



PROSTATE CANCER **BIOREPOSITORY NETWORK**

SOP No: 010

Collection, Handling and Disposal of Fresh Biopsy Samples- ICR

| | |
|---|--|
| STANDARD OPERATING PROCEDURE | SOP No. 010 Collection, Handling and Disposal of Fresh Biopsy Samples- ICR |
| <i>UNAUTHORIZED COPYING PROHIBITED</i> | Version Number: 1.0 (May 2019) Number of Pages: 5 |
| Electronic Filename: PCBN.SOP10.v1.0 Fresh Biopsy Samples | |



PROSTATE CANCER **BIOREPOSITORY NETWORK**

SOP No: 010

Collection, Handling and Disposal of Fresh Biopsy Samples- ICR

1. PURPOSE

To describe the procedures for processing of fresh biopsy samples by the Cancer Biomarker (CB) Team at the Institute of Cancer Research to either FFPE (formalin fixed paraffin embedded) samples or frozen biopsy samples. This procedure applies to all the fresh biopsy samples received by the CB team for further processing.

The following SOP for Blood and Cytology Sample processing is followed by the Institute of Cancer Research Network Site of the PCBN ONLY.

2. RESPONSIBILITIES

Authorized personnel processing fresh biopsy samples must:

- Comply with the procedure
- Follow all other precautions required for the handling of human blood and tissue samples
- Obey Team Leader who has overall responsibility of the procedure
- All fresh biopsy samples received are logged into the Histopathology Sample Entry (HSE) and on the Progeny.

3. HEALTH AND SAFETY

Personnel carrying out this procedure must maintain safe working practices and observe all relevant Environmental Health and Safety (EH&S) guidelines. This includes the appropriate use of Personal Protective Equipment (PPE), and the procedures for waste disposal, disinfection & spill clean-up and biosafety.

4. EQUIPMENT AND MATERIALS

| Equipment | Materials |
|-----------------------|---|
| Class II Cabinet | Dry Ice |
| Liquid Nitrogen Dewar | Bijoux tubes |
| | Foil |
| | Polystyrene box (or suitable container) |
| | Isopentane |
| | Cryomolds |
| | OCT |



5. PROCEDURES

5.1 Processing by Freezing Using Dry Ice

- The following reagents and materials are required:
 - Dry ice
 - Bijoux tubes
 - Foil
 - Polystyrene box (or suitable container)
- These biopsies must be attended, and frozen as soon as possible and suitable PPE must be worn.
- Label the Bijoux tubes with the following details:
 - Patient initials and trial and/or Progeny number
 - Trial name
 - Date of collection
 - Pre dose or cycle number post dose if necessary
- Pre-cool the Bijoux tube by placing it in the dry ice.
- Place biopsy as flat as possible on to a small piece of foil using clean forceps.
- Wrap the foil around the biopsy, place in the dry ice as rapidly as possible and cover with dry ice to freeze the sample.
- When the biopsy is frozen, place in the labelled Bijoux for storage.
- Store at -80°C until required.

5.2 Snap Freezing

- The following reagents and materials are required:
 - Liquid Nitrogen
 - Bijoux tubes
 - Foil
 - Liquid nitrogen dewar
- These biopsies must be attended, and frozen as soon as possible and suitable PPE must be worn.
- Label the Bijoux tubes with the following details:
 - Patient initials and trial and/or Progeny number
 - Trial name
 - Date of collection
 - Pre dose or cycle number post dose if necessary
- Place the biopsy as flat as possible on to a small piece of foil using clean forceps.
- Wrap the foil around the biopsy, place in the tube, close the lid, and place in the liquid nitrogen as rapidly as possible,
- Store at -80°C until required.



5.3 Freezing Using Dry Ice, Isopentane and OCT

- The following reagents and materials are required:
 - Dry ice
 - Isopentane
 - Cryomolds
 - OCT (Optimal Cutting Temperature Compound)
 - Polystyrene box (or suitable container)
 - Metal Container
 - Foil
 - Plastic bags
- These biopsies must be attended, and frozen as soon as possible and suitable PPE must be worn.
- Label a piece of foil and the cryomolds with the following details, using a solvent resistant pen:
 - Patient initials and trial and/or Progeny number
 - Trial name
 - Date of collection
 - Pre dose or cycle number post dose if necessary
- Pre-cool the isopentane by pouring at least 100 mL of it into the metal container which should be placed in the dry ice. The isopentane needs to be cooled at least 15 minutes in advance of this procedure.
- Place the biopsy as flat as possible in the cryomold using clean forceps, fill with OCT, and immerse in the isopentane using forceps.
- When the sample is completely frozen, remove from the isopentane using forceps, wrap in the labelled foil, and then cover with dry ice for transport purposes.
- Label a plastic bag with the above details in 5.2, seal, and store at -80°C until required.

5.4 Processing for FFPE Biopsies

- The following reagents and materials are required:
 - 10% NBF (neutral buffered formalin) pot
- These biopsies must be attended, fixed within one minute of being taken if possible and suitable PPE must be worn.
- Label the NBF pot with the following details:
 - Patient initials and trial and/or Progeny number
 - Trial name
 - Date of collection
 - Pre dose or cycle number post dose if necessary
- Place the biopsy into the NBF and assess the quality. If necessary, and if it is safe for the patient to do so, request for further samples to be taken.
- Note: Follow the SOP No.011 for further procedures.



PROSTATE CANCER **BIOREPOSITORY NETWORK**

SOP No: 010

Collection, Handling and Disposal of Fresh Biopsy Samples- ICR

5.5 Processing of Cell Pellets for Other Studies and Control Material

- The following reagents and materials are required:
 - NBF (neutral buffered formalin)
- The cells are grown to confluency and harvested, with as many cells as possible.
- The cells are then rinsed in PBS or TBS and pelleted in a universal container. This is done by spinning the sample in a centrifuge for 2 minutes at 300g.
- The buffer is tipped off and approximately 3 mL NBF added very gently to the pellet, so as not to disturb it.
- Note: Follow the SOP No.011 for further procedures.

5.6 Disposal of Fresh Biopsy Samples

- Once a trial has finished, biopsy samples may be retained for future research if consent allows so, according to the HTA guidance, and if no consent has been obtained, for 12 months after submitting the end of trial notification to REC and/or MHRA.
- If requested, the samples shall be returned to the Sponsor Study Team. If the samples are to be destroyed it shall be done in accordance with any written permission provided by the Sponsor Study Team by placing it in a separate bag which is then disposed of in a yellow biohazard bag.
- The return of samples or their destruction shall be documented with the Sample Tracking Log and Database Histories. Email correspondence from the trial sponsor giving permission for sample disposal should be filed in the "Sample Disposal" folder found at V:\Cancer Biomarkers\Clinical Trial Folder\Clinical Studies\ for each trial. This folder needs to be created whenever it is needed.