to have surgery, or not. There are several parts involved in this research study, which are repeated at three time points, Baseline startup, 12 weeks, 18 months:

- Thinking and Memory Tasks
- Various questionnaires including but not limited to things such as activity level, mood, eating habits, etc which you may be asked to fill in at home.
- Blood Work
- Brain MRI Scan, possibly two

Research Visit Summary-

Paperwork, Thinking Tasks, Blood work and MRI

- Potential participants will be pre-screened at the time of their initial contact to be sure they fit the guidelines for this research study.

- If you meet all guidelines to participate, you will be scheduled for two visits, Visits 1 & 2.

- At the first visit, participants will be given study information to consider, including this Informed Consent document. This Informed Consent Form will be reviewed with you by one of our trained research staff, in a private location, and you will be given as much time as you need to consider enrolling in the study. You may want

to discuss the information with friends or family. You will have many opportunities to ask questions and get those questions answered right now, and also at any time during the study visit also.

- We would like to audio record the cognitive sessions for quality assurance. These recordings are for the examiners to accurately note participant's responses and score assessments. The audio recordings will be securely storage in our study's secure computer system. Only research assistants and coordinators who have conducted the study visit will have access to them. The recordings will be deleted upon their attended use
- If you **do not** want the study visit to be audio recorded, please initial in the box below, this will not disqualify you from the study.

  ☐
- If you choose to sign this form, and agree to participate, you will be further screened for things related to the safety of your participating in the MRI brain scan, including pregnancy. All women of child-bearing potential under the age of 62 will be given a pregnancy test, based on a urine sample at each MRI session. Women who have previously had a hysterectomy do not need to complete a pregnancy test. Pregnant women will not be allowed to participate in the MRI portion of the research for safety reasons.
- The size constraints of the MRI and the ability to tolerate the closed environment for at least one hour will be discussed. We may ask to take measurements of your body to determine which MRI scanner would be the most suitable for you. You may be shown a MRI measurement device to demonstrate the size of the inside of the MRI scanner and asked to try it on to gain a greater understanding of the size constraints related to the MRI scanner.
- We will review a very detailed Medical History form with you, asking many questions about you and your family medical history.
- Then, we will do a series of thinking tasks, which are routinely used to screen for thinking and memory problems.
- You will be asked to participate in a computerized series of thinking and memory tasks, called the NIH Toolbox for Cognitive Performance, which is like a series of memory and thinking games done on an iPad.
- You will be given another task assessing your language ability.
- A research staff person experienced in drawing blood will ask your permission to take a small blood sample, generally from the arm, approximately (2TBSP. or less). This blood will be used for a series of tests, looking at "biomarkers" or proteins located in your blood, and analyzing your genetic material, called DNA, to look at how those biomarkers relate to your genetic makeup. Some of the

blood specimens could be sent to study collaborators for further analysis. These samples will be coded and will not have any PHI associated with them. These collaborators will have signed Confidentiality Agreements with UF to secure privacy. You will not get any information back regarding these blood tests; they are only being done for the purpose of this research. We will also look at the sugar levels you have in your blood as a result of your body's processing the

food that you eat. Blood specimens will be sent to Quest Diagnostics for this test. The specimens will be coded.

- You will also be asked to complete a few brief questionnaires asking about things such as your level of general physical activity, mood and eating habits. It is possible that you will be asked to take these questionnaires home to fill out at your convenience and return them at your next visit.
- This part just described, will take approximately 3.5 hours.
- If at any point in the visit, it is determined that you do not qualify to be included in the study, for any reason, you will be given a $10.00 pre-paid debit card to thank you for your limited participation.
- If you choose to complete the Thinking and Memory Tasks, you will be given a $60 pre-paid debit card to thank you for your time and effort.
- If you choose to complete the blood draw, you will be given a $15 pre-paid debit card to thank you for your time and effort.

MRI Scan

The following procedures will take place at the UFHealth and Shands Siemens 3T MRI Scanner at the hospital MRI suite. We recommend a different day than your other testing, so you do not feel too tired.

- We recommend that you wear very comfortable clothing, with no metal snaps, buttons or zippers. If necessary, you will be given more comfortable clothing to wear while in the scanner, and there is a private room for changing.
- You will then begin the scanning session in the MRI, which will be performed for approximately one hour. You will be able to talk to and hear the technician doing the scan, while you are in the MRI. If at any time you are uncomfortable, or need any assistance, the technician can come to assist you in being more comfortable. If you choose to stop the scan at any time, you may do so. Most of the time, you will just be resting quietly, not thinking about anything in particular.
- During approximately 15 minutes of the scanning time, you will be able to see some images on a video screen or through goggles in the scanner, and you will be asked to perform simple tasks as directed, by pushing a button switch on and

off that is located in your hand. There will be two different thinking tasks of this type for you to participate in.

- After successful completion of the scan, you will be given a $60 pre-paid debit card to thank you for your participation and effort.
- A copy of your brain scan image will be made available to you at the end of the 18 month scan, which we recommend you share with your family doctor. The scan will not be used for diagnostic purposes, but only for collecting research data. If anything obviously abnormal is discovered, Dr. Cohen will contact you with further information for a referral to a specialist or your family physician. You will not receive any written information about the brain scan, only the pictures of your brain. You may have to repeat this test sometime in the future for your own medical care, because this is not a diagnostic brain scan.

This same routine will be repeated at week 12, and again at 18 months. Our trained study staff will keep track of your time in the study and alert you when it is close to time for the next appointment.

We may contact you by phone, email or mailings throughout your time in the study in order to remind you of your next visit and/or to ask follow-up questions related to your general well-being.

We will also offer thank-you items at various points throughout the study, including but not limited to:

- Magnetic refrigerator clips
- Water bottles
- Cooling towels
- Pedometers
- Measuring spoons

These items will be mailed to your home between follow-up visits or offered during your in-person visits.

Please review this table for a brief summary of your participation in the WISE Brain Study:

	Baseline		**12 Weeks**		**18 Months**	
Study Activity	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Blood Draw	☐		☐		☐	
Medical History/Demographics	☐					
Thinking/Memory Tasks	☐		☐		☐	

NIH Toolbox Thinking Tasks	☐		☐		☐	
Pregnancy Test (F<62yrs.)		☐		☐		☐
MRI Brain Scan		☐		☐		☐

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form

8. How long will you be in this research study?

You will be considered enrolled in this study for a total of approximately 18 months, or until you have finished the 18 month time point visits. Your time involved with the research staff and research visits will be limited to the visits described above, and will happen exactly the same way as described above at each time point.

9. How many people are expected to take part in this research study?

We are planning to enroll up to 200 adults for the study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

Psychological. There are several thinking and memory tasks which may produce small levels of frustration. Some people find these tasks to be more challenging, and other people are very comfortable doing these tasks.

Magnetic resonance imaging. (MRI) is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. The risks of MRI are:

- The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for

example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Someone will ask you questions about this before you have the MRI.

- There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan
- The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk, and headphones for added protection.
- If you are a woman of childbearing potential, there may be unknown risks to the fetus. Therefore, before you can have the MRI, you must have a pregnancy test unless you have previously had a hysterectomy.
- If an obvious abnormality is discovered during your MRI scan, you will be informed about it by the research team, you will be provided with a copy of your MRI scan and we will encourage you to see your primary care physician.
- You will be monitored very carefully while in the scanner, and repeatedly checked to ensure comfort.

Blood Draw. The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. Minor discomfort is experienced from the finger stick for blood sugar.

Computer based tests. There is a risk that you will find memory and concentration tests challenging, because it may be difficult to remember the things that you are asked to remember. You may skip any question you do not wish to answer. Research staff will explain what to do and help you take the tests during your clinic visits. There is no right or wrong answer on these tasks.

Personal Health Information. Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

Unknown Risks. This study may include risks that are unknown at this time.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at: http://irb.ufl.edu/gina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

There are not any direct benefits to you from participating in this study.

11b. How could others possibly benefit from this study?

Information obtained from this study will provide valuable information about normal brain structure and function associated with weight loss and blood sugar changes. Participation in this type of study helps further the knowledge required for better diagnosis and treatment of degenerative brain disorders in the future, like dementia and Alzheimer's Disease.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

This is not a treatment study. Your participation is entirely up to you. The option to taking part in this study is doing nothing. If you choose not to participate, this decision will have no effect on the clinical care that you receive at this medical center. If you

do not want to participate in the study, please inform the study team member and do not sign this consent form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from the study, no new information will be collected about you. However, information that was already collected will still be used because the researchers rely on it to complete the research.

13c. Can the Principal Investigator withdraw you from this study?

The investigator may withdraw you from the study if:

- You are unable to follow instructions
- The investigator decides that your participation in the study could be harmful to you
- The study is cancelled
- Other administrative reasons

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

The Sponsor will provide all activities required as part of your participation in this study as described above in the question “What Will Be Done Only Because You Are In This Research Study”.

If you receive a bill for these services, please contact Dr. Ron Cohen or his study coordinator at 294-5837.

Any other medical services you receive would have been provided to you even if you were not in the study. These services will be billed to you or your insurance

company. You will be responsible for paying any deductible, co-insurance, and/or co-payments for these services, and any non-covered or out-of-network services.

15. Will you be paid for taking part in this study?

- To compensate you for your time, you will receive a pre-paid debit card(s) as described above upon completion of the study visit activities, to thank you for your time and effort.
  - After completion of thinking and memory assessments: $60 ○ After blood draw and glucose test: $15 ○ After completion of each MRI Brain Scan: $60
- A $10 pre-paid debit card will also be provided if you travel more than 20 miles (one way) from your home to the research center for each visit. If you travel from 40 or more miles away, another $10 pre-paid debit card will be provided to compensate you for associated fuel and transportation expenses.
- If you do not fall within the guidelines for participating in this study, (after we have begun the cognitive screening battery) you will still receive a $10 pre-paid debit card to thank you for your time and limited participation.

If you are paid for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more, the
University must report the amount you received to the Internal Revenue Service (IRS). If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Ron Cohen, 352-294-5840 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called Protected Health Information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Name
- Contact Information
- Date of birth
- Socio-economic status
- Education
- Social Security Number for compensation purposes
- Information about your past and present medical history
- Your height and weight
- Your blood pressure and pulse
- Information about your physical activity
- Results of physical activity tests
- Laboratory results of blood analysis
- Results from memory and thinking tests
- MRI safety screening results
- Results of MRI and MRS scans
- Sleep activity results (retrieved from Sleep Lab Staff or EPIC-UF's electronic medical record system)
- Research study results

- Information about your mental status
- Hospital/Physician Medical Records

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Your Social Security number is collected because the University is specifically authorized by law to do so, or it is necessary for the performance of the University's legal duties and responsibilities associated with this research study. If you have questions about the collection and use of Social Security numbers, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To determine your eligibility for the study
- For purposes of analyzing the MRI, blood, sleep results and cognitive testing.
- For these analyses we will use your age, education, and medical history values to examine their effect on brain structure and function.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project
- Other professionals at the University of Florida or Shands Hospital that provide study-related treatments or procedures

- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research)

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- Other professionals at other institutions who are involved in this research

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be collected until the end of the study. This information will be used and disclosed forever since it will be stored for an indefinite period of time in a secure database.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected will still be used and shared with others because the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date