



TISSUE BANK AT THE  
IU SIMON CANCER CENTER

## **Standard Operating Procedure (SOP) 001V5.0**

### **Acquisition of Normal Breast Tissue**

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Approved by:

#### **Materials:**

**Atec Breast Biopsy Device:** Hologic, Inc. Indianapolis, IN

**Biopsy Needles:** ATEC 0912-20

**Incision and Drainage Kit:** McKesson (cat.# 302290)

**Betadine swab packs :** McKesson (cat.# 68550)

**Lidocaine:** McKesson (cat#239936)

**Chloropreps :** McKesson (cat#84109)

**Wound Wash Saline:** McKesson (cat#636352)

**Telfa Pads:** McKesson (cat# 10119)

**Speciman cups (with lids)** Fisher # 14-955-102

**Other medical supplies** i.e. syringes, chuks, gauze, linens, wash cloths

**Consent:** Prior to commencing the tissue acquisition process, the surgeon/radiologist will review with the donor the risks of the procedure which include, but are not limited to, bleeding, infection and suboptimal cosmesis. After verbally ascertaining that the donor understands these risks and willingly accepts them, the surgeon/radiologist will then sign and date the Informed Consent document.

**Position for donation:** supine.

**Preparation of skin:** Betadine. In the event of a Betadine allergy the skin is to be prepared with chlorhexidine.

**Local Anesthetic:** 10cc's of 1% lidocaine without epinephrine. The maximum dose should not exceed 4.5 mg/kg, and the maximum total dose should not exceed 280 mg.

**Tissue Aquisition:** A nick incision is to be made in the skin using a scalpel; a #11 blade is preferred. Four core samples are to be taken from the upper outer quadrant of the breast, (donor and/or MD choice left or right), using the ATEC Breast Biopsy System. If in the judgment of the surgeon or radiologist obtaining the tissue, one of the tissue specimens is inadequate, the donor will be asked for permission for the acquisition of additional cores.

The cores are removed from the biopsy handpiece, placed on telfa, sprayed with wound wash saline and placed into a specimen cup. The cores are then transported to the tissue processing area within 5 minutes (or less) of procurement. The tissue is processed following SOP005V4.0.

Manual compression of the breast in the region of the biopsy is to be continued for at least 10 minutes or until there is no bleeding from the incision. The incision is to be dressed with a sterile dressing; the type of dressing is at the discretion of the surgeon/radiologist obtaining the biopsy.

**Oversight:** All adverse and unexpected events will be recorded in the database and will be addressed by the Internal Advisory Committee. This includes all phases of the process: donation, storage and retrieval, processing, and utilization.

### **Bibliography:**

Karlsson JO, Toner M. *Long-term storage of tissues by cryopreservation: critical issues.* Biomaterials. 1996; **17**(3):243-56

Morente MM, Mager R, Alonso S, Pezzella F, Spatz A, Knox K, Kerr D, Dinjens WN, Oosterhuis JW, Lam KH, Oomen MH, van Damme B, van de Vijver M, van Boven H, Kerjaschki D, Pammer J, Lopez-Guerrero JA, Llombart Bosch A, Carbone A, Gloghini A, Teodorovic I, Isabelle M, Passiukov A, Lejeune S, Therasse P, van Veen EB, Ratcliffe C, Riegman PH. *TuBaFrost 2: Standardising tissue collection and quality control procedures for a European virtual frozen tissue bank network.* Eur J Cancer. 2006; **42**(16):2684-91.

Qualman SJ, France M, Grizzle WE, LiVolsi VA, Moskaluk CA, Ramirez NC, Washington MK. *Establishing a tumour bank: banking, informatics and ethics.* Br J Cancer. 2004; **90**(6):1115-9

Villalba R, Eisman M, Fornes G, Mesa A, De Torres P, Ariza MJ, Gutierrez Guzman A, Gomez Villagran JL. *Implementation of a Quality Plan (ISO 9002) In a Regional Tissue Bank.* Cell Tissue Bank. 2001;**2**(1):45-49.

### **Electronic Resources**

First-Generation Guidelines for NCI-Supported Biorespositories

[http://biospecimens.cancer.gov/biorepositories/guidelines\\_full\\_formatted.asp](http://biospecimens.cancer.gov/biorepositories/guidelines_full_formatted.asp)

[http://ctep.cancer.gov/forms/guidelines\\_fresh\\_tissue.pdf](http://ctep.cancer.gov/forms/guidelines_fresh_tissue.pdf)

<http://www.cnio.es/ing/programas/progTumor11.asp#protocolo08> ( CNIO, Spanish National Cancer Research Centre, Madrid)

<http://www.hologic.com>