

Standard Operating Procedure (SOP) 001V7.0

Acquisition of Normal Breast Tissue at a Tissue Collection Event

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Approved by:

Materials:

Atec Breast Biopsy Device: Hologic, Inc. Bedford, MA
Biopsy Needles: ATEC 0912-20
Incision and Drainage Kit: McKesson (cat.# 302290)
Betadine swab packs: McKesson (cat.# 337531)
Lidocaine: McKesson (cat#239936)
Chloropreps: Mckesson (cat#84109)
Wound Wash Saline: McKesson (cat# 851138)
Telfa Pads: (cat# 10119)
Speciman cups: Fisher # 14-955-103
Specimen cup lids: Fisher # 14-955-108
Other medical supplies: i.e. syringes, chuks, gauze, linens, wash cloths, steri-strips

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 and infection. 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. Up to six core samples will 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 additional, cores are needed, the surgeon or radiologist will do so until adequate tissue samples are acquired.

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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 SOP005V6.0.

Manual compression of the breast in the region of the biopsy is to be continued for 5-10 minutes or until there is no bleeding from the incision. The incision is to be closed with steri-strip and 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. Any adverse events related to the donation itself will be recorded and reviewed by the Data Safety Monitoring Board and reported to the IRB. Any adverse or unexpected events involving storage and retrieval, processing, and utilization will be documented in the database and will be in the database and will be addressed by the Internal Advisory Committee.

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, Passioukov 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://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>

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