Official Title of study: Assessment of Outcomes Following Bariatric Surgery for Mississippi State Employees

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The University of Mississippi
Institutional Review Board
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Signature Diane W. Lindley

CONSENT FORM

Consent to Participate in an Experimental Study

Title: Assessment of Outcomes Following Bariatric Surgery for Mississippi State Employees

Investigator
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Description
We want to know if having bariatric surgery (weight loss surgery) can improve patients' health in Mississippi. You have already chosen to have this surgery as part of the Mississippi State Employees' Life and Health Insurance Plan's Obesity Treatment Program (OTP). This study will look at the benefits and costs of the patients who have weight loss surgery as part of the program. The surgery itself is not a part of this study.

We will give you three surveys at some of your weight loss doctor visits that will ask you how your weight affects your day-to-day activities and feelings. We will also ask you questions about how your weight affects your ability to work and do activities, as well as questions about how happy you are with the surgery and your goals from the surgery. You will also be asked a few background questions. Every time we give you the surveys, we will explain the surveys to you and you can ask any questions you have about the surveys. The surveys will be given at most of the doctor visits, and we anticipate it will take you less than 30 minutes to complete the surveys. In addition to the surveys, we will also use your medical records and insurance billing records to look at whether or not your health is getting better, and the costs of your health care (for example, costs of medicine, doctor visits, emergency room visits, etc).

Risks and Benefits
You may feel uncomfortable because some of the questions ask personal information. If you do not wish to answer some questions, you can leave them blank, and we will verify that you left them blank on purpose (instead of by accident). We do not think that there are any other risks. There are probably no direct benefits to you, but you may learn more about yourself by doing the surveys. By helping with this study, you may help future patients who want surgery.

Cost and Payments
The surveys will take about 30 minutes to finish and will be given to you at some of the visits to the weight loss center. There are no other costs for helping us with this study.

Confidentiality
We will not put your name on any of your surveys, but will assign you an ID number to track your responses. Therefore, we do not believe that you can be identified from any of your surveys. We will store your surveys in a locked cabinet in a locked room, to protect your information. Information we collect will also be stored on a computer, which will have a password that must be used before the computer can be used.

Right to Withdraw
You do not have to take part in this study to continue to receive your weight loss surgery and the care from your physician. If you start the study and decide that you do not want to finish, all you have to do is to tell Dr. McClendon or a doctor at your weight loss center. Dr. McClendon can be contacted in person, by letter, or by telephone at the Department of Pharmacy Practice, School of Pharmacy, University of Mississippi, 2500 North State Street, Office Annex I, Jackson, Mississippi 39216 or (601) 984-2638. You can contact your doctor at a visit, or you can call your doctor and tell them you no longer want to be in the study. Whether or not you choose to participate (or if you decide to withdraw), this will not affect your care from your medical providers at the weight loss center, or the care from any of your other medical providers or your health insurance.

Protected Health Information
Protected health information is any personal health information that identifies you in some way. The data collected in this study includes: your date of birth and dates of surgery. Additional health information will include your past medical and surgical history (what diseases and surgeries you have had), medication history (medicines you have taken, doses, costs, etc), and information about doctor and hospital visits. A decision to participate in this research means that you agree that this study can use your health information. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept indefinitely. While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

IRB Approval
This study has been reviewed by The University of Mississippi's Institutional Review Board (IRB). The IRB has determined that this study fulfills the human research subject protections and obligations required by state and federal law and University policies. If you have any questions, concerns, or reports regarding your rights as a participant of research, please contact the IRB at (662) 915-7482.

Statement of Consent
I have read the above information. I have been given a copy of this form. I have had an opportunity to ask questions, and I have received answers. I consent to participate in the study.

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Signature of Participant　　　Date　　　Signature of Investigator　　　Date

NOTE TO PARTICIPANTS: DO <u>NOT</u> SIGN THIS FORM
IF THE IRB APPROVAL STAMP ON THE FIRST PAGE HAS EXPIRED.