National Accreditation Board for Hospitals and Healthcare Providers (NABH)

Accreditation Standards for Clinical Trial in India
Ethics Committee, Investigator and Clinical Trial Site

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SUMMARY

The criteria to be followed for accreditation of Ethics Committee, Investigator and the Site where clinical trials are to be carried out are given in Section 1, 2 and 3 respectively of this document. A summary is given below:

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• Frequency of ethics committee meetings.  
• Receipt, review and decision making of proposals.  
• Review of protocol amendments.  
• Procedure for deliberations and maintaining minutes.  
• Periodic review and oversight.  
• Procedure to be followed for vulnerable population.  
• Review of Informed Consent Document (subject information sheet and informed consent form) and informed consent process.  
• Reporting, analysis of SAEs and making opinion on compensation.  
• Handling issues related to non-compliances, protocol violation, complaints by the participants and other stakeholders.  
• Declaration of conflict of interest and confidentiality agreement.  
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• Control and archiving of records.  
• SOP on SOP. |
| Section 2: Accreditation of Investigator      | Standards: 7 Objective Elements: 39 | • Investigator roles and responsibilities  
• Investigator education, qualification and experience  
*Investigator will follow site SOPs and Study Protocol for all essential trial activities. If |

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there is a contradiction, the study protocol requirement will be followed

Investigator will follow procedures but not limited to on informed consent, safety reporting and management, delegation of responsibilities and training, investigational product, protocol compliance and protocol deviations, clinical trial documentation, records retention and archival and destruction.

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<th>Section 3: Accreditation of Clinical Trial Site</th>
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<td>b) Informed consent, including procedures for audio-visual recording of consent.</td>
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Objective of Section 1: Ethics Committee (EC) is adequately qualified, experienced, and knowledgeable in ethical issues and applicable rules and regulations for conduct of clinical trials ensuring scientific integrity and protection of subject rights, safety and wellbeing.

Outcome of Section 1:

- Ethics Committee competently assesses risk and scientific validity of trials.
- Ethics Committee has appropriate measures to ensure protection of subject rights, safety and wellbeing.
- There shall be transparency in Ethics Committee functioning and procedures are followed for all essential activities.
## Summary of Standards

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<td>1.1</td>
<td>Authority for formation of Ethics Committee: There shall be documented procedures to establish the authority for formation of Ethics Committee as per applicable rules and regulations.</td>
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<td>1.2</td>
<td>Standard Operating Procedures (SOPs): The Ethics Committee has and follows written SOPs for its different functions as per applicable rules and regulations.</td>
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<tr>
<td>1.3</td>
<td>Ethics Committee Composition: The Ethics Committee meets the requirement for membership as per applicable rules and regulations. Procedures are documented and followed.</td>
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<td>1.4</td>
<td>Protection of subject rights, safety and wellbeing: The Ethics Committee follows documented procedures for subject protection.</td>
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<td>1.5</td>
<td>Administrative support: The Ethics Committee follows documented procedures/terms of reference to ensure that administrative support for its activities is adequate.</td>
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<td>1.6</td>
<td>Review Process: The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and periodic reviews.</td>
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<td>1.7</td>
<td>Decision making and post meeting activities: The Ethics Committee follows documented procedures for decision making process and post meeting activities.</td>
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<td>1.8</td>
<td>Monitoring: The Ethics Committee follows documented procedures for monitoring and for-cause assessment.</td>
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<td>1.9</td>
<td>Self-Assessment: The Ethics Committee has and follows documented procedures for self-assessment.</td>
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<td>1.10</td>
<td>Record keeping and archival: The Ethics Committee follows documented procedures for record keeping and archiving.</td>
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## Standards and Objective Elements

### Standard

| 1.1 | Authority for formation of Ethics Committee: There shall be documented procedures to establish the authority for formation of Ethics Committee as per applicable rules and regulations. |

### Objective Elements

1.1.1 Procedures shall be followed to specify the authority under which the Ethics Committee is established and administratively governed.

1.1.2 There shall be a documented policy to ensure the independence of the Ethics Committee in its functioning and decision making.

1.1.3 Ethics Committee shall function as per applicable rules and regulations.

### Standard

| 1.2 | Standard Operating Procedures (SOPs): The Ethics Committee has and follows written SOPs for its different functions as per applicable rules and regulations. |

### Objective Elements

1.2.1 Procedures shall be in place and well defined for the development, review and revision of SOPs.

1.2.2 List of mandatory procedures for Ethics Committee are as follows:

   a. Terms of reference for Ethics Committees
      i. Composition (names and qualification of the members), new induction, resignation, replacement or removal of members.
      ii. Declaration of conflict of interest and confidentiality agreement.
      iii. Frequency of ethics committee meetings.
      iv. Financial declaration of payments received and disbursed.
      v. Policy regarding training for new and existing committee members.
      vi. Policy of communication with different stake holders.
      vii. Any other or to do all such other lawful acts, deeds and things as are incidental & conducive to attainment of objects of any of them.

   b. Protocol submission
      i. Procedure for receipt of applications – original, revised, amended with supporting annexes.
c. Ethical review  
   i. Review and decision making of proposals.  
   ii. Procedure to be followed for vulnerable population.  
   iii. Procedure for risk-benefit analysis.  
   iv. Procedure for review of Informed Consent Document (subject Information Sheet and Informed Consent Form) and informed consent process.  
   v. Generally to do all such other things as are incidental or conducive to the attainments of above objects.

d. Decision making, minutes recording, post meeting activities including monitoring  
   i. Procedure for deliberations and maintaining minutes  
   ii. Procedure for reporting, analysis of SAEs and making opinion on compensation.  
   iii. Procedure for periodic review and oversight.  
   iv. Procedure for handling issues related to non-compliance, protocol violation, negligence, complaints by the participants and other stake holders.  
   v. Procedure for review of protocol amendments.

e. Documentation and archiving  
   i. Procedure for control and archiving of records with confidentiality.

Standard

1.3 Ethics Committee Composition: The Ethics Committee meets the requirement for membership as per applicable rules and regulations. Procedures are documented and followed.

Objective Elements

1.3.1 Composition shall be multidisciplinary and multisectorial and adequate for its functioning.

1.3.2 Subject experts and representatives of vulnerable subjects shall be invited as required with prior intimation.

1.3.3 Membership, appointment, reconstitution and resignation shall be defined as per terms of reference.

1.3.4 Roles and responsibilities of members shall be well defined.

1.3.5 Ethics Committee members shall be trained (initial and ongoing) in applicable rules and regulations and Ethics Committee SOPs.

1.3.6 Conflict of interest and confidentiality shall be addressed at the time of composition.
Standard 1.4  Protection of subject rights, safety and wellbeing: The Ethics Committee follows documented procedures for subject protection.

Objective Elements

1.4.1. Rights and responsibilities of subject shall be documented and are specified.

1.4.2. Subject’s participation and withdrawal from the trial shall be voluntary and with prior intimation.

1.4.3. Subjects shall be informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial.

1.4.4. Confidentiality and privacy of subjects shall be protected.

1.4.5. Monitoring of trials shall be done to ensure equitable selection of subjects, with special attention to vulnerable and high risk subjects.

1.4.6. Compensation provided to subjects for participation in the trial shall be appropriate and as per the rules and regulation and is reflected in the contract.

1.4.7. Serious adverse events shall be addressed, adequate medical care provided and an appropriate reporting mechanism is followed as per applicable rules and regulations.

1.4.8. Compensation for injury to the subject shall be as per the rules and regulations and monitored for noncompliance.

1.4.9. Complaints and concerns of subjects shall be addressed and managed appropriately, if the need arises.

Standard 1.5  Administrative support: The Ethics Committee follows documented procedures / terms of reference (TOR) to ensure that administrative support for its activities is adequate.

Objective Elements

1.5.1. Adequate finance, human resource allocation and secretariat for administrative work and record keeping shall be ensured, with due care and confidentiality.

1.5.2. There shall be financial transparency of Ethics Committee activities and functioning.
1.5.3. There shall be a procedure for communication between ethics committee, investigator/relevant site staff, institution and regulatory authority.

Standard

| 1.6  | **Review Process:** The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and periodic review. |

**Objective Elements**

1.6.1 Review shall be done by the Ethics Committee in a formal meeting within a reasonable time following appropriate submission of documents by investigator as per rules and regulations and Ethics committee requirement.

1.6.2 Initial review of proposed clinical trial shall evaluate the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations.

1.6.3 Informed consent document, assent form (as applicable) and translations shall be reviewed for appropriateness of language, accuracy and completeness of information.

1.6.4 Ethics Committee shall review the informed consent processes proposed to be followed at the site for a particular trial to ensure that subject/LAR are provided appropriate information, adequate time is given and impartial witness used as applicable.

1.6.5 Recruitment strategies shall be evaluated.

1.6.6 Proposals involving special group and vulnerable population shall be evaluated as per rules and regulations.

1.6.7 Contract and budget shall be evaluated, for indemnity, compensation, roles and responsibilities as per applicable rules and regulations.

1.6.8 Review of amendments to the originally approved protocol, consent forms and investigators brochure shall be done in formal meetings to evaluate the risk to trial subjects.

1.6.9 Periodic review of trial shall be done for continuation, risk evaluation and adverse event monitoring.
Standard

1.7 Decision making and post meeting activities: The Ethics Committee follows documented procedures for decision making process and post meeting activities.

Objective Elements

1.7.1 Decision making process (approval/disapproval/pending/revoking) shall be as per applicable rules and regulations, ensuring quorum and consensus/voting requirements are fulfilled.

1.7.2 The subject shall be recruited into the trial only after written approval from Ethics Committee and approval by regulatory authority.

1.7.3 Conflict of interest shall be declared prior to the review and voluntary withdrawal during decision making process is documented.

1.7.4 Decisions shall be based on risk assessment, scientific validity and adherence to ethical principles for the initial and periodic approvals.

1.7.5 Deliberations and decisions made during the meetings shall be documented, approved, signed and maintained as minutes of meeting.

1.7.6 Protocol deviations and non-compliances shall be evaluated and appropriate actions shall be taken as per rules & regulations.

1.7.7 Serious adverse events shall be analysed and compensation amount assessed and reported to regulatory authority as per rules and regulations.

1.7.8 All decisions/opinions shall be notified to the investigator in writing.

Standard

1.8 Monitoring: The Ethics Committee follows documented procedures for monitoring and for-cause assessment.

Objective Elements

1.8.1 Subject’s rights, safety and wellbeing shall be monitored.

1.8.2 Adequacy and continuity of consent process shall be ensured.

1.8.3 For-cause assessments shall be conducted following non-compliance and/or complaints for the trials approved by the ethics committee.

1.8.4 Opportunities for improvement shall be identified and appropriate actions initiated.
Standard

1.9 Self-Assessment: The Ethics Committee has and follows documented procedures for self-assessment.

Objective Elements

1.9.1 Periodic self-assessments shall be conducted.

1.9.2 Corrective and preventive actions (as required) shall be implemented accordingly.

Standard

1.10 Record keeping and archival: The Ethics Committee follows documented procedures for record keeping and archiving.

Objective Elements

1.10.1 Security, confidentiality and integrity of all proposals and associated documents shall be reviewed from time to time and administrative communication shall be maintained as per regulatory requirement and with confidentiality.

1.10.2 Documents and records shall be archived after completion /termination of trial as per applicable rules and regulations.

1.10.3 Record retrieval policies and procedures shall be in place to ensure access to information for inspection and audit and continual protection of trial subjects post trial closure with prior permission in writing.
Note: Investigator refers to the Principal Investigator in this document. Investigator follows documented procedures i.e SOPs for clinical trial conduct. If there is a contradiction between SOPs and study protocol, the protocol requirements should be followed.

Objective of Section 2: Investigators are adequately qualified, experienced and knowledgeable in trial processes, ethical issues and applicable rules and regulations for conduct of clinical trials ensuring data integrity and protection of subject rights, safety and wellbeing.

Outcome of Section 2:

- Clinical trial conduct is ethical and in compliance with the applicable rules and regulations.
- There are appropriate measures to ensure protection of subject rights, safety and wellbeing.
- There is transparency in the conduct of clinical trials and documented procedures are followed by the investigators/relevant site staff for all essential activities.
## Summary of Standards

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<td>2.1</td>
<td>Qualification, Experience and Training: The Investigator follows documented procedures to ensure that investigator/relevant site staff is qualified, knowledgeable and follow the applicable rules and regulations.</td>
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<td>2.2</td>
<td>Compliance to standard operations procedures (SOPs): The Investigator follows documented procedures to ensure that clinical trial is conducted in compliance to applicable rules and regulations.</td>
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<td>2.3</td>
<td>Protection of subject rights, safety and wellbeing: The Investigator follows documented procedures to provide adequate protection to subjects and addresses their concerns.</td>
</tr>
<tr>
<td>2.4</td>
<td>Informed consent process: The Investigator follows documented procedures to ensure adequate consent process as per applicable rules and regulations:</td>
</tr>
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<td>2.5</td>
<td>Safety Reporting and Management: The Investigator follows documented procedures for safety reporting and management as per applicable rules and regulations.</td>
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<tr>
<td>2.6</td>
<td>Clinical Trial documents and materials: The Investigator follows documented procedures to maintain clinical trial documents and materials as per applicable rules and regulations.</td>
</tr>
<tr>
<td>2.7</td>
<td>Clinical Trial Conduct: The Investigator conducts the clinical trial as per study protocol and applicable rules and regulations.</td>
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## Objective Elements

### 2.1.1 Criteria for qualifications and experience of an investigator to qualify for accreditation shall be as follows:

- **a)** Should have a medical degree registered with the Medical Council of India (MCI)/State Medical Councils or a dental degree registered with the Dental Council of India/State Dental Councils.

- **b)** Should have training in Good Clinical Practice and be aware of regulatory requirements for clinical trials.

- **c)** Should be well-versed with principles and procedures of informed consent process.

- **d)** Should have a clear understanding of ethical issues involved in clinical trials including rights of subjects.

- **e)** Should have knowledge and expertise in the area being studied in a particular trial and also should have experience of minimum two years in clinical trial/research.

### 2.1.2 Initial and ongoing training shall be conducted for the investigator/relevant site staff at regular interval.

### 2.1.3 Investigator shall have adequate number of qualified site staff for proper conduct of trial.

## Standard

### 2.2 Compliance to Standard Operations Procedures (SOPs): The Investigator follows documented procedures to ensure that clinical trial is conducted in compliance to applicable rules and regulations.

## Objective Elements

### 2.2.1 Clinical trial conducted by the investigator shall be in compliance with SOPs and applicable rules and regulations.
2.2.2 Investigator shall follow procedures for submission of clinical trial proposal to the Ethics Committee for review and approval.

2.2.3 Investigator shall follow procedures on informed consent, safety reporting and management, delegation of responsibilities and training, investigational product, protocol compliance and protocol deviations, clinical trial documentation, records retention and archival and destruction.

Standard

| 2.3 | Protection of subject rights, safety and wellbeing: The Investigator follows documented procedures to provide adequate protection to subjects and addresses their concerns. |

Objective Elements

2.3.1 Investigator shall be aware of subject's rights and responsibilities.

2.3.2 Subject selection shall be fair and equitable as per applicable rules and regulations.

2.3.3 Subject's participation and withdrawal from the trial shall be voluntary and with prior intimation.

2.3.4 Subjects shall be informed (initial and ongoing) of the associated risks and benefits of the trial.

2.3.5 Confidentiality and privacy of subjects shall be well protected.

2.3.6 Investigator shall provide continuous information and education to subjects and addresses their concerns and queries.

2.3.7 Compensation provided to subjects for participation in the trial shall be appropriate and as per the contract.

2.3.8 Investigator shall provide adequate medical care and safety management of trial subjects and reports and analyses serious adverse events as per applicable rules and regulations.
Standard

2.4 Informed consent process: The Investigator follows documented procedures to ensure adequate consent process as per applicable rules and regulations.

Objective Elements

2.4.1 Investigator shall have and follows a documented informed consent process (initial and ongoing) adhering to the obligation and responsibility of an investigator as per applicable rules and regulations.

2.4.2 Investigator shall obtain ethics committee approval for the Informed Consent Document to be provided to subject/LAR.

2.4.3 The Subject/Legally Acceptable Representative shall be adequately informed to understand the information given in the informed consent document.

2.4.4 Adequate measures shall be in place for consenting of vulnerable subjects.

2.4.5 Withdrawal of consent by the subject shall be documented and reported.

Standard

2.5 Safety Reporting and Management: The Investigator follows documented procedures for safety reporting and management as per applicable rules and regulations.

Objective Elements

2.5.1 Safety reporting and management of trial subjects shall be done as per the applicable rules and regulations.

2.5.2 Adequate medical and emergency care for any adverse events and serious adverse events (SAEs) shall be provided in a timely manner.

2.5.3 Investigator shall report all serious adverse events as per the regulatory requirements to the Ethics Committee and regulatory authorities and follows ethics committee recommendation to terminate or suspend a trial (as applicable).

2.5.4 Investigator shall report and provides adequate information as per the regulatory requirements to Ethics Committee and regulatory authority in case of death in a clinical trial.

2.5.5 Continuity in medical and emergency care shall be provided as per applicable rules and regulations.
2.5.6 Protocol deviations affecting safety of subjects and integrity of data shall be reported, analyzed and accordingly appropriate action be taken, if need arises, without prior intimation.

Standard

2.6 Clinical Trial documents and materials: The Investigator follows documented procedures to maintain clinical trial documents and materials as per applicable rules and regulations.

Objective Elements

2.6.1 The records and documents shall be attributable, legible, contemporaneous, original and accurate (ALCOA).

2.6.2 Confidentiality/privacy of subjects and trial data shall be maintained.

2.6.3 Subject files and clinical trial related documents shall be maintained adequately and with confidentiality.

2.6.4 All trial related documents shall be stored in a secure and systematic manner to prevent loss or accidental destruction of the documents.

2.6.5 Clinical trial materials shall be maintained, accounted and stored safely and with confidentiality.

Standard

2.7 Clinical Trial Conduct: The Investigator conducts the clinical trial as per study protocol and applicable rules and regulations.

Objective Elements

2.7.1 Approval of the accredited Ethics Committee and regulatory authority shall be obtained before initiation of the study at the site.

2.7.2 Clinical trial conducted by the investigator shall be registered in the Clinical Trials Registry of India (www.ctri.nic.in) before enrolling the first subject for the trial.

2.7.3 Investigator shall declare financial aspects for the clinical trial to the Ethics Committee prior to conduct of trial.

2.7.4 Clinical trial shall be conducted in compliance to the approved protocol.

2.7.5 Investigator shall oversee the activities of the site staff.
2.7.6 Investigator shall have appropriate communication with the Ethics Committee, sponsor and clinical trial site authority.

2.7.7 Investigator shall have appropriate coordination with other departments for multidisciplinary activities for subject safety (as applicable).

2.7.8 Investigator shall follow procedures for appropriate receipt, storage, dispensing and accountability of investigational product in compliance to the study protocol, applicable rules and regulations.

2.7.9 Periodic status report of clinical trial shall be submitted to the Ethics Committee and recommendations shall be followed accordingly.
Objective of Section 3: Clinical Trial Sites shall have adequate infrastructure, facilities, documented procedures and oversight mechanism to support clinical trial conduct as per applicable rules and regulations ensuring trial integrity and protection of subject rights, safety and wellbeing.

Outcome of Section 3:

- Clinical Trial conduct must be ethical and in compliance with the applicable rules and regulations.

- There are appropriate measures to ensure protection of subject rights, safety and wellbeing.

- There is transparency in the conduct of Clinical Trials and documented procedures are available and followed by accredited investigators associated with the clinical trial site.

- There is an oversight mechanism by the Clinical Trial Site to maintain the ethical and quality standards.
## Summary of Standards

<table>
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<th>3.1</th>
<th>Responsibility of management for the Clinical Trial Site(s): The Clinical Trial site has adequate infrastructure and facilities to support clinical trial conduct as per applicable rules and regulations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.2</td>
<td>Qualification, Experience and Training: The Clinical Trial Site follows documented procedures to ensure that investigators and relevant site staff is qualified and knowledgeable about applicable rules and regulations.</td>
</tr>
<tr>
<td>3.3</td>
<td>Site SOPs and documented procedures: The Clinical Trial Site has documented procedures to describe clinical trial conduct in compliance to applicable rules and regulations.</td>
</tr>
<tr>
<td>3.4</td>
<td>Protection of subject rights, safety and wellbeing: Clinical Trial Site follows documented procedures to ensure adequate protection of research subjects and addresses concerns of research subjects.</td>
</tr>
<tr>
<td>3.5</td>
<td>Clinical Trial materials, documentation and IT systems: Clinical Trial Site follows documented procedures for maintenance of clinical trial materials, documentation and IT systems as per applicable rules and regulations.</td>
</tr>
<tr>
<td>3.6</td>
<td>Clinical Trial Oversight: The Clinical Trial Site follows quality control procedures to support and oversee clinical trial conduct at the site in compliance to applicable rules and regulations.</td>
</tr>
</tbody>
</table>
### Standard 3.1

**Responsibility of management for the Clinical Trial Site(s):** The Clinical Trial site has adequate infrastructure and facilities to support clinical trial conduct as per applicable rules and regulations.

#### Objective Elements

3.1.1 General facilities and equipment that are considered essential for clinical trial sites shall be available.

3.1.2 Basic equipment for subject evaluation and medical emergencies shall be available and maintained appropriately throughout the duration of trial.

3.1.3 Appropriate diagnostics facilities for conduct of clinical trials shall be available.

3.1.4 Necessary resources (as required) shall be provided to the Ethics Committee for its proper functioning.

3.1.5 There shall be appropriate storage and inventory management of investigational product in compliance to applicable rules and regulations.

### Standard 3.2

**Qualification, Experience and Training:** The Clinical Trial Site follows documented procedures to ensure that investigators and relevant site staff is qualified and knowledgeable about applicable rules and regulations.

#### Objective Elements

3.2.1 Qualifications, experience and research credentials of investigator and relevant site staff shall be well defined and specified.

3.2.2 Relevant policies and procedures shall be made available to investigators, research site staff and the Ethics Committee.

3.2.3 Training and education program shall be in place for investigator, relevant research site staff and the Ethics Committee.
Standard

3.3  Site SOPs and documented procedures: The Clinical Trial Site has documented procedures to describe clinical trial conduct in compliance to applicable rules and regulations.

Objective Elements

3.3.1  Site standard operating procedures (SOPs) for essential activities for conduct of clinical trial shall be in place. Procedures include the following (but not limited to):
   a) Subject protection policy (including transparent mechanism of enrolment and continuity of care of subjects in clinical trials)
   b) Informed consent, including procedures for audio-visual recording of consent
   c) Medical management of adverse events
   d) Adverse events and serious adverse events reporting (including emergency care) and compensation for trial injury
   e) Roles and responsibilities of study team
   f) Site research team training
   g) Research pharmacy (investigational product management)
   h) Protocol compliance and protocol deviations
   i) Documentation policy
   j) Storage and retention of trial related documents
   k) Conflict of interest disclosure policy
   l) Resources (Access to adequate laboratory facilities (preferably a certified/accredited), adequate space and required medical and paramedical personnel, adequate arrangement for volunteers, subjects for isolation, recreation, food as applicable)
   m) Equipment calibration and maintenance
   n) Quality management plan (including quality control measures)
   o) Oversight by Ethics Committee

Any other or to do all such other lawful acts, deeds and things as are incidental & conducive to attainment of objects of any of them.

Standard

3.4  Protection of subject rights, safety and wellbeing: Clinical Trial Site follows documented procedures to ensure adequate protection of research subjects and addresses concerns of research subjects.

Objective Elements

3.4.1  Rights and responsibilities of subject shall be documented.

3.4.2  Subject selection shall be fair and equitable as per applicable rules and regulations.
3.4.3 Subject’s voluntary participation and withdrawal from the trial shall be ensured, with prior intimation.

3.4.4 Subjects shall be informed (initial and ongoing) of the associated risks and benefits of the trial.

3.4.5 Confidentiality and privacy of subjects shall be protected.

3.4.6 Adequate resources for conducting consent process (initial and ongoing) shall be provided.

3.4.7 Proper procedures shall be in place to address concerns and queries of research subjects/family.

3.4.8 Adequate medical emergency care and safety shall be provided for trial subject.

3.4.9 Procedures shall be available for arrangement of volunteers, isolation, recreation, food and other facilities as and when required.

**Standard**

| 3.5 | Clinical Trial materials, documentation and IT systems: Clinical Trial Site follows documented procedures for maintenance of clinical trial materials, documentation and IT systems as per applicable rules and regulations. |

**Objective Elements**

3.5.1 Procedures shall be in place for subject registration, identification and documentation of medical records.

3.5.2 Subject files and clinical trial related information/documentation (paper and/or electronic) shall be well maintained.

3.5.3 Procedures shall be in place for adequate receipt, identification, safe storage and maintenance of clinical trials material, investigational products and biological samples.
Standard

3.6 Clinical Trial Oversight: The Clinical Trial Site follows quality control procedures to support and oversee clinical trial conduct at the site in compliance to applicable rules and regulations.

Objective Elements

3.6.1 Clinical Trial Site shall ensure regulatory compliance of Ethics Committee functioning.

3.6.2 There shall be a plan for monitoring the conduct of study and addressing deviations and improvements are made as required to ensure compliance to SOPs and applicable rules and regulations.

3.6.3 Clinical Trial Site shall ensure that medical care and medical emergencies are handled as per applicable rules and regulations.

3.6.4 There shall be a process to ensure appropriate execution of clinical trial agreements in compliance to applicable rules and regulations.

3.6.5 There shall be a process to address grievances and non-compliance which could affect the rights, safety and privacy of research subjects or affect the quality of data.

3.6.6 Procedures shall be in place and implemented to identify, manage and eliminate financial conflicts of interest of the Researchers/Investigators/Ethics Committee/Clinical Trial Site that could influence the conduct of the trial.

3.6.7 There shall be a policy to ensure continuity of trial in case of staff and investigator attrition.
Abbreviations

1. **AE**: Adverse Event
2. **BA/BE**: Bioavailability / Bioequivalence
3. **CDSCO**: Central Drugs Standard Control Organization
4. **COI**: Conflict of Interest
5. **DCGI**: Drugs Controller General of India
6. **DSMB**: Data Safety Monitoring Board
7. **EC**: Ethics Committee
8. **ICMR**: Indian Council of Medical Research
9. **GCP**: Good Clinical Practice
10. **IP**: Investigational product
11. **IT**: Information Technology
12. **LAR**: Legally Acceptable Representative
13. **SAE**: Serious Adverse Events
14. **SOP**: Standard Operating Procedures
15. **TOR**: Terms of Reference