

Standard Operating Procedure (SOP) 012V6.0

Acquisition of Normal Breast Tissue and Blood from an Operating Room

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2020 Revision: Pamela Rockey, M.S., Biospecimen Manager

Approved by:



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Identifying potential donors: Potential donors are identified by the Department of Surgery Physicians. Notification of potential donors **must** be sent to the following people at the KTB **at least 48 hours** ahead of scheduled surgery time.

Julia von Arx- Event and Regulatory Coordinator of the KTB (jurmccar@iupui.edu)

Pam Rockey-Biospecimen Manager of the KTB (prockey@iu.edu)

The following information will need to be revealed when notifying the KTB:

- 1) What is the importance of the donor's sample, e.g. cancer type, BRCA+, etc.
- 2) When is the donor's surgery scheduled?
- 3) Specifics of the surgery, e.g. mastectomy, tumor removal only, etc.

Notifications:

- A) KTB staff will coordinate with the Surgery Staff, the potential donor, and the KTB Biospecimen Manager Pam Rockey (prockey@iu.edu) for the following events:
 - 1) Obtaining Informed Consent
 - 2) Administering the Medical Questionnaire
 - 3) Blood draw for the KTB
 - 4) Surgery date and time
- B) KTB staff will notify Mary Cox (marmacox@iupui.edu) operations manager for the Tissue Procurement and Distribution Core that a KTB designee will be present in the OR to collect tissue from the donor undergoing surgery.
- C) The Tissue Procurement Core will notify whoever is working in the pathology lab at the time of procurement.

Consent Informed consent will be obtained by designated KTB staff (Appendix B) using a barcoded KTB consent form.

Blood Draw: The consented donor will have three tubes of blood drawn after the consenting process is completed. Blood is drawn following SOP 001V8.0 and immediately given to the KTB staff for processing.

Tissue Acquisition: The OR staff will call the KTB staff when tissue is ready for acquisition. KTB staff will enter the OR, receive the tissue and transport it to the Frozen Section lab where it will be processed within ten minutes of acquisition by KTB staff following SOP 005V7.0.

If the tissue collected is both tumor and contralateral normal:

The contralateral sample should be taken from the upper outer quadrant of the breast. The tissue is processed by the KTB staff within ten minutes of acquisition following SOP 001V8.0 and SOP 005V7.0.

If the tissue is from a prophylactic mastectomy:

The tissue sample for the KTB is removed from the upper outer quadrant of the breast before the removal of the entire breast tissue. The tissue is processed by the KTB staff within ten minutes of acquisition following SOP 005V7.0.

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 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.

Appendix A: Indiana University Tissue Procurement and Distribution Core staff

- 1) Mary Cox
- 2) Mary James

Appendix B: Komen Tissue Bank Consenters

- 1) Jill Henry
- 2) Anna Maria Storniolo MD
- 3) Julia McCarty

Appendix C: Abbreviations:

- 1) KTB: Susan G. Komen Tissue Bank at the Indiana University Simon Cancer Center
- 2) OR: Operating room