

## **BOLD™ Study Patient Information Sheet**

Surgical Review Corporation (SRC), a nonprofit healthcare organization, is conducting a study about bariatric/weight-loss surgery. SRC developed the BOLD™ database to support surgeons' decisions regarding patient care and to track outcomes of bariatric surgeries. BOLD is now the world's largest database for bariatric surgery, containing information on hundreds of thousands of patients.

### **WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to record and investigate the short-term and long-term results of different types of bariatric surgery. SRC will compare the surgical procedure performed with the health of patients for at least five years after surgery. This information will enable us to learn about the types of surgery that are most effective for weight loss and managing conditions related to obesity.

### **WHAT ARE THE BENEFITS OF THE STUDY?**

The information and knowledge gained from the BOLD study will help surgeons improve the way bariatric surgical care is delivered and better understand the risks and benefits of each type of bariatric surgery.

### **WHO IS TAKING PART IN THE STUDY?**

All patients who have bariatric surgery performed by a surgeon who utilizes the BOLD database are included in the BOLD study.

### **HOW IS THE STUDY CONDUCTED?**

As part of your surgeon's involvement in the BOLD study, he/she collects the following information for every bariatric surgery patient and enters it into the BOLD database:

- Personal information: gender, race, employment status, insurance status, medical record number, year of birth, height, weight and prior surgeries. Your surgeon has the option of entering your name for internal tracking purposes.
- Information about your surgery: date of admission, date of surgery and date of discharge.
- Information about your medical condition before, during and after your surgery.

*Data that is used for research does not include your name or medical record number.*

Information about your surgery will be combined with data from all other study participants in a separate research database, and SRC research staff will analyze this combined information. The results of the study will be reported or published for the total population – no individual patient information will be published.

### **WHAT ABOUT MY CONFIDENTIALITY?**

Your information is entered into BOLD through a secure website and permanently stored in a database that is managed by SRC. This database is secure and meets the requirements for the protection of patient confidentiality as required by the Health Insurance Portability and Accountability Act (HIPAA).

Your privacy is further protected by a Certificate of Confidentiality from the National Institutes of Health. This certificate means that SRC and surgeons submitting data to BOLD cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state or local legal proceeding. However, the certificate does not restrict you from voluntarily disclosing your information.

### **WHAT ARE THE RISKS OF THE STUDY?**

There are no physical risks associated with this study. However, there is a slight risk of loss of confidentiality. Every effort is made to keep your information confidential, but this cannot be guaranteed.

### **WHAT ARE THE COSTS?**

There are no costs to you or your insurance provider for participating in the BOLD study, and no additional medical or surgical procedures or tests are performed as part of the study. You will not be paid for participating in the study, and SRC assumes no responsibility for paying, discounting or providing free medical care before, during or after your surgery.

### **WHAT ARE MY RIGHTS?**

Your participation in the BOLD study is voluntary. You do not have to take part in this study in order to have bariatric surgery. You may withdraw from the study at any time. If you withdraw from the study, your data will not be used for research purposes. Your decision to not participate in or to withdraw from the study will not affect your medical care in any way. If you decide to withdraw from the study, you will need to let your surgeon know in writing.



You are not required to sign a consent form to participate in this study. However, you must let your bariatric surgeon or his/her staff know if you **do not wish to participate** either before you leave the office today or prior to your surgery.

You will receive a copy of this information to take home with you. If you are a minor, this information is being provided to you and your parent or legal guardian.

If you have any questions about the BOLD study, please visit [www.surgicalreview.org/bold/bariatric](http://www.surgicalreview.org/bold/bariatric) or call SRC Support at 1-866-790-4772.