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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Ti**tle: **Reviewing and Obtaining Informed Consent** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

**8.1 Purpose**

To describe the information and essential elements required to be included in the informed consent documents associated with research study.

To describe the procedure for obtaining voluntary informed consent from a prospective subject for a research study and also to ensure that a subject’s consent is sought in such a way that the subject or his/her representative has ample opportunity to consider whether to participate in the study and under conditions that minimize the possibility of coercion or undue influence.

To ensure that freely & voluntarily given written Informed Consent is obtained from each participant in accordance with applicable regulatory requirement, Schedule Y, ICH-GCP and Declaration of Helsinki.

**8.2 Scope**

This SOP will apply to all research studies conducted at [INSTITUTION] for informed consent procedure.

**8.3 Procedure**

Informed Consent must be obtained prior to performing any study specific procedures.

**8.3.1 Reviewing the Draft Informed Consent**

Prior to submission of Informed Consent Form (ICF) to Institutional Ethics Committee (IEC) for approval, the PI must check the IEC SOP requirements for element of ICF, to learn if specific formatting or wording requirements for informed consent / Assent in addition to those listed in the regulations are fulfilled.

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| STANDARD OPERATING PROCEDURES. | DEPARTMENT OF CLINICAL RESEARCH [INSTITUTION]S. |
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In addition, the PI must ensure that the as per the guideline (Gazette dated 30.01.2013), the following should be inserted namely for regulated studies:

* Subject Initials:
* Date of Birth: Age:
* Subject Name:
* Add & Contact No:
* Qualification: Occupation: Student / Self Employed / Service / House wife ,other (please specify), If any \_\_\_\_\_
* Annual Income: INR,
* Name and address of the Nominee (s) and relation to subject: Name:
* Relation to subject:
* Address & Contact No.:

Before the consent form is submitted to the IEC, the PI will review the document to ensure that, it is in compliance with the IEC’s requirements and with applicable regulations, Schedule Y and ICH GCP guidelines.

If there is any discrepancy or missing element in the ICF, contact Sponsor/CRO or PI (in case of Investigator initiated study) for appropriate action.

In order to assess the informed consent process, the submission to the IEC should be detailed enough to allow the IEC to determine that an appropriate process will be followed. In addition to providing a description of the consent process including the person who would conduct the counseling, and the information to be communicated to the prospective participant or the Legally Authorized Representative, the Research Plan should include:

* the person who would provide consent or permission;
* any waiting period between informing the prospective participant and obtaining consent;
* steps taken to minimize the possibility of coercion or undue influence; the language used by those obtaining consent; and,
* the language understood by the prospective participant or the legally authorized representative.

The language used in the written informed consent form, should be nontechnical and should be understandable to the subject or the subject's Legally Acceptable Representative (LAR) and or to the Impartial Witness (IW), wherever applicable.

The Informed Consent must be available in the appropriate required local languages with the translation certificate.

* The informed consent process may be periodically audited by the IEC or appropriate compliance or designated personnel to assess conduct. Information presented in order for the IEC to approve research will be reviewed and must include, but is not limited to the following:
* The investigator obtained the legally effective informed consent of the participant and Impartial Witness and or participant’s legally authorized representative, where applicable.
* The circumstances of the consent process provided the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate.
* The circumstances of the consent process minimized the possibility of coercion or undue influence.
* The individuals communicating information to the participant or the legally authorized representative during the consent process provided was in the language understandable to the participant or the representative.
* The information being communicated to the participant or the representative during the consent process did not include exculpatory language through which the participant or the legally authorized representative was made to waive or appear to waive any of the participant’s legal rights.

The IEC will determine that the required disclosures (mentioned in 8.3.2.a) provided to each subject or a legally authorized representative in accordance with legal and regulatory requirements as required elements of informed consent. The IEC will also consider whether additional disclosures are required for inclusion in the consent process.

**8.3.2 General procedure for obtaining Informed Consent from Subjects / patients:**

The Investigator and CTC are responsible for ensuring that the informed consent and assent, if applicable, have been approved by the IEC before they are used in a study and that the correct version of the documents are used when the study is ongoing.

The process of Informed Consent should begin after identification of a prospective subject. Subject must be asked regarding the literacy and the language he/she would prefer for communication, reading and writing.

No investigator may involve a human being as a subject in research, unless the investigator has obtained the legally effective informed consent of the subject

The PI / Co I should conduct the consent procedure and obtain freely & voluntarily given consent from a subject.

Before requesting an individual's consent to participate in research, the investigator must provide the below mentioned required disclosures to each participants and Impartial witness and or legally authorized representative (if applicable) in accordance with legal and regulatory requirements.

a. The disclosure should be in the language he or she is able to understand which should not only be scientifically accurate but should also be sensitive to their social and cultural context :

* Statement that the study involves research and explanation of the purpose of the research.
* The aims and methods of the research.
* The expected duration of the subject’s participation.
* Description of the procedures to be followed, including all invasive procedures.
* Any foreseeable risk or discomfort to the subject resulting from participation in the study.
* The benefits that might reasonably be expected as an outcome of research to the subject or to others. If no benefit is expected subject should be made aware of this.
* Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment to which she/he is being subjected.
* The extent to which confidentiality of records could be able to safeguard, confidentiality and the anticipated consequences of breach of confidentiality.
* Information regarding direct access to the participants original medical records for verification of clinical trial procedures or data to the monitor, the auditor, the IEC, and the regulatory authority will be granted, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written consent form, the participant or the participants legally acceptable representative is authorizing such access.
* Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials).
* Compensation and/or controlled available to the Subject in the event of a trial-related injury.
* An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury, with appropriate XXXXXXXXXXXXX HILLS and contact numbers.
* The anticipated prorated payment, if any, to the Subject for participating in the trial.
* Subject's responsibilities on participation in the trial.
* Freedom of individual / family to participate and to withdraw from research any time without penalty or loss of benefits which the subject would otherwise be entitled to.
* Right to prevent use of his/her biological sample (DNA, cell-line, etc.) at any time during the conduct of the research.
* Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same.
* Publication, if any, including photographs and pedigree charts.
* Any other pertinent information. Additional elements, which may be required
* Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
* Additional costs to the Subject that may result from participation in the study.
* The consequences of a Subject’s decision to withdraw from the research and procedures for orderly termination of participation by Subject.
* Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provide
* A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable
* Approximate number of Subjects to be enrolled in the study

b. The person (PI/Co I) who explains the study will allow enough time for the potential subject to read the consent form and will answer any questions that are raised.

c. The PI/Co I obtaining the consent will ensure the following:

* Adequate time provided to subject before participation All of the subject’s questions were answered.
* The subject understands the study requirements. The subject signed the consent freely & voluntarily.
* The consent form is signed and dated by the subject and the PI/Co I who obtained the consent, and Impartial Witness and or LAR, if applicable.
* The subject is given a copy of the signed & dated consent form.

d. PI / CTC should ensure that prior to a participant’s participation in the research study; the written consent document should be personally signed and dated by the subject and by the PI/Co I who conducts the informed consent discussion.

e. The PI/CTC will ensure that the original, signed copy of the consent is stored in the separate file and a copy is given to subject.

f. After initial consent process or participating in the study, if participant is not willing to consent or want to prematurely withdraw consent for the study, PI should respect the participant decision and should document the same in the source notes. Although a participant is not obliged to give his or her reasons for not consenting or prematurely withdrawing from the study, the PI/Co I can make a reasonable effort to ascertain the reason, while fully respecting the participant’s rights.

8.3.3 Obtaining Informed Consent from literate subjects / patients:

* PI/ Co I must explain the study to the potential subject verbally (in the preferred language of the subject), providing all pertinent information (mentioned in 8.3.2.a), and must allow the potential subject ample opportunity to ask questions.
* Following this verbal explanation, the potential subject should be provided with a written consent form/ Patient Information Sheet (PIS) and should
* give sufficient time to consider whether or not to participate in the research study.

c. After allowing the potential subject time to read the consent form, an Investigator should meet with the potential subject and answer any additional questions he/she may have.

d. Once an individual had all his/her questions answered and has agreed to voluntarily participate in the study, the subject should sign and date the consent form.

e. The PI/ Co I who has explained and taken consent from the subject must also sign and date the consent form.

f. The Investigator’s signature means that the informed consent process has taken place with the subject and that the subject meets all eligibility criteria as per protocol was appropriately consented (as described above) understands the requirements of the study

g. The entire consent process including the questions asked by the subject and answers given by the PI/ Co I must be documented according to legal and regulatory requirements in the source notes, additionally the documentation should include:

* Subject name
* Enrollment number/ Trial ID number
* Date of birth and completed age
* Language, version number and date of Informed consent Form
* Date on which the Subject & Investigator signed the Consent Form

h. The Investigator obtaining the consent (delegated by the PI) will document the process in the subject’s source notes. The CTC present at the time of consent process can document the consent process in the source notes and will sign and date the consent process. The PI/Co I sign and date the same consent process and confirm the process written by CTC is appropriate.

**8.3.4 Obtaining Informed Consent from non-English speaking subjects / patients:**

a. If the patient population contains numerous non-English speaking people who may qualify for the study, the PI/Co I will ensure that the informed consent is translated into the local languages and that the translated consent form is also approved by the IEC.

b. The CTC will file the certificate of translation in the TMF with the translated consent

c. PI/Co I who speaks the same language as the potential subject will explain the study to the subject and will also be available at subsequent study visits to ensure that the subject’s questions can be answered as the study progresses.

d. Before obtaining the consent from the potential patient kindly follow the above mentioned points 8.3.2.a, b, and c.

e. The subject must sign and date the consent in the preferred language. The Investigator obtaining the consent will document the process in the subject’s source notes as mentioned in 8.3.3.g

f. The CTC present at the time of consent process can document the consent process in the source notes and will sign and date the consent process. The PI/Co I sign and date the same consent process and confirm the process written by CTC is appropriate

**8.3.5 Obtaining Informed Consent from illiterate subjects / patients:**

a. If a person identified for the study who speaks and understand English and or any other local language, but cannot read and write, can be enrolled in a study as illiterate subject, consistent with applicable regulations.

b. The PI must ensure (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to participate in the research study.

a. The information should be given (as mentioned in point 8.3.2.a) to the Subjects and / or their legal representatives in a language and at a level of complexity that is understandable to the Subject(s) and or his/ her LAR in both written and oral form, whenever possible.

b. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study.

c. An impartial third party should witness the entire consent process and sign the consent document. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

d. The subject must give consent by putting his / her thumb impression on the consent form. By convention subject should give left thumb impression.

e. Alternatively the subject (if capable) can sign the consent form. In such case it has to be documented in the source notes that though the subject is illiterate but is capable to sign.

f. Impartial Witness and or LAR present during the entire consent process must sign the consent form with date in presence of investigator obtaining consent.

g. After obtaining consent, follow the above mentioned points 8.3.2.b, c & d

h. For documenting the process in source notes, follow the points 8.3.3.g & h

**8.3.6 Obtaining Informed Consent from Children**

a. PI/Co I must obtain assent form from a subject and consent form from a parent in case of children between 7-17 years of age.

b. If recommended by IEC both parents should sign assent as well as consent for child.

c. An assent form is required for the study will be determined by the IEC. If it is required and the minor is reasonably able to understand the study purpose and requirements, then in addition to having consent form signed by the parent, the minor must sign the assent form. (Child in between 7 – 17 year of age are eligible for assent)

d. The PI/Co I will explain the study in language appropriate to the child’s age before any study procedures, including screening evaluations, will be accomplished. This explanation will include a discussion of the discomforts or inconveniences the child may experience if he/she agrees to participate.

e. The PI/Co I who explains the study will ensure that a parent or legal guardian for the child is present during the explanation and observes the assent procedure.

f. The PI/Co I who explains the study will allow enough time for the minor to read the assent form and will answer any questions that are raised.

g. The PI/Co I obtaining the assent will ensure the following:

* All of the parent’s and minor’s questions were answered.
* The parent and minor understand the study requirements.
* The parent or legal guardian signed the assent and consent freely & voluntarily.
* The minor signed the assent voluntarily.
* The assent signed and dated by the subject, parent or legal guardian and the PI/Co I who obtained the consent.
* The consent form was signed and dated by the parent or legal guardian and the PI/Co I who obtained the consent.
* The parent and minor are given copies of the signed consent and assent.

h. The CTC will ensure that the original, signed copies of the assent and consent are stored in the separate file and one copy should be given to parent and minor.

i. After obtaining consent from parent and assent from children, follow the above mentioned points 8.3.2.a, b, c & d

**8.3.7 Revised Informed Consent Form**

When the Investigator / CTC receive updates to the Investigator’s Brochure, IND Safety Reports, or protocol amendments, he/she should also review the informed consent to determine if it should be revised to reflect the new information.

No changes to the study procedures that are a result of the protocol amendment will be implemented until the IEC approval of the amendment is received.

If the consent form is changed as a result of a protocol amendment, the PI/CTC will ensure that the revised consent is approved by the IEC.

The PI/ Co I will explain the changes to the subject and will provide the subject with the revised consent form for review and signature.

If the subject decides to continue in the study and signs the consent form, the CTC/delegated member will provide the subject with a copy of the revised consent and will place the original in the separate file.

**8.3.8 If Incorrect version of ICF used**

If the Investigator/CTC discovers that an outdated version of the consent form was used for a subject whose participation in the trial has not been completed, he/she will:

* Contact the subject and explain the reason for re-consenting the subject the correct version.
* Instruct the subject to sign the consent with current date while signing and dating the correct version (i.e., do not back-date the consent form).
* Maintain both signed versions of the consent in the separate file.
* Write an explanatory memo in the file so that future auditors will understand why two signed informed consent documents for the same subject are present in the file. If the CTC is unable to contact the subject, the explanatory memo should also document the dates and methods by which the attempts to reach the subject were made.

**8.4 Applicable staff**

This SOP applies to all the personnel of the clinical research team and others who may be responsible for making decisions about participation in clinical research at [Institution].

These include the following:

* Investigator
* Legal Expert CTC
* Support staff if required

**8.5 Staff responsible for Implementation**

DEPARTMENT OF CLINICAL RESEARCH 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 [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 312.60 – General Responsibilities of Investigators

2. 21 CFR 50.20 – General Requirements for Informed Consent

3. 21 CFR 50.25 – Elements of Consent

4. 21 CFR 50.27 – Documentation of Informed Consent

5. 45 CFR 46.116 – General Requirements for Informed Consent

6. 45 CFR 46.117 – Documentation of Informed Consent

7. GCP Informed Consent Process

8. ICH Guidelines for Good Clinical Practice (E6) section 1.28 – Informed Consent

9. ICH Guidelines for Good Clinical Practice (E6) section 1.37 – Legally Authorized Representative

10.Schedule Y – Appendix V