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

**15.1 Intent / Purpose**

This SOP describes the procedures involved in reimbursement to the study subject for their involvement in the research and research related activities as agreed in CTA and mentioned in ICF.

**15.2 Scope**

This SOP applies to all study team member who are engaged in study related activities and delegated in the delegation log for research related reimbursement (if applicable) to all subjects in the studies being conducted in [INSTITUTION].

**15.3 Procedure**

**15.3.1Information regarding reimbursement**

Subjects may be paid for the inconvenience and time present, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. However, payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in research against their better judgment (inducement). All payments, reimbursement and medical services to be provided to research subjects should be approved by the IEC. [INSTITUTION] should be taken:

* When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;
* When a subject is withdrawn from research for medical reasons related to the study the subject should get the benefit for full participation;
* When a subject withdraws for any other reasons he/she should be paid in proportion to the amount of participation.
* Reimbursement must be given as agreed by the investigator and sponsor/CRO in the Clinical Trial Agreement (CTA) and as defined in the Informed consent document.

**15.3.2 Procedure for reimbursement**

The CTC as designated will reimburse the amount to the patient as mentioned below:

* Should open a particular study account in the [INSTITUTION] accounts department and maintain the account number. Always deposit the cheque in the same account received by the sponsor/CRO.
* Keep a track of patient’s visits as mentioned in the protocol, travel, concomitant medication prescribed for adverse event (if any), and if any unscheduled visit scheduled during the study period for reimbursement.
* Must reimburse travel cost, upon presentation of receipt of a valid ticket (if available or as agreed in the CTA) or bills of the protocol specified visits or unscheduled visits if any.
* Must collect the original bills from the patient for above listed things for reimbursement
* Payment voucher must be prepared for the same; it will include patient hospital case number, name, amount to be paid, study account number and reason for reimbursement.
* Investigator or designee will approve and sign the voucher. Patient will sign or put his/her thumb impression in case patient is illiterate on the copy of the voucher (patient will sign/thumb while submitting the voucher to the accounts department).
* Copy of signed voucher (by investigator/designee and subject) and bills should be filed in a separate file.
* Original voucher and bills will be forwarded to the concerned authority as per the hospital policy for approval.
* The voucher and bills will be forwarded to the accounts department of the [INSTITUTION].
* The competent authority from accounts department will sanction and release the amount.
* In case of Serious Adverse Event (SAE) which found to be related to the IP, PI/ Co I will make sure that subject should get reimbursed for every expense occurred during the management of the adverse event.
* CTC will always keep a copy of the updated account statement to make sure the account has sufficient balance for reimbursement.
* CTC should send the expense invoices to sponsor on regular intervals, to receive the amount on time.

**15.4 Applicable Staff**

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

These include the following:

* Investigator
* CTC
* Research Team (listed in the delegation log)

**15.5 Staff responsible for Implementation**

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

The 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.

Inform IEC that the site SOP will be implemented within the institution.

**References**

1. Good clinical practice.