Dear Patient: In addition to the Consent to Operation, Procedure and Administration of Anesthesia form, the purpose of this consent form is to advise you of important information regarding your Breast Needle Biopsy. **PLEASE READ THE ENTIRE FORM CAREFULLY BEFORE SIGNING.**

DESCRIPTION OF PROCEDURE: Calcifications are biopsied with stereotactic (x-ray) guidance using a special core (larger, vacuum-assisted) needle. Masses are biopsied with the imaging system that is best able to visualize the mass, or by palpation (feeling the mass with examining fingers), using a fine (small), core (larger), or special core (larger, vacuum-assisted) needle that is appropriate for the size and position of the mass. Your breast will be sterilized with an alcohol scrub. The physician will inject local anesthetic (usually Lidocaine, sometimes supplemented by Bupivicaine) into the skin and breast to numb the area needing the biopsy. The physician will then insert a special needle into your breast, to the area of abnormality. **Stereotactic**-guided biopsies are done with the patient lying face down on a special table, the breast suspended through a hole in the table, and the breast firmly compressed. The compression will feel uncomfortably tight at first, but later is usually quite well tolerated. **Ultrasound**-guided biopsies are done with the patient lying face up with one arm positioned above the head. **MRI**-guided biopsies are done with the patient lying face down, mild or no breast compression, and intravenous injection of Gadolinium. Multiple breast biopsy samples are removed and sent for microscopic examination by a pathologist. After removal of the biopsy specimens, one or more small metal markers measuring about 1/8th inch (3 mm) are usually placed in the breast to mark the biopsy site in case post-biopsy surgery is needed. The markers also help us read the follow-up imaging studies. There are no known harmful effects from the metal markers, but occasionally the marker is placed at or moves to a site in the breast that is suboptimal for guiding later surgery. The markers do not set off metal detectors at the airport.

RISKS OF PROCEDURE: During the biopsy procedure, pain and bleeding are usually mild, but occasionally they are significant. Patients having a stereotactic biopsy may have neck pain during the procedure. Patients having an ultrasound biopsy may have arm pain during the procedure. With some biopsies guided by ultrasound, MRI, or palpation, there is a very small risk of a lung puncture and collapse that may need to be treated by inserting a small flexible tube into the chest to re-expand the lung. Following the biopsy procedure, pain, bruising, and bleeding at the biopsy site are all usually mild, but occasionally they are significant. Severe bleeding rarely occurs and may need to be treated with a surgical procedure. A post-biopsy breast infection rarely occurs and may need to be treated with antibiotics. On occasion, a definitive diagnosis cannot be made due to removal of insufficient material, and that may mean a surgical biopsy or repeat needle biopsy will be needed. Even when there is removal of what is thought to be sufficient material, cancer can be missed by any needle or surgical biopsy, and follow-up breast imaging is needed to find those misses at 6, 12, and 24 months following biopsy. In patients with an implant in the breast being biopsied, there is a small risk that the compression, needle, or post-biopsy metal marker could damage the implant. The implant could also be damaged by surgical biopsy. The companies manufacturing the metal markers have not studied their use in patients with implants, and, thus, the Food and Drug Administration has not approved the markers for that use. This is called an “off-label-use” of the markers. To the best of our knowledge, there are no known harmful

effects of the markers in patients with breast implants.

ALTERNATIVES TO THIS PROCEDURE: The abnormal area in the breast can be removed by surgical excision, which is a more extensive and costly procedure. That approach is used with breast abnormalities that can be palpated (felt by the physician's fingers) but are not seen on the imaging studies, and in certain other circumstances. Alternatively, the abnormality can be followed on serial imaging studies, and not removed at all. That approach is used when there is deemed to be a very low likelihood of breast cancer.

BENEFITS OF PROCEDURE: The goal is to eliminate or reduce the number of surgical operations. A definitive diagnosis of the breast abnormality is usually made. If the biopsy results are benign, usually just follow-up imaging is needed at 6, 12, and 24 months following biopsy. If the biopsy results are malignant (cancer) or atypical (pre-cancerous), usually surgical treatment can be done.

PATIENT: By my signature below, I confirm that:

1. I have read and understand the information provided on this form and the additional information contained in the Consent to Operation, Procedure and Administration of Anesthesia form. The procedure and its risks have been explained to me.
2. I have had the opportunity to ask questions and have received all the information I desire about the procedure.
3. I understand that after breast needle biopsy I should check with my own health care provider to determine the correct follow-up procedure for my breast abnormality. **I understand that this may include open surgical biopsy, re-aspiration**, **core biopsy, or periodic imaging follow-up because it might be cancer.** I understand that if the abnormality is not removed from my breast (by open surgical biopsy), and if the abnormality was seen by mammography, MRI, or ultrasound, that I need to return for follow-up at 6 months for another mammogram, MRI, or ultrasound of that same breast. I also understand that if the 6-month follow-up is stable, I need to return for a yearly mammogram, MRI, or ultrasound for 2 years to ensure continued stability of my breast abnormality, unless otherwise indicated by my own healthcare provider.
4. I consent to the performance of the procedure designated above.

_____ _____ _____

Date Time SIGNATURE (Patient, Parent, or Properly Designated Representative)

_____

RELATIONSHIP to Patient

If this document was translated:

_____ _____ _____ _____

SIGNATURE (Interpreter) Date Time Language

_____ _____

SIGNATURE OF PRACTITIONER TITLE