National Accreditation Board for Hospitals and Healthcare Providers (NABH)

Accreditation Standards for Clinical Trials

Ethics Committee, Investigator and Clinical Trial Site

1st Draft
SUMMARY

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

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List of mandatory procedures for Ethics Committee:

- Composition, procedures for new induction and resignation of members
- 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
- Financial declaration of payments received and disbursed
- Training for committee members
- Communication with different stakeholders
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<td>• Investigator role and responsibilities</td>
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<td>• Investigator education, qualification and experience</td>
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<td>• Subject Protection Policy (including transparent mechanism of enrolment)</td>
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<td>• Informed Consent, including procedures for Audio-visual recording of consent</td>
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<td>• Adverse Events and Serious Adverse Events Reporting (including emergency care)</td>
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<td>• Quality Management Plan (including quality control measures)</td>
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</table>
*Both Independent Ethics Committee for BA/BE studies and Institutional EC for clinical trials.

**Objective of Section 1:** Ethics Committee (ECs) 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 is *transparency in Ethics Committee functioning* and procedures are followed for all essential activities.
## Summary of Standards

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

Standard

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

Objective Elements

1.1.1 Procedures are in place to specify the authority under whom the Ethics Committee is established and administratively governed.

1.1.2 Documented Policy to ensure the Independence of the Ethics Committee in its functioning and decision making.

1.1.3 Ethics Committee must be registered.

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 are in place for the update of SOPs (i.e SOP on SOPs)

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

a). SOPs (Terms of reference) for Ethics Committees
   • Composition (names and qualification of the members), new induction, resignation, replacement or removal of members.
   • Declaration of conflict of interest and confidentiality agreement.
   • Frequency of ethics committee meetings.
   • Financial declaration of payments received and disbursed.
   • Policy regarding training for new and existing committee members.
   • Policy of communication with different stakeholders.

b). SOPs for protocol submission
   • Procedure for receipt of applications – original, revised, amended with supporting annexes.

c). SOPs for ethical review
   • Review and decision making of proposals.
• Procedure to be followed for vulnerable population.
• Risk-benefit analysis.
• Procedure for review of Informed Consent Document (subject Information Sheet and Informed Consent Form) and informed consent process.

d). SOPs for post meeting activities including monitoring
• Procedure for deliberations and maintaining minutes
• Procedure for reporting, analysis of SAEs and making opinion on compensation.
• Procedure for periodic review and oversight.
• Procedure for handling issues related to non-compliance, protocol violation, negligence, complaints by the participants and other stakeholders.
• Procedure for review of protocol amendments.

e). SOPs for documentation and archiving
• 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 is multidisciplinary and multisectorial and is adequate for its functioning.

1.3.2 Subject experts and representatives of vulnerable subjects are invited as required.

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

1.3.4 Roles and responsibilities of members are well defined.

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

1.3.6 Conflict of interest and confidentiality is 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. Procedures include the following (but not limited to):

Objective Elements

1.4.1. Rights and responsibility of subject are documented.

1.4.2. Subject's participation and withdrawal from the trial is voluntary.

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

1.4.4. Confidentiality and privacy of subjects is protected.

1.4.5. Monitoring of trials is 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 is appropriate and as per the contract.

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

1.4.8. Compensation for injury to the subject is appropriate as per the regulations and monitored for noncompliance.

1.4.9. Complaints and concerns of subjects are addressed and managed appropriately.

Standard

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

Objective Elements

1.5.1. Adequate financial, human resource allocation and secretariat for administrative work and record keeping is ensured.

1.5.2. There is financial transparency of Ethics Committee activities and functioning.

1.5.3. There is a procedure for communication between Ethics Committee, investigator/relevant site staff and institution.
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** is done by the Ethics Committee in a formal meeting within a reasonable time following appropriate submission of documents by investigator as per rules and regulation. Investigator conducts only three trials at a time.

1.6.2 **Initial review** of proposed clinical trial evaluates the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations. Minimal risk is defined.

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

1.6.4 Ethics Committee reviews the **informed consent processes** to ensure that subject/LAR are provided appropriate information, adequate time is given and impartial witness used as applicable.

1.6.5 **Recruitment strategies** are evaluated.

1.6.6 Proposals involving Special group (pregnant mother and children) and vulnerable **population** are evaluated as per regulations.

1.6.7 **Contract and budget** is evaluated, for indemnity, compensation, roles and responsibility as per applicable rules and regulations.

1.6.8 Review of **amendments** except minor ones of the originally approved protocol, consent forms, investigators brochure is done in formal meetings to evaluate the risk to trial subjects.

1.6.9 **Periodic review** of study is done for continuation, risk evaluation and adverse event monitoring.
NABH-Accreditation Standards for Ethics Committee, Investigator, Clinical Trial Site

Standard

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

Objective Elements

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

1.7.2 Ensure that subject is recruited into the trial only after written favorable opinion from Ethics committee and approval by regulatory authority.

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

1.7.4 Decisions are 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 are documented, approved, signed and maintained as minutes of Meeting

1.7.6 Protocol deviations, violations and noncompliance are evaluated and appropriate actions are taken.

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

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

Standard

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

Objective Elements

1.8.1 Subject’s rights, safety and wellbeing are monitored.

1.8.2 Adequacy and continuity of consent process is ensured.

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

1.8.4 Opportunities for improvement are identified and appropriate actions are initiated.

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Standard

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

Objective Elements

1.9.1 Periodic **self-assessments** are conducted.

1.9.2 **Corrective and preventive actions** (as required) are implemented.

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 are reviewed and administrative communication is maintained as per regulatory requirement.

1.10.2 **Documents and records are archived** after completion /termination of trial for a minimum period of 5 years.

1.10.3 **Record retrieval** policies and procedures are in place to ensure access to information for inspection and audit and continual protection of trial subjects post trial closure.
Section 2
Accreditation of Investigator

*Investigator refers to the Principal Investigator in this document
** Investigator follows documented procedures i.e site SOPs for clinical trial conduct

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 (ex. from subject selection, informed consent to follow up of trial subjects).

- There is transparency in the conduct of clinical trials and documented procedures are followed by the investigators/relevant teams for all essential activities.
### Summary of Standards

<table>
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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>
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<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>
<tr>
<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>
</tr>
</tbody>
</table>
### Standard

| 2.1 | Qualification, Experience and Training: The Investigator follows documented procedures to ensure that investigator/relevant site staff are qualified, knowledgeable and follow the applicable rules and regulations. Procedures include the following: |

### Objective Elements

2.1.1 **Criteria for qualifications and experience** of an investigator to qualify for accreditation is as follows:

a) Should have a medical degree registered with the Medical Council of India (MCI)/State Medical Councils or a dental surgeon 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) Be well-versed with principles and procedures of informed consent process.

d) Have a clear understanding of ethical issues involved in clinical trials including rights of participants.

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

2.1.2 **Initial and ongoing training** is conducted for the investigator/relevant site staff.

2.1.3 Investigator has **adequate number of qualified 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 is in compliance with SOPs and applicable rules and regulations.

2.2.2 Investigator follows procedures for submission of clinical trial proposal to the ethics committee for review and approval.

2.2.3 Investigator follows 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. Procedures include the following (but not limited to):

Objective Elements

2.3.1 Investigator is aware of subject’s rights and responsibilities.

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

2.3.3 Subject’s participation and withdrawal from the trial is voluntary.

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

2.3.5 Confidentiality and privacy of subjects is protected.

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

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

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2.3.8 Investigator provides **adequate medical care and safety management** of trial subjects and reports and analyses **serious adverse events** as per applicable 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 Has 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 obtains ethics committee approval for the **Informed Consent Document (Subject Information Sheet and Informed Consent Form)** to be provided to subject/LAR/impartial witness.

2.4.3 The **subject/LAR/witness is adequately informed** and understands the information in the informed consent document.

2.4.4 Adequate measures are in place for consenting **vulnerable subjects**.

2.4.5 **Withdrawal of consent** by subject is documented.

**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 is done as per the required regulations.

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

2.5.3 Investigator **reports all serious adverse events** to the Ethics Committee and regulatory authorities and follows ethics committee recommendation to terminate or suspend a trial (as applicable).
2.5.4 Investigator reports and provides adequate information to Ethics Committee and regulatory authority in case of death due to clinical trial.

2.5.5 Continuity in medical and emergency care, follow up care is provided after completion of study or withdrawal from study.

2.5.6 Protocol deviations/violations affecting safety of subjects and integrity of data are reported analyzed and appropriate action is taken.

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 are accurate, complete and legible.

2.6.2 Confidentiality/privacy of subjects and trial data is maintained.

2.6.3 Subject files and clinical trial related documents are maintained adequately.

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

2.6.5 Clinical trial materials are maintained, accounted and stored safely.

Standard

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

Objective Elements

2.7.1 Approval of the registered, accredited Ethics Committee and regulatory authority is obtained before initiation of the study at the site.

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

2.7.3 Declares financial aspects for the clinical trial to the Ethics committee prior to conduct of trial.

2.7.4 Clinical trial is conducted in compliance to the approved protocol.
2.7.5 Oversees the activities of the research staff.

2.7.6 Investigator has **appropriate communication** with the Ethics Committee, sponsor and clinical trial site authority.

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

2.7.8 Follows procedures for appropriate **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 is submitted to the Ethics Committee and recommendations are followed.
Clinical Trial Site must specify in the application, the list of departments/investigators being submitted for accreditation.

Objective of Section 3: Clinical Trial Sites 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 is ethical and in compliance with the applicable rules and regulations.

- There are appropriate measures to ensure protection of subject rights, safety and wellbeing (ex. from subject selection, informed consent to follow up of trial subjects).

- 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>
<thead>
<tr>
<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>
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<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. This includes the following:

Objective Elements

3.1.1 Availability of the general facilities and equipment that are considered essential for clinical research sites.

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

3.1.3 Appropriate Diagnostics facilities for conduct of clinical trials are available.

3.1.4 Necessary resources (as required) are provided to the ethics committee for its proper functioning.

3.1.5 There is 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 are well defined.

3.2.2 Relevant policies and procedures are made available to investigators, research site staff and the ethics committee.
3.2.3 **Training and education program** is in place for investigator, relevant research site staff and the ethics committee.

### Objective Elements

3.3.1 Site **standard operating procedures** (SOPs) for essential activities for conduct of clinical trial should be in place. Procedures include the following (but not limited to):

- Access to adequate laboratory facilities
- Adequate space and required medical and paramedical personnel
- Adequate arrangement for volunteers, subjects for isolation, recreation, food as and when required
- Facility for emergency care and management of SAEs
- Facility for control of systems and archiving
- Storage facility, procedure for safe dispensing and inventory control of IP
- Oversight by ethics committee
- Transparent mechanism for enrolment
- Quality control
- Appropriate for compensation including insurance
- Institutional mechanism for ensuring continuity of care of subjects and of the clinical trial
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. Procedures include the following (but not limited to):

Objective Elements

3.4.1 Rights and responsibility of subject are documented.

3.4.2 Subject selection is fair and equitable as per applicable rules and regulations.

3.4.3 Subject’s voluntary participation and withdrawal from the trial is ensured.

3.4.4 Subjects are informed [initial and ongoing] of the associated risks and benefits of the trial.

3.4.5 Confidentiality and privacy of subjects is protected.

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

3.4.7 Procedures in place to address concerns and queries of research subjects/family.

3.4.8 Compensation provided to subjects for participation in the trial is appropriate and as per the contract.

3.4.9 Adequate medical emergency care and safety is provided for trial subject.

3.4.10 Procedures for arrangement for volunteers, subjects for isolation, recreation food and other facilities 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 are in place for subject registration, identification and documentation of medical records.
3.5.2 **Subject files and clinical trial related information/documentation are maintained.**

3.5.3 Procedures are in place for adequate **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 Ensure regulatory compliance of **ethics committee functioning.**

3.6.2 Ensure that **Institutional Ethics Committee** is registered.

3.6.3 There is a plan for **monitoring the conduct of study** and **addressing deviations and improvements are made as required** to ensure compliance to regulations, guidelines and SOPs.

3.6.4 Oversee that **medical care and medical emergencies** are handled as per applicable rules and regulations.

3.6.5 There is a process to ensure appropriate execution of **clinical trial agreements** in compliance to applicable rules and regulations.

3.6.6 **Process to Address grievances and non-compliance** which could affect the rights safety and privacy of research participant or affect the quality of data.

3.6.7 Procedures are in place 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.

3.6.8 Follows Policy and procedure to ensure **continuity of trial in case of staff and investigator attrition.**
Glossary

The commonly-used terminologies in the NABH standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated, wherever possible. Notwithstanding the accuracy of the explanations given, in the event of any discrepancy with a legal requirement enshrined in the law of the land, the provisions of the latter shall apply.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event (AE):</td>
<td>Any untoward medical occurrence (including a symptom / disease or an abnormal laboratory finding) during treatment with a pharmaceutical product in a subject or a human volunteer that does not necessarily have a relationship with the treatment being given. Also see Serious Adverse Event</td>
</tr>
<tr>
<td>Central Drugs Standard Control Organization (CDSCO)</td>
<td>National Regulatory Authority under the administrative control of Directorate General of Health Services, Ministry of Health &amp; Family Welfare (MoH&amp;FW) which regulates quality, safety and efficacy of drugs in India.</td>
</tr>
<tr>
<td>Clinical trials (as defined in Rule 122DAA of the Drugs and Cosmetics Act in India)</td>
<td>Systemic study of new drugs in human subject(s) to generate data for discovery and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetics) and/or adverse effects with the objective of determining safety and/or efficacy of the new drugs.</td>
</tr>
<tr>
<td>Clinical Trial Site</td>
<td>The hospital/institute/organization where the clinical trial is being conducted.</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>Maintenance of privacy of study subjects including their personal identity and all medical information, from individuals other than those prescribed in the Protocol. Confidentiality also covers the prevention of disclosure of sponsor’s proprietary information to unauthorised persons.</td>
</tr>
</tbody>
</table>

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| **Contract** | A written, dated and signed document describing the agreement between two or more parties involved in a biomedical study, namely Investigator, Sponsor, Institution. Typically, a contract sets out delegation / distribution of responsibilities, financial arrangements and other pertinent terms. The “Protocol” may form the basis of “Contract”. |
| **Documentation** | All records (including written documents, electronic, magnetic or optical records, scans, x-rays etc.) that describe or record the methods, conduct and results of the study, and the actions taken. The Documents include Protocol, copies of submissions and approvals from the office of the Drugs Controller General of India, ethics committee, investigator(s)’ particulars, consent forms, monitor reports, audit certificates, relevant letters, reference ranges, raw data, completed CRFs and the final report. Also see: Essential Documents |
| **Drug Controller General of India** | Central Licence Approving Authority appointed by the Central Government to perform the duties of licensing authority under Drugs and Cosmetic Act, 1940 and Rules, 1945. |
| **Essential Documents** | The Documents that permit evaluation of the conduct of a study and the quality of the data generated. |
| **Ethics Committee** | An independent review board or committee comprising of medical / scientific and non – medical / non – scientific members, whose responsibility is to verify the protection of the rights, safety and well – being of the human subjects involved in the study. |
| **Ethical Principles** | It upholds and adheres to the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research by the National Commission for the Protection of Human Subjects in Biomedical and Behavioural Research (1979). These principles are:
  a) Principles of essentiality.
  b) Principles of voluntariness, informed consent and community Agreement
  c) Principles of non-exploitation.
  d) Principles of privacy and confidentiality.
  e) Principles of precaution and risk minimization.
  f) Principles of professional competence.
  g) Principles of accountability and transparency. |
| **h)** Principles of institutional arrangements.  
| **i)** Principles of totality of responsibility.  
| **j)** Principles of compliance  
| **h)** Principles of the maximization of the public interest and of distributive justice  

**Financial interests**
- Anything concerning monetary benefits, equity interests, e.g., stocks, stock options, and intellectual property rights.

**Good Clinical Practice (GCP)**
- An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected consistent with the principles that have their origin in the Declaration of Helsinki and that the clinical trial data are credible.

**Human Subject (Study Subject)**
- A human research participant is an individual participating in a clinical trial who is a recipient of the investigational can be used interchangeably with the Human subjects as per Indian GCP guidelines. The term human subject, 'study subject' and subject are equivalent.

**Impartial Witness**
- An impartial independent witness who will not be influenced in any way by those who are involved in the Clinical Trial, who assists at the informed consent process and documents the freely given oral consent by signing and dating the written confirmation of this consent.

**Indian Council of Medical Research (ICMR)**
- Apex body in India that formulates coordinates and promotes biomedical research.

**ICMR Code**
- Statement of general principles in biomedical research involving human participants. This statement of ethical guidelines for biomedical research on human participants shall be known as the ICMR code and shall consist of the following:
  - **a.** Statement of general principles on research using human participants in biomedical research.
  - **b.** Statement of specific principles on research

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using human participants in specific areas of biomedical research. These statements of general and specific principles may be varied, amended, Substituted and added from time to time.

<table>
<thead>
<tr>
<th><strong>Informed Consent</strong></th>
<th>Voluntary written assent of a subject's willingness to participate in a particular study and in its documentation. The confirmation is sought only after information about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available and of the subject's rights and responsibilities has been provided to the potential subject.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Institution</strong></td>
<td>Any public or private medical facility where a clinical study is conducted.</td>
</tr>
<tr>
<td><strong>Investigator</strong></td>
<td>A person responsible for the conduct of the study at the trial site. Investigator is responsible for the rights, health and welfare of the study subjects. In case the study is conducted by a team of investigators at the study site then the designated leader of the team should be the Principal Investigator.</td>
</tr>
<tr>
<td><strong>Investigational Product</strong></td>
<td>A pharmaceutical product (including the Comparator Product) being tested or used as reference in a clinical study. An Investigational Product may be an active chemical entity or a formulated dosage form.</td>
</tr>
<tr>
<td><strong>Investigator's Brochure</strong></td>
<td>A collection of data (including justification for the proposed study) for the Investigator consisting of all the clinical as well as non-clinical information available on the Investigational Product(s) known prior to the onset of the trial. There should be adequate data to justify the nature, scale and duration of the proposed trial and to evaluate the potential safety and need for special precautions. If new substantially relevant data is generated during the trial, the information in the Investigator's Brochure must be updated. See Appendix IV.</td>
</tr>
<tr>
<td><strong>Protocol</strong></td>
<td>A document that states the background, objectives, rationale, design, methodology (including the methods for dealing with AEs, withdrawals etc.) and statistical considerations of the study. It also states the conditions under which the study shall be performed and managed.</td>
</tr>
<tr>
<td><strong>Protocol Amendment(s):</strong> Quality Control (QC)</td>
<td>The operational techniques and activities undertaken within the system of QA to verify that the requirements for quality of the trial related activities have been fulfilled. QC activities concern everybody involved with planning, conducting, monitoring, evaluating, data handling and reporting. The objective of QC is to avoid exposure of study subjects to unnecessary risks and to avoid false conclusions being drawn from unreliable data.</td>
</tr>
<tr>
<td><strong>Regulatory Authority</strong></td>
<td>The Drug Controller General of India is the regulatory authority responsible for regulating Clinical Trials in India.</td>
</tr>
<tr>
<td><strong>Research</strong></td>
<td>is a systematic investigation designed to contribute or develop generalizable knowledge.</td>
</tr>
<tr>
<td><strong>Schedule Y</strong></td>
<td>Requirements and Guidelines for permission to Import and/or manufacture of New drugs for marketing or to undertake Clinical Trials in India.</td>
</tr>
<tr>
<td><strong>Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (SADR)</strong></td>
<td>An AE or ADR that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.</td>
</tr>
<tr>
<td><strong>Source Data</strong></td>
<td>Original documents (or their verified and certified copies) necessary for evaluation of the Clinical Trial. These documents may include Study Subjects’ files, recordings from automated instruments, tracings, X-Ray and other films, laboratory notes, photographic negatives, magnetic media, hospital records, clinical and office charts, Subjects’ diaries, evaluation check-lists, and pharmacy dispensing records.</td>
</tr>
<tr>
<td><strong>Sponsor</strong></td>
<td>An individual or a company or an institution that takes the responsibility for the initiation, management and/or financing of a Clinical Study. An Investigator who independently initiates and takes full responsibility for a trial automatically assumes the role of a Sponsor.</td>
</tr>
<tr>
<td><strong>Subject Files / Patient Files</strong></td>
<td>A file containing demographic and medical information about a study subject. It includes hospital files, consultation records or special subject files allowing the authenticity of the information presented in CRF to be verified and where necessary allowing it to be completed or corrected. The conditions regulating the use and consultation of such documents must be honoured as prescribed under Confidentiality.</td>
</tr>
<tr>
<td><strong>Standard Operating Procedures (SOP)</strong></td>
<td>Standard elaborate written instructions to achieve uniformity of performance in the management of clinical</td>
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</tbody>
</table>
SOPs provide a general framework for the efficient implementation and performance of all the functions and activities related to a particular study.

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<tr>
<th><strong>Subject Identification Code</strong></th>
<th>A unique identification number / code assigned by the Investigator to each Study Subject to protect the Subject’s identity. Subject Identification Code is used in lieu of the Subject’s name for all matters related to the study.</th>
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</thead>
<tbody>
<tr>
<td><strong>Suspension of a trial</strong></td>
<td>Recruiting or enrolling participants has halted prematurely but potentially will resume.</td>
</tr>
</tbody>
</table>
2. **CDSCO**: Central Drugs Standard Control Organization
3. **COI**: Conflict of Interest
4. **DCGI**: Drug Controller General of India
5. **EC**: Ethics Committee
6. **ICMR**: Indian Council of Medical Research
7. **ICH-GCP**: International Committee on Harmonization of Good Clinical Practice
8. **IP**: Investigational product
9. **IT**: Information Technology
10. **LAR**: Legally Acceptable Representative
11. **PI**: Principal Investigator
12. **SAE**: Serious Adverse Events
13. **SOP**: Standard Operating Procedures
14. **TOR**: Terms of Reference

**APPLICABLE RULES AND REGULATIONS**

Trials in India are regulated by the following guidelines and rules:


- It is also mandatory that the clinical trial is conducted as per the Indian GCP guidelines and ICH GCP Guideline.

- Ethical guidelines for Biomedical Research on Human Subjects by ICMR.

- A Clinical Trials can only be initiated after obtaining written permission from ethics committee and DCG (I)