|  |  |
| --- | --- |
| **TGHN-256x151px****Standard Operating Procedure** | **SOP No:** **Version: 1****Effective Date:**  |
| **Title: Clinical Trial Agreement (CTA) with Sponsors and/or Contract Research Organizations (CRO)** |
|  | NAME | **SIGNATURE** | **DATE** |
| **PREPARED BY** |  |  |  |
| **REVIEWED BY** |  |  |  |
| **QA UNIT****AUTHORITY** |  |  |  |
| **APPROVAL****AUTHORITY** |  |  |  |

* 1. **Purpose**

This Standard Operating Procedure (SOP) describes the manner in which the Clinical Trial Agreement (CTA) are to be received, processed and accepted by the Institution and/or principal investigator to another entity for the purpose of conducting research. These other entities may include, but are not limited to; industry or commercial sponsors, contract research organizations (CROs), or other research collaborators.

This SOP is in place to ensure that both, [Institution] and the Principal Investigator (PI), are legally protected in all necessary areas applicable to their specific project.

**3.2 Scope**

This SOP will apply to all industry-sponsored trials conducted at [Institution] or trials initiated at [Institution] for multicentre purpose.

Any new trial which initiated during active period of the SOP will be covered under the SOPs, unless otherwise indicated. If necessary a study specific SOP may be prepared.

**3.3 Procedure**

All the Research Agreements (whether having the financial implications or not) will be tripartite – The PI, Institution and the Sponsor / CRO shall be the signatories to the Clinical Trial agreement.

**Institutional Signatories:** The Medical Director of the unit will sign the agreement on behalf of the institution. If the Medical Director is the Investigator, then CMD or CEO can be the Institutional signatories.

Alternatively, the Head of Department (HOD) / CEO / CMD can sign any Research Agreement on behalf of the Institution. But, no two signatories shall be same.

All CTAs must clearly mention the contact details of the signatories with their - Name, Address, telephone no., fax no, and email id’s.

All CTAs must clearly mention how they shall manage the injury caused to the study subject due to the study medication or the study procedure. If a CRO is the signatory to the CTA, then there should be a clear mention regarding who from the Sponsor’s side needs to be contacted for the same, with his /her full contact details. This should be accompanied by the Insurance Statement in detail.

All CTAs must clearly mention and carry the Indemnity Statement for the Institution and the Investigator.

Dispute resolution: Any dispute shall be mutually resolved between the signatories, failing which process of arbitration shall be put into place. If that too fails, then resolution thru’ the courts be resorted to. The Law to be followed has to be the Indian Law (Law of the Land where the site exists).

**Intellectual property Rights**: In case the research collaboration is for exchange of data sans any financial returns, then the final results shall be shared between the parties. No party shall individually claim any right over the Publication. Any unilateral claim shall attract penal provisions. The courts for any such claim settlements shall be the courts of Zzzzzzz.

**3.3.1. Review of draft CTA**

Sponsor/CRO will provide draft CTA to Principal Investigator for finalization.

The Principal Investigator (PI) will inform the same to the Institution head, (Medical Director) and send one copy each of the CTA along with the study protocol to the institution head, Legal department.

The PI must check that the following elements, when applicable should be included in the contract to cover GCP and other responsibilities:

* Sponsor's name
* Institution name
* PI name
* Protocol title with IP name
* A listing of the study, clinical, and legal responsibilities of Investigator site
* Effective date of CTA
* Estimated study start and finish dates
* Terms of payment including terms for delays and termination of the study
* Number of study subjects required to enter and complete the study and the criteria for a "completed" (fully paid) study subject
* Confidentiality agreement
* Information on personal data and biological material if any Dissemination of findings, and publication rights
* Data ownership rights Indemnification
* Research related injury responsibilities including the provision and payment and/or reimbursement of necessary medical AAAAAA for research participants when appropriate Compensation guidelines
* Guidelines or requirements for promptly reporting of the findings that could affect the safety of participants or influence the conduct of the study
* Data and safety monitoring process and reporting requirements
* The notification of the research department by the Sponsor and/or CRO of study results after the study has ended when participant safety could be directly affected by those study results, in order to consider informing participants
* Other legal issues as necessary per [INSTITUTION] Legal expert(s).

*[Note: While preparing budgets for Industry sponsor study, one should always, consider changes as per “D” category (Schedule of charges) or higher if offered by the Industry.]*

PI/Legal expert must check for the availability of clause in Contracts or other funding agreements that require the sponsor to promptly (no longer than within 30 days) report to the organization in case of any findings that could:

* Affect the safety of participants.
* Influence the conduct of the study or alter the IEC’s approval to continue the study.

The Legal department and IEC will correspond with the PI regarding any revisions that are required in the CTA.

The legal expert will approach Institutional head, in case of queries.

**3.3.2 Revision of CTA**

The Legal expert(s) will correspond with the PI in case of suggestion/revision including the revision suggested by Institutional head.

The IEC will also correspond with the PI regarding any revisions that are required in the CTA.

In case of sponsored study PI will further correspond with the Sponsor/CRO/collaborators for all the relevant suggestion/revision and changes if any put forward by Legal expert and IEC.

The Institution head will be included in all correspondence between the Legal department, IEC and Sponsor/CRO/collaborator.

PI or Sponsor (in case of sponsored study) will study the revision suggested and incorporate the suggested changes as applicable.

**3.3.3 Finalization of CTA**

Once the CTA is approved by the Legal expert and IEC, PI will further correspond with the Sponsor/CRO/collaborators.

A minimum of three originals should be prepared on stamp paper (INR100) or as many originals as the Sponsor/CRO/collaborator specifies.

The PI is responsible for assuring that all required signatures are obtained. All originals should be identical and have consistent signatures and dates.

*Note: Institutional Head will sign the CTA only after IEC approval.*

After signature of the Institution head (along with the institution stamp) and Principal Investigator the originals will be sent to the Sponsor/CRO for signature.

A copy will be retained in the interim; this copy will be discarded when the signed original is returned from the sponsor/CRO.

One copy will be retained by the Institution head, one by Principal Investigator and the other will be with the Sponsor/CRO. The PI should keep the signed CTA in TMF.

One copy of the CTA will be submitted to the IEC for approval before the conduct of the study at site.

**3.3.4 Addendum/Amendment to CTA**

During the course of the study, the PI/Sponsor can amend the CTA if required.

Any addendum/amendment to the CTA also needs to be reviewed by legal experts and a copy will be submitted to IEC for review and opinion if any.

If any changes suggested by the PI and IEC, the same will be discussed with the Sponsor (for sponsored study) and should be incorporated in the CTA.

A copy of the amended CTA will be submitted to IEC for review and opinion if any.

One copy each of finalized (signed and dated) amended CTA will be retained by PI, one by the Institution head and one by the sponsor.

**3.4 Applicable staff**

This SOP applies to those members of the clinical research team involved in the process of finalizing the Clinical Trial Agreement at site. These include the following:

* Institution Head
* Principal Investigator
* Legal Expert
* IEC

**3.5 Staff responsible for Implementation**

The Dept of Clinical Research 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.

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

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

**References**

1. FDA Code of Federal Regulations: 21 CFR Part 312.53

2. International Conference on Harmonization (ICH) Guidelines (E6) for Good Clinical Practices (GCPs): 4.5.1 and 4.9.6