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| **TGHN-256x151px****Standard Operating Procedure** | **SOP No:** **Version: 1****Effective Date:**  |
| **Title: Communication with Sponsor or Contract Research Organization (CRO)** |
|  | NAME | **SIGNATURE** | **DATE** |
| **PREPARED BY** |  |  |  |
| **REVIEWED BY** |  |  |  |
| **QA UNIT****AUTHORITY** |  |  |  |
| **APPROVAL****AUTHORITY** |  |  |  |

**6.1 Purpose**

This standard operating procedure (SOP) describes the communication between key research personnel at site and the sponsor/Contract Research Organization (CRO), including telephone and written interactions, during the entire course of a research study conducted at [INSTITUTION] and to ensure proper documentation of communications with the Sponsor/CRO concerning study activities.

**6.2 Scope**

This SOP applies to communications between the site and sponsors/CROs involved in the conduct of research study.

These communications serve to protect the safety and well-being of subjects by assuring that studies are conducted compliantly, sponsors/CROs are fully appraised of study site activities, and key research personnel are informed of new information about the study provided by the sponsor/CRO.

Any new study 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.

**6.3Procedure**

**6.3.1 General communications**

Provide the sponsor/CRO with a contact list of site personnel involved in study start up, along with each individual’s role and responsibilities.

Communicate regularly, courteously and in accordance with [INSTITUTION] standards, with the sponsor/CRO about all study related issues.

Be familiar with the sponsor’s SOPs pertaining to communications, including reporting timelines and preferred communication mode.

Keep originals or photocopies of all study-related communications, including faxes with corresponding confirmations, e-mails, and written summaries of phone conversations. File all communication documents in the appropriate section of the TMF.

Retain all sponsor-generated communications regarding conduct of the study (e.g., teleconference announcement) in the correspondence section of the TMF. Budget, payment and other contractual or financial communications should be filed separately from the regulatory binder. Ensure information is communicated to the Principal Investigator (PI) and other key research personnel as applicable.

**6.3.2 Pre-Study communication**

The CTC is responsible for sending the Confidentiality Agreement to the sponsor/CRO once reviewed and signed by PI.

Notify the sponsor/CRO of the PI’s decision to conduct the research study at [INSTITUTION].

Review the protocol and submit if any questions concerning interpretation of the protocol or conduct of the study to the sponsor/CRO in writing and file the copy in the TMF.

Fill the questionnaires provided by the sponsor/CRO regarding the study related requirements.

Prepare questions to clarify protocol procedures, subject eligibility criteria, and other study-related issues in writing and file the reply in the TMF.

The PI/Co I will discuss how the site is equipped to perform the study. This discussion will include a description of the potential subjects available for the study and methods being considered for recruitment.

**6.3.3 Communications while the study is ongoing**

The Investigator/CTC will submit the updated screening and/or enrollment logs to the sponsor/CRO by the preferred mode of communication.

Notify Sponsor/CRO about unanticipated issues, including adverse events (AEs) and Serious Adverse Events (SAEs), per the sponsor’s definitions and timelines, as defined in the protocol or SOP.

Communicate protocol deviations, as they occur, according to the sponsor requirements.

Submit completed CRFs (paper-based or e-CRF) to the sponsor/CRO in accordance with the Clinical Trial Agreement (CTA).

Respond promptly to data queries as requested via fax, e-mail, and/or direct electronic data capture resolution, per the sponsor’s requirements and document the same in the specified TMF

Communicate significant regulatory changes as per the sponsor’s requirements (e.g., IEC acknowledgement of an unanticipated issues or protocol deviation, IEC approval of a revised consent document, etc.). Typically these documents are reviewed during interim monitoring visits; however specific sponsors/CROs may require prompt notification in specific circumstances.

Submit sponsor-generated protocol amendments to the IEC. Once approval is obtained, PI will train the study team regarding the changes prior to implementation and same will be documented and informed to Sponsor/CRO

Forward safety reports received from the sponsor (e.g., off-site SAE/SUSAR) to the PI who will review the event and report to the IEC as per IEC SOP. Notification of other key research personnel and/or enrolled subjects may be necessary (e.g., new risk identified related to investigational treatment).

**6.3.4 Communication after study is completed**

Inform IEC regarding scheduled site close out visit.

Communicate with sponsor and confirm the close out date.

Provide the sponsor/CRO with any IEC required correspondence (e.g information requires in the IEC study closure letter) related to the study close out.

Ensure that all close out activities are performed and all sponsors requirements are met.

After receiving the final close out letter and study result from the sponsor, submit the same to the IEC in the required IEC format.

File all the communication in the appropriate section of the TMF.

**6.4 Sponsor Contact**

Telephone Contacts – All study personnel will document critical conversations with the Sponsor/CRO in the source notes, especially those pertaining to eligibility criteria, protocol deviations, and serious adverse experiences. If requires the CTC or delegate will file the Telephone Contact copy in the TMF.

Letters and Faxes – All study personnel will make copies of all correspondence written to the Sponsor/CRO. The CTC or delegate will file this correspondence in the TMF.

E-mails – All study personnel will print out copies of critical e-mails with the Sponsor/CRO. The CTC or delegate will file this correspondence in the TMF and if required in the source notes.

At a minimum, the Sponsor/CRO should be notified:

* When the first subject is enrolled in the study.
* When there is a question concerning a potential subject’s eligibility.
* When recruitment issues occur.
* When a protocol violation occurs.
* When an SAE occurs.

**6.5 Applicable Staff**

This SOP applies to all the personals of the clinical research team involved in communication with the Sponsor/CRO and responsible for the management of the data.

These include the following:

* Principal Investigator
* Sub Investigator
* CTC
* Pharmacist
* Support Staff

**6.6 Staff responsible for Implementation**

The PI and Senior CTC will ensure that the research team involved in the conduct of the study will comply with this site SOP and research members involved in the study are following this SOP while communicating with sponsor/CRO.

Site staff 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 this site SOP will be implemented within the institution.

**References**

1. 21 CFR 312.32 IND safety reports

2. 21 CFR 312.33 Annual reports

3. 21 CFR 312.44 Termination

4. 21 CFR 50 Protection of Human Subjects

5. 21 CFR 56 Institutional Review Boards

6. Beaumont SOP Site-Sponsor/CRO communications dated 21/9/2010

7. FDA Information Sheet, October 1998: Sponsor-Investigator-

8. IEC Interrelationship

9. May 1997 International Conference on Harmonization (ICH) Good Clinical Practices