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| **TGHN-256x151px****Standard Operating Procedure** | **SOP No:** **Version: 1****Effective Date:**  |
| **Title: Transfer of patients between hospitals** |
|  | NAME | **SIGNATURE** | **DATE** |
| **PREPARED BY** |  |  |  |
| **REVIEWED BY** |  |  |  |
| **QA UNIT****AUTHORITY** |  |  |  |
| **APPROVAL****AUTHORITY** |  |  |  |

**17.1 Purpose**

This SOP describes the procedure for transferring of patients enrolled in the research studies between [institution] and [institution].

**17.2 Scope**

This SOP will apply to all research studies including investigator initiated and or sponsored being carried out in [institution] which requires transfer of patient between [institution] and [institution].

**17.3 Procedure**

For [institution] trials, there will always be a preferred site either [institution] or [institution , which will be decided by the PI.

The PI will list the procedures that will be done at [institution] and [institution], based on the availability of facilities, protocol requirements, patients convenience, safety requirements, sponsors requirements, etc. e.g. For study patients CT scan is preferably done in [institution]. The same must be informed to sponsor and IEC before study initiation.

The patients need to travel between [institution] and [institution] for which they can avail the Inter Institutional transport facilities.

**17.3.1 Documents required for transfer of patients**

In case of transfer of patient form [institution] to [institution] or vice versa, Inter Institutional referral form (AX1-V3/SOP 17/V3) should be filled by the PI/ Co-I/CTC.

The form describes the reason of the transfer of the patient giving the brief case summary/ purpose with specific instructions.

Project approval letter from IEC and copy of signed informed consent form is also required to be attached along with Inter Institutional referral form.

**17.3.2 Transfer of Source Documents**

Any time during transfer of patients to other site, patient must carry source notes, investigational reports (if applicable) or other relevant documents which will be required by the treating doctors for reference or for adding new source data, etc.

The source data will be carried by the patient to other site by any of following ways:

When it is not possible for patient to travel along with source document, any authorized employee of [institution], who is traveling using [institution] Inter Institutional transport or using own personal vehicle can carry the source documents to other site.

Under any circumstances, traveling using public transport is not allowed while carrying the source data of patients. The transfer using authorized employee will be supervised and ensured by CTC. Source document can be transferred via the Satellite Centre liaison counter located at [institution] and Dispatch section in Satellite Centre. Such transfer will be supervised and ensured by CTC.

**17.3.3 Return of Source Document**

The source document will be returned to the preferred site immediately after completion of the procedure at the other site. Such return will be supervised and ensured by CTC.

**17.3.4 Transfer of IP**

IP is generally stored at site conducting research. If any IP is to be transferred along with patient to other site it will be done as follows.

The respective CTC or any other study member should be identified by the PI for IP transfer

The CTC or study member, will travel using [institution] Inter Institutional transport or using own personal vehicle. Traveling using public transport is prohibited while carrying the IP.

Storage conditions like temperature, light and humidity as per requirements of the IP will be maintained and monitored throughout the traveling time. IP accountability must be checked and documented at both ends. Documentation of such transfer of IP must be done in the source notes and in addition following details but not limited to, must be documented;

Patients visit details, dose, specific instruction for administration (if any)

Details of study nurse or identified member by the PI to administered the IP, storage till the administration, dilutions, additions, dose calculations, procedure of administration, etc.

Instruction for returning and/ or destruction of used IP

Presence of CTC or any other identified member by the PI is must, during administration at the other site, if the IP are to be administered.

**17.4 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 doing the activities mentioned in this SOP (as per the delegation log).

\*These include the following:

-Investigator

-Research Team (listed in the delegation log)

-Satellite Centre liaison and concerned staff at Satellite Centre

**17.5 Staff responsible for Implementation**

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

PI will ensure that at the time of implementation of the SOP, that the research team at the clinical research unit in [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