TISSUE BANK AT THE IU SIMON CANCER CENTER

Standard Operating Procedure (SOP) 001V8.0

Acquisition of Normal Breast Tissue and Blood at a Tissue Collection Event

Effective Date: March 2, 2020
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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.# 854753)
Lidocaine: McKesson (cat# 239936 and cat# 747088)
Chloropreps: Mckesson (cat#439864)
Wound Wash Saline: McKesson (cat# 636352)
Telfa Pads: (cat# 9962)
Specimen cups: Fisher # 14-955-103
Specimen cup lids: Fisher # 14-955-108
SST Collection tube: BD Vacutainer™ Venous Blood Collection Tubes: SST* Serum Separation Tubes Red/Gray top 8.5ml (Fisher cat. #02-683-96)
EDTA 9ml Collection tube: Greiner Bio-One Hematology K_3 EDTA Evacuated Tubes 9ml (Fisher cat. # 22-040-037)
EDTA 2 ml Collection tube: Greiner Bio-One Hematology K_3 EDTA Evacuated Tubes 2ml (Fisher cat. # 22-040-101)
Blood collection sets: BD (Becton, Dickinson and Company) Vacutainer™ Blood Collection Set, 21 gauge butterfly (Fisher cat. # 02-664-1)
Other medical supplies: i.e. syringes, chuks, gauze, linens, wash cloths, steri-strips, coflex, tourniquets, alcohol wipes, gloves

Labelling: All blood tubes, cryovials, and consent forms are pre-labeled with bar code stickers prior to venipuncture and tissue collection. Bar code packets are assigned during the donor registration process.

BLOOD COLLECTION:
Position for venipuncture: sitting

Blood Draw: The consented donor will have three tubes of blood drawn after the consenting process is completed. Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes [1]. The order of draw is 1) SST 2) EDTA 9ml, and 3) EDTA 2ml.

Blood Processing: Serum, Plasma and DNA are extracted and processed per SOP 002V8.0, SOP 003V8.0, and SOP 004V8.0. Whole Blood in EDTA 2ml tube is held at room temperature until all donor collections are complete then stored at -80°C.

BREAST TISSUE COLLECTION:
Consent: Prior to commencing the tissue acquisition process, the surgeon/radiologist will review with the donor the eligibility criteria and 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 Eligibility Checklist.

Position for Tissue 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 (1% lidocaine with epinephrine may be used per MD's choice). The maximum dose should not exceed 4.5 mg/kg, and the maximum total dose should not exceed 280 mg.

Tissue Acquisition: 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.

The cores are removed from the biopsy hand piece, 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 10 minutes (or less) of procurement. The tissue is processed following SOP 005V7.0.

Manual compression of the breast in the region of the biopsy is to be continued for 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 on the clipboard, reviewed by the Data Safety Monitoring Board and reported to the IRB when required. Any adverse or unexpected events involving storage and retrieval, processing, and utilization will be documented in the database and will be addressed by the Internal Advisory Committee.

References:

1. WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy. Geneva: World Health Organization; 2010. 2, Best practices in phlebotomy. Available from: https://www.ncbi.nlm.nih.gov/books/NBK138665/

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, et al. TuBaFrost 2: Standardising tissue collection and quality control procedures for a European virtual frozen tissue bank network. *Eur J Cancer*. 2006; **42**(16):2684–2691. doi:10.1016/j.ejca.2006.04.029
- 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, Fornés G, et al. Implementation of a Quality Plan (ISO 9002) In a Regional Tissue Bank. *Cell Tissue Bank*. 2001; **2**(1):45–49. doi:10.1023/A:1011576332362

Electronic Resources

- NCI-BBRB Biorepositories & Biospecimen Research Branch https://biospecimens.cancer.gov/default.asp
- NIH-CTEP Guidelines https://ctep.cancer.gov/default.htm
- CNIO, Spanish National Cancer Research Centre, Madrid https://www.cnio.es/
- https://www.hologic.com/