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| TGHN-256x151px  Standard Operating Procedure | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Managing Biological Samples** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

**14.1 Purpose**

This SOP describes the procedures for collection, preparation, storage and shipment of biological sample.

**14.2 Scope**

This SOP will apply to all biological samples collected, processed, stored and shipped by [institution], unless alternate directions are provided by the sponsor or Contract Research Organization (CRO).

**14.3 Procedure**

**14.3.1Collection of Samples**

Study Nurse or the person delegated in the duty delegation log will collect the biological samples on scheduled visit as described in the protocol.

After collecting the sample, the study nurse or delegated person will record the details in the biological sample collection form (AX1-V3/SOP 14/V3)

**14.3.2 Preparation of Samples**

The sample either is stored as collected and/or processed as mentioned in the protocol or laboratory manual provided by the sponsor/CRO.

Using a permanent marker, study nurse or CTC will record the patient initials, patient ID and the date and time when the sample was obtained on each sample labels.

In case of any damage to sample or if samples is unusable immediately inform to Sponsor/ CRO (in case of sponsored study) and report deviation to IEC and document the same in the source note, if required.

**14.3.3 Storage of Samples**

Before shipments, site personnel will store both urine and plasma samples at a temperature of at least - 20ºC – or at a temperature mentioned in the protocol

Other biological samples should be stored as mentioned in the protocol.

**14.3.4 Shipment of Samples**

Site personnel will:

* Call the courier person as agreed by the sponsor/as mentioned in the protocol and schedule the date and time for shipping the sample.
* Inform the courier person to bring the required materials for shipment as mentioned in the protocol.
* Complete all the biological sample inventory form available in the collection kit listing all the samples in the shipment.
* Arrange a gate pass as per [institution] policy
* Keep a photocopy of the Biological Sample Inventory page in the [institution]

**14.4 Applicable Staff**

This SOP applies to all the existing personals of the clinical research team and any new member appointed who may be responsible for study related activities as mentioned in this SOP( per the delegation log). These include following

* Investigator
* Research Team (listed in the delegation log)
* Study Nurse

**14.5 Staff responsible for Implementation**

The department and the Investigator will ensure that the research team involved in the conduct of the study will comply with this site SOP.

The department and PI at his level will ensure that at the time of implementation of the SOP, that the research team at [institution] are trained and in the event that an SOP is modified, provide training regarding the change(s) and ensure their compliance with the changes.

**References**

None