

## **PATIENT INFORMED CONSENT FOR CLINICAL RESEARCH**

### **TITLE**

A Critical Appraisal of Local Complications and Long-term Management of the Augmented Breast: Defining Standards and Resources for Improved Patient Care

### **PROTOCOL NUMBER**

NWH 07-002

### **SPONSOR and FUNDING**

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### **INVESTIGATOR**

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### **RESEARCH SITE**

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### **STATEMENT OF RESEARCH**

It is a principle of medical practice that a subject who is to participate in the research investigation of a new medical treatment, device or procedure must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the treatment, device or procedure. This document provides information important for this understanding.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. If you have any questions, please ask.

## **RESEARCH INFORMATION**

You are invited to participate in a research study that will investigate patient safety and cosmetic results of women who have undergone, or are candidates for, breast augmentation surgery. You are being asked to be a possible subject because you are a woman who has decided to undergo cosmetic breast augmentation or has undergone this procedure in the past. This study does not include patients who have or seek implants for reconstruction following breast cancer surgery.

Breast augmentation is one of the most commonly performed cosmetic surgical procedures, and there are literally millions of women living in the United States with breast implants. Many of these women do not remain in regular follow-up with their cosmetic surgeons, and thus the true natural history and complication rate of implant surgery are not well defined.

An additional important concern is the fact that no well-defined criteria for interval examination and radiological follow-up of implants have been developed for these women. Cosmetic surgeons performing breast augmentation procedures, and patients alike, would greatly benefit from clear direction toward the best type of follow-up strategy to use following surgery and at what time intervals.

## **STUDY PROCEDURE**

We plan to address these important issues by looking back through all of the cosmetic breast augmentation patients and procedures performed in our Surgical practice since 2002 as well as inviting new cosmetic breast augmentation candidates or patients with implants being seen for the first time in our Practice to join this study. If you agree to participate we will gather information from a variety of sources to include a patient questionnaire, your office chart, billing data and hospital medical records. Five general areas will be covered and will include the following:

- demographics and lifestyle
- implant details
- operative procedure
- complications
- cosmetic results

We will assemble the results of the questionnaire and other sources in order to better understand the many factors that impact the safety, complications and cosmetic results of breast augmentation or other related secondary procedures performed in patients with cosmetic implants.

Since no established criteria exists for following cosmetic implants over time, we have developed a recommended schedule of radiology tests combined with clinical exam by your doctor or designated staff that we will use to follow a patient's implant after surgery. These tests are in no way meant to replace check ups and radiology tests for usual breast cancer screening. While some of these tests may overlap with tests for breast cancer screening, the goal of the tests used by your cosmetic surgeon are to maintain the health of the implant and the overall best cosmetic appearance of the breast. Therefore it is important to continue with routine breast health care with your chosen health care professional while you participate in this study.

The results of this follow-up strategy will be recorded over time to include detection, types of complications, treatments used and when they occurred. It is unknown for instance, if the detection of implant problems in advance of patient symptoms or clinical signs would aid in

early treatment and improve general and cosmetic outcomes. We hope to describe the impact of this follow-up strategy on the clinical management of breast augmentation patients as well as the patient and surgeon's satisfaction with the cosmetic result.

### **STUDY RISKS AND DISCOMFORTS**

There will be no added risk since patients will undergo no experimental treatments. Primary breast augmentation procedures and any secondary procedures will be carried out using evidence-based risk and benefit recommendations discussed between the physician and the patient.

You do not have to answer any questions that you do not want to answer.

### **BENEFITS**

You will not personally benefit from this study. Benefits to society may include improved information regarding cosmetic breast augmentation and how cosmetic results may be improved and how complications are detected and managed. Depending on the findings, the study results may benefit others or the patient at some time in the future.

### **COSTS**

Your surgical procedure (i.e. primary breast augmentation, any related secondary procedure, revision surgery) is not part of this research study: You or your insurance company will be financially responsible for the cost of the surgical procedure as well as all pre-operative and post-operative care, recommended follow-up tests or consultation visits.

### **PAYMENT FOR PARTICIPATION**

You will NOT be paid for your participation in this study.

### **ALTERNATIVE PROCEDURES AND TREATMENTS**

This is not a treatment study. You have the option not to participate in this study at all.

### **QUESTIONS ABOUT RESEARCH**

If you have any questions about the research or other concern, you should contact Dr Michael Rosenberg at (914) 242-7610. During non-business hours you should contact Dr. Rosenberg, through the answering service at 914-242-7610. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at Northern Westchester Hospital at 914-666-1200.

### **VOLUNTARY PARTICIPATION/ WITHDRAWAL**

Your participation in this study is voluntary. Your refusal to participate will not prejudice your present or future treatment or benefits at the Institute of Aesthetic Surgery and Medicine at Northern Westchester Hospital. You are free to discontinue participation in the study at any time without fear of penalty or loss of medical care by sending written notice to the study doctor. If you withdraw your permission, no new health information will be gathered after that date. Information that has already been gathered may still be used however. Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

### **CONFIDENTIALITY**

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The

