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Tissue Collection and Transportation

1.0 PURPOSE

The purpose of this document is to outline standardized procedures for the ARGO biobanking to follow during the process of receiving and transporting tissue samples. Tissue samples can be collected and stored from patients only if there is tissue in excess of that required for pathological assessment and diagnosis.

2.0 SCOPE

This Standard Operating Procedure (SOP) describes how tissues are collected and transported. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) and it is recommended that personnel follow institutional biosafety guidelines outlined in the safety manual available at the workbench.

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all ARGO personnel that are responsible for collecting from samples arriving at the ARGO biobanking. Applicable staff may include the following roles:

ARGO/ OAUTHC Personnel	Responsibility/Role
Physician/Surgeon/Nurse/Research Assistant	Obtain Patient Consents.
Pathologist/Pathologist Resident	Gross of tissue and resection of excess tissue for the ARGO. Communicates and works closely with ARGO Research Assistant.
Surgeon / ARGO Research Assistant	Harvests, processes, and stores tissue samples.
ARGO Research Assistant	Transports tissue from the operating room to ARGO biobank.

4.0 MATERIALS, EQUIPMENT AND FORMS

Materials and Equipment
Container with ice

Metal ice plate
Appropriate container for resected tissue (Petri dishes)
Markers and pens
Forceps
Cold saline for rinsing tissue if needed
Clean scalpels for trimming tissue
Tissue collection kits (tubes containing culture media or Phosphate Buffered Saline)
Gloves worn to protect personnel handling tissue

5.0 PROCEDURES

This procedure is intended to ensure that tissue samples will be collected in a safe, timely, and efficient manner while eliminating the risks of contamination. To facilitate the use of innovative genomic and proteomic techniques, banked tissue that has been adequately processed is vital in obtaining products with high integrity and quality.

5.1 Tissue Collection – General Considerations

- 5.1.1 The scientific utility of the data obtained from the analysis of tissues is directly related to the quality of the tissue specimen.
- 5.1.2 Cellular and molecular integrity are most affected by factors such as specimen and tissue type, temperature conditions of the sample tissue, method of preservation, condition of storage and tissue product extraction methods. All efforts should be made to obtain and maintain tissue with suitable integrity for innovative research.
 - a. Minimize the time the tissue is subjected to hypoxic conditions because this initiates the cell death mechanism and subsequent degradation process.
 - b. Avoid contamination with histological distinct tissue. For example, avoid contamination between normal and tumor samples.
 - c. Use agents or treatments to inactivate degrading enzymes for preserving nucleic acid integrity, if applicable.
 - d. Preserve the tissue as fresh, frozen in cryogenic vials in -80°C freezer, liquid nitrogen vapor tank, or frozen in an OCT block at -80°C.
 - e. Store frozen tissue and products at appropriate temperatures, especially if storage is for longer periods of time.
- 5.1.3 Never place tissue intended for banking in formalin, unless for paraffin block generation.

5.2 Receiving Tissue from the Operating Room to the ARGO Biobank

- 5.2.1 The person responsible for obtaining the sample from the theatre will arrange to transport it to the ARGO biobank in a manner optimal for preservation of cellular and molecular integrity.

- 5.2.2 The ARGO Research Assistants are responsible for logging in all samples coming to the ARGO biobank and documented in the RedCap database.
- 5.2.3 The ARGO Research staff will prepare any petri dishes, cryovial, media or sterile equipment, depending on the collecting protocol requirements, and together with the sample will hand it to the surgery/pathology team assigned to procure the samples for the ARGO biobanking
- 5.2.4 The petri dishes are divided in half; the tumor will go on one half and the normal tissue in the other. The procuring personnel will fill in the appropriate information on the lid, but it is the responsibility of the Research Technician to verify the information. Alternatively, each normal and tumor tissues will be placed in their own separate cryovials and labeled accordingly.
- 5.2.5 Quad petri dishes can also be used when appropriate to collect from different sites of the same tumor, prostates, bladder, and gastro-esophageal junction samples.

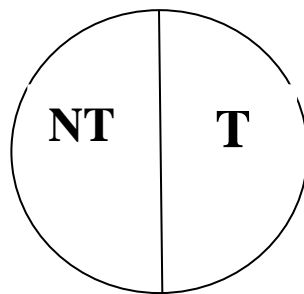
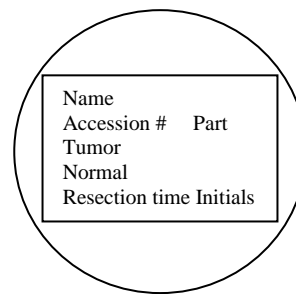


Plate inside



Lid

- 5.2.6 Only surplus tumor tissues from consented participants will be received at the ARGO biobanking. Thus, surplus samples refer to tissues left after fulfilling all clinical and diagnostic needs
- 5.2.7 The tissue collection time will be documented on the petri dishes and used when accessioning the sample by ARGO research assistant. Temperature conditions, harvesting personnel and different time points will be documented.
- 5.2.8 The surgeon, pathologist, or designated qualified personnel will harvest tumor and normal samples according to ARGO staff or specific-protocol instructions. Only excess tissue will be used for tissue banking and research purposes. Diagnostic procedures take priority over any research protocol.
- 5.2.9 The tissue may be banked as:
- Samples snap frozen in liquid nitrogen suitable for extraction of DNA, RNA and protein.
 - Tissue samples given in preservation media directly to research investigators for the extraction of DNA, RNA, protein, organoids or PDX.
 - Samples frozen in optimal cutting temperature (OCT) compound suitable for producing frozen tissue sections.
 - Samples fixed in formalin for paraffin block generation.

- 5.2.10 Depending on the method or processing/storage, transfer the tissue to the appropriate receptacle for the processing step.
 - a. Paraffin Embedding: Place the paraffin blocks in a formalin container for processing the following day.
 - b. Fresh Samples: Hand it to the ARGO research assistant.
 - c. Frozen in OCT: Assigned a location in trays and stored in -80°C Revco Freezers.
- 5.2.11 The ARGO biobank will anonymize samples submitted for biobanking by assigning the tissue sample a unique identifier.

6.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- 7.1 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER)
http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/ISBER_Best_Practices_3rd_Edi.pdf
- 7.2 US National Biospecimen Network Blueprint
<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>
- 7.3 International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8
<http://www.ich.org/products/guidelines.html>

7.0 REVISION HISTORY

SOP Number	Date Reviewed	Reviewed By	Comments